AMA
AMERICAN MEDICAL ASSOCIATION

MEMBERSHIP MOVES MEDICINE™

2020 Special Meeting of the AMA House of Delegates

Nov. 13–17

Visit ama-assn.org/nov20-hod-business to access the handbook online.

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LIST OF MATERIAL INCLUDED IN THIS HANDBOOK

NOVEMBER 2020 SPECIAL MEETING OF THE AMA HOUSE OF DELEGATES

Resolutions and reports have been collated by referral according to reference committee assignment. In the listing below, referral is indicated by letter in parenthesis following the title of the report. Resolutions have been numbered according to referrals (i.e., those referred to the Reference Committee on Amendments to Constitution and Bylaws begin with 001, Reference Committee B begins with 201, etc.).

The informational reports contain no recommendations and will be filed on Saturday, November 14, unless a request is received for referral and consideration by a Reference Committee (similar to the use of a consent calendar).

1. **Memorandum from the Speaker**

2. **Understanding the Recording of American Medical Association Policy**

3. **Declaration of Professional Responsibility - Medicine's Social Contract with Humanity**

4. **Delegate / Alternate Delegate Job Description, Roles and Responsibilities**

5. **Seating Chart**

6. **Official Call to the Officers and Members of the AMA**
   Listing of Delegates and Alternate Delegates
   Officials of the Association and AMA Councils
   House of Delegates Reference Committee

7. **Note on Order of Business**

8. **Summary of Fiscal Notes**

FOLLOWING COLLATED BY REFERRAL

9. **Report(s) of the Board of Trustees - Russ Kridel, MD, Chair**
   01 2019 Grants and Donations (Info. Report)
   02 Update on Corporate Relationships (Info. Report)
   03 AMA Performance, Activities and Status in 2019 (Info. Report)
   04 Annual Update on Activities and Progress in Tobacco Control: March 2019 through February 2020 (Info. Report)
   05 FDA Conflict of Interest (B)
   06 Covenants Not to Compete (B)
   07 Opposition to Involuntary Civic Commitment for Substance Use Disorder (B)
   08 White House Initiative on Asian Americans and Pacific Islanders (Info. Report)
   09 Bullying in the Practice of Medicine (D)
   10 Compassionate Release for Incarcerated Patients (D)
   11 Redefining AMA's Position on ACA and Healthcare Reform (Info. Report)
   12 2020 AMA Advocacy Efforts (Info. Report)

13 Merit-based Incentive Payment System (MIPS) Update (B)

14 Advocating for the Standardization and Regulation of Outpatient Addiction Rehabilitation Facilities (B)

15 Plan for Continued Progress Toward Health Equity (Center for Health Equity Annual Report) (Info. Report)

16 Enabling Methadone Treatment of Opioid Use Disorder in Primary Care Settings (B)

17 Hospital Website Voluntary Physician Inclusion (G)

18* Specialty Society Representation in the House of Delegates - Five Year Review (Amendments to C&B)

10. Report(s) of the Council on Constitution and Bylaws - Madelyn E. Butler, MD, Chair

01 Bylaw Accuracy: Name Change for Accreditation Body for Osteopathic Medical Schools (Amendments to C&B)

02 Discordance between Policy and Bylaws--CEJA Membership on AMA Committee on Conduct at AMA Meetings and Events (Amendments to C&B)

11. Report(s) of the Council on Ethical and Judicial Affairs - Monique A. Spillman, MD, Chair

01 Amendment to Opinion 1.2.2, "Disruptive Behavior and Discrimination by Patients" (Amendments to C&B)

02 Amendment to Opinion 8.7, "Routine Universal Immunization of Physicians" (Amendments to C&B)

12. Opinion(s) of the Council on Ethical and Judicial Affairs - Monique A. Spillman, MD, Chair

01 Physician Competence, Self-Assessment and Self-Awareness (Info. Report)

13. Report(s) of the Council on Long Range Planning and Development - Shannon Pryor, MD, Chair

01 International Medical Graduates Section Five-Year Review (F)

02 Organized Medical Staff Section Five-Year Review (F)

03 Establishment of the Private Practice Physicians Section (F)

14. Report(s) of the Council on Medical Education - Liana Puscas, MD, Chair

01 An Update on Continuing Board Certification (C)

02 Graduate Medical Education and the Corporate Practice of Medicine (C)

03 Protection of Resident and Fellow Training in the Case of Hospital or Training Program Closure (C)

04 Preparedness for Pandemics Across the Medical Education Continuum (Info. Report)

15. Report(s) of the Council on Medical Service - Lynda M. Young, MD, Chair

01 Options to Maximize Coverage under the AMA Proposal for Reform (A)

02 Mitigating the Negative Effects of High-Deductible Health Plans (G)

03 Medicare Prescription Drug and Vaccine Coverage and Payment (A)

04 Economic Discrimination in the Hospital Practice Setting (G)

05 Medicaid Reform (A)

06 Value-Based Management of Drug Formularies (A)

07 Health Plan Initiatives Addressing Social Determinants of Health (A)

16. Report(s) of the Council on Science and Public Health - Kira A. Geraci-Ciardullo, MD, Chair

01 Drug Shortages: 2020 Update (E)

02 Neuropathic Pain as a Disease Update (E)

03 Dietary Supplements: Update on Regulation, Industry, and Product Trends (E)

04 Public Health Impacts of Cannabis Legalization (E)

17. Report(s) of the HOD Committee on Compensation of the Officers - Diana E. Fite, MD, Chair

01 Report of the House of Delegates Committee on the Compensation of the Officers (F)

18. Resolutions

001 AMA Resident/Fellow Councilor Term Limits (Amendments to C&B)

002 Resident and Fellow Access to Fertility Preservation (Amendments to C&B)

003 Ensuring Consent for Educational Physical Exams on Anesthetized and Unconscious Patients (Amendments to C&B)

004 Nonconsensual Audio/Video Recording at Medical Encounters (Amendments to C&B)

005 Racism as a Public Health Threat (Amendments to C&B)

006 Addressing Maternal Discrimination (Amendments to C&B)

007 Access to Confidential Health Care Services for Physicians and Trainees (Amendments to C&B)

008 Delegate Apportionment During COVID-19 Pandemic Crisis (Amendments to C&B)

009 Support of Learner and Trainee Participation in Peaceful Demonstrations and Other Forms of Public Advocacy (Amendments to C&B)

010 Racial Essentialism in Medicine (Amendments to C&B)

011 Elimination of Race as a Proxy for Ancestry, Genetics, and Biology in Medical Education, Research and Clinical Practice (Amendments to C&B)

101 End of Life Care Payment (A)

102 Hospice Recertification for Non-Cancer Diagnosis (A)

103 Recognizing the Need to Move Beyond Employer-Sponsored Health Insurance (A)

104 Reinstatement of Consultation Codes (A)

105 Access to Medication (A)

106 Bundling Physician Fees with Hospital Fees (A)

107 COBRA for College Students (A)

108 Consumer Operated and Oriented Plans (CO-OPs) as a Public Option for Health Care Financing (A)

109 Health Insurance that Fairly Compensates Physicians (A)

110 Medicaid Tax Benefits (A)

111 Payment for Regadenoson (Lexiscan) (A)

112 Private Payor Payment Integrity (A)

113 Most Favored Nation Executive Order (A)

201 Permitting the Dispensing of Stock Medications for Post Discharge Patient Use and the Safe Use of Multi-dose Medications for Multiple Patients (B)

202 Cares Act Equity and Loan Forgiveness in the Medicare Accelerated Payment Program (B)

203 COVID-19 Emergency and Expanded Telemedicine Regulations (B)

204 Studying Physician Supervision of Allied Health Professionals Outside of Their Fields of Graduate Medical Education (B)

205 Telehealth Post SARS-COV-2 (B)

206 Strengthening the Accountability of Health Care Reviewers (B)

207 AMA Position on All Payer Database Creation (B)

208 Insurance Claims Data (B)

209 Physician Tax Fairness (B)

210 Prohibit Ghost Guns (B)

211 Creating a Congressionally- Mandated Bipartisan Commission to Examine the U.S. Preparations for and Response to the COVID-19 Pandemic to Inform Future Efforts (B)

212 Copay Accumulator Policies (B)

213 Pharmacies to Inform Physicians When Lower Cost Medication Options are on Formulary (B)

214 Increase Advocacy Efforts in Support of the Treat and Reduce Obesity Act (B)

301 Creating a More Accurate Accounting of Medical Education Financial Costs (C)

302 Student Loan Forgiveness (C)

303 CME for Preceptorship (C)

304 Establishing Minimum Standards for Parental Leave During Graduate Medical Education Training (C)

305 Parental Leave and Planning Resources for Medical Students (C)

306 Retirement of the National Board of Medical Examiners Step 2 Clinical Skills Exam for US Medical Graduates: Call for expedited action by the American Medical Association (C)

307 USMLE Step Examination Failures During the Covid-19 Pandemic (C)

308 ECFMG 2024 Accreditation Requirement for World Federation Medical Education (WFME) Recognition (C)

309* Preserve and Increase Graduate Medical Education Funding (C)

401 Fatigue Mitigation Respite for Faculty and Residents (D)

402 Air Quality and the Protection of Citizen Health (D)

403 Support for Impairment Research (D)

404 Early Vaccination for Correctional Workers and Incarcerated Persons (D)

405 Attacking Disparities in COVID-19 Underlying Health Conditions (D)

406 Face Masking in Hospitals During Flu Season (D)

407* Full Commitment by our AMA to the Betterment and Strengthening of Public Health Systems (D)

501 CBD Oil Use and the Marketing of CBD Oil (E)

502 Drug Manufacturing Safety (E)

503 Federal Initiative to Treat Cannabis Dependence (E)

504 Supplemental Resources for Inflight Medical Kit (E)

505 Regulation and Control of Self-Service Labs (E)

506 Education for Patients on Opiate Replacement Therapy (E)

507 Pharmacy Benefit Managers and Drug Shortages (E)

508 Home Infusion of Hazardous Drugs (E)

509* Hydroxychloroquine and Combination Therapies – Off-Label Use (E)

510* Access to Opioid Agonist Treatment for Incarcerated Persons (E)

601 Support for the Establishment of Medical-Legal Partnerships (F)

602 Towards Diversity and Inclusion: A Global Nondiscrimination Policy Statement and Benchmark for our AMA (F)

603 Report on the Preservation of Independent Medical Practice (F)

604 Timely Promotion and Assistance in Advance Care Planning and Advance Directives (F)

605 Development of Resources on End of Life Care (F)

701 Degradation of Medical Records (G)

702 Eliminating Claims Data for Measuring Physician and Hospital Quality (G)

703 Medicare Advantage Record Requests (G)

704 Government Imposed Volume Requirements for Credentialing (G)

705 The Quadruple Aim - Promoting Improvement in the Physician Experience of Providing Care (G)

706 Physician Burnout is an OSHA Issue (G)
707 Physician Well-Being as an Indicator of Health System Quality (G)
708 Reducing Prior Authorization Burden (G)
709 Addressing Inflammatory and Untruthful Online Ratings (G)
710 A Resolution to Amend the AMA's Physician and Medical Staff Bill of Rights (G)
711 Prevent Medicare Advantage Plans from Limiting Care (G)
712 Increase Insurance Company Hours for Prior Authorization for Inpatient Issues (G)

* *Contained in the Handbook Addendum*

MEMORANDUM FROM THE SPEAKER OF THE HOUSE OF DELEGATES

• All Delegates, Alternate Delegates and others receiving this material are reminded that it refers only to items THAT MAY BE CONSIDERED by the House.

- **ALL ITEMS HAVE NOT YET BEEN REVIEWED BY THE RESOLUTIONS COMMITTEE FOR PRIORITY/URGENCY FOR THIS SPECIAL MEETING**

• No action has been taken on anything herein contained, and it is informational only.

• Only those items that have been acted on finally by the House can be considered official.

• REMINDER*: Only the Resolve portions of the resolutions are considered by the House of Delegates. The Whereas portions or preambles are informational and explanatory only.*

AMA
AMERICAN MEDICAL ASSOCIATION

UNDERSTANDING THE RECORDING OF AMERICAN MEDICAL ASSOCIATION POLICY

Current American Medical Association (AMA) policy is catalogued in PolicyFinder, an electronic database that is updated after each AMA House of Delegates (HOD) meeting and available online. Each policy is assigned to a topical or subject category. Those category headings are alphabetical, starting with "abortion" and running to "women"; the former topic was assigned the number 5, and "women" was assigned 525. Within a category, policies are assigned a 3 digit number, descending from 999, meaning that older policies will *generally* have higher numbers within a category (eg, 35.999 was initially adopted before 35.984). A policy number is not affected when it is modified, however, so a higher number may have been altered more recently than a lower number. Numbers are deleted and not reused when policies are rescinded.

AMA policy is further categorized into one of four types, indicated by a prefix:

- "H" – for statements that one would consider positional or philosophical on an issue
- "D" – for statements that direct some specific activity or action. There can be considerable overlap between H and D statements, with the assignment made on the basis of the core nature of the statement.
- "G" – for statements related to AMA governance
- "E" – for ethical opinions, which are the recommendations put forward in reports prepared by the Council on Ethical and Judicial Affairs and adopted by the AMA-HOD

AMA policy can be accessed at ama-assn.org/go/policyfinder.

The actions of the AMA-HOD in developing policy are recorded in the *Proceedings*, which are available online as well. Annotations at the end of each policy statement trace its development, from initial adoption through any changes. If based on a report, the annotation includes the following abbreviations:

BOT – Board of Trustees
CCB – Council on Constitution and Bylaws
CEJA – Council on Ethical and Judicial Affairs
CLRPD – Council on Long Range Planning and Development
CME – Council on Medical Education
CMS – Council on Medical Service
CSAPH – Council on Science and Public Health

If a resolution was involved, "Res" is indicated. The number of the report or resolution and meeting (A for Annual; I for Interim) and year (two digits) are also included (eg, BOT Rep. 1, A-14 or Res. 319, I-12).

AMA policy is recorded in the following categories, and any particular policy is recorded in only a single category.

5.000 Abortion	10.000 Accident Prevention/Unintentional Injuries
15.000 Accident Prevention: Motor Vehicles	20.000 Acquired Immunodeficiency Syndrome
25.000 Aging	30.000 Alcohol and Alcoholism
35.000 Allied Health Professions	40.000 Armed Forces
45.000 Aviation Medicine	50.000 Blood
55.000 Cancer	60.000 Children and Youth
65.000 Civil and Human Rights	70.000 Coding and Nomenclature
75.000 Contraception	80.000 Crime
85.000 Death and Vital Records	90.000 Disabled
95.000 Drug Abuse	100.000 Drugs
105.000 Drugs: Advertising	110.000 Drugs: Cost
115.000 Drugs: Labeling and Packaging	120.000 Drugs: Prescribing and Dispensing
125.000 Drugs: Substitution	130.000 Emergency Medical Services
135.000 Environmental Health	140.000 Ethics
145.000 Firearms: Safety and Regulation	150.000 Foods and Nutrition

155.000 Health Care Costs	160.000 Health Care Delivery
165.000 Health Care/System Reform	170.000 Health Education
175.000 Health Fraud	180.000 Health Insurance
185.000 Health Insurance: Benefits and Coverage	190.000 Health Insurance: Claim Forms and Claims Processing
195.000 Health Maintenance Organizations	200.000 Health Workforce
205.000 Health Planning	210.000 Home Health Services
215.000 Hospitals	220.000 Hospitals: Accreditation Standards
225.000 Hospitals: Medical Staff	230.000 Hospitals: Medical Staff - Credentialing and Privileges
235.000 Hospitals: Medical Staff - Organization	240.000 Hospitals: Reimbursement
245.000 Infant Health	250.000 International Health
255.000 International Medical Graduates	260.000 Laboratories
265.000 Legal Medicine	270.000 Legislation and Regulation
275.000 Licensure and Discipline	280.000 Long-Term Care
285.000 Managed Care	290.000 Medicaid and State Children's Health Insurance Programs
295.000 Medical Education	300.000 Medical Education: Continuing
305.000 Medical Education: Financing and Support	310.000 Medical Education: Graduate
315.000 Medical Records and Patient Privacy	320.000 Medical Review
330.000 Medicare	335.000 Medicare: Carrier Review
340.000 Medicare: PRO	345.000 Mental Health
350.000 Minorities	355.000 National Practitioner Data Bank
360.000 Nurses and Nursing	365.000 Occupational Health
370.000 Organ Donation and Transplantation	373.000 Patients
375.000 Peer Review	380.000 Physician Fees
383.000 Physician Negotiation	385.000 Physician Payment
390.000 Physician Payment: Medicare	400.000 Physician Payment: Medicare - RBRVS
405.000 Physicians	406.000 Physician-Specific Health Care Data
410.000 Practice Parameters	415.000 Preferred Provider Arrangements
420.000 Pregnancy and Childbirth	425.000 Preventive Medicine
430.000 Prisons	435.000 Professional Liability
440.000 Public Health	445.000 Public Relations
450.000 Quality of Care	455.000 Radiation and Radiology
460.000 Research	465.000 Rural Health
470.000 Sports and Physical Fitness	475.000 Surgery
478.000 Technology - Computer	480.000 Technology - Medical
485.000 Television	490.000 Tobacco Use, Prevention and Cessation
495.000 Tobacco Products	500.000 Tobacco: AMA Corporate Policies and Activities
505.000 Tobacco: Federal and International Policies	510.000 Veterans Medical Care
515.000 Violence and Abuse	520.000 War
525.000 Women	600.000 Governance: AMA House of Delegates
605.000 Governance: AMA Board of Trustees and Officers	610.000 Governance: Nominations, Elections, and Appointments
615.000 Governance: AMA Councils, Sections, and Committees	620.000 Governance: Federation of Medicine
625.000 Governance: Strategic Planning	630.000 Governance: AMA Administration and Programs
635.000 Governance: Membership	640.000 Governance: Advocacy and Political Action

DECLARATION OF PROFESSIONAL RESPONSIBILITY: MEDICINE'S SOCIAL CONTRACT WITH HUMANITY

Preamble

Never in the history of human civilization has the well-being of each individual been so inextricably linked to that of every other. Plagues and pandemics respect no national borders in a world of global commerce and travel. Wars and acts of terrorism enlist innocents as combatants and mark civilians as targets. Advances in medical science and genetics, while promising great good, may also be harnessed as agents of evil. The unprecedented scope and immediacy of these universal challenges demand concerted action and response by all.

As physicians, we are bound in our response by a common heritage of caring for the sick and the suffering. Through the centuries, individual physicians have fulfilled this obligation by applying their skills and knowledge competently, selflessly and at times heroically. Today, our profession must reaffirm its historical commitment to combat natural and man-made assaults on the health and well-being of humankind. Only by acting together across geographic and ideological divides can we overcome such powerful threats. Humanity is our patient.

Declaration

We, the members of the world community of physicians, solemnly commit ourselves to:

1. Respect human life and the dignity of every individual.

2. Refrain from supporting or committing crimes against humanity and condemn all such acts.

3. Treat the sick and injured with competence and compassion and without prejudice.

4. Apply our knowledge and skills when needed, though doing so may put us at risk.

5. Protect the privacy and confidentiality of those for whom we care and breach that confidence only when keeping it would seriously threaten their health and safety or that of others.

6. Work freely with colleagues to discover, develop, and promote advances in medicine and public health that ameliorate suffering and contribute to human well-being.

7. Educate the public and polity about present and future threats to the health of humanity.

8. Advocate for social, economic, educational, and political changes that ameliorate suffering and contribute to human well-being.

9. Teach and mentor those who follow us for they are the future of our caring profession.

We make these promises solemnly, freely, and upon our personal and professional honor.

Adopted by the House of Delegates of the American Medical Association
in San Francisco, California on December 4, 2001

Delegate/Alternate Delegate Job Description, Roles and Responsibilities

At the 1999 Interim Meeting, the House of Delegates adopted as amended Recommendation 16 of the final report of the Special Advisory Committee to the Speaker of the House of Delegates. This recommendation included a job description and roles and responsibilities for delegates and alternate delegates. The description and roles and responsibilities were modified at the 2002 Annual Meeting by Recommendation 3 of the Joint Report of the Board of Trustees and Council on Long Range Planning and Development. The modified job description, qualifications, and responsibilities are listed below.

Delegates and Alternate Delegates should meet the following job description and roles and responsibilities:

Job Description and Roles and Responsibilities of AMA Delegates/Alternate Delegates

Members of the AMA House of Delegates serve as an important communications, policy, and membership link between the AMA and grassroots physicians. The delegate/alternate delegate is a key source of information on activities, programs, and policies of the AMA. The delegate/alternate delegate is also a direct contact for the individual member to communicate with and contribute to the formulation of AMA policy positions, the identification of situations that might be addressed through policy implementation efforts, and the implementation of AMA policies. Delegates and alternate delegates to the AMA are expected to foster a positive and useful two-way relationship between grassroots physicians and the AMA leadership. To fulfill these roles, AMA delegates and alternate delegates are expected to make themselves readily accessible to individual members by providing the AMA with their addresses, telephone numbers, and e-mail addresses so that the AMA can make the information accessible to individual members through the AMA web site and through other communication mechanisms. The qualifications and responsibilities of this role are as follows:

A. Qualifications
- AMA member.
- Elected or selected by the principal governing body or the membership of the sponsoring organization.
- The AMA encourages that at least one member of each delegation be involved in the governance of their sponsoring organization.

B. Responsibilities
- Regularly communicate AMA policy, information, activities, and programs to constituents so he/she will be recognized as the representative of the AMA.
- Relate constituent views and suggestions, particularly those related to implementation of AMA policy positions, to the appropriate AMA leadership, governing body, or executive staff.
- Advocate constituent views within the House of Delegates or other governance unit, including the executive staff.
- Attend and report highlights of House of Delegates meetings to constituents, for example, at hospital medical staff, county, state, and specialty society meetings.
- Serve as an advocate for patients to improve the health of the public and the health care system.
- Cultivate promising leaders for all levels of organized medicine and help them gain leadership positions.
- Actively recruit new AMA members and help retain current members.
- Participate in the AMA Membership Outreach Program.

NOVEMBER 2020 SPECIAL MEETING OF THE AMA HOUSE OF DELEGATES

SEATING CHART

Your speakers have determined that each participant at the Special Meeting may sit anywhere they wish so long as whomever is sitting near you doesn't object. This will be left to the discretion of the individuals with whom you must live.

To: HOD Delegates and Alternate Delegates
Board of Trustees
AMA Councils, Section Governing Councils, Staff
Federation Staff and Leadership

From: Bruce A. Scott, MD, Speaker
Lisa Bohman Egbert, MD, Vice Speaker

Pursuant to the action of the American Medical Association (AMA) Board of Trustees (BOT) on August 30, 2020, this notice will serve as the official call to convene a Special Meeting of the AMA House of Delegates (HOD) on November 13-17, 2020. The purpose of this meeting as defined by the request of the BOT is to **conduct priority and urgent business of the Association.** This Special Meeting will be convened on a virtual platform with the Opening Session to commence at 7 pm CT, Friday, Nov. 13.

We encourage you to read this entire message carefully and save it for future reference as it includes important information and dates. These are the details that are known at this time. We will share more details as they are developed.

Your speakers recognize the challenges that physicians and their practices are facing during this pandemic. We have thus created a schedule that is confined to the previously scheduled meeting days to the extent possible. The total number of hours needed to conduct our business will be dependent upon the volume of business submitted and accepted for consideration.

Resolution Deadlines and **Tentative Agenda** are listed on the attached page.

Please check the Pictorial Directory to assure that we have correct email addresses for you. It is essential that we have correct email addresses for ALL members of the HOD including alternate delegates and any other involved individuals. While this document is being sent electronically and by postal mail, delivery delays and the need to expedite communication as we approach the upcoming meeting require that we can communicate with you electronically. Accordingly, we strongly suggest that chairs and/or staff confirm that all members of their delegation have received this communication electronically. In some cases it may have been sent to “spam” or been removed by a security filter. If a member of your delegation needs to correct or update their email address, please contact the HOD office at HOD@ama-assn.org as soon as possible.

All delegates and delegations are reminded that only urgent or priority items of business will be considered at this Special Meeting. Our councils and the board have already responded favorably to this request. In fact, the BOT has decided to hold half of their reports for later consideration.

Urgency may be thought of as requiring action before the 2021 Annual Meeting; taking no action before that time would have some detrimental effect. Priority is a bit more nebulous and weighs both the subject matter and the recommended actions. For

example, a high priority topic that recommends a study, monitoring a situation, or reaffirmation of current policy is likely not a priority resolution, while a resolution on a priority topic that calls for some specific, near-term action or fills a policy void may be considered a priority resolution. Priority might also be determined by the relationship to our strategic arcs as well as the number of physicians or their patients affected. More details on determining urgency and priority will be shared in subsequent communication.

A Resolution Committee, similar to our regular interim meetings, will be convened to review all submitted resolutions for urgency and priority. As promised, the typical interim meeting focus on advocacy will not be applied at this Special Meeting and all resolutions will be measured equally. Also similar to interim meetings, the Resolution Committee recommendations for this Special Meeting will be presented for consideration and the final decision of what becomes the business of the House will be determined by the HOD.

To facilitate the work of the Resolutions Committee, delegates submitting resolutions are encouraged to submit a statement of urgency and/or priority. This statement should not exceed 250 words.

A concern has been expressed that alternate delegates had limited access during the June Special Meeting. Be assured that arrangements are being made for alternate delegates to be able to fully engage in all sessions of the HOD including reference committees. As in our in-person meetings, the delegate and their alternate will share a single vote, and alternates will only be allowed the privilege of the floor when they are "seated" for their delegate. Accordingly, all delegates are reminded to establish a method to communicate with their alternate in real time during the meeting that is separate from the device that they will use to join the meeting.

Your speakers are sensitive to the fact that our schedule begins after sundown on Friday November 13 and continues through Sunday. The Friday evening Opening Session will not require any votes of the House, and the session will be recorded in order to make it available to be viewed at a different time. The Second Session of the HOD will be held on Saturday morning and will include voting on the rules and the Resolution Committee report; delegates with religious concerns may wish to coordinate with their alternate delegates for this portion. Saturday and Sunday will also include reference committees where attendance is optional, and individuals are reminded of the opportunity to present testimony in the open forum which will be active for several weeks. If further accommodations are needed please contact us at HOD@ama-assn.org.

Rules and Credentials and Reference Committees:
In response to multiple requests from members of the House, it is our intent to hold "live" virtual reference committees for this Special Meeting. To facilitate robust discussion of ALL items of business on our Online Forums prior to the live reference committee hearings, we have moved the final deadline for resolution submission a week earlier. At this time we have not determined how many reference committees will be needed. This will be dependent on how many items of business will be considered. We hope to limit

the number of items in each reference committee so that the hearings will be more easily managed in the virtual setting.

Given the unique nature of our virtual meeting, **your speakers are seeking volunteers** who are comfortable working via the Zoom platform. We ask that all who are interested in serving on one of the Reference Committees or the Rules & Credentials Committee submit a *"November 2020 Reference Committee Volunteer Form"* which is included with this call or can be downloaded from The Speaker's Page on the AMA site. Note that due to the unique nature of this meeting and the need for multiple volunteers comfortable with a virtual meeting format, our usual embargo on those who have served in the recent past will not be observed.

Resolutions Committee Volunteers:
A Resolutions Committee will be convened for this Special Meeting and charged with determining if resolutions submitted are urgent or a priority. The details for this committee's responsibilities, including when and how often it will meet, have not been finalized. Any Delegate or Alternate Delegate interested in serving on this committee is asked to indicate their interest by email to the speakers at HOD@ama-assn.org.

While we are saddened by yet another meeting going by without seeing all of you in-person, your speakers are looking forward to an opportunity to interact with you virtually in a more robust fashion than at our June Special Meeting. Again, as noted above, please take the time to confirm that we have valid email addresses for all Delegates, Alternates and other participants of our HOD. Please watch for further communication from us as more details become available. We look forward to "seeing" you in November.

Attached to this email are the following documents:

- Resolution deadline and tentative agenda
- Reference committee volunteer form
- A copy of this official call

<u>RESOLUTION DEADLINES and TENTATIVE AGENDA</u> *(Central Standard Time)***:**

Wednesday, October 14:

Resolution Submission Deadline

Societies whose meetings adjourn after Oct. 9 will have 7 days from their adjournment to submit their urgent/priority business but no later than Nov. 8. NOTE: Reports and resolutions will be posted to the Online Member Forum as soon as feasible.

Sunday, November 8, Midnight:

Deadline for late or supplemental resolution submission ("Sunday Tote")

Thursday November 12:

Online Member Forums open until noon Thursday November 12

Friday, November 13, 7-9 pm:

HOD Opening Session

Ceremonial Opening
Speeches
Awards Presentation

Saturday, November 14:

10:00 am - Second Session of the HOD

Rules & Credentials Report
Resolutions Committee Report

11:30 am - Reference Committee Hearings begin (number and length to be determined by volume of business)

Sunday November 15:

9:00 am - Reference Committee Hearings resume (number and length to be determined by volume of business)

Monday November 16

Morning - Open for Caucuses

1:00 pm - Third Session of HOD presentation of reference committee reports (length to be determined by volume of business)

Tuesday, November 17

9 am until completed - Fourth Session HOD (length to be determined by volume of business)

NOVEMBER 2020 SPECIAL MEETING OF THE AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Official Call to the Officers and Members of the American Medical Association to participate in the November 2020 Special Meeting of the House of Delegates on November 13-17, 2020. The House of Delegates will convene at 7 p.m. (CT) on November 13, on a virtual platform.

STATE ASSOCIATION REPRESENTATION IN THE HOUSE OF DELEGATES

Alabama 4
Alaska 1
Arizona 5
Arkansas 3
California 33
Colorado 5
Connecticut 4
Delaware 1
District of Columbia 3
Florida 16
Georgia 6
Guam 1
Hawaii 2
Idaho 1
Illinois 12
Indiana 5
Iowa 4
Kansas 3
Kentucky 5
Louisiana 6
Maine 2
Maryland 5
Massachusetts 13
Michigan 13
Minnesota 5
Mississippi 3
Missouri 6
Montana 1
Nebraska 2
Nevada 2
New Hampshire 1
New Jersey 8
New Mexico 2
New York 22
North Carolina 6
North Dakota 1
Ohio 13
Oklahoma 4
Oregon 3
Pennsylvania 14
Puerto Rico 2
Rhode Island 2
South Carolina 5
South Dakota 2
Tennessee 5
Texas 20
Utah 2
Vermont 1
Virgin Islands 1
Virginia 8
Washington 5
West Virginia 2
Wisconsin 5
Wyoming 1

SPECIALTY SOCIETY REPRESENTATION IN THE HOUSE OF DELEGATES

AMDA-The Society for Post-Acute and Long-Term Care Medicine 2
American Academy of Child and Adolescent Psychiatry 2
American Academy of Dermatology 4
American Academy of Family Physicians 16
American Academy of Hospice and Palliative Medicine 2
American Academy of Neurology 4
American Academy of Ophthalmology 4
American Academy of Orthopaedic Surgeons 5
American Academy of Otolaryngology-Head and Neck Surgery 3
American Academy of Pediatrics 5
American Academy of Physical Medicine and Rehabilitation 2
American Academy of Sleep Medicine 2
American Association for Geriatric Psychiatry 2
American Association of Clinical Endocrinologists 2
American Association of Gynecologic Laparoscopists 3
American Association of Neurological Surgeons 2
American Association of Neuromuscular & Electrodiagnostic Medicine 2
American College of Allergy, Asthma and Immunology 2
American College of Cardiology 7
American College of Chest Physicians (CHEST) 3
American College of Emergency Physicians 8
American College of Gastroenterology 2
American College of Obstetricians and Gynecologists 13
American College of Occupational and Environmental Medicine 2
American College of Physicians 24
American College of Preventive Medicine 2
American College of Radiology 7
American College of Rheumatology 2
American College of Surgeons 13
American Gastroenterological Association 3
American Geriatrics Society 2
American Institute of Ultrasound in Medicine 2
American Psychiatric Association 9
American Roentgen Ray Society 3
American Society for Clinical Pathology 3
American Society for Dermatologic Surgery 2
American Society for Gastrointestinal Endoscopy 2
American Society for Radiation Oncology 2
American Society for Reproductive Medicine 2
American Society of Addiction Medicine 2
American Society of Anesthesiologists 7
American Society of Breast Surgeons 2
American Society of Cataract and Refractive Surgery 2
American Society of Clinical Oncology 3
American Society of Echocardiography 2
American Society of Hematology 2
American Society of Interventional Pain Physicians 2
American Society of Nuclear Cardiology 2
American Society of Plastic Surgeons 2
American Society of Retina Specialists 2
American Thoracic Society 3
American Urological Association 2
Association of Military Surgeons of the United States 2
College of American Pathologists 4
Congress of Neurological Surgeons 2
Heart Rhythm Society 2
Infectious Diseases Society of America 2
North American Spine Society 2
Radiological Society of North America 3
Renal Physicians Association 2
Society for Vascular Surgery 2
Society of American Gastrointestinal Endoscopic Surgeons 2
Society of Critical Care Medicine 3
Society of Hospital Medicine 3
Society of Interventional Radiology 2
Society of Laparoscopic and Robotic Surgeons 2
Society of Thoracic Surgeons 2
The Endocrine Society 2
United States and Canadian Academy of Pathology 2

Remaining eligible national medical specialty societies (56) are entitled to one delegate each.

The Academic Physicians Section, Integrated Physician Practice Section, International Medical Graduates Section, Medical Student Section, Minority Affairs Section, Organized Medical Staff Section, Resident and Fellow Section, Senior Physicians Section, Women Physicians Section, Young Physicians Section, Army, Navy, Air Force, Public Health Service, Department of Veterans Affairs, Professional Interest Medical Associations, AMWA, AOA and NMA are entitled to one delegate each.

State Medical Associations	307
National Medical Specialty Societies	305
Professional Interest Medical Associations	3
Other National Societies (AMWA, AOA, NMA)	3
Medical Student Regional Delegates	28
Resident and Fellow Delegate Representatives	28
Sections	10
Services	5
Total Delegates	**689**

Susan R. Bailey, MD
President

Bruce A. Scott, MD
Speaker, House of Delegates

Sandra Adamson Fryhofer, MD
Secretary

2020-2021

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Mario E. Motta (2022) .....Salem, Massachusetts
Bobby Mukkamala (2021), *Chair-Elect* .....Flint, Michigan
Blake Elizabeth Murphy (2021) ..... Chicago, Illinois
Harris Pastides (2024) .....Folly Beach, South Carolina
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Secretary: Elliott Crigger, Chicago, Illinois.

COUNCIL ON LEGISLATION
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Secretary: George Cox, Washington, District of Columbia.

COUNCIL ON LONG RANGE PLANNING AND DEVELOPMENT
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Secretary: Susan Close, Chicago, Illinois.

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Secretary: Tanya Lopez, Chicago, Illinois.

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Secretary: Val Carpenter, Chicago, Illinois.

COUNCIL ON SCIENCE AND PUBLIC HEALTH
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Secretary: Andrea Garcia, Chicago, Illinois.

AMERICAN MEDICAL ASSOCIATION POLITICAL ACTION COMMITTEE
Lyle S. Thorstenson, Nacogdoches, Texas, Chair; Stephen A. Imbeau, Florence, South Carolina, Secretary; Miriam J. R. Bareman, Grand Rapids, Michigan (Student); Brooke M. Buckley, Annapolis, Maryland; Paul J. Carniol, Summit, New Jersey; Ricardo Correa, Phoenix, Arizona; Linda B. Ford, Bellevue, Nebraska; Benjamin Z. Galper, McLean, Virginia; Dev A. GnanaDev, Colton, California; Pratistha Koirala, New York, New York (Resident); James L. Milam, Libertyville, Illinois; L. Elizabeth Peterson, Spokane, Washington.
Executive Director and Treasurer: Kevin Walker, Washington, District of Columbia.

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The Former Presidents and Former Trustees of the Association, the Chairs of the Councils of the AMA and the current General Officers, with the exception of the Speaker and Vice Speaker of the House of Delegates, are ex officio, nonvoting members of the House of Delegates.

FORMER PRESIDENTS

David O. Barbe	2017-2018	Daniel H. Johnson, Jr.	1996-1997	William G. Plested, III	2006-2007
Lonnie R. Bristow	1995-1996	Jeremy A. Lazarus	2012-2013	Thomas R. Reardon	1999-2000
Peter W. Carmel	2011-2012	Robert E. McAfee	1994-1995	J. James Rohack	2009-2010
Yank D. Coble, Jr.	2002-2003	Barbara L. McAneny	2018-2019	Randolph D. Smoak, Jr.	2000-2001
Richard F. Corlin	2001-2002	Alan R. Nelson	1989-1990	Steven J. Stack	2015-2016
Nancy W. Dickey	1998-1999	John C. Nelson	2004-2005	Robert M. Wah	2014-2015
Andrew W. Gurman	2016-2017	Nancy H. Nielsen	2008-2009	Cecil B. Wilson	2010-2011
J. Edward Hill	2005-2006	Donald J. Palmisano	2003-2004	Percy Wootton	1997-1998
Ardis D. Hoven	2013-2014				

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Herman I. Abromowitz	1997-2005	Omar Z. Maniya	2016-2017
Susan Hershberg Adelman	1998-2002	Robert E. McAfee	1984-1993
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Raj S. Ambay	2009-2011	William A. McDade	2016-2020
Joseph P. Annis	2006-2014	Mary Anne McCaffree	2008-2016
John H. Armstrong	2002-2006	Joe T. McDonald	2005-2006
Maya A. Babu	2013-2017	Samuel J. Mackenzie	2014-2015
Timothy E. Baldwin	1987-1989	Robert R. McMillan	2002-2008
David O. Barbe	2009-2016	Sandeep “Sunny” Mistry	2000-2001
Regina M. Benjamin	1995-1998	Alan R. Nelson	1980-1988
Scott L. Bernstein	1991-1992	John C. Nelson	1994-2003
Stefano M. Bertozzi	1986-1988	Nancy H. Nielsen	2005-2007
David J. Brailer	1985-1986	Albert J. Osbahr, III	2011-2019
Lonnie R. Bristow	1985-1994	Donald J. Palmisano	1996-2002
Peter Carmel	2002-2010	Rebecca J. Patchin	1988-1989
Alice A. Chenault	1984-1985	Rebecca J. Patchin	2003-2011
Yank D. Coble	1994-2001	Stephen R. Permut	2010-2018
David S. Cockrum	1993-1994	Pamela Petersen-Crair	1996-1998
MaryAnn Contogiannis	1989-1993	Dina Marie Pitta	2015-2016
Malini Daniel	2012-2013	William G. Plested, III	1998-2005
Christopher M. DeRienzo	2006-2008	Stephen Pool	1995-1996
Nancy W. Dickey	1989-1997	Liana Puscas	1999-2001
Alexander Ding	2011-2013	Thomas R. Reardon	1990-1998
William A. Dolan	2007-2011	Kevin C. Reilly	2003-2005
Timothy T. Flaherty	1994-2003	Ryan J. Ribeira	2013-2014
Melissa J. Garretson	1992-1993	J. James Rohack	2001-2008
Michael S. Goldrich	1993-1997	David A. Rosman	2002-2004
Julie K. Goonewardene	2012-2016	Samantha L. Rosman	2005-2009
Andrew W. Gurman	2007-2015	Raymond Scalettar	1985-1994
Alan C. Hartford	1989-1990	Bruce A. Scott	1998-2002
William A. Hazel, Jr	2004-2009	Carl A. Sirio	2010-2018
Cyril M. Hetsko	2003-2011	Sarah Mae Smith	2019-2020
Joseph M. Heyman	2002-2010	Randolph D. Smoak, Jr.	1992-1999
J. Edward Hill	1996-2004	Steven J. Stack	2006-2014
Ardis D. Hoven	2005-2012	Michael Suk	1994-1995
William E. Jacott	1989-1998	Andrew M. Thomas	1997-1999
Hillary D. Johnson	2001-2002	Jeffrey A. Towson	1998-1999
Matthew D. Kagan	1999-2000	Georgia A. Tuttle	2011-2019
Christopher K. Kay	2008-2012	Jordan M. VanLare	2011-2012
William E. Kobler	2012-2020	Robert M. Wah	2005-2013
Edward L. Langston	2003-2011	Peter Y. Watson	2001-2003
Matthew C. Lawyer	2004-2005	Monica C. Wehby	2011-2013
Jeremy A. Lazarus	2005-2011	Kevin W. Williams	2016-2020
W. J. Lewis	1979-1984	Meredith C. Williams	2010-2011
Audrey J. Ludwig	1990-1991	Cecil B. Wilson	2002-2009
Justin B. Mahida	2009-2010	Percy Wootton	1991-1996

SPECIALTY AND SERVICE SOCIETY REPRESENTATIVES

(The following are not members of the House of Delegates but are representatives of the following societies which are represented in the SSS.)

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American Academy of Addiction Psychiatry ..... Alëna Balasonova, MD
American Academy of Emergency Medicine.....Joseph Wood, MD, JD
American Association of Endocrine Surgeons .....Steven De Jong, MD
American Association of Hip and Knee Surgeons .....Edward Tanner, MD
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American Society for Laser Medicine and Surgery.....George Hruza, MD
American Society of Nuclear Cardiology.....Saurabh Malhotra, MD
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Americas Hernia Society ..... John Fischer, MD
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Association of Professors of Dermatology ..... Christopher R. Shea, MD
Korean American Medical Association ..... John Yun, MD
Outpatient Endovascular and Interventional Society..... Eric Dippel, MD
Society for Cardiovascular Magnetic Resonance .....Edward T. Martin, MD
Society of Pediatric Dermatology.....Dawn Davis, MD
Society of Cardiovascular Computed Tomography.....Dustin Thomas, MD
Society of Gynecologic Oncologists.....Carol Brown, MD

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The following is a list of delegates and alternate delegates to the House of Delegates as reported to the Executive Vice President

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B Jerry Harrison, Haleyville AL
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John Meigs Jr, Brent AL
William Schneider, Huntsville AL

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Regional Medical Student Alternate Delegate(s)
Shri Rajan, Bessemer AL

Alaska State Medical Association

Delegate(s)
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Alternate Delegate(s)
Mary Ann Foland, Anchorage AK

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Delegate(s)
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Gary R. Figge, Tucson AZ
Thomas H. Hicks, Tucson AZ
M Zuhdi Jasser, Phoenix AZ

Alternate Delegate(s)
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Arizona Medical Association

Alternate Delegate(s)
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Michael Hamant, Tucson AZ
Jennifer Hartmark-Hill, Phoenix AZ
Marc Leib, Phoenix AZ

Regional Medical Student Delegate(s)
Akshara Malla, Phoenix AZ

Regional Medical Student Alternate Delegate(s)
Meera Kapadia, Chandler AZ

Arkansas Medical Society

Delegate(s)
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Eugene Shelby, Little Rock AR
Alan Wilson, Monticello AR

Alternate Delegate(s)
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Regional Medical Student Delegate(s)
Anveshi Guha, Little Rock AR

California Medical Association

Delegate(s)
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Barbara J. Arnold, Sacramento CA
Patricia L. Austin, Alamo CA
Edward Bentley, Santa Barbara CA
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Jacob Burns, Sacramento CA
J Brennan Cassidy, Newport Beach CA
Luther Cobb, Eureka CA

California Medical Association

Delegate(s)

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Alexander Ding, Belmont CA

Maisha Draves, Fairfield CA

Kyle P. Edmonds, San Diego CA

Dev A. GnanaDev, Redlands CA

James T. Hay, Del Mar CA

Robert Hertzka, Rancho Santa Fe CA

James G. Hinsdale, San Jose CA

Samuel Huang, Los Angeles CA

Vito Imbasciani, Los Angeles CA

Melissa Jones, Sacramento CA

Kermit Jones, Vacaville CA

Edward Lee, Sacramento CA

Arthur N. Lurvey, Los Angeles CA

Michael Luszczak, Carmichael CA

Ramin Manshadi, Stockton CA

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Kelly McCue, Davis CA

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California Medical Association

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Current as of: 10/21/2020

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Brigitta J. Robinson, Centennial CO

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Stacy Taylor, New Hartford CT

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Alternate Delegate(s)

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Ryan Englander, Farmington CT

Ian Whittall, Farmington CT

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Delegate(s)

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Raymond K. Tu, Washington DC

Alternate Delegate(s)

Neal D Barnard, Washington DC

Regional Medical Student Alternate Delegate(s)

Alicia Khan, Gaithersburg MD

Florida Medical Association

Delegate(s)

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Ankush Bansal, Palm Beach Gardens FL

David Becker, Safety Harbor FL

Florida Medical Association

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Ronald Frederic Giffler, Davie FL

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John Montgomery, Fleming Island FL

Douglas Murphy, Ocala FL

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Eva Crooke, Tampa FL

Aaron Elkin, Hollywood FL

Raphael C. Haciski, Naples FL

Ryan Hall, Lake Mary FL

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Karen Harris, Gainesville FL

Rebecca Lynn Johnson, Tampa FL

Arthur E. Palamara, Hollywood FL

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David Tyson, Gainesville FL

Florida Medical Association

Regional Medical Student Alternate Delegate(s)

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Samantha Pavlock, Jupiter FL

Medical Association of Georgia

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S William Clark III, Waycross GA

Michael E. Greene, Savannah GA

Billie Luke Jackson, Macon GA

Sandra B. Reed, Atlanta GA

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John Goldman, Atlanta GA

Zachary Lopater, Macon GA

Ali Rahimi, Atlanta GA

Gary Richter, Atlanta GA

Charles Wilmer, Atlanta GA

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Jessica Walsh O'Sullivan, Atlanta GA

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Delegate(s)

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Hawaii Medical Association

Delegate(s)

Jone Geimer-Flanders, Honolulu HI

Roger Kimura, Honolulu HI

Alternate Delegate(s)

Christopher Flanders, Honolulu HI

Idaho Medical Association

Delegate(s)
A. Patrice Burgess, Boise ID

Alternate Delegate(s)
Keith Davis, Shoshone ID

Illinois State Medical Society

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Sofia Aronson, Chicago IL

Christine Bishof, Elmhurst IL

Howard Chodash, Springfield IL

Peter E. Eupierre, Oak Brook IL

Steve Malkin, Peoria AZ

James L. Milam, Libertyville IL

Robert Panton, Elmwood Park IL

Nestor Ramirez-Lopez, Champaign IL

Laura Shea, Springfield IL

Shastri Swaminathan, Westmont IL

Piyush Vyas, Lake Forest IL

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Smitha Arekapudi, Chicago IL

Howard Axe, Grayslake IL

Kenneth G. Busch, Chicago IL

Scott A. Cooper, Chicago IL

Richard A. Geline, Glenview IL

Tariq Issa, Springfield IL

Niva Lubin-Johnson, Chicago IL

Vikram B. Patel, South Barrington IL

Holly Rosencranz, Champaign IL

Katherine Tynus, Chicago IL

Steven D. Williams, Bourbonnais IL

Illinois State Medical Society

Resident and Fellow Sectional Delegate(s)
Christiana Shoushtari, Chicago IL

Resident and Fellow Sectional Alternate Delegate(s)
Zoran Pavlovic, Chicago IL

Regional Medical Student Delegate(s)
Titus Hou, Rockford IL

Indiana State Medical Association

Delegate(s)
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Vidya S. Kora, Michigan City IN

William Mohr, Kokomo IN

Stephen Tharp, Indianapolis IN

David Welsh, Batesville IN

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Heidi Dunniway, Evansville IN

Brent Mohr, Granger IN

Thomas Vidic, Elkhart IN

Stacie Wenk, Evansville IN

Regional Medical Student Delegate(s)
Brandon Francis, Evansville IN

Regional Medical Student Alternate Delegate(s)
Megan Chiu, Bloomington IN

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Delegate(s)
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Anne Langguth, Hiawatha IA

Robert Lee, Johnston IA

Victoria Sharp, Iowa City IA

Alternate Delegate(s)
Jeffrey Anderson, West De Moines IA

Iowa Medical Society

Alternate Delegate(s)

Douglas Peters, W Burlington IA

Brian Privett, Cedar Rapids IA

Kansas Medical Society

Delegate(s)

Robert Gibbs, Parsons KS

Arthur D. Snow Jr, Shawnee Mission KS

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November 2020 Special Meeting

Note on Orders of Business
(All Times are Central Standard Time)

FIRST SESSION, Friday, November 13, 7:00 pm

SECOND SESSION, Saturday, November 14, 10:00 am

THIRD SESSION, Monday, November 16, 1:00 – 6:00 pm

FOURTH SESSION, Tuesday, November 17, 9:00 am - adjournment

SUMMARY OF FISCAL NOTES (NOVEMBER 2020)

BOT Report(s)

01 2019 Grants and Donations: Informational report
02 Update on Corporate Relationships: Informational report
03 AMA Performance, Activities and Status in 2019: Informational report
04 Annual Update on Activities and Progress in Tobacco Control: March 2019 through February 2020: Informational report
05 FDA Conflict of Interest: Minimal
06 Covenants Not to Compete: Modest
07 Opposition to Involuntary Civic Commitment for Substance Use Disorder: Minimal
08 White House Initiative on Asian Americans and Pacific Islanders: Informational report
09 Bullying in the Practice of Medicine: Minimal
10 Compassionate Release for Incarcerated Patients: Modest
11 Redefining AMA's Position on ACA and Healthcare Reform: Informational report
12 2020 AMA Advocacy Efforts: Informational report
13 Merit-based Incentive Payment System (MIPS) Update: Minimal
14 Advocating for the Standardization and Regulation of Outpatient Addiction Rehabilitation Facilities: Modest
15 Plan for Continued Progress Toward Health Equity (Center for Health Equity Annual Report): Informational report
16 Enabling Methadone Treatment of Opioid Use Disorder in Primary Care Settings: Minimal
17 Hospital Website Voluntary Physician Inclusion: Moderate
18* Specialty Society Representation in the House of Delegates - Five Year Review: Minimal

CC&B Report(s)

01 Bylaw Accuracy: Name Change for Accreditation Body for Osteopathic Medical Schools: Minimal
02 Discordance between Policy and Bylaws--CEJA Membership on AMA Committee on Conduct at AMA Meetings and Events: Minimal

CEJA Opinion(s)

01 Physician Competence, Self-Assessment and Self-Awareness: Informational report

CEJA Report(s)

01 Amendment to Opinion 1.2.2, “Disruptive Behavior and Discrimination by Patients”: Minimal
02 Amendment to Opinion 8.7, “Routine Universal Immunization of Physicians”: Minimal

CLRPD Report(s)

01 International Medical Graduates Section Five-Year Review: Minimal
02 Organized Medical Staff Section Five-Year Review: Minimal
03 Establishment of the Private Practice Physicians Section: $325,000 annually

CME Report(s)

01 An Update on Continuing Board Certification: Modest
02 Graduate Medical Education and the Corporate Practice of Medicine: Minimal
03 Protection of Resident and Fellow Training in the Case of Hospital or Training Program Closure: Minimal
04 Preparedness for Pandemics Across the Medical Education Continuum: Informational report

SUMMARY OF FISCAL NOTES (NOVEMBER 2020)

CMS Report(s)

01 Options to Maximize Coverage under the AMA Proposal for Reform: Minimal
02 Mitigating the Negative Effects of High-Deductible Health Plans: Minimal
03 Medicare Prescription Drug and Vaccine Coverage and Payment: Between $15,000 - $20,000
04 Economic Discrimination in the Hospital Practice Setting: Minimal
05 Medicaid Reform: Minimal
06 Value-Based Management of Drug Formularies: Minimal
07 Health Plan Initiatives Addressing Social Determinants of Health: Minimal

CSAPH Report(s)

01 Drug Shortages: 2020 Update: Minimal
02 Neuropathic Pain as a Disease Update: Minimal
03 Dietary Supplements: Update on Regulation, Industry, and Product Trends: Minimal
04 Public Health Impacts of Cannabis Legalization: Minimal

HOD Comm on Compensation of the Officers

01 Report of the House of Delegates Committee on the Compensation of the Officers: None

Resolution(s)

001 AMA Resident/Fellow Councilor Term Limits: Minimal
002 Resident and Fellow Access to Fertility Preservation: Modest
003 Ensuring Consent for Educational Physical Exams on Anesthetized and Unconscious Patients: Minimal
004 Nonconsensual Audio/Video Recording at Medical Encounters: Minimal
005 Racism as a Public Health Threat: Moderate
006 Addressing Maternal Discrimination: Minimal
007 Access to Confidential Health Care Services for Physicians and Trainees: Moderate
008 Delegate Apportionment During COVID-19 Pandemic Crisis: Minimal
009 Support of Learner and Trainee Participation in Peaceful Demonstrations and Other Forms of Public Advocacy: Moderate
010 Racial Essentialism in Medicine: Estimated cost of $25,000 includes staff costs, expense, conference calls, etc.
011 Elimination of Race as a Proxy for Ancestry, Genetics, and Biology in Medical Education, Research and Clinical Practice: Minimal
101 End of Life Care Payment: Modest
102 Hospice Recertification for Non-Cancer Diagnosis: Modest
103 Recognizing the Need to Move Beyond Employer-Sponsored Health Insurance: Minimal
104 Reinstatement of Consultation Codes: Modest
105 Access to Medication: Modest
106 Bundling Physician Fees with Hospital Fees: Minimal
107 COBRA for College Students: Modest
108 Consumer Operated and Oriented Plans (CO-OPs) as a Public Option for Health Care Financing: Modest
109 Health Insurance that Fairly Compensates Physicians: Modest
110 Medicaid Tax Benefits: Modest
111 Payment for Regadenoson (Lexiscan): Modest
112 Private Payor Payment Integrity: Modest

SUMMARY OF FISCAL NOTES (NOVEMBER 2020)

Resolution(s)

113 Most Favored Nation Executive Order: Modest
201 Permitting the Dispensing of Stock Medications for Post Discharge Patient Use and the Safe Use of Multi-dose Medications for Multiple Patients: Modest
202 Cares Act Equity and Loan Forgiveness in the Medicare Accelerated Payment Program: Modest
203 COVID-19 Emergency and Expanded Telemedicine Regulations: Modest
204 Studying Physician Supervision of Allied Health Professionals Outside of Their Fields of Graduate Medical Education: Estimated cost of $100,000 for staff expenses and consultant fees
205 Telehealth Post SARS-COV-2: Modest
206 Strengthening the Accountability of Health Care Reviewers: Modest
207 AMA Position on All Payer Database Creation: Modest
208 Insurance Claims Data: Modest
209 Physician Tax Fairness: Modest
210 Prohibit Ghost Guns: Minimal
211 Creating a Congressionally- Mandated Bipartisan Commission to Examine the U.S. Preparations for and Response to the COVID-19 Pandemic to Inform Future Efforts: Modest
212 Copay Accumulator Policies: Modest
213 Pharmacies to Inform Physicians When Lower Cost Medication Options are on Formulary: Minimal
214 Increase Advocacy Efforts in Support of the Treat and Reduce Obesity Act: Modest
301 Creating a More Accurate Accounting of Medical Education Financial Costs: Modest
302 Student Loan Forgiveness: Modest
303 CME for Preceptorship: Modest
304 Establishing Minimum Standards for Parental Leave During Graduate Medical Education Training: Minimal
305 Parental Leave and Planning Resources for Medical Students: Minimal
306 Retirement of the National Board of Medical Examiners Step 2 Clinical Skills Exam for US Medical Graduates: Call for expedited action by the American Medical Association: Modest
307 USMLE Step Examination Failures During the Covid-19 Pandemic: Modest
308 ECFMG 2024 Accreditation Requirement for World Federation Medical Education (WFME) Recognition: Modest
309* Preserve and Increase Graduate Medical Education Funding: Modest
401 Fatigue Mitigation Respite for Faculty and Residents: Modest
402 Air Quality and the Protection of Citizen Health: Modest
403 Support for Impairment Research: Modest
404 Early Vaccination for Correctional Workers and Incarcerated Persons: Minimal
405 Attacking Disparities in COVID-19 Underlying Health Conditions: Minimal
406 Face Masking in Hospitals During Flu Season: Moderate
407* Full Commitment by our AMA to the Betterment and Strengthening of Public Health Systems: Moderate
501 CBD Oil Use and the Marketing of CBD Oil: Minimal
502 Drug Manufacturing Safety: Modest
503 Federal Initiative to Treat Cannabis Dependence: Modest
504 Supplemental Resources for Inflight Medical Kit: Modest
505 Regulation and Control of Self-Service Labs: Modest
506 Education for Patients on Opiate Replacement Therapy: Estimated cost of $72K to create and implement an educational program includes contracting an outside vendor for materials and promotion and staff costs.
507 Pharmacy Benefit Managers and Drug Shortages: Modest

SUMMARY OF FISCAL NOTES (NOVEMBER 2020)

Resolution(s)

508 Home Infusion of Hazardous Drugs: Minimal
509* Hydroxychloroquine and Combination Therapies – Off-Label Use: Modest
510* Access to Opioid Agonist Treatment for Incarcerated Persons: Minimal - less than $1,000
601 Support for the Establishment of Medical-Legal Partnerships: Minimal
602 Towards Diversity and Inclusion: A Global Nondiscrimination Policy Statement and Benchmark for our AMA: Moderate
603 Report on the Preservation of Independent Medical Practice: Modest
604 Timely Promotion and Assistance in Advance Care Planning and Advance Directives: Estimated cost in excess of $250K includes media buys, professional fees, staff time, marketing and promotion, with ongoing annual costs to support a national day of recognition.
605 Development of Resources on End of Life Care: Moderate
701 Degradation of Medical Records: Minimal
702 Eliminating Claims Data for Measuring Physician and Hospital Quality: Modest
703 Medicare Advantage Record Requests: Modest
704 Government Imposed Volume Requirements for Credentialing: Moderate
705 The Quadruple Aim - Promoting Improvement in the Physician Experience of Providing Care: Minimal
706 Physician Burnout is an OSHA Issue: Modest
707 Physician Well-Being as an Indicator of Health System Quality: Minimal
708 Reducing Prior Authorization Burden: Modest
709 Addressing Inflammatory and Untruthful Online Ratings: Minimal
710 A Resolution to Amend the AMA's Physician and Medical Staff Bill of Rights: Minimal
711 Prevent Medicare Advantage Plans from Limiting Care: Modest
712 Increase Insurance Company Hours for Prior Authorization for Inpatient Issues: Modest

*** Contained in the Handbook Addendum**

Minimal - less than $1,000
Modest - between $1,000 - $5,000
Moderate - between $5,000 - $10,000

Reference Committee on Amendments to Constitution and Bylaws

BOT Report(s)

18* Specialty Society Representation in the House of Delegates - Five Year Review

CC&B Report(s)

01 Bylaw Accuracy: Name Change for Accreditation Body for Osteopathic Medical Schools

02 Discordance between Policy and Bylaws--CEJA Membership on AMA Committee on Conduct at AMA Meetings and Events

CEJA Report(s)

01 Amendment to Opinion 1.2.2, “Disruptive Behavior and Discrimination by Patients”

02 Amendment to Opinion 8.7, “Routine Universal Immunization of Physicians”

Resolution(s)

001 AMA Resident/Fellow Councilor Term Limits

002 Resident and Fellow Access to Fertility Preservation

003 Ensuring Consent for Educational Physical Exams on Anesthetized and Unconscious Patients

004 Nonconsensual Audio/Video Recording at Medical Encounters

005 Racism as a Public Health Threat

006 Addressing Maternal Discrimination

007 Access to Confidential Health Care Services for Physicians and Trainees

008 Delegate Apportionment During COVID-19 Pandemic Crisis

009 Support of Learner and Trainee Participation in Peaceful Demonstrations and Other Forms of Public Advocacy

010 Racial Essentialism in Medicine

011 Elimination of Race as a Proxy for Ancestry, Genetics, and Biology in Medical Education, Research and Clinical Practice

**** contained in the Handbook Addendum***

REPORT OF THE BOARD OF TRUSTEES

B of T Report 18, November 2020

Subject: Specialty Society Representation in the House of Delegates - Five-Year Review

Presented by: Russ Kridel, MD, Chair

Referred to: Reference Committee on Amendments to Constitution and Bylaws (Charles J. Rainey, MD, JD, Chair)

The Board of Trustees (BOT) has completed its review of the specialty organizations seated in the House of Delegates (HOD) scheduled to submit information and materials for the 2020 American Medical Association (AMA) Annual Meeting and the 2020 Interim Meeting in compliance with the five-year review process established by the HOD in Policy G-600.020, "Summary of Guidelines for Admission to the House of Delegates for Specialty Societies," and AMA Bylaw 8.5, "Periodic Review Process."

Organizations are required to demonstrate continuing compliance with the guidelines established for representation in the HOD. Compliance with the five responsibilities of professional interest medical associations and national medical specialty organizations is also required as set out in AMA Bylaw 8.2, "Responsibilities of National Medical Specialty Societies and Professional Interest Medical Associations."

The following organizations were reviewed in anticipation of the 2020 Annual Meeting:

American Academy of Otolaryngic Allergy
American Association for Geriatric Psychiatry
American College of Legal Medicine
American College of Mohs Surgery
American College of Obstetricians and Gynecologists
American College of Physicians
American College of Preventive Medicine
American College of Radiology
American College of Surgeons
American Society of Breast Surgeons
American Society of Retina Specialists
American Vein and Lymphatic Society
Heart Rhythm Society
International Academy of Independent Medical Evaluators
Society of Hospital Medicine
Undersea and Hyperbaric Medical Society

The following organizations were also reviewed in anticipation of the 2020 Annual Meeting, having failed to meet the requirements at the 2019 Annual Meeting:

American Society for Aesthetic Plastic Surgery

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American Society of Interventional Pain Physicians
Association of University Radiologists
Infectious Diseases Society of America
International Society for the Advancement of Spine Surgery

The following organizations were reviewed in anticipation of the 2020 Interim Meeting:

American College of Occupational and Environmental Medicine
American Gastroenterological Association
American Geriatrics Society
American Orthopaedic Association
American Psychiatric Association
American Roentgen Ray Society
American Society of Abdominal Surgeons
The Triological Society

Each organization was required to submit materials demonstrating compliance with the guidelines and requirements along with appropriate membership information. A summary of each group's membership data is attached to this report (Exhibit A). A summary of the guidelines for specialty society representation in the AMA HOD (Exhibit B), the five responsibilities of national medical specialty organizations and professional medical interest associations represented in the HOD (Exhibit C), and the AMA Bylaws pertaining to the five-year review process (Exhibit D) are also attached.

The materials submitted indicate that: American Academy of Otolaryngic Allergy, American Association of Geriatric Psychiatry, American College of Legal Medicine, American College of Mohs Surgery, American College of Obstetricians and Gynecologists, American College of Occupational and Environmental Medicine, American College of Physicians, American College of Preventive Medicine, American College of Radiology, American College of Surgeons, American Gastroenterological Association, American Geriatrics Society, American Orthopaedic Association, American Psychiatric Association, American Roentgen Ray Society, American Society of Breast Surgeons, American Society of Interventional Pain Physicians, American Society of Retina Specialists, American Vein and Lymphatic Society, Association of University Radiologists, Heart Rhythm Society, Infectious Disease Society of America, International Society for the Advancement of Spine Surgery, Society of Hospital Medicine, The Triological Society and the Undersea and Hyperbaric Medical Society meet all guidelines and are in compliance with the five-year review requirements of specialty organizations represented in the HOD.

The materials submitted also indicated that the American Society for Aesthetic Plastic Surgery and the International Academy of Independent Medical Examiners did not meet all guidelines and are not in compliance with the five-year review requirements of specialty organizations represented in the HOD.

The American Society of Abdominal Surgeons did not submit materials and is therefore not in compliance.

RECOMMENDATIONS

In light of the cancellation of the 2020 Annual and Interim Meetings and with an intention to continue compliance with the five-year review process, the Board of Trustees recommends that the following be adopted, and the remainder of this report be filed:

1. That the American Academy of Otolaryngic Allergy, American Association of Geriatric Psychiatry, American College of Legal Medicine, American College of Mohs Surgery, American College of Obstetricians and Gynecologists, American College of Occupational and Environmental Medicine, American College of Physicians, American College of Preventive Medicine, American College of Radiology, American College of Surgeons, American Gastroenterological Association, American Geriatrics Society, American Orthopaedic Association, American Psychiatric Association, American Roentgen Ray Society, American Society of Breast Surgeons, American Society of Interventional Pain Physicians, American Society of Retina Specialists, American Vein and Lymphatic Society, Association of University Radiologists, Heart Rhythm Society, Infectious Disease Society of America, International Society for the Advancement of Spine Surgery, Society of Hospital Medicine, The Triological Society and the Undersea and Hyperbaric Medical Society retain representation in the American Medical Association House of Delegates. (Directive to Take Action)

2. Having failed to meet the requirements for continued representation in the AMA House of Delegates as set forth in AMA Bylaw B-8.5, the International Academy of Independent Medical Evaluators and the American Society of Abdominal Surgeons be placed on probation and be given one year to work with AMA membership staff to increase their AMA membership. (Directive to Take Action)

3. Having failed to meet the requirements for continued representation in the AMA House of Delegates as set forth in AMA Bylaw B-8.5 after a year's grace period to increase membership, the American Society for Aesthetic Plastic Surgery not retain representation in the House of Delegates. (Directive to Take Action)

Fiscal Note: Less than $500 to implement.

APPENDIX

Exhibit A - Summary Membership Information

Organization	AMA Membership of Organization's Total Eligible Membership
American Academy of Otolaryngic Allergy	259 of 997 (26%)
American Association for Geriatric Psychiatry	233 of 829 (28%0
American College of Legal Medicine	52 of 176 (30%)
American College of Mohs Surgery	306 of 1,088 (28%)
American College of Obstetrician and Gynecologists	13,123 of 43,410 (30%)
American College of Occupational and Environmental Medicine	646 of 2,633 (25%)
American College of Physicians	33,190 of 102,042 (32%)
American College of Preventive Medicine	326 of 1,193 (27%)
American College of Radiology	7.370 of 34,011 (22%)
American College of Surgeons	5,869 of 29,938 (20%)
American Gastroenterological Association	1,273 of 7,791 (16%)
American Geriatrics Society	724 of 2,750 (26%)
American Orthopaedic Association	387 of 1,665 (23%)
American Psychiatric Association	6,837 of 25,719 (27%)
American Roentgen Ray Society	2,533 of 13,859 (18%)
American Society for Aesthetic Plastic Surgery	330 of 1,888 (17%)
American Society of Abdominal Surgeons	no data
American Society of Breast Surgeons	609 of 2,473 (25%)
American Society of Interventional Pain Physicians	652 of 2,587 (25%)
American Society of Retina Specialists	575 of 2,154 (26%)
American Vein and Lymphatic Society	238 of 957 (25%)
Association of University Radiologists	179 of 861 (20%)

Organization	AMA Membership of Organization's Total Eligible Membership
Heart Rhythm Society	656 of 3,040 (22%)
Infectious Disease Society of America	1062 of 3,515 (30%)
International Academy of Independent Medical Evaluators	61 of 139 (44%)
International Society for the Advancement of Spine Surgery	109 of 369 (29%)
Society of Hospital Medicine	2,389 of 12,827 (19%)
The Triological Society	123 of 534 (23%)
Undersea and Hyperbaric Medical Society	123 of 586 (21%)

Exhibit B - Summary of Guidelines for Admission to the House of Delegates for Specialty Societies (Policy G-600.020)

Policy G-600.020

1. The organization must not be in conflict with the Constitution and Bylaws of the American Medical Association with regard to discrimination in membership.

2. The organization must:

   (a) represent a field of medicine that has recognized scientific validity;
   (b) not have board certification as its primary focus; and
   (c) not require membership in the specialty organization as a requisite for board certification.

3. The organization must meet one of the following criteria:

   (a) a specialty organization must demonstrate that it has 1,000 or more AMA members; or
   (b) a specialty organization must demonstrate that it has a minimum of 100 AMA members and that twenty percent (20%) of its physician members who are eligible for AMA membership are members of the AMA; or
   (c) a specialty organization must demonstrate that it was represented in the House of Delegates at the 1990 Annual Meeting and that twenty percent (20%) of its physician members who are eligible for AMA membership are members of the AMA.

4. The organization must be established and stable; therefore it must have been in existence for at least five years prior to submitting its application.

5. Physicians should comprise the majority of the voting membership of the organization.

6. The organization must have a voluntary membership and must report as members only those who are current in payment of dues, have full voting privileges, and are eligible to hold office.

7. The organization must be active within its field of medicine and hold at least one meeting of its members per year.

8. The organization must be national in scope. It must not restrict its membership geographically and must have members from a majority of the states.

9. The organization must submit a resolution or other official statement to show that the request is approved by the governing body of the organization.

10. If international, the organization must have a US branch or chapter, and this chapter must be reviewed in terms of all of the above guidelines.

Exhibit C

8.2 **Responsibilities of National Medical Specialty Societies and Professional Interest Medical Associations.** Each national medical specialty society and professional interest medical association represented in the House of Delegates shall have the following responsibilities:

8.2.1 To cooperate with the AMA in increasing its AMA membership.

8.2.2 To keep its delegate(s) to the House of Delegates fully informed on the policy positions of the society or association so that the delegates can properly represent the society or association in the House of Delegates.

8.2.3 To require its delegate(s) to report to the society on the actions taken by the House of Delegates at each meeting.

8.2.4 To disseminate to its membership information as to the actions taken by the House of Delegates at each meeting.

8.2.5 To provide information and data to the AMA when requested.

Exhibit D – AMA Bylaws on Specialty Society Periodic Review

8 - Representation of National Medical Specialty Societies and Professional Interest Medical Associations in the House of Delegates

8.5 **Periodic Review Process.** Each specialty society and professional interest medical association represented in the House of Delegates must reconfirm its qualifications for representation by demonstrating every 5 years that it continues to meet the current guidelines required for granting representation in the House of Delegates, and that it has complied with the responsibilities imposed under Bylaw 8.2. The SSS may determine and recommend that societies currently classified as specialty societies be reclassified as professional interest medical associations. Each specialty society and professional interest medical association represented in the House of Delegates must submit the information and data required by the SSS to conduct the review process. This information and data shall include a description of how the specialty society or the professional interest medical association has discharged the responsibilities required under Bylaw 8.2.

8.5.1 If a specialty society or a professional interest medical association fails or refuses to provide the information and data requested by the SSS for the review process, so that the SSS is unable to conduct the review process, the SSS shall so report to the House of Delegates through the Board of Trustees. In response to such report, the House of Delegates may terminate the representation of the specialty society or the professional interest medical association in the House of Delegates by majority vote of delegates present and voting, or may take such other action as it deems appropriate.

8.5.2 If the SSS report of the review process finds the specialty society or the professional interest medical association to be in noncompliance with the current guidelines for representation in the House of Delegates or the responsibilities under Bylaw 8.2, the specialty society or the professional interest medical association will have a grace period of one year to bring itself into compliance.

8.5.3 Another review of the specialty society's or the professional interest medical association's compliance with the current guidelines for representation in the House of Delegates and the responsibilities under Bylaw 8.2 will then be conducted, and the SSS will submit a report to the House of Delegates through the Board of Trustees at the end of the one-year grace period.

8.5.3.1 If the specialty society or the professional interest medical association is then found to be in compliance with the current guidelines for representation in the House of Delegates and the responsibilities under Bylaw 8.2, the specialty society or the professional interest medical association will continue to be represented in the House of Delegates and the current review process is completed.

8.5.3.2 If the specialty society or the professional interest medical association is then found to be in noncompliance with the current guidelines for representation in the House of Delegates, or the responsibilities under Bylaw 8.2, the House may take one of the following actions:

8.5.3.2.1 The House of Delegates may continue the representation of the specialty society or the professional interest medical association in the House of Delegates, in which case the result will be the same as in Bylaw 8.5.3.1.

8.5.3.2.2 The House of Delegates may terminate the representation of the specialty society or the professional interest medical association in the House of Delegates. The specialty society or the professional interest medical association shall remain a member of the SSS, pursuant to the provisions of the Standing Rules of the SSS. The specialty society or the professional interest medical association may apply for reinstatement in the House of Delegates, through the SSS, when it believes it can comply with all of the current guidelines for representation in the House of Delegates.

REPORT OF THE COUNCIL ON CONSTITUTION AND BYLAWS

CCB Report 1, November 2020

Subject: Bylaw Accuracy: Name Change for Accreditation Body for Osteopathic Medical Schools

Presented by: Madelyn E. Butler, MD, Chair

Referred to: Reference Committee on Amendments to Constitution and Bylaws

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Recently, the Council learned that existing bylaw language regarding the accrediting body for osteopathic medical schools is inaccurate. The Commission on Osteopathic College Accreditation is the U.S. Department of Education-recognized accreditor; the American Osteopathic Association is the sponsoring organization.

The Council has prepared this report with appropriate bylaw amendments to ensure that the AMA Constitution and Bylaws remains an accurate document. The Council also will amend the glossary to the Bylaws which references American Osteopathic Association accreditation of medical schools.

RECOMMENDATIONS

The Council on Constitution and Bylaws recommends that the following amendments to the AMA Bylaws be adopted and that the remainder of this report be filed. Adoption requires the affirmative vote of two-thirds of the members of the House of Delegates present and voting.

1.1 Categories.

Categories of membership in the American Medical Association (AMA) are: Active Constituent, Active Direct, Affiliate, Honorary, and International.

1.1.1 Active Membership.

1.1.1.1 Active Constituent. Constituent associations are recognized medical associations of states, commonwealths, districts, territories, or possessions of the United States of America. Active constituent members are members of constituent associations who are entitled to exercise the rights of membership in their constituent associations, including the right to vote and hold office, as determined by their respective constituent associations and who meet one of the following requirements:

a. Possess the United States degree of doctor of medicine (MD) or doctor of osteopathic medicine (DO), or a recognized international equivalent.

b. Are medical students in educational programs provided by a college of medicine or osteopathic medicine accredited by the Liaison Committee on Medical Education or the Commission on Osteopathic College Accreditation

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~~American Osteopathic Association~~ leading to the MD or DO degree. This includes those students who are on an approved sabbatical, provided that the student will be in good standing upon returning from the sabbatical.

1.1.1.2 **Active Direct.** Active direct members are those who apply for membership in the AMA directly. Applicants residing in states where the constituent association requires all of its members to be members of the AMA are not eligible for this category of membership unless the applicant is serving full time in the Federal Services that have been granted representation in the House of Delegates. Active direct members must meet one of the following requirements:

a. Possess the United States degree of doctor of medicine (MD) or doctor of osteopathic medicine (DO), or a recognized international equivalent.

b. Are medical students in educational programs provided by a college of medicine or osteopathic medicine accredited by the Liaison Committee on Medical Education or the Commission on Osteopathic College Accreditation ~~American Osteopathic Association~~ leading to the MD or DO degree. This includes those students who are on an approved sabbatical, provided that the student will be in good standing upon returning from the sabbatical.

(Modify Bylaws)

REPORT OF THE COUNCIL ON CONSTITUTION AND BYLAWS

CCB Report 2, November 2020

Subject: Discordance between Policy and Bylaws--CEJA Membership on AMA Committee on Conduct at AMA Meetings and Events

Presented by: Madelyn E. Butler, MD, Chair

Referred to: Reference Committee on Amendments to Constitution and Bylaws

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At the 2019 Annual Meeting, our House of Delegates adopted Policy H-140.837, "Policy on Conduct at AMA Meetings and Events." This policy establishes a Committee on Conduct at AMA Meetings and Events (CCAM), "to be comprised of 5-7 AMA members who are nominated by the Office of General Counsel (or through a nomination process facilitated by the Office of General Counsel) and approved by the Board of Trustees. The CCAM should include one member of the Council on Ethical and Judicial Affairs (CEJA)."

Current AMA Bylaw 6.5.5.1, however, states in part that "Members elected to the Council on Ethical and Judicial Affairs shall resign all other positions held by them in the AMA upon their election to the Council. No member, while serving on the Council on Ethical and Judicial Affairs, shall be a delegate or an alternate delegate to the House of Delegates, or an Officer of the AMA, or serve on any other council, committee, or as representative to or Governing Council member of an AMA Section."

The bylaw prohibition against a member of CEJA serving in any other AMA leadership or governance capacity was adopted by the House at the 1976 Annual Meeting, when CEJA was known as the Judicial Council. It and a similar provision that pertains to members of the Board of Trustees ensure a separation and independence of function for AMA's judicial, executive and legislative activities. The Council on Constitution and Bylaws understand that the CEJA member is an integral member of the CCAM. Also, one of the CCAM's options is referral to CEJA for further review and action.

The Council has developed an amendment to the AMA Bylaws for House consideration to allow service on the CCAM by a CEJA member. The Council will define the purpose of the CCAM in the glossary to the Bylaws.

RECOMMENDATIONS

The Council on Constitution and Bylaws recommends: 1) that the following amendments to the AMA Constitution and Bylaws be adopted; and 2) that the remainder of this report be filed. Adoption requires the affirmative vote of two-thirds of the members of the House of Delegates present and voting.

6.5 Council on Ethical and Judicial Affairs.

6.5.5 Membership.

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6.5.5.1 Nine active members of the AMA, one of whom shall be a resident/fellow physician and one of whom shall be a medical student. Members elected to the Council on Ethical and Judicial Affairs shall resign all other positions held by them in the AMA upon their election to the Council. No member, while serving on the Council on Ethical and Judicial Affairs, shall be a delegate or an alternate delegate to the House of Delegates, or an Officer of the AMA, or serve on any other council, committee, or as representative to or Governing Council member of an AMA Section, with the exception of service on the Committee on Conduct at AMA Meetings (CCAM) as specified in AMA Policy.

(Modify Bylaws)

RELEVANT AMA POLICY

H-140.837, Policy on Conduct at AMA Meetings and Events
It is the policy of the American Medical Association that all attendees of AMA hosted meetings, events and other activities are expected to exhibit respectful, professional, and collegial behavior during such meetings, events and activities, including but not limited to dinners, receptions and social gatherings held in conjunction with such AMA hosted meetings, events and other activities. Attendees should exercise consideration and respect in their speech and actions, including while making formal presentations to other attendees, and should be mindful of their surroundings and fellow participants.
Any type of harassment of any attendee of an AMA hosted meeting, event and other activity, including but not limited to dinners, receptions and social gatherings held in conjunction with an AMA hosted meeting, event or activity, is prohibited conduct and is not tolerated. The AMA is committed to a zero tolerance for harassing conduct at all locations where AMA business is conducted. This zero tolerance policy also applies to meetings of all AMA sections, councils, committees, task forces, and other leadership entities (each, an AMA Entity), as well as other AMA-sponsored events. The purpose of the policy is to protect participants in AMA-sponsored events from harm.
Definition
Harassment consists of unwelcome conduct whether verbal, physical or visual that denigrates or shows hostility or aversion toward an individual because of his/her race, color, religion, sex, sexual orientation, gender identity, national origin, age, disability, marital status, citizenship or otherwise, and that: (1) has the purpose or effect of creating an intimidating, hostile or offensive environment; (2) has the purpose or effect of unreasonably interfering with an individual s participation in meetings or proceedings of the HOD or any AMA Entity; or (3) otherwise adversely affects an individual s participation in such meetings or proceedings or, in the case of AMA staff, such individual s employment opportunities or tangible job benefits.
Harassing conduct includes, but is not limited to: epithets, slurs or negative stereotyping; threatening, intimidating or hostile acts; denigrating jokes; and written, electronic, or graphic material that denigrates or shows hostility or aversion toward an individual or group and that is placed on walls or elsewhere on the AMA s premises or at the site of any AMA meeting or circulated in connection with any AMA meeting.
Sexual Harassment
Sexual harassment also constitutes discrimination, and is unlawful and is absolutely prohibited. For the purposes of this policy, sexual harassment includes:
- making unwelcome sexual advances or requests for sexual favors or other verbal, physical, or visual conduct of a sexual nature; and
- creating an intimidating, hostile or offensive environment or otherwise unreasonably interfering with an individual s participation in meetings or proceedings of the HOD or any AMA Entity or, in the case of AMA staff, such individual s work performance, by instances of such conduct.
Sexual harassment may include such conduct as explicit sexual propositions, sexual innuendo, suggestive comments or gestures, descriptive comments about an individual s physical appearance, electronic stalking or lewd messages, displays of foul or obscene printed or visual material, and any unwelcome physical contact.
Retaliation against anyone who has reported harassment, submits a complaint, reports an incident witnessed, or participates in any way in the investigation of a harassment claim is forbidden. Each complaint of

harassment or retaliation will be promptly and thoroughly investigated. To the fullest extent possible, the AMA will keep complaints and the terms of their resolution confidential.

Operational Guidelines

The AMA shall, through the Office of General Counsel, implement and maintain mechanisms for reporting, investigation, and enforcement of the Policy on Conduct at AMA Meetings and Events in accordance with the following:

1. Conduct Liaison and Committee on Conduct at AMA Meetings and Events (CCAM)

The Office of General Counsel will appoint a Conduct Liaison for all AMA House of Delegates meetings and all other AMA hosted meetings or activities (such as meetings of AMA councils, sections, the RVS Update Committee (RUC), CPT Editorial Panel, or JAMA Editorial Boards), with responsibility for receiving reports of alleged policy violations, conducting investigations, and initiating both immediate and longer-term consequences for such violations. The Conduct Liaison appointed for any meeting will have the appropriate training and experience to serve in this capacity, and may be a third party or an in-house AMA resource with assigned responsibility for this role. The Conduct Liaison will be (i) on-site at all House of Delegates meetings and other large, national AMA meetings and (ii) on call for smaller meetings and activities. Appointments of the Conduct Liaison for each meeting shall ensure appropriate independence and neutrality, and avoid even the appearance of conflict of interest, in investigation of alleged policy violations and in decisions on consequences for policy violations.

The AMA shall establish and maintain a Committee on Conduct at AMA Meetings and Events (CCAM), to be comprised of 5-7 AMA members who are nominated by the Office of General Counsel (or through a nomination process facilitated by the Office of General Counsel) and approved by the Board of Trustees. The CCAM should include one member of the Council on Ethical and Judicial Affairs (CEJA). The remaining members may be appointed from AMA membership generally, with emphasis on maximizing the diversity of membership. Appointments to the CCAM shall ensure appropriate independence and neutrality, and avoid even the appearance of conflict of interest, in decisions on consequences for policy violations. Appointments to the CCAM should be multi-year, with staggered terms.

2. Reporting Violations of the Policy

Any persons who believe they have experienced or witnessed conduct in violation of Policy H-140.837, Policy on Conduct at AMA Meetings and Events during any AMA House of Delegates meeting or other activities associated with the AMA (such as meetings of AMA councils, sections, the RVS Update Committee (RUC), CPT Editorial Panel or JAMA Editorial Boards) should promptly notify the (i) Conduct Liaison appointed for such meeting, and/or (ii) the AMA Office of General Counsel and/or (iii) the presiding officer(s) of such meeting or activity.

Alternatively, violations may be reported using an AMA reporting hotline (telephone and online) maintained by a third party on behalf of the AMA. The AMA reporting hotline will provide an option to report anonymously, in which case the name of the reporting party will be kept confidential by the vendor and not be released to the AMA. The vendor will advise the AMA of any complaint it receives so that the Conduct Liaison may investigate.

These reporting mechanisms will be publicized to ensure awareness.

3. Investigations

All reported violations of Policy H-140.837, Policy on Conduct at AMA Meetings and Events, pursuant to Section 2 above (irrespective of the reporting mechanism used) will be investigated by the Conduct Liaison. Each reported violation will be promptly and thoroughly investigated. Whenever possible, the Conduct Liaison should conduct incident investigations on-site during the event. This allows for immediate action at the event to protect the safety of event participants. When this is not possible, the Conduct Liaison may continue to investigate incidents following the event to provide recommendations for action to the CCAM. Investigations should consist of structured interviews with the person reporting the incident (the reporter), the person targeted (if they are not the reporter), any witnesses that the reporter or target identify, and the alleged violator.

Based on this investigation, the Conduct Liaison will determine whether a violation of the Policy on Conduct at AMA Meetings and Events has occurred.

All reported violations of the Policy on Conduct at AMA Meetings and Events, and the outcomes of investigations by the Conduct Liaison, will also be promptly transmitted to the AMA s Office of General Counsel (i.e. irrespective of whether the Conduct Liaison determines that a violation has occurred).

4. Disciplinary Action

If the Conduct Liaison determines that a violation of the Policy on Conduct at AMA Meetings and Events has occurred, the Conduct Liaison may take immediate action to protect the safety of event participants, which may include having the violator removed from the AMA meeting, event or activity, without warning or refund.

Additionally, if the Conduct Liaison determines that a violation of the Policy on Conduct at AMA Meetings and Events has occurred, the Conduct Liaison shall report any such violation to the CCAM, together with recommendations as to whether additional commensurate disciplinary and/or corrective actions (beyond those taken on-site at the meeting, event or activity, if any) are appropriate.

The CCAM will review all incident reports, perform further investigation (if needed) and recommend to the Office of General Counsel any additional commensurate disciplinary and/or corrective action, which may include but is not limited to the following:

- Prohibiting the violator from attending future AMA events or activities;
- Removing the violator from leadership or other roles in AMA activities;
- Prohibiting the violator from assuming a leadership or other role in future AMA activities;
- Notifying the violator s employer and/or sponsoring organization of the actions taken by AMA;
- Referral to the Council on Ethical and Judicial Affairs (CEJA) for further review and action;
- Referral to law enforcement.

The CCAM may, but is not required to, confer with the presiding officer(s) of applicable events activities in making its recommendations as to disciplinary and/or corrective actions. Consequence for policy violations will be commensurate with the nature of the violation(s).

5. Confidentiality

All proceedings of the CCAM should be kept as confidential as practicable. Reports, investigations, and disciplinary actions under Policy on Conduct at AMA Meetings and Events will be kept confidential to the fullest extent possible, consistent with usual business practices.

6. Assent to Policy

As a condition of attending and participating in any meeting of the House of Delegates, or any council, section, or other AMA entities, such as the RVS Update Committee (RUC), CPT Editorial Panel and JAMA Editorial Boards, or other AMA hosted meeting or activity, each attendee will be required to acknowledge and accept (i) AMA policies concerning conduct at AMA HOD meetings, including the Policy on Conduct at AMA Meetings and Events and (ii) applicable adjudication and disciplinary processes for violations of such policies (including those implemented pursuant to these Operational Guidelines), and all attendees are expected to conduct themselves in accordance with these policies.

Additionally, individuals elected or appointed to a leadership role in the AMA or its affiliates will be required to acknowledge and accept the Policy on Conduct at AMA Meetings and Events and these Operational Guidelines.

REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Report 1, November 2020

Subject: Amendment to Opinion 1.2.2, "Disruptive Behavior and Discrimination by Patients"

Presented by: Monique A. Spillman, MD, Chair

Referred to: Reference Committee on Amendments to Constitution and Bylaws

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Policy D-65.991, "Discrimination against Physicians by Patients," directs the American Medical Association (AMA) to study: "(1) the prevalence, reasons for, and impact of physician, resident/fellow and medical student reassignment based upon patients' requests; (2) hospitals' and other health care systems' policies or procedures for handling patient bias; and (3) the legal, ethical, and practical implications of accommodating or refusing such reassignment requests."

The following analysis by the Council on Ethical and Judicial Affairs (CEJA) examines ethics concerns in this area and offers guidance for physicians when they encounter patients who refuse or demand care based on what the patient perceives to be the physician's personal, rather than professional, characteristics. The Council recognizes that surrogates and family members may also engage in conduct that is disrespectful, derogatory or prejudiced but focuses here on such conduct directed toward physicians in light of physicians' unique fiduciary obligations to patients. Based on its deliberations and review of relevant literature, CEJA recommends that D-65.991 be addressed by amending Opinion 1.2.2, "Disruptive Behavior by Patients."

REASONS MATTER: DISTINGUISHING PREFERENCE FROM PREJUDICE

It is not known how often patients discriminate against or sexually harass physicians (and other health care personnel) as data are not systematically collected or publicly reported. However, a growing number of studies and an expanding body of anecdotal reports suggest that such behavior is pervasive in health U.S. care [e.g., 1–7]. In the words of one analyst discrimination by patients is medicine's "open secret" [4].

A survey of physicians conducted jointly by Medscape and WebMD in 2017 found that 59% of respondents overall heard an offensive remark from a patient about the physician's personal characteristic, including comments about the physician's weight and political views in addition to comments about age, ethnicity or national origin, gender, race, and sexual orientation [8]. Emergency physicians were significantly more likely to report having experienced bias (83%) than primary care physicians (62%) or specialists (59%). Among respondents, more African American (70%), Asian (69%), and Hispanic (63%) physicians reported hearing biased comments compared to white physicians (55%). The same survey found that male and female physicians experience bias differently, notably in terms of the physician characteristics targeted. For example, female respondents reported experiencing bias more often on the basis of their gender or age than male

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physicians (41% versus 6% and 36% versus 23%, respectively), while male physicians experienced bias based on their ethnicity or religion somewhat more often than their female colleagues (24% versus 20% and 15% versus 8%, respectively) [8].

A variety of factors can result in patient behavior that is disrespectful, derogatory, or prejudiced, including mental illness or incapacity or individual life experience, as well as personal beliefs and bias. Different factors carry different implications for whether, or to what degree, patients can reasonably be held responsible for their problematic behavior. It would not be appropriate to hold patients responsible or blameworthy for statements or actions that are beyond their control in the moment [9]. Thus, physicians' first response to problematic behavior should be to explore insofar as possible the reasons underlying the behavior so that they can identify, appreciate, and address potentially treatable conditions. Behavior that outright threatens the safety of health care personnel or other patients calls for prompt action to de-escalate the situation or remove the threat [e.g., 10, 11].

Lingering systemic racism and health disparities in the United States shape the experience of both patients and health care professionals, especially those from nondominant communities [1, 3, 12]. Against this background, patients' reasons for refusing care by a specific physician or requesting a different physician cover a "spectrum of justifiability" [13].

Requests not to be treated by a specific physician may reflect fears or concerns about care that are rooted in systemic discrimination against members of the patient's community or traumatic experiences in a patient's personal history [4, 9, 13]. Requests *for* a physician concordant in ethnicity, religion, or gender may reflect cultural preferences or traditions, for example, a Muslim woman's preference to receive care from a female physician. Such requests may also reflect patients' experience, or reasonable expectation, that they will be better understood by a physician "like them." Evidence suggests that at least for some patients, racial/ethnic or cultural concordance between patient and physician supports more effective communication, enhances satisfaction, and may have clinical benefit [4]. In these situations, it is appropriate to respect patient concerns and preferences, when doing so is clinically feasible.

Requests for an alternative physician based solely on prejudice against personal characteristics of the physician, however, are not justifiable and need not—perhaps should not—be accommodated [4, 9, 13]. Requests based on a physician's (actual or perceived) race, ethnicity or national origin, creed, gender identity, sexual orientation, disability, or other personal characteristic are ethically objectionable.

For physicians and health care institutions faced with patients' strongly held views about who should provide care, then, a central task is distinguishing when a patient's stated preference rests on ethically acceptable reasons and when it reflects unacceptable bias or prejudice [2, 9]. One challenge in making such an assessment, of course, is that in some situations time constraints or other factors may preclude being able to explore the factors that influence a patient's behavior.

PROTECTING INTERESTS, MINIMIZING HARMS

Patient refusals of care or demands for an alternative clinician challenge physicians, and the institutions in which they work, to protect both the interests of patients and those of physicians. In such situations, physicians' professional obligations to promote patient well-being, respect patients as moral agents and autonomous decision makers, and fulfill the duty to treat without discrimination come into tension in potentially novel ways. Nor do these responsibilities align with physicians' own interests in upholding professional autonomy and themselves being free from

discrimination. There are potential harms to both parties whether the physician/institution accommodates bigoted requests and removes the physician or requires patient and physician to engage one another in a troubled relationship.

Physicians' fiduciary obligations are fundamental. Physicians are expected to promote patients' interests and well-being without regard to individuals' personal characteristics or behavior, up to and including providing care to individuals whose behavior may be morally repugnant [13, 14]. But whether continuing to provide care or allowing oneself to be withdrawn from a case better fulfills that fiduciary obligation is only intelligible in the individual case. So too are interpretations of how a physician is to respect the autonomy of a patient who asserts moral agency in the form of prejudice, and what the duty to care entails when the recipient behaves in a way that, arguably, is not morally worthy or acceptable. Reaching sound determinations in these matters cannot be done by rote; instead, as one commentator observed, doing so calls for "nuanced ethical judgment" [13].

The American Medical Association *Code of Medical Ethics* enjoins physicians to provide "competent medical care, with compassion and respect for human dignity and rights" [15]. It also acknowledges that, except in emergencies, physicians shall be "free to choose whom to serve" [16].

The *Code* further delineates the conditions under which a physician may decline to accept a new patient (or provide a specific service to an existing patient [17]. These include when the care requested is outside the physician's competence or scope of practice; when the physician lacks the resources to provide safe, competent, respectful care for the individual; and when meeting this patient's medical needs seriously compromises the physician's ability to provide the care needed by other patients. Importantly, guidance acknowledges that, except in emergencies, a physician may decline to provide care when the patient "is abusive or threatens the physician, staff, or other patients" [17]. At the same time, the *Code* provides that physicians may terminate a relationship with a patient who "uses derogatory language or acts in a prejudicial manner *only if the patient will not modify the behavior*," in which case the physician should arrange to transfer the patient's care [emphasis added] [18].

One approach to determining the ethically appropriate response to prejudiced behavior by patients is to explore the harms—to patients, to physicians and other health care professionals, and to health care institutions and even the wider community—that can result from different possible responses. Who, that is, is harmed by a given response, and in what way?

Thwarting the requests of seemingly bigoted patients for alternative clinicians exposes patients to possible delays in care and poorer health outcomes, should they choose to leave the facility (with or without assistance from the institution). If they do not, or cannot leave, patients are subjected to the experience of receiving medical care from a physician against whom they are biased. Distinguishing between a preference for a different physician and a demand for one is important in thinking about the nature and degree of harm the patient may experience. A preference is "an expression of an inclination that may be gratified or not"; a demand is "more of an ultimatum, in which failure to meet its indicia may be met not only with disappointment but also anger and resentment" [9]. Further, it is important to determine why the patient is making the request/demand, which may have a clinical source, such as delirium, dementia, or psychosis [4, 13], that is outside the patient's control, as opposed to being a stance the patient has voluntarily adopted. And as noted previously, requests/demands may also reflect life experiences that color a patient's response to clinicians for which accommodation may be appropriate.

For physicians and other clinicians, acceding to bigoted demands can send powerful, but unintended and potentially hurtful messages—that minority or female physicians are "not as good"

as white male physicians or that patient satisfaction scores are more important to the institution than promoting a safe and ethical working environment [1, 19]. Accommodating bigotry can make institutions complicit in discrimination [19], in the process tacitly condoning or reinforcing an institutional culture that routinely subjects minority physicians to "barrages of microaggressions and biases" or expects them to serve as "race/ethnicity ambassadors" [1].

Institutions that fail to support staff in the face of prejudice convey that complying with patient demands "is more important than respecting the dignity of both their staff members and the majority of patients, who do not hold such repugnant views (or at least do not openly act on them)" [9]. Institutions, some argue, "have a duty to present a moral face to their community by refusing to honor bigoted or prejudicial requests or demands as a matter of course, up to and including declining to care for such patients (except in emergency situations)" [9, cp. 20].

Regardless of how their institutions respond, for many minority health care professionals, interactions with prejudiced patients are painful and degrading and contribute to moral distress and burnout [4]. *Requiring* physicians to provide care when a patient has openly expressed bias is not ethically tenable. As one physician described his own experience of ultimately declining to work with a particular patient, "After years of feeling that my race was a nonissue, I was subjected to the same kind of hurtful name-calling that I faced in childhood. Even as self-loathing for not having thicker skin began to creep in, I decided that, on this occasion, my feelings would count" [21]. Absent unique situations, institutions should allow physicians to control the decision about whether they will continue to provide care [19]. Some have argued that institutions have a responsibility to monitor such encounters and their effects on an ongoing basis "with the goal of supporting staff and improving the handling of these situations" [4].

Whether patient prejudice against physicians adversely affects quality of care has not been well studied. One experimental study among family practice physicians in the Netherlands concluded that "disruptive behaviours displayed by patients seem to induce doctors to make diagnostic errors" [22]. A companion study attributed this to the fact that the "mental resources" devoted to dealing with patient behavior interfered with "adequate processing of clinical findings" [23]. Evidence does indicate that physician "burnout" can adversely affect patient outcomes [e.g., 24–26]. To the extent that being the target of patient prejudice contributes to the emotional exhaustion, sense of depersonalization, and sense of low personal accomplishment characteristic of burnout, it is reasonable to expect biased behavior to be associated with lower quality of care, particularly if targeted physicians feel they do not have the support of their colleagues or institutions when bias occurs [1, 21, 27, 28].

LAW AND POLICY

Legally, at the federal level how a health care institution responds to prejudiced behavior by patients falls within the scope of the *Emergency Medical Treatment and Active Labor Act* (EMTALA) and by anti-discrimination law in Title VII of the *Civil Rights Act of 1965* (CRA). For example, when weighing patient requests for accommodation based on the physician's race, hospitals are in the position of having to meet EMTALA requirements while respecting physicians' employment rights [4]. Hospitals can "inform patients of their right to seek care elsewhere and their responsibility to refrain from hateful speech," but their ability "to remove physicians in response to race-based requests is circumscribed" [4]. Although physicians have not sued under CRA [4], in a case that ultimately settled, an African-American nurse in Michigan sued her employer when she was barred from caring for a white baby at the request of the child's father, a white supremacist [29].

At present, relatively few institutions have formal policy or procedures for dealing with incidents of patient prejudice, although an increasing number broadly enjoin patients to behave in a respectful manner under policies delineating patient rights and responsibilities and indicate that misconduct will not be tolerated [e.g., 30, 31]. Two notable exceptions are Toronto's University Health Network (UHN) and Mayo Clinic, both of which explicitly seek to balance the interests of patients and health care personnel.

UHN's *Caregiver Preference Guidelines* focus on three key questions: whether the preference for an alternative clinician appears to discriminate against the health care professional on the basis of race, ancestry or other characteristic as provided in the *Ontario Human Rights Code*; whether the request is clinically feasible and/or indicated to a reasonable degree; and whether the clinician wishes to excuse themselves from caring for the patient [27]. Mayo's recently adopted policy directs staff to step in when they observe behavior that is not in keeping with Mayo Clinic values; address the behavior with the patient, focusing the conversation on Mayo's published values; explain the institution's expectations and set boundaries with the individual; and report the incident to supervisors and document it via a patient misconduct form [27].

RECOMMENDATION

In light of the foregoing analysis, the Council on Ethical and Judicial Affairs recommends that Policy D-65.991, "Discrimination against Physicians by Patients," be rescinded; that the title of Opinion 1.2.2, be amended to read "Disruptive Behavior and Discrimination by Patients"; that the body of Opinion 1.2.2 be amended by addition and deletion as follows; and the remainder of this report be filed:

> The relationship between patients and physicians is based on trust and should serve to promote patients' well-being while respecting ~~their~~ the dignity and rights of both patients and physicians.
>
> Disrespectful, ~~or~~ derogatory, or prejudiced, language or conduct, or prejudiced requests for accommodation of personal preferences on the part of either ~~physicians~~ patients or physicians can undermine trust and compromise the integrity of the patient-physician relationship. It can make individuals who themselves experience (or are members of populations that have experienced) prejudice reluctant to seek care as patients or to provide care as health care professionals, and create an environment that strains relationships among patients, physicians, and the health care team.
>
> Trust can be established and maintained only when there is mutual respect. Therefore, in their interactions with patients, physicians should:
>
> (a) Recognize that disrespectful, derogatory, or prejudiced language or conduct can cause psychological harm to those ~~they target~~ who are targeted.
>
> (b) Always treat patients with compassion and respect.
>
> (c) Explore the reasons for which a patient behaves in disrespectful, derogatory, or prejudiced ways insofar as possible. Physicians should identify, appreciate, and address potentially treatable clinical conditions or personal experiences that influence patient behavior. Regardless of cause, when a patient's behavior threatens the safety of health care personnel or other patients, steps should be taken to de-escalate or remove the threat.

(d) Prioritize the goals of care when deciding whether to decline or accommodate a patient's ~~prejudiced~~ request for an alternative physician. Physicians should recognize that some requests for a concordant physician may be clinically useful or promote improved outcomes.

(e) Within the limits of ethics guidance, trainees should not be expected to forgo valuable learning opportunities solely to accommodate prejudiced requests.

(f) Make patients aware that they are able to seek care from other sources if they persist in opposing treatment from the physician assigned. If patients require immediate care, inform them that, unless they exercise their right to leave, care will be provided by appropriately qualified staff independent of their expressed preference.

(g) Terminate the patient-physician relationship ~~who uses derogatory language or acts in a prejudiced manner~~ only when the patient will not modify disrespectful, derogatory or prejudiced behavior that is within the patient's control, in keeping with ethics guidance.

Physicians, especially those in leadership roles, should encourage the institutions with which they are affiliated to:

(h) Be mindful of the messages the institution conveys within and outside its walls by how it responds to prejudiced behavior by patients.

(i) Educate staff, patients, and the community about the institution's expectations for behavior.

(j) Promote a safe and respectful working environment and formally set clear expectations for how disrespectful, derogatory, or prejudiced behavior by patients will be managed.

(k) Clearly and openly support physicians, trainees, and facility personnel who experience prejudiced behavior and discrimination by patients, including allowing physicians, trainees, and facility personnel to decline to care for those patients, without penalty, who have exhibited discriminatory behavior specifically toward them.

(l) Collect data regarding incidents of discrimination by patients and their effects on physicians and facility personnel on an ongoing basis and seek to improve how incidents are addressed to better meet the needs of patients, physicians, other facility personnel, and the community.

(Modify HOD/CEJA Policy)

Fiscal Note: Less than $500

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REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Report 2, November 2020

Subject: Amendment to Opinion 8.7, "Routine Universal Immunization of Physicians"

Presented by: Monique A. Spillman, MD, Chair

Referred to: Reference Committee on Amendments to Constitution and Bylaws

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Growing public skepticism about immunization, falling rates of immunization and the associated resurgence of infectious childhood diseases, and the emergence of new zoonotic diseases that have spread rapidly through human populations underscore the importance of physicians' responsibilities to protect the welfare not only of individual patients, but also of communities. Given heightened awareness of physicians' public health role, the Council on Ethical and Judicial Affairs reviewed ethics guidance set out in Opinion 8.7, "Routine Universal Immunization of Physicians." The following report summarizes the council's deliberations and clarifies its guidance on physicians' responsibility to accept immunization when a safe, effective vaccine is available, especially for a disease that has potential to become epidemic or pandemic.

VACCINATION OF HEALTH CARE WORKERS

Vaccination of health care workers, including physicians, is a logical measure to decrease transmission of vaccine-preventable diseases during patient encounters. Yet despite extensive education on the benefit of vaccination, recommendations from the Society for Healthcare Epidemiology of America [1,2], and strong efforts by health care institutions to promote this preventive measure, rates of vaccination among health care workers can be surprisingly low, especially for seasonal influenza [3].

Requiring vaccination of health care workers does increase vaccination rates for seasonal influenza [3,4]. One multispecialty medical center achieved an influenza vaccination rate of approximately 98 percent among health care workers by requiring vaccination, with exemptions for medical and religious reasons [3]. A study comparing medical centers with and without an influenza vaccine mandate showed a 30 percent difference in vaccination rate between the two groups [4]. The study also found a decrease in days absent for symptomatic influenza-like illness (ILI) for the mandatory vaccination group.

However, the available evidence, most of which comes from observational studies, is mixed regarding the extent to which mandated vaccination of physicians and other health care workers benefits patients [5,6,7]. One meta-analysis of studies from facilities that offered influenza vaccination reported a reduction in all-cause mortality and ILI, but did not show changes in hospitalizations and confirmed cases of influenza [8]. A Cochrane meta-analysis that focused on assessing whether influenza vaccination for health care workers in long-term care institutions similarly did not find significant effect of vaccination in decreasing hospitalizations or confirmed

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cases of influenza among residents [9]. There is a paucity of randomized controlled trials that directly assess the effect of vaccination mandates or campaigns on patient health. One European trial that assessed the impact of a multi-faceted influenza vaccination program for health care workers did find a 5.8 percent reduction in nosocomial cases of influenza and/or pneumonia among hospitalized patients [10].

Critics have observed significant methodological flaws in these studies, including multiple sources of bias and violation of the principle of dilution, casting doubt on the studies' validity [6,7]. This has led proposals for alternatives to mandatory vaccination of health care workers, such as strategies to reduce "presenteeism" (working while ill), which can drastically affect the transmission of influenza [6].

LAW & POLICY

Law and policy throughout the United States require immunizations or other documentation of immunity as a condition of public school attendance and, in some cases, as a condition of employment [11]. Historically, in decisions in *Jacobson v. Massachusetts* [12] and *Zucht v. King* [13], the U.S. Supreme Court has held that states can mandate immunizations to protect public health, but, if they do, they must also allow medical exemptions. Courts have further held that the exemption process must not violate the individual's constitutional rights. Thus, most states must also provide for non-medical exemptions to accommodate religious beliefs of some individuals who oppose immunization [14]. Some states also provide non-medical exemptions for individuals who oppose immunization for personal or philosophical reasons [14].

State laws mandating vaccination of health care workers vary across the country. For example, as of 2017, eight states require that a hospital "ensure" its health care personnel are vaccinated for seasonal influenza; 11 others require only that hospitals "offer" a flu vaccine to their employees [15]. States also vary with respect to whether they recognize exemptions and which exemptions—medical, religious, philosophical—they allow [15].

Employers of health care workers may implement their own mandatory vaccination programs under contractual employment law, as hundreds of facilities around the country have done [16]. Title VII of the Civil Rights Act prohibit religious discrimination and thus requires that employers consider religious exemptions to vaccination and implement such exemptions so as to ensure that any vaccine mandate is nondiscriminatory. Employers must also generally ensure that mandatory vaccination programs allow appropriate medical exemptions for individuals with a disability that would be adversely affected by vaccination [17]. In requiring employers to keep the workplace free of hazards, the Occupational Health and Safety Act may impose a duty on employers to encourage or mandate vaccination to prevent employees from contracting or spreading serious diseases in the workplace [17].

Policies of the AMA House of Delegates generally support physician immunization. H-225.959, Staff Medical Testing, maintains that, when local statute and regulation do not provide for immunization of health care personnel, hospital medical staffs should determine which tests or immunizations are to be required for members of the medical staff and "delineate under what circumstances such tests or immunizations should be administered."

Policy also opposes non-medical exemptions, including non-medical exemptions from mandated pediatric immunizations. H-440.970, Non-Medical Exemptions from Immunization, supports eliminating non-medical exemptions from immunization and encourage physicians to grant exemption requests "only when medical contraindications are present." AMA policy further

supports restricting the activity of medical staff who are not immunized. In the specific context of Hepatitis B, for example, H-440.949, Immunity to Hepatitis B Virus, requires that medical staff who do not have immunity from a natural infection or who have not been immunized, "either be immunized or refrain from performing invasive procedures."

PHYSICIANS' ETHICAL RESPONSIBILITIES

Physicians have well-recognized professional responsibilities to protect the health of their individual patients (Principle VIII, Opinion 8.11, "Health Promotion and Disease Prevention"). They also have responsibilities to protect the health of the community at large (Principle VII, Opinion 8.3, "Physicians' Responsibilities in Disaster Response and Preparedness"). And they have an obligation to protect their own health and that of their colleagues and other members of the health care workforce (Principle X, Opinion 9.3.1, "Physician Health and Wellness"; Opinion 8.3; Opinion 8.4, "Ethical Use of Quarantine and Isolation").

Responsibility to Protect

In the context of a health care crisis—e.g., epidemic, disaster, or terrorism—physicians' ethical obligation is to subordinate their personal interests to those of their patients. Their first duty, set out in Opinion 8.3, is to "provide urgent medical care . . . even in the face of greater than usual risk to physicians' own safety, health or life." Opinion 8.3 recognizes that the physician workforce itself is not an unlimited resource, however. Thus, physicians are expected to assess the risks of providing care to individual patients in the moment against the ability to provide care in the future. Opinion 8.4 similarly requires physicians to "protect their own health to ensure that they remain able to provide care."

Taken together, these considerations argue strongly for a responsibility on the part of physicians to accept immunization against vaccine-preventable diseases—unless there are compelling reasons for the individual not to receive a specific vaccine. Medical exemptions from vaccination are intended to prevent harm to individuals who are at increased risk of adverse events from the vaccine because of underlying conditions. Vaccines are medically contraindicated for individuals who have histories of severe allergic reactions from prior doses of vaccine. Many underlying conditions also place individuals at increased risk of complications from certain vaccines as well as from the diseases they prevent. For example, individuals who are severely immunocompromised should not be inoculated with vaccines containing live attenuated viruses, such as the varicella zoster (chicken pox or shingles) or measles, mumps, and rubella (MMR) vaccines [18]. Individuals for whom vaccines are medically contraindicated are protected from exposure to vaccine-preventable diseases through herd immunity by ensuring high rates of coverage among the rest of the population.

The relative strength of the responsibility to accept vaccination is conditioned on several factors, including how readily a given disease is transmitted; what medical risk the disease represents for patients, colleagues, and society; the individual's risk of occupational exposure; the safety and efficacy of available vaccine(s); the effectiveness and appropriateness of immunization relative to other strategies for preventing disease transmission; the medical value or possible contraindication of immunization for the individual [19], and the prevalence of the disease. Unless medically contraindicated, the more readily transmissible the disease and the greater the risk to patients and others with whom the physician comes into contact relative to risks of immunization to the physician, the stronger the physician's duty to accept immunization. Physicians should not be required to accept immunization with a novel agent until and unless there is a body of scientifically well-regarded evidence of safety and efficacy.

It is not ethically problematic to exempt from vaccination an individual with medical contraindications. Ethical concerns arise when individuals are allowed to decline vaccinations for non-medical reasons. The rationale for non-medical exemptions must strike a prudent balance among multiple interests and values, including the welfare of individuals, groups and communities; respect for civil liberties and autonomy; and fairness.

In general, society respects individuals' freedom to make health care decisions for themselves in keeping with their religious commitments, and within limits, decisions based on personal beliefs that are not encoded in specific religious doctrine per se. Ideally, those beliefs will comprise a "substantive, coherent, and relatively stable set of values and principles" to which the individual is genuinely committed and that are reflected broadly in the individual's decisions and actions [20].

Individuals who have direct patient contact should rightly expect their autonomy to be respected when their personal health choices do not put others at risk of harm [21]. In certain circumstances physicians should refrain from being immunized in order to protect the well-being of their patients; for example, if receiving a live virus vaccine would put immune-compromised or never-immunized patients at risk during the time the physician may transmit the attenuated virus.

Aside from these limited circumstances, however, physicians and other health care workers who decline to be vaccinated do put others at risk for vaccine-preventable disease. In deciding whether to decline vaccination, therefore, physicians have a responsibility to strike an ethically acceptable balance between their personal commitments as moral individuals and their obligations as medical professionals. Those who cannot or choose not to be immunized when a safe, effective, and well-tested vaccine is available must take other steps to protect themselves and those to whom they may transmit a vaccine-preventable disease, which may include refraining from patient contact.

Arguably, physicians' responsibility to protect patients' well-being extends to ensuring that all staff in their own practices are vaccinated, absent medical contraindication; when they or their staff are not immunized, physicians must protect themselves and patients in other ways. At a minimum, physician-leaders in practices and health organizations should require that staff who come into contact with high-risk patients take appropriate protective measures.

Responsibility to Promote Shared Decision Making

As trusted sources of information and guidance, physicians can play a significant role in shaping their patients' perspectives about vaccines and the decisions patients make about immunizing themselves and their families [22-27]. In keeping with practices recognized for increasing uptake of childhood immunizations, physicians have a responsibility to educate patients about the risks of forgoing or delaying a recommended immunization [28]. Exploring with vaccine hesitant patients their reasons for declining recommended immunizations is crucial. Vaccine hesitant patients commonly misunderstand physicians' motivation for urging immunization, but when reminded that their physician is motivated first and foremost by their welfare instead of public health concerns are more receptive to considering immunization [28]. Candor, willingness to listen, encouraging questions, and respectfully acknowledging patients'—or parents—concerns are essential elements of conversations with vaccine-hesitant individuals [28].

Physicians also serve as role models for their patients, consciously or otherwise. Physicians who adhere to immunization requirements and recommendations for themselves and their children can be powerful motivators for patients, colleagues, and others in the community to pursue immunization [2]. Physicians can take advantage of their power to motivate by communicating that

they themselves have been immunized. By the same token, physicians who fail to follow their own advice risk compromising patients' trust and undermining their credibility as advisors.

RESPONSIBILITIES OF HEALTH CARE INSTITUTIONS

Medicine is fundamentally a moral activity, and as sites in which that activity is carried out, health care institutions share the profession's "commitment to fidelity and service" [29]. They have obligations to the communities of patients the institution serves, to the physicians and other health care professionals who provide hands-on care, and to the other personnel who support those activities. Opinion 11.2.6, "Mergers of Secular and Religiously Affiliated Institutions," holds that "[p]rotecting the community that the institution serves as well as the integrity of the institution, the physicians and other professionals who practice in association with it" is an essential responsibility.

Health care institutions discharge this responsibility by proactively developing policies and procedures for responding to epidemic or pandemic disease with input from practicing physicians, institutional leadership, and appropriate specialists. Such policies and procedure should include robust infection control practices, providing appropriate protective equipment, and a program for making appropriate immunization readily available to staff. During outbreaks of vaccine-preventable disease for which there is a safe, effective vaccine, institutions' responsibility may extend to requiring immunization of their staff. Health care institutions have a further responsibility to limit patient and staff exposure to individuals who are not immunized, which may include requiring unimmunized individuals to refrain from patient care activities or other direct patient contact.

RECOMMENDATION

In light of these considerations, the Council on Ethical and Judicial Affairs recommends that Opinion 8.7, "Routine Universal Immunization of Physicians," be amended by insertion and deletion as follows and that the remainder of this report be filed:

> As professionals committed to promoting the welfare of individual patients and the health of the public and to safeguarding their own and their colleagues' well-being, physicians have an ethical responsibility to encourage patients to accept immunization when the patient can do so safely, and to take appropriate measures in their own practice to prevent the spread of infectious disease in health care settings. Conscientious participation in routine infection control practices, such as hand washing and respiratory precautions is a basic expectation of the profession. In some situations, however, routine infection control is not sufficient to protect the interests of patients, the public, and fellow health care workers.
>
> In the context of a highly transmissible disease that poses significant medical risk for vulnerable patients or colleagues, or threatens the availability of the health care workforce, particularly a disease that has potential to become epidemic or pandemic, and for which there is an available, safe, and effective vaccine, physicians ~~should:~~
>
> ~~Accept~~ have a responsibility to accept immunization absent a recognized medical~~, religious, or philosophic reason to not be immunized~~ contraindication or when a specific vaccine would pose a significant risk to the physician's patients.
>
> ~~(b) Accept a decision of the medical staff leadership or health care institution, or other appropriate authority to adjust practice activities if not immunized (e.g., wear masks or refrain~~

~~from direct patient care). It may be appropriate in some circumstances to inform patients about immunization status.~~

Physicians who are not or cannot be immunized have a responsibility to voluntarily take appropriate action to protect patients, fellow health care workers and others. They must adjust their practice activities in keeping with decisions of the medical staff, institutional policy, or public health policy, including refraining from direct patient contact when appropriate.

Physician practices and health care institutions have a responsibility to proactively develop policies and procedures for responding to epidemic or pandemic disease with input from practicing physicians, institutional leadership, and appropriate specialists. Such policies and procedures should include robust infection control practices, provision and required use of appropriate protective equipment, and a process for making appropriate immunization readily available to staff. During outbreaks of vaccine-preventable disease for which there is a safe, effective vaccine, institutions' responsibility may extend to requiring immunization of staff. Physician practices and health care institutions have a further responsibility to limit patient and staff exposure to individuals who are not immunized, which may include requiring unimmunized individuals to refrain from direct patient contact.

(Modify HOD/CEJA Policy)

Fiscal Note: Less than $500

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AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 001
(November 2020)

Introduced by: Resident and Fellow Section

Subject: AMA Resident/Fellow Councilor Term Limits

Referred to: Reference Committee on Amendments to Constitution and Bylaws

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Whereas, Based on a review of the foundational reports leading to the development of resident/fellow Council and BOT positions, the purpose of these roles is to maintain a resident voice in these bodies and to allow for residents and fellows to both gain experience in the election process and contribute meaningfully to practices of the Councils and BOT; and

Whereas, BOT Report A at the 1976 AMA Annual Convention, which codified resident and non-voting medical student representation on the Councils with three-year term lengths and a maximum three-term limit for the Council on Medical Education, Council on Medical Service, Council on Scientific Affairs, and the Council on Long Range Planning and Development (CLRPD); and

Whereas, Starting at the 1991 Annual Meeting, AMA House of Delegates Resolution 202 “Leadership Opportunities in the American Medical Association” called for a review of the AMA Board and Councils to increase the rate of involvement of, “various demographic segments of the AMA physician population in AMA leadership” and the subsequent study period yielded a survey of AMA members showing, “57% favored reducing the maximum tenure of Council members”; and

Whereas, During the 1996 Interim Meeting of the AMA, CLRPD presented Report 2 “Terms of Service of AMA Councils” which discussed some of the history of Council term lengths and presented arguments for and against one-, three-, five-, and seven-year terms for AMA Councils, considering “(a) the frequency of campaigns for Council positions, (b) the responsiveness of Council members to the AMA membership, the House and the Board, (c) opportunities to replace Council members whose performance is problematic, and (d) compatibility with the maximum total number of years that individuals can serve on each Council”; and

Whereas, CLRPD I-96 Report 2 noted that shorter terms would lead to increased member responsiveness and ease in removal of ineffective Council members, but increase time and cost devoted to campaigns, while shorter terms would be better suited for task-oriented Councils such as the Council on Legislation; and

Whereas, The RFS has concerns that three-year resident/fellow Council positions would disproportionately inhibit members of specialties with shorter residency training periods from being represented, including Internal Medicine, Emergency Medicine, Pediatrics and Family Medicine; and

Whereas, Due to current term lengths residents/fellows in longer training programs are unintentionally favored for Council positions; and

Whereas, From 2005-2019 only five residents in three-year residencies without subsequent fellowship positions served as residents on AMA Councils over this 15-year period; and

Whereas, Of 120 Council and BOT seats (seven Councils and BOT over 15 years), 48 seats (40.0%) were held by residents in three-year residencies, though only 13 seats (10.8%) were held by residents in three-year residencies without subsequent fellowship positions despite 57% of residents matching to a specialty with only 3 years of training; and

Whereas, Of 120 Council and BOT seats (seven Councils and BOT over 15 years), 65.8% were held by residents either in training programs of 5 or more years or went on to fellowship training totaling 5 or more years during their term; and

Whereas, BOT Report W from 1983 titled “Resident Member of the AMA Board of Trustees” was adopted allowing for the creation of a resident Trustee with a term length of two years and a maximum three-term limit; and

Whereas, The Resident Member of the Board of Trustees has been an effective member of the Board of Trustees despite a term of only two years; and

Whereas, Residents with shorter training periods are disproportionately underrepresented in elected and appointment Council positions thus creating a disparity in representation between primary care residents and specialty-trained ones; and

Whereas, Two-year terms would allow for more opportunities for residents at all training programs, especially those in 3 or 4 year residencies to be represented on AMA councils; therefore be it

RESOLVED, That our American Medical Association amend the AMA “Constitution and Bylaws” by addition and deletion to read as follows:

6.5 Council on Ethical and Judicial Affairs.

6.5.7 Term.

6.5.7.2 Except as provided in Bylaw 6.11, the resident/fellow physician member of the Council shall be elected for a term of 2~~3~~ years provided that if the resident/fellow physician member ceases to be a resident/fellow physician at any time prior to the expiration of the term for which elected, the service of such resident/fellow physician member on the Council shall thereupon terminate, and the position shall be declared vacant.

6.5.8 Tenure. Members of the Council may serve only one term, except that the resident/fellow physician member shall be eligible to serve for 3 terms and the medical student member shall be eligible to serve for 2 terms. A member elected to serve an unexpired term shall not be regarded as having served a term unless such member has served at least half of the term.

6.5.9 Vacancies.

6.5.9.2 Resident/Fellow Physician Member. If the resident/fellow physician member of the Council ceases to complete the term for which elected, the remainder of the term shall be deemed to have expired. The successor shall be elected by the House of Delegates at the next Annual Meeting, on nomination by the President, for a 2~~3~~-year term. (Modify Bylaws)

RESOLVED, That our AMA amend the AMA "Constitution and Bylaws" by addition and deletion to read as follows:

6.6 Council on Long Range Planning and Development.

6.6.3 Term.

6.6.3.2 Resident/Fellow Physician Member. The resident/fellow physician member of the Council shall be appointed for a term of 2~~3~~ years beginning at the conclusion of the Annual Meeting provided that if the resident/fellow physician member ceases to be a resident/fellow physician at any time prior to the expiration of the term for which appointed except as provided in Bylaw 6.11, the service of such resident/fellow physician member on the Council shall thereupon terminate, and the position shall be declared vacant.

6.6.5 Vacancies.

6.6.5.2 Resident/Fellow Physician Member. If the resident/fellow physician member of the Council ceases to complete the term for which appointed, the remainder of the term shall be deemed to have expired. The successor shall be appointed by the Speaker of the House of Delegates for a 2~~3~~-year term. (Modify Bylaws)

RESOLVED, That our AMA amend the AMA "Constitution and Bylaws" by addition and deletion to read as follows:

6.9 Term and Tenure - Council on Constitution and Bylaws, Council on Medical Education, Council on Medical Service, and Council on Science and Public Health.

6.9.1 Term.

6.9.1.2 Resident/Fellow Physician Member. The resident/fellow physician member of these Councils shall be elected for a term of 2~~3~~ years. Except as provided in Bylaw 6.11, if the resident/fellow physician member ceases to be a resident/fellow physician at any time prior to the expiration of the term for which elected, the service of such resident/fellow physician member on the Council shall thereupon terminate, and the position shall be declared vacant.

6.9.3 Vacancies.

6.9.3.2 Resident/Fellow Physician Member. If the resident/fellow physician member of these Councils ceases to complete the term for which elected, the remainder of the term shall be deemed to have expired. The successor shall be elected by the House of Delegates for a 2~~3~~-year term. (Modify Bylaws)

Fiscal Note: Minimal - less than $1,000

Received: 08/25/20

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 002
(November 2020)

Introduced by: Resident and Fellow Section

Subject: Resident and Fellow Access to Fertility Preservation

Referred to: Reference Committee on Amendments to Constitution and Bylaws

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Whereas, The average age at completion of medical training in the United States is approximately 31.6 years overall[1] and 36.8 years for surgical trainees[2]; and

Whereas, Female fertility is known to decrease substantially after age 35,[3,4] with a nearly 50% drop from the early 20s to late 30s[5]; and

Whereas, Female physicians have a chance of infertility that is twice that of the general population (24.1% vs. 10.9%), with an average age at diagnosis of 33.7 years[1]; and

Whereas, The demands of residency increase the risk of pregnancy complications, with a higher rate of gestational hypertension, placental abruption, preterm labor, and intrauterine growth restriction among female residents[6–8]; and

Whereas, A majority of recent trainees perceive a stigma associated with pregnancy during training[9] and have concerns about workplace support,[10] which may deter medical students from choosing a career in a surgical or other field with longer and demanding training; and

Whereas, Approximately one third of program directors have reported discouraging pregnancy among residents in surgical training programs[10]; and

Whereas, Oocyte cryopreservation is an established method of preserving fertility[11] that can cost $10,000 per cycle, often with multiple cycles required, and $500 per year for storage,[12] in addition to requiring timely injection of ovarian stimulation medications and numerous outpatient visits for cycle monitoring and egg retrieval[13]; and

Whereas, Companies such as Google, Apple, and Facebook have been offering oocyte cryopreservation benefits to their workforce, who are similarly largely of reproductive age, for several years[14]; therefore be it

RESOLVED, That our American Medical Association support education for residents and fellows regarding the natural course of female fertility in relation to the timing of medical education, and the option of fertility preservation and infertility treatment (New HOD Policy); and be it further

RESOLVED, That our AMA advocate inclusion of insurance coverage for fertility preservation and infertility treatment within health insurance benefits for residents and fellows offered through graduate medical education programs (Directive to Take Action); and be it further

1 RESOLVED, That our AMA support the accommodation of residents and fellows who elect to
2 pursue fertility preservation and infertility treatment, including the need to attend medical visits
3 to complete the oocyte preservation process and to administer medications in a time-sensitive
4 fashion. (New HOD Policy)

Fiscal Note: Modest - between $1,000 - $5,000

Received: 08/25/20

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RELEVANT AMA POLICY:

Disclosure of Risk to Fertility with Gonadotoxic Treatment H-425.967

Our AMA: (1) supports as best practice the disclosure to cancer and other patients of risks to fertility when gonadotoxic treatment is used; and (2) supports ongoing education for providers who counsel patients who may benefit from fertility preservation.
Citation: Res. 512, A-19

Infertility and Fertility Preservation Insurance Coverage H-185.990

1. Our AMA encourages third party payer health insurance carriers to make available insurance benefits for the diagnosis and treatment of recognized male and female infertility.
2. Our AMA supports payment for fertility preservation therapy services by all payers when iatrogenic infertility may be caused directly or indirectly by necessary medical treatments as determined by a licensed physician and will lobby for appropriate federal legislation requiring payment for fertility preservation therapy services by all payers when iatrogenic infertility may be caused directly or indirectly by necessary medical treatments as determined by a licensed physician.
Citation: Res. 150, A-88; Reaffirmed: Sunset Report, I-98; Reaffirmed: CMS Rep. 4, A-08; Appended: Res. 114, A-13; Modified: Res. 809, I-14

Infertility Benefits for Veterans H-510.984
1. Our AMA supports lifting the congressional ban on the Department of Veterans Affairs (VA) from covering in vitro fertilization (IVF) costs for veterans who have become infertile due to service-related injuries.
2. Our AMA encourages interested stakeholders to collaborate in lifting the congressional ban on the VA from covering IVF costs for veterans who have become infertile due to service-related injuries.
3. Our AMA encourages the Department of Defense (DOD) to offer service members fertility counseling and information on relevant health care benefits provided through TRICARE and the VA at pre-deployment and during the medical discharge process.
4. Our AMA supports efforts by the DOD and VA to offer service members comprehensive health care services to preserve their ability to conceive a child and provide treatment within the standard of care to address infertility due to service-related injuries. Citation: CMS Rep. 01, I-16Appended: Res. 513, A-19

Right for Gamete Preservation Therapies H-65.956
1. Fertility preservation services are recognized by our AMA as an option for the members of the transgender and non-binary community who wish to preserve future fertility through gamete preservation prior to undergoing gender affirming medical or surgical therapies.
2. Our AMA supports the right of transgender or non-binary individuals to seek gamete preservation therapies. Citation: Res. 005, A-19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution 003
(November 2020)

Introduced by: Resident and Fellow Section

Subject: Ensuring Consent for Educational Physical Exams on Anesthetized and Unconscious Patients

Referred to: Reference Committee on Amendments to Constitution and Bylaws

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1 Whereas, Patient autonomy is one of the basic tenets of medical ethics and includes the
2 patient's right to accept, modify, and refuse treatment[1,2]; and
3
4 Whereas, A patient desiring treatment must provide informed consent which can only be given
5 after being informed of their diagnosis, if known, the nature and purpose of any recommended
6 interventions, and the anticipated risks, benefits, and consequences of all options[3–5]; and
7
8 Whereas, The American College of Obstetricians and Gynecologists (ACOG) defines informed
9 consent as "a process of communication whereby a patient is enabled to make an informed and
10 voluntary decision about accepting or declining medical care"[6]; and
11
12 Whereas, A patient's provider is legally and ethically obligated to inform patients as part of the
13 consent process any party who can be reasonably anticipated to be part in their care team
14 including but not limited to residents, nurses, students, and allied health professionals[3,7]; and
15
16 Whereas, Teaching hospitals historically used the generalized consent form as permission to
17 perform exams of the genital areas, including for educational purposes, without deliberately
18 informing patients of opportunities to limit how any care teams or their members could be
19 involved in their care experience[4,8–14]; and
20
21 Whereas, In the 1980s, women vocalized demands to be asked for additional explicit consent
22 prior to undergoing educational pelvic exams in the operating room and indicated that doing so
23 without this consent constituted physical asssult[15]; and
24
25 Whereas, Surveys conducted in 2003 in Philadelphia and 2005 in Oklahoma found medical
26 students were still conducting educational pelvic and rectal exams on anesthetized or
27 unconscious patients without having obtained prior consent to do so[12,16,17]; and
28
29 Whereas, Educational pelvic exams were historically performed on patients under anesthesia in
30 operating rooms without explicit patient consent, including by medical students not directly
31 involved or not reasonably anticipating to be involved with the patient's ongoing care and when
32 the patient's surgical indications did not warrant a pelvic exam[18]; and
33
34 Whereas, Varying attitudes on educating medical students on invasive exams compounded with
35 pressures on students to achieve high academic and clinical marks may contribute to erosion of
36 consideration for scenarios when additional patient consent is indicated[16,19–24]; and

Whereas, The Association of American Medical Colleges (AAMC) and ACOG both emphasize that pelvic exams performed under anesthesia for educational purposes should only be done with a patient's informed consent prior to conducting the exam[4,24]; and

Whereas, Various states have passed legislation outlawing educational pelvic exams and/or pelvic exams in general, potentially even when indicated as part of a procedure, on a woman who is anesthetized or unconscious without prior consent to specifically do so[14,25–32]; and

Whereas, The Joint Commission maintains that patients may decline participating in elements of clinical training programs, such as working with medical students[12,33]; and

Whereas, The *AMA Code of Medical Ethics* states that patient "participation in medical education is to the mutual benefit of patients and the health care system; nonetheless, patients' (or surrogates') refusal of care by a trainee should be respected in keeping with ethics guidance."[34]; and

Whereas, While patients are often open to learner involvement in their care, they may deem scrutiny of more private body parts, particularly when solely for educational purposes, to warrant specific consent beyond the level provided for general care and treatment[15,35–37]; and

Whereas, Use of professional standardized patients who teach female pelvic, male genitourinary, and rectal exams have already demonstrated significant value in medical education and further highlight the unnecessary nature of educational genital exams performed without explicit patient consent[38–40]; therefore be it

RESOLVED, That our American Medical Association oppose performing physical exams on patients under anesthesia or on unconscious patients that offer the patient no personal benefit and are performed solely for teaching purposes without prior informed consent to do so (New HOD Policy); and be it further

RESOLVED, That our AMA encourage institutions to align current practices with published guidelines, recommendations, and policies to ensure patients are educated on pelvic, genitourinary, and rectal exams that occur under anesthesia (New HOD Policy); and be it further

RESOLVED, That our AMA strongly oppose issuing blanket bans on student participation in educational physical exams (New HOD Policy); and be it further

RESOLVED, That our AMA reaffirm policy H-320.951, "AMA Opposition to "Procedure-Specific" Informed Consent." (Reaffirm HOD Policy)

Fiscal Note: Minimal - less than $1,000

Received: 08/25/20

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RELEVANT AMA POLICY:

Code of Medical Ethics
2.1.1 Informed Consent
Informed consent to medical treatment is fundamental in both ethics and law. Patients have the right to receive information and ask questions about recommended treatments so that they can make well-considered decisions about care. Successful communication in the patient-physician relationship fosters trust and supports shared decision making.

The process of informed consent occurs when communication between a patient and physician results in the patient's authorization or agreement to undergo a specific medical intervention. In seeking a patient's informed consent (or the consent of the patient's surrogate if the patient lacks decision-making capacity or declines to participate in making decisions), physicians should:
(a) Assess the patient's ability to understand relevant medical information and the implications of treatment alternatives and to make an independent, voluntary decision.
(b) Present relevant information accurately and sensitively, in keeping with the patient's preferences for receiving medical information. The physician should include information about:
(i) the diagnosis (when known);
(ii) the nature and purpose of recommended interventions;
(iii) the burdens, risks, and expected benefits of all options, including forgoing treatment.
(c) Document the informed consent conversation and the patient's (or surrogate's) decision in the medical record in some manner. When the patient/surrogate has provided specific written consent, the consent form should be included in the record.
In emergencies, when a decision must be made urgently, the patient is not able to participate in decision making, and the patient's surrogate is not available, physicians may initiate treatment without prior informed consent. In such situations, the physician should inform the patient/surrogate at the earliest opportunity and obtain consent for ongoing treatment in keeping with these guidelines.

2.1.6 Substitution of Surgeon
Patients are entitled to choose their own physicians, which includes being permitted to accept or refuse having an intervention performed by a substitute. A surgeon who allows a substitute to conduct a medical procedure on his or her patient without the patient's knowledge or consent risks compromising the trust-based relationship of patient and physician.

When one or more other appropriately trained health care professionals will participate in performing a surgical intervention, the surgeon has an ethical responsibility to:
(a) Notify the patient (or surrogate if the patient lacks decision-making capacity) that others will participate, including whether they will do so under the physician's personal supervision or not.
(b) Obtain the patient's or surrogate's informed consent for the intervention, in keeping with ethical and legal guidelines.

2.3.6 Surgical Co-Management
Surgical co-management refers to the practice of allotting specific responsibilities of patient care to designated clinicians. Such arrangements should be made only to ensure the highest quality of care.

When engaging in this practice, physicians should:
(a) Allocate responsibilities among physicians and other clinicians according to each individual's expertise and qualifications.
(b) Work with the patient and family to designate one physician to be responsible for ensuring that care is delivered in a coordinated and appropriate manner.
(c) Participate in the provision of care by communicating with the coordinating physician and encouraging other members of the care team to do the same.

(d) Obtain patient consent for the surgical co-management arrangement of care, including disclosing significant aspects of the arrangement such as qualifications of clinicians, services each clinician will provide, and billing arrangement.
(e) Obtain informed consent for medical services in keeping with ethics guidance, including provision of all relevant medical facts.
(f) Employ appropriate safeguards to protect patient confidentiality.
(g) Ensure that surgical co-management arrangements are in keeping with ethical and legal restrictions.
(h) Engage another caregiver based on that caregiver's skill and ability to meet the patient's needs, not in the expectation of reciprocal referrals or other self-serving reasons, in keeping with ethics guidance on consultation and referrals.
(i) Refrain from participating in unethical or illegal financial agreements, such as fee-splitting.

7.1.2 Informed Consent in Research
Informed consent is an essential safeguard in research. The obligation to obtain informed consent arises out of respect for persons and a desire to respect the autonomy of the individual deciding whether to volunteer to participate in biomedical or health research. For these reasons, no person may be used as a subject in research against his or her will.

Physicians must ensure that the participant (or legally authorized representative) has given voluntary, informed consent before enrolling a prospective participant in a research protocol. With certain exceptions, to be valid, informed consent requires that the individual have the capacity to provide consent and have sufficient understanding of the subject matter involved to form a decision. The individual's consent must also be voluntary.

A valid consent process includes:
(a) Ascertaining that the individual has decision-making capacity.
(b) Reviewing the process and any materials to ensure that it is understandable to the study population.
(c) Disclosing:
(i) the nature of the experimental drug(s), device(s), or procedure(s) to be used in the research;
(ii) any conflicts of interest relating to the research, in keeping with ethics guidance;
(iii) any known risks or foreseeable hazards, including pain or discomfort that the participant might experience;
(iv) the likelihood of therapeutic or other direct benefit for the participant;
(v) that there are alternative courses of action open to the participant, including choosing standard or no treatment instead of participating in the study;
(vi) the nature of the research plan and implications for the participant;
(vii) the differences between the physician's responsibilities as a researcher and as the patient's treating physician.
(d) Answering questions the prospective participant has.
(e) Refraining from persuading the individual to enroll.
(f) Avoiding encouraging unrealistic expectations.
(g) Documenting the individual's voluntary consent to participate.
Participation in research by minors or other individuals who lack decision-making capacity is permissible in limited circumstances when:
(h) Consent is given by the individual's legally authorized representative, under circumstances in which informed and prudent adults would reasonably be expected to volunteer themselves or their children in research.
(i) The participant gives his or her assent to participation, where possible. Physicians should respect the refusal of an individual who lacks decision-making capacity.
(j) There is potential for the individual to benefit from the study.
In certain situations, with special safeguards in keeping with ethics guidance, the obligation to obtain informed consent may be waived in research on emergency interventions.

9.2.1 Medical Student Involvement in Patient Care
Having contact with patients is essential for training medical students, and both patients and the public benefit from the integrated care that is provided by health care teams that include medical students. However, the obligation to develop the next generation of physicians must be balanced against patients' freedom to choose from whom they receive treatment. All physicians share an obligation to ensure that

patients are aware that medical students may participate in their care and have the opportunity to decline care from students. Attending physicians may be best suited to fulfill this obligation. Before involving medical students in a patient's care, physicians should: (a) Convey to the patient the benefits of having medical students participate in their care. (b) Inform the patients about the identity and training status of individuals involved in care. Students, their supervisors, and all health care professionals should avoid confusing terms and properly identify themselves to patients. (c) Inform the patient that trainees will participate before a procedure is undertaken when the patient will be temporarily incapacitated. (d) Discuss student involvement in care with the patient's surrogate when the patient lacks decision-making capacity. (e) Confirm that the patient is willing to permit medical students to participate in care.

9.2.2 Resident & Fellow Physicians' Involvement in Patient Care
Residents and fellows have dual roles as trainees and caregivers. Residents and fellows share responsibility with physicians involved in their training to facilitate educational and patient care goals. Residents and fellows are physicians first and foremost and should always regard the interests of patients as paramount. When they are involved in patient care, residents and fellows should: (a) Interact honestly with patients, including clearly identifying themselves as members of a team that is supervised by the attending physician and clarifying the role they will play in patient care. They should notify the attending physician if a patient refuses care from a resident or fellow. (b) Participate fully in established mechanisms in their training programs and hospital systems for reporting and analyzing errors. They should cooperate with attending physicians in communicating errors to patients. (c) Monitor their own health and level of alertness so that these factors do not compromise their ability to care for patients safely. Residents and fellows should recognize that providing patient care beyond time permitted by their programs (for example, "moonlighting" or other activities that interfere with adequate rest during off hours) might be harmful to themselves and patients. Physicians involved in training residents and fellows should: (d) Take steps to help ensure that training programs are structured to be conducive to the learning process as well as to promote the patient's welfare and dignity. (e) Address patient refusal of care from a resident or fellow. If after discussion, a patient does not want to participate in training, the physician may exclude residents or fellows from the patient's care. If appropriate, the physician may transfer the patient's care to another physician or nonteaching service or another health care facility. (f) Provide residents and fellows with appropriate faculty supervision and availability of faculty consultants, and with graduated responsibility relative to level of training and expertise. (g) Observe pertinent regulations and seek consultation with appropriate institutional resources, such as an ethics committee, to resolve educational or patient care conflicts that arise in the course of training. All parties involved in such conflicts must continue to regard patient welfare as the first priority. Conflict resolution should not be punitive, but should aim at assisting residents and fellows to complete their training successfully.

9.2.5 Medical Students Practicing Clinical Skills on Fellow Students
Medical students often learn basic clinical skills by practicing on classmates, patients, or trained instructors. Unlike patients in the clinical setting, students who volunteer to act as "patients" are not seeking to benefit medically from the procedures being performed on them. Their goal is to benefit from educational instruction, yet their right to make decisions about their own bodies remains.

To protect medical students' privacy, autonomy, and sense of propriety in the context of practicing clinical skills on fellow students, instructors should:
(a) Explain to students how the clinical skills will be performed, making certain that students are not placed in situations that violate their privacy or sense of propriety.
(b) Discuss the confidentiality, consequences, and appropriate management of a diagnostic finding.
(c) Ask students to specifically consent to clinical skills being performed by fellow students. The stringency of standards for ensuring explicit, noncoerced informed consent increases as the invasiveness and intimacy of the procedure increase.
(d) Allow students the choice of whether to participate prior to entering the classroom.
(e) Never require that students provide a reason for their unwillingness to participate.
(f) Never penalize students for refusing to participate. Instructors must refrain from evaluating students' overall performance based on their willingness to volunteer as "patients."
Citation: Issued 2016

AMA Opposition to "Procedure-Specific" Informed Consent H-320.951
Our AMA opposes legislative measures that would impose procedure-specific requirements for informed consent or a waiting period for any legal medical procedure.
Citation: Res. 226, A-99; Reaffirmed: Res. 703, A-00; Reaffirmed: BOT Rep. 6, A-10; Reaffirmed: BOT Rep. 04, A-20

Informed Consent and Decision-Making in Health Care H-140.989
(1) Health care professionals should inform patients or their surrogates of their clinical impression or diagnosis; alternative treatments and consequences of treatments, including the consequence of no treatment; and recommendations for treatment. Full disclosure is appropriate in all cases, except in rare situations in which such information would, in the opinion of the health care professional, cause serious harm to the patient.
(2) Individuals should, at their own option, provide instructions regarding their wishes in the event of their incapacity. Individuals may also wish to designate a surrogate decision-maker. When a patient is incapable of making health care decisions, such decisions should be made by a surrogate acting pursuant to the previously expressed wishes of the patient, and when such wishes are not known or ascertainable, the surrogate should act in the best interests of the patient.
(3) A patient's health record should include sufficient information for another health care professional to assess previous treatment, to ensure continuity of care, and to avoid unnecessary or inappropriate tests or therapy.
(4) Conflicts between a patient's right to privacy and a third party's need to know should be resolved in favor of patient privacy, except where that would result in serious health hazard or harm to the patient or others.
(5) Holders of health record information should be held responsible for reasonable security measures through their respective licensing laws. Third parties that are granted access to patient health care information should be held responsible for reasonable security measures and should be subject to sanctions when confidentiality is breached.
(6) A patient should have access to the information in his or her health record, except for that information which, in the opinion of the health care professional, would cause harm to the patient or to other people.
(7) Disclosures of health information about a patient to a third party may only be made upon consent by the patient or the patient's lawfully authorized nominee, except in those cases in which the third party has a legal or predetermined right to gain access to such information.
Citation: BOT Rep. NN, A-87; Reaffirmed: Sunset Report, I-97; Reaffirmed: Res. 408, A-02; Reaffirmed: BOT Rep. 19, I-06; Reaffirmation A-07; Reaffirmation A-09; Reaffirmed: BOT Rep. 05, I-16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 004
(November 2020)

Introduced by: Virginia, American Association of Clinical Urologists, Oklahoma, West Virginia, Maryland, Mississippi, North Carolina, Kentucky, American Urological Association

Subject: Nonconsensual Audio/Video Recording at Medical Encounters

Referred to: Reference Committee on Amendments to Constitution and Bylaws

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1 Whereas, Fifteen percent of physician-patient visits may be unknowingly recorded with the
2 ubiquitous use of smartphones and other technologies; and
3
4 Whereas, Thirty-nine states and the District of Columbia conform to a single-party consent rule
5 for recording a conversation between two parties. Eleven states (California, Florida, Illinois,
6 Maryland, Massachusetts, Michigan, Montana, New Hampshire, Oregon, Pennsylvania, and
7 Washington) require consent of both parties[1]; and
8
9 Whereas, Audio/video recording of a medical encounter may be of benefit for a patient to recall
10 the pertinent issues and instructions given. Conversely, a covert recording made without the
11 physician or patient's knowledge may erode trust and harm the physician-patient relationship;
12 therefore be it
13
14 RESOLVED, That our American Medical Association encourage that any audio or video
15 recording made during a medical encounter should require both physician and patient
16 notification and consent. (New HOD Policy)

Fiscal Note: Minimal - less than $1,000

Received: 06/08/20

References:

1 Elwyn G, Barr PJ, Castaldo M. Can Patients Make Recordings of Medical Encounters? What Does the Law Say? JAMA. 2017;318(6):513–514. doi:10.1001/jama.2017.7511

RELEVANT AMA POLICY

E-3.1.3. Audio or Visual Recording Patients for Education in Health Care
Audio or visual recording of patients can be a valuable tool for educating health care professionals, but physicians must balance educational goals with patient privacy and confidentiality. The intended audience is bound by professional standards of respect for patient autonomy, privacy, and confidentiality, but physicians also have an obligation to ensure that content is accurate and complete and that the process and product of recording uphold standards of professional conduct.
To safeguard patient interests in the context of recording for purposes of educating health care professionals, physicians should:
(a) Ensure that all nonclinical personnel present during recording understand and agree to adhere to medical standards of privacy and confidentiality.
(b) Restrict participation to patients who have decision-making capacity. Recording should not be permitted when the patient lacks decision-making capacity except in rare circumstances and with the consent of the parent, legal guardian, or authorized decision maker.
(c) Inform the patient (or authorized decision maker, in the rare circumstances when recording is authorized for minors or patients who lack decision-making capacity):

(i) about the purpose of recording, the intended audience(s), and the expected distribution;
(ii) about the potential benefits and harms (such as breach of privacy or confidentiality) of participating;
(iii) that participation is voluntary and that a decision not to participate (or to withdraw) will not affect the patients care;
(iv) that the patient may withdraw consent at any time and if so, what will be done with the recording;
(v) that use of the recording will be limited to those involved in health care education, unless the patient specifically permits use by others.
(d) Ensure that the patient has had opportunity to discuss concerns before and after recording.
(e) Obtain consent from a patient (or the authorized decision maker):
(i) prior to recording whenever possible; or
(ii) before use for educational purposes when consent could not be obtained prior to recording.
(f) Respect the decision of a patient to withdraw consent.
(g) Seek assent from the patient for participation in addition to consent by the patients parent or guardian when participation by a minor patient is unavoidable.
(h) Be aware that the act of recording may affect patient behavior during a clinical encounter and thereby affect the films educational content and value.
(i) Be aware that the information contained in educational recordings should be held to the same protections as any other record of patient information. Recordings should be securely stored and properly destroyed, in keeping with ethics guidance for managing medical records.
(j) Be aware that recording creates a permanent record of personal patient information and may be considered part of the medical record and subject to laws governing medical records.
AMA Principles of Medical Ethics: I,IV,V,VIII
The Opinions in this chapter are offered as ethics guidance for physicians and are not intended to establish standards of clinical practice or rules of law.
Issued: 2016

E-3.1.4 Audio or Visual Recording of Patients for Public Education
Audio and/or visual recording of patient care for public broadcast is one way to help educate the public about health care. However, no matter what medium is used, such recording poses challenges for protecting patient autonomy, privacy, and confidentiality. Filming cannot benefit a patient medically and may cause harm. As advocates for their patients, physicians have an obligation to protect patient interests and ensure that professional standards are upheld. Physicians also have a responsibility to ensure that information conveyed to the public is complete and accurate (including the risks, benefits, and alternatives of treatments).
Physicians involved in recording patients for public broadcast should:
(a) Participate in institutional review of requests to record patient interactions.
(b) Require that persons present for recording purposes who are not members of the health care team:
(i) minimize third-party exposure to the patients care; and
(ii) adhere to medical standards of privacy and confidentiality.
(c) Encourage recording personnel to engage medical specialty societies or other sources of independent expert review in assessing the accuracy of the product.
(d) Refuse to participate in programs that foster misperceptions or are otherwise misleading.
(e) Restrict participation to patients who have decision-making capacity. Recording should not be permitted when the patient lacks decision-making capacity except in rare circumstances and with the consent of the parent, legal guardian, or authorized decision maker.
(f) Inform a patient (or authorized decision maker) who is to be recorded:
(i) about the purpose for which patient encounters with physicians or other health care professionals will be recorded;
(ii) about the intended audience(s);
(iii) that the patient may withdraw consent at any time prior to recording and up to an agreed on time before the completed recording is publicly broadcast, and if so, what will be done with the recording;
(iv) that at any time the patient has the right to have recording stopped and recording personnel removed from the area;
(v) whether the patient will be allowed to review the recording before broadcast and the degree to which the patient may edit the final product; and
(vi) whether the physician was compensated for his participation and the terms of that compensation.
(g) Ensure that the patient has had the opportunity to address concerns before and after recording.
(h) Ensure that the patients consent is obtained by a disinterested third party not involved with the production team to avoid potential conflict of interest.
(i) Request that recording be stopped and recording personnel removed if the physician (or other person involved in the patients care) perceives that recording may jeopardize patient care.
(j) Ensure that the care they provide and the advice they give to patients regarding participation in recording is not influenced by potential financial gain or promotional benefit to themselves, their patients, or the health care institution.
(k) Remind patients and colleagues that recording creates a permanent record and may in some instances be considered part of the medical record.
AMA Principles of Medical Ethics: I,IV,VII,VIII
The Opinions in this chapter are offered as ethics guidance for physicians and are not intended Issued: 2016

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 005
(November 2020)

Introduced by: Medical Student Section

Subject: Racism as a Public Health Threat

Referred to: Reference Committee on Amendments to Constitution and Bylaws

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Whereas, Underrepresented or marginalized racial and ethnic populations in the United States have shorter lifespans, greater physical and mental illness burden, earlier onset and more aggressive progression of disease, higher maternal and infant mortality, and less access to healthcare services[1-11]; and

Whereas, Systemic racism is defined as a structural and legalized system that results in differential access to goods and services, including health services[5,9,12,13]; and

Whereas, Cultural racism refers to negative and harmful racial stereotypes portrayed in culturally shared media and experiences[5,9,12,13]; and

Whereas, Interpersonal racism is implicit and explicit racial prejudice, including explicitly expressed racist beliefs and implicitly held racist attitudes and actions based upon or resulting from these prejudices[5,9,12,13]; and

Whereas, Systemic racism results in segregation of marginalized, racialized groups to less financially supported neighborhoods, schools, and jobs, lower salary for the same work, lower rates of promotion despite similar performance and higher rates of incarceration and police violence, all of which contribute to health inequities and have been independently associated with worse health outcomes[5,9,13-23]; and

Whereas, Interpersonal racism has been independently associated with chronic pain, poorer sleep, lower likelihood of accessing preventive screenings or prenatal care, psychosocial distress, greater likelihood of alcohol use and smoking, and lower overall health[5,24-26,28-31]; and

Whereas, In healthcare, systemic and cultural racism result in less access to care for minority groups and in different groups routinely receiving different treatment for the same complaints[9-10,13,32-34]; and

Whereas, When interpersonal racism is committed by healthcare workers, which occurs frequently, it undermines the physician-patient relationship, harms patients' trust in the healthcare field as a whole, and makes patients less likely to seek needed care[9,12,26,27,33-39]; and

Whereas, Experiencing perceived racial discrimination induces a chronic stress response causing heritable, intergenerational epigenetic changes, compounding disparities in health outcomes and chronic disease incidence that exist even when controlling for other socioecological factors[3,40-45]; and

Whereas, Rates of reported hate-based crimes and public expressions of discrimination against racial and ethnic minorities have increased in recent years[30,46-53]; and

Whereas, The role of racism in creating and perpetuating health disparities is frequently overlooked in research and healthcare literature and policy[5,13]; and

Whereas, Though developing technologies have potential to provide great improvement to health and well-being, they have also been shown to have an alarming capacity for absorbing, perpetuating, and compounding racism in healthcare on a massive, industry-wide scale, making it clear that a proactive approach to prevent or identify and eliminate racism in technologies as they are created is crucial[54-57]; and

Whereas, Though AMA policies emphasize the need to eliminate racial and ethnic disparities in health (H-350.974, D-350.984, D-350.995, H-350.953, D-350.991, H-440.869, H-65.963) and calls upon physicians to actively work to prevent violence of all kinds (H-515.964, H-515.971, H-515.979, H-145.970), AMA policy currently does not recognize the role of racism in perpetuating health disparities and inciting violence against minority groups; and

Whereas, At the June 2020 Special Meeting our AMA Board of Trustees made a statement recognizing racism as an urgent threat to public health and resolving to “actively work to dismantle racist and discriminatory policies and practices across all of health care"; therefore be it

RESOLVED, That our American Medical Association acknowledge that historic and present racist medical practices have caused and continue to cause harm to marginalized communities (New HOD Policy); and be it further

RESOLVED, That our AMA recognize racism, in its systemic, cultural, interpersonal, and other forms, as a serious threat to public health, to the advancement of health equity, and a barrier to appropriate medical care (New HOD Policy); and be it further

RESOLVED, That our AMA identify a set of current best practices for healthcare institutions, physician practices, and academic medical centers to recognize, address, and mitigate the effects of racism on patients, providers, and populations (Directive to Take Action); and be it further

RESOLVED, That our AMA encourage the development, implementation, and evaluation of undergraduate, graduate, and continuing medical education programs and curricula that engender greater understanding of:

1. The causes, influences, and effects of systemic, cultural, institutional, and interpersonal racism; and
2. How to prevent and ameliorate the health effects of racism (New HOD Policy); and be it further

RESOLVED, That our AMA: (a) support the development of policy to combat racism and its effects; (b) encourage governmental agencies and nongovernmental organizations to increase funding for research into the epidemiology of risks and damages related to racism and how to prevent or repair them (New HOD Policy); and be it further

RESOLVED, That our AMA work to prevent and combat the influences of racism and bias in innovative health technologies. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000

Received: 10/13/20

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RELEVANT AMA POLICY

Violence Activities H-515.964

Our AMA: (1) endorses the Declaration of Washington, which urges national medical associations worldwide to promote an international ethos condemning the development, production, or use of toxins and biological agents that have no justification for peaceful purposes;
(2) specifically endorses the WHO's World Report on Violence and Health and recognizes the value of its global perspective on all forms of violence; and
(3) supports investment in primary prevention activities related to violence as well as in research and services that encourage physicians to get involved in violence prevention (e.g., detect violence among patients, advocate for legislation), and encourages the development of curricula for teaching of violence prevention in schools of medicine. (BOT Rep. 9, A-03, Reaffirmed: CSAPH Rep. 1, A-13, Reaffirmation: A-18)

Public Health Policy Approach for Preventing Violence in America H-515.971

The AMA supports the ongoing efforts of the CDC to develop appropriate and useful surveillance methodologies for tracking violence-related injuries and encourages the CDC to develop tracking strategies that can be efficiently implemented by physicians, with careful evaluations of pilot programs and demonstration projects prior to their implementation, and will report back on these CDC efforts. (BOT Rep. 34, A-95, Reaffirmed: BOT Rep. 16, A-96, Reaffirmed: CSAPH Rep. 3, A-06, Reaffirmation: A-13, Reaffirmation: A-18)

Violence as a Public Health Issue H-515.979

The AMA reaffirms and expands current policy by (a) declaring violence in America to be a major public health crisis; and (b) supporting research into the causes of violent behavior and appropriate interventions which may result in its prevention or cure. (Sub Res. 408, I-92, Amended: CSA Rep. 8, A-03, Reaffirmation: A-13, Reaffirmed: CSAPH Rep. 1, A-13, Reaffirmation: A-18)

Nondiscrimination in Responding to Terrorism H-65.978
Our AMA: (1) affirms its commitment to work with appropriate agencies and associations in responding to terrorist attacks; and (2) opposes discrimination or acts of violence against any person on the basis of religion, culture, nationality, or country of education or origin in the nation's response to terrorism. (Res. 1, I-01, Modified: CSAPH Rep. 1, A-11)

E-8.10 Preventing, Identifying and Treating Violence and Abuse
All patients may be at risk for interpersonal violence and abuse, which may adversely affect their health or ability to adhere to medical recommendations. In light of their obligation to promote the well-being of patients, physicians have an ethical obligation to take appropriate action to avert the harms caused by violence and abuse.

To protect patients' well-being, physicians individually should:
(a) Become familiar with:
(i) how to detect violence or abuse, including cultural variations in response to abuse;
(ii) community and health resources available to abused or vulnerable persons;
(iii) public health measures that are effective in preventing violence and abuse;
(iv) legal requirements for reporting violence or abuse.
(b) Consider abuse as a possible factor in the presentation of medical complaints.
(c) Routinely inquire about physical, sexual, and psychological abuse as part of the medical history.
(d) Not allow diagnosis or treatment to be influenced by misconceptions about abuse, including beliefs that abuse is rare, does not occur in "normal" families, is a private matter best resolved without outside interference, or is caused by victims' own actions.
(e) Treat the immediate symptoms and sequelae of violence and abuse and provide ongoing care for patients to address long-term consequences that may arise from being exposed to violence and abuse.
(f) Discuss any suspicion of abuse sensitively with the patient, whether or not reporting is legally mandated, and direct the patient to appropriate community resources.
(g) Report suspected violence and abuse in keeping with applicable requirements. Before doing so, physicians should:
(i) inform patients about requirements to report;
(ii) obtain the patient's informed consent when reporting is not required by law. Exceptions can be made if a physician reasonably believes that a patient's refusal to authorize reporting is coerced and therefore does not constitute a valid informed treatment decision.
(h) Protect patient privacy when reporting by disclosing only the minimum necessary information.

Collectively, physicians should:
(i) Advocate for comprehensive training in matters pertaining to violence and abuse across the continuum of professional education.
(j) Provide leadership in raising awareness about the need to assess and identify signs of abuse, including advocating for guidelines and policies to reduce the volume of unidentified cases and help ensure that all patients are appropriately assessed.
(k) Advocate for mechanisms to direct physicians to community or private resources that might be available to aid their patients.
(l) Support research in the prevention of violence and abuse and collaborate with public health and community organizations to reduce violence and abuse.
(m) Advocate for change in mandatory reporting laws if evidence indicates that such reporting is not in the best interests of patients. (Issued: 2016)

Reducing Discrimination in the Practice of Medicine and Health Care Education D-350.984
Our AMA will pursue avenues to collaborate with the American Public Health Association's National Campaign Against Racism in those areas where AMA's current activities align with the campaign. (BOT Action in response to referred for decision, Res. 602, I-15)

Racial and Ethnic Disparities in Health Care H-350.974
1. Our AMA recognizes racial and ethnic health disparities as a major public health problem in the United States and as a barrier to effective medical diagnosis and treatment. The AMA maintains a position of zero tolerance toward racially or culturally based disparities in care; encourages individuals to report physicians to local medical societies where racial or ethnic discrimination is suspected; and will continue to support physician cultural awareness initiatives and related consumer education activities. The elimination of racial and ethnic disparities in health care an issue of highest priority for the American Medical Association.
2. The AMA emphasizes three approaches that it believes should be given high priority:
A. Greater access - the need for ensuring that black Americans without adequate health care insurance are given the means for access to necessary health care. In particular, it is urgent that Congress address the need for Medicaid reform.
B. Greater awareness - racial disparities may be occurring despite the lack of any intent or purposeful efforts to treat patients differently on the basis of race. The AMA encourages physicians to examine their own practices to ensure that inappropriate considerations do not affect their clinical judgment. In addition, the profession should help increase the awareness of its members of racial disparities in medical treatment decisions by engaging in open and broad discussions about the issue. Such discussions should take place in medical school curriculum, in medical journals, at professional conferences, and as part of professional peer review activities.
C. Practice parameters - the racial disparities in access to treatment indicate that inappropriate considerations may enter the decision-making process. The efforts of the specialty societies, with the coordination and assistance of our AMA, to develop practice parameters, should include criteria that would preclude or diminish racial disparities
3. Our AMA encourages the development of evidence-based performance measures that adequately identify socioeconomic and racial/ethnic disparities in quality. Furthermore, our AMA supports the use of evidence-based guidelines to promote the consistency and equity of care for all persons.
4. Our AMA: (a) actively supports the development and implementation of training regarding implicit bias, diversity and inclusion in all medical schools and residency programs; (b) will identify and publicize effective strategies for educating residents in all specialties about disparities in their fields related to race, ethnicity, and all populations at increased risk, with particular regard to access to care and health outcomes, as well as effective strategies for educating residents about managing the implicit biases of patients and their caregivers; and (c) supports research to identify the most effective strategies for educating physicians on how to eliminate disparities in health outcomes in all at-risk populations. (CLRPD Rep. 3, I-98, Appended and Reaffirmed: CSA Rep. 1, I-02, Reaffirmed: BOT Rep. 4, A-03, Reaffirmed in lieu of Res. 106, A-12, Appended: Res. 952, I-17, Reaffirmed: CMS Rep. 10, A-19)

Reducing Racial and Ethnic Disparities in Health Care D-350.995
Our AMA's initiative on reducing racial and ethnic disparities in health care will include the following recommendations:
(1) Studying health system opportunities and barriers to eliminating racial and ethnic disparities in health care.
(2) Working with public health and other appropriate agencies to increase medical student, resident physician, and practicing physician awareness of racial and ethnic disparities in health care and the role of professionalism and professional obligations in efforts to reduce health care disparities.
(3) Promoting diversity within the profession by encouraging publication of successful outreach programs that increase minority applicants to medical schools, and take appropriate action to support such programs, for example, by expanding the "Doctors Back to School" program into secondary schools in minority communities. (BOT Rep. 4, A-03, Reaffirmation: A-11, Reaffirmation: A-16, Reaffirmed: CMS Rep. 10, A-19)

Racial Housing Segregation as a Determinant of Health and Public Access to Geographic Information Systems (GIS) Data H-350.953
Our AMA will: (1) oppose policies that enable racial housing segregation; and (2) advocate for continued federal funding of publicly-accessible geospatial data on community racial and economic disparities and disparities in access to affordable housing, employment, education, and healthcare, including but not limited to the Department of Housing and Urban Development (HUD) Affirmatively Furthering Fair Housing (AFFH) tool. (Res. 405, A-18)

Guiding Principles for Eliminating Racial and Ethnic Health Care Disparities D-350.991
Our AMA: (1) in collaboration with the National Medical Association and the National Hispanic Medical Association, will distribute the Guiding Principles document of the Commission to End Health Care Disparities to all members of the federation and encourage them to adopt and use these principles when addressing policies focused on racial and ethnic health care disparities; (2) shall work with the Commission to End Health Care Disparities to develop a national repository of state and specialty society policies, programs and other actions focused on studying, reducing and eliminating racial and ethnic health care disparities; (3) urges medical societies that are not yet members of the Commission to End Health Care Disparities to join the Commission, and (4) strongly encourages all medical societies to form a Standing Committee to Eliminate Health Care Disparities. (Res. 409, A-09, Appended: Res. 416, A-11)

Research the Effects of Physical or Verbal Violence Between Law Enforcement Officers and Public Citizens on Public Health Outcomes H-515.955
Our AMA:
1. Encourages the National Academies of Sciences, Engineering, and Medicine and other interested parties to study the public health effects of physical or verbal violence between law enforcement officers and public citizens, particularly within ethnic and racial minority communities.
2. Affirms that physical and verbal violence between law enforcement officers and public citizens, particularly within racial and ethnic minority populations, is a social determinant of health.
3. Encourages the Centers for Disease Control and Prevention as well as state and local public health agencies to research the nature and public health implications of violence involving law enforcement.
4. Encourages states to require the reporting of legal intervention deaths and law enforcement officer homicides to public health agencies.
5. Encourages appropriate stakeholders, including, but not limited to the law enforcement and public health communities, to define “serious injuries” for the purpose of systematically collecting data on law enforcement-related non-fatal injuries among civilians and officers. (Res. 406, A-16, Modified: BOT Rep. 28, A-18)

AMA Initiatives Regarding Minorities H-350.971
The House of Delegates commends the leaders of our AMA and the National Medical Association for having established a successful, mutually rewarding liaison and urges that this relationship be expanded in all areas of mutual interest and concern. Our AMA will develop publications, assessment tools, and a survey instrument to assist physicians and the federation with minority issues. The AMA will continue to strengthen relationships with minority physician organizations, will communicate its policies on the health care needs of minorities, and will monitor and report on progress being made to address racial and ethnic disparities in care. It is the policy of our AMA to establish a mechanism to facilitate the development and implementation of a comprehensive, long-range, coordinated strategy to address issues and concerns affecting minorities, including minority health, minority medical education, and minority membership in the AMA. Such an effort should include the following components:
(1) Development, coordination, and strengthening of AMA resources devoted to minority health issues and recruitment of minorities into medicine;
(2) Increased awareness and representation of minority physician perspectives in the Association's policy development, advocacy, and scientific activities;
(3) Collection, dissemination, and analysis of data on minority physicians and medical students, including AMA membership status, and on the health status of minorities;
(4) Response to inquiries and concerns of minority physicians and medical students; and
(5) Outreach to minority physicians and minority medical students on issues involving minority health status, medical education, and participation in organized medicine. (CLRPD Rep. 3, I-98, Reaffirmed: CLRPD Rep. 1, A-08, Reaffirmed: CEJA Rep. 01, A-20)

Establishment of State Commission / Task Force to Eliminate Racial and Ethnic Health Care Disparities H-440.869
Our AMA will encourage and assist state and local medical societies to advocate for creation of statewide commissions to eliminate health disparities in each state. (Res. 914, I-07, Modified: BOT Rep. 22, A-17)

Discriminatory Policies that Create Inequities in Health Care H-65.963
Our AMA will: (1) speak against policies that are discriminatory and create even greater health disparities in medicine; and (2) be a voice for our most vulnerable populations, including sexual, gender, racial and ethnic minorities, who will suffer the most under such policies, further widening the gaps that exist in health and wellness in our nation. (Res. 001, A-18)

Support of Human Rights and Freedom H-65.965
Our AMA: (1) continues to support the dignity of the individual, human rights and the sanctity of human life, (2) reaffirms its long-standing policy that there is no basis for the denial to any human being of equal rights, privileges, and responsibilities commensurate with his or her individual capabilities and ethical character because of an individual's sex, sexual orientation, gender, gender identity, or transgender status, race, religion, disability, ethnic origin, national origin, or age; (3) opposes any discrimination based on an individual's sex, sexual orientation, gender identity, race, religion, disability, ethnic origin, national origin or age and any other such reprehensible policies; (4) recognizes that hate crimes pose a significant threat to the public health and social welfare of the citizens of the United States, urges expedient passage of appropriate hate crimes prevention legislation in accordance with our AMA's policy through letters to members of Congress; and registers support for hate crimes prevention legislation, via letter, to the President of the United States. (CCB/CLRPD Rep. 3, A-14, Reaffirmed in lieu of: Res. 001, I-16, Reaffirmation: A-17)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 006
(November 2020)

Introduced by: Women Physicians Section

Subject: Addressing Maternal Discrimination

Referred to: Reference Committee on Amendments to Constitution and Bylaws

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Whereas, AMA Policy H-65.961, "Principles for Advancing Gender Equity in Medicine," notes that the AMA opposes any exploitation and discrimination in the workplace based on personal characteristics (i.e., gender); and

Whereas, Findings from a study by Adesoye, Mangurian, Choo et al. on physician mothers and their experiences with workplace discrimination indicated that 77.9% of the respondents experienced some form of discrimination;[1] and

Whereas, Of these respondents, 66.3% of physician mothers reported experiencing gender discrimination and 35.8% reported experiencing maternal discrimination, which is defined as self-reported discrimination based on pregnancy, maternity leave, or breastfeeding;[1] and

Whereas, Employment laws, such as the Pregnancy Discrimination Act and the Title VII of the Civil Rights Act of 1964, protects individuals from discrimination based on protected class such as, sex, gender and pregnancy;[2] and

Whereas, The Fair Labor Standards Act includes some breastfeeding protections;[3] and

Whereas, Maternal discrimination was associated with higher self-reported burnout (45.9% in physicians experiencing maternal discrimination compared to 33.9% burnout in those not experiencing maternal discrimination);[1] and

Whereas, Male physicians are increasingly expressing interest in flexible family leave and work options, yet female physicians continue to bear primary responsibility for caregiving and may face more challenges in aligning their career goals with family needs; and

Whereas, Conflicts between work and life responsibilities can have adverse consequences for women physicians; and

Whereas, Findings from a study by Templeton, Bernstein, Sukhera, et al. noted that women who are employed full time spend an additional 8.5 hours per week on childcare and other domestic activities;[4] and

Whereas, AMA Policy H-405.954, "Parental Leave," supports the establishment and expansion of paid parental leave; calls for improved social and economic support for paid family leave to care for newborns, infants and young children; and advocates for federal tax incentives to support early child care and unpaid child care by extended family members; and

1 Whereas, Assistance with lactation support and flexible scheduling, coupled with
2 comprehensive parental leave policies, can foster work-life integration and help mitigate
3 maternal discrimination in the workplace; therefore be it
4
5 RESOLVED, That our American Medical Association encourage key stakeholders to implement
6 policies and programs that help protect against maternal discrimination and promote work-life
7 integration for physician parents, which may encompass pregnancy, parental leave,
8 breastfeeding, and breast pumping. (Directive to Take Action)

Fiscal Note: Minimal - less than $1,000

Received: 09/30/20

References:
1. Adesoye T, Mangurian C, Choo EK, et al. Perceived Discrimination Experienced by Physician Mothers and Desired Workplace Changes: A Cross-sectional Survey. *JAMA Intern Med.* 2017;177(7):1033-1036.
2. U.S. Equal Employment Opportunity Commission. Available at https://www.eeoc.gov/laws/types/. Accessed 3/2/2020.
3. Section 7(r), Fair Labor Standards Act - Break Time for Nursing Mothers Provision. Available at https://www.dol.gov/agencies/whd/nursing-mothers/law. Accessed 3/2/2020.
4. Templeton K, Bernstein CA, Sukhera J, et al. Gender-Based Differences in Burnout: Issues Faced by Women Physicians. Available at https://nam.edu/gender-based-differences-in-burnout-issues-faced-by-women-physicians/. Accessed 3/10/2020.

RELEVANT AMA POLICY

Principles for Advancing Gender Equity in Medicine H-65.961
Our AMA:
1. declares it is opposed to any exploitation and discrimination in the workplace based on personal characteristics (i.e., gender);
2. affirms the concept of equal rights for all physicians and that the concept of equality of rights under the law shall not be denied or abridged by the U.S. Government or by any state on account of gender;
3. endorses the principle of equal opportunity of employment and practice in the medical field;
4. affirms its commitment to the full involvement of women in leadership roles throughout the federation, and encourages all components of the federation to vigorously continue their efforts to recruit women members into organized medicine;
5. acknowledges that mentorship and sponsorship are integral components of one's career advancement, and encourages physicians to engage in such activities;
6. declares that compensation should be equitable and based on demonstrated competencies/expertise and not based on personal characteristics;
7. recognizes the importance of part-time work options, job sharing, flexible scheduling, re-entry, and contract negotiations as options for physicians to support work-life balance;
8. affirms that transparency in pay scale and promotion criteria is necessary to promote gender equity, and as such academic medical centers, medical schools, hospitals, group practices and other physician employers should conduct periodic reviews of compensation and promotion rates by gender and evaluate protocols for advancement to determine whether the criteria are discriminatory; and
9. affirms that medical schools, institutions and professional associations should provide training on leadership development, contract and salary negotiations and career advancement strategies that include an analysis of the influence of gender in these skill areas.

Our AMA encourages: (1) state and specialty societies, academic medical centers, medical schools, hospitals, group practices and other physician employers to adopt the AMA Principles for Advancing Gender Equity in Medicine; and (2) academic medical centers, medical schools, hospitals, group practices and other physician employers to: (a) adopt policies that prohibit harassment, discrimination and retaliation; (b) provide anti-harassment training; and (c) prescribe disciplinary and/or corrective action should violation of such policies occur.
Citation: BOT Rep. 27, A-19

Policies for Parental, Family and Medical Necessity Leave H-405.960
AMA adopts as policy the following guidelines for, and encourages the implementation of, Parental, Family and Medical Necessity Leave for Medical Students and Physicians:
1. Our AMA urges medical schools, residency training programs, medical specialty boards, the Accreditation Council for Graduate Medical Education, and medical group practices to incorporate and/or encourage development of leave policies, including parental, family, and medical leave policies, as part of the physician's standard benefit agreement.
2. Recommended components of parental leave policies for medical students and physicians include: (a) duration of leave allowed before and after delivery; (b) category of leave credited; (c) whether leave is paid or unpaid; (d) whether provision is made for continuation of insurance benefits during leave, and who pays the premium; (e) whether sick leave and vacation time may be accrued from year to year or used in advance; (f) how much time must be made up in order to be considered board eligible; (g) whether make-up time will be paid; (h) whether schedule accommodations are allowed; and (i) leave policy for adoption.
3. AMA policy is expanded to include physicians in practice, reading as follows: (a) residency program directors and group practice administrators should review federal law concerning maternity leave for guidance in developing policies to assure that pregnant physicians are allowed the same sick leave or disability benefits as those physicians who are ill or disabled; (b) staffing levels and scheduling are encouraged to be flexible enough to allow for coverage without creating intolerable increases in other physicians' workloads, particularly in residency programs; and (c) physicians should be able to return to their practices or training programs after taking parental leave without the loss of status.
4. Our AMA encourages residency programs, specialty boards, and medical group practices to incorporate into their parental leave policies a six-week minimum leave allowance, with the understanding that no parent should be required to take a minimum leave.
5. Residency program directors should review federal and state law for guidance in developing policies for parental, family, and medical leave.
6. Medical students and physicians who are unable to work because of pregnancy, childbirth, and other related medical conditions should be entitled to such leave and other benefits on the same basis as other physicians who are temporarily unable to work for other medical reasons.
7. Residency programs should develop written policies on parental leave, family leave, and medical leave for physicians. Such written policies should include the following elements: (a) leave policy for birth or adoption; (b) duration of leave allowed before and after delivery; (c) category of leave credited (e.g., sick, vacation, parental, unpaid leave, short term disability); (d) whether leave is paid or unpaid; (e) whether provision is made for continuation of insurance benefits during leave and who pays for premiums; (f) whether sick leave and vacation time may be accrued from year to year or used in advance; (g) extended leave for resident physicians with extraordinary and long-term personal or family medical tragedies for periods of up to one year, without loss of previously accepted residency positions, for devastating conditions such as terminal illness, permanent disability, or complications of pregnancy that threaten maternal or fetal life; (h) how time can be made up in order for a resident physician to be considered board eligible; (i) what period of leave would result in a resident physician being required to complete an extra or delayed year of training; (j) whether time spent in making up a leave will be paid; and (k) whether schedule accommodations are allowed, such as reduced hours, no night call, modified rotation schedules, and permanent part-time scheduling.
8. Our AMA endorses the concept of equal parental leave for birth and adoption as a benefit for resident physicians, medical students, and physicians in practice regardless of gender or gender identity.
9. Staffing levels and scheduling are encouraged to be flexible enough to allow for coverage without creating intolerable increases in the workloads of other physicians, particularly those in residency programs.
10. Physicians should be able to return to their practices or training programs after taking parental leave, family leave, or medical leave without the loss of status.
11. Residency program directors must assist residents in identifying their specific requirements (for example, the number of months to be made up) because of leave for eligibility for board certification and must notify residents on leave if they are in danger of falling below minimal requirements for board eligibility. Program directors must give these residents a complete list of requirements to be completed in order to retain board eligibility.
12. Our AMA encourages flexibility in residency training programs, incorporating parental leave and alternative schedules for pregnant house staff.
13. In order to accommodate leave protected by the federal Family and Medical Leave Act, our AMA encourages all specialties within the American Board of Medical Specialties to allow graduating residents

to extend training up to 12 weeks after the traditional residency completion date while still maintaining board eligibility in that year.
14. These policies as above should be freely available online and in writing to all applicants to medical school, residency or fellowship.
Citation: (CCB/CLRPD Rep. 4, A-13; Modified: Res. 305, A-14; Modified: Res. 904, I-14)

Support of Human Rights and Freedom H-65.965
Our AMA: (1) continues to support the dignity of the individual, human rights and the sanctity of human life, (2) reaffirms its long-standing policy that there is no basis for the denial to any human being of equal rights, privileges, and responsibilities commensurate with his or her individual capabilities and ethical character because of an individual's sex, sexual orientation, gender, gender identity, or transgender status, race, religion, disability, ethnic origin, national origin, or age; (3) opposes any discrimination based on an individual's sex, sexual orientation, gender identity, race, religion, disability, ethnic origin, national origin or age and any other such reprehensible policies; (4) recognizes that hate crimes pose a significant threat to the public health and social welfare of the citizens of the United States, urges expedient passage of appropriate hate crimes prevention legislation in accordance with our AMA's policy through letters to members of Congress; and registers support for hate crimes prevention legislation, via letter, to the President of the United States.
Citation: CCB/CLRPD Rep. 3, A-14; Reaffirmed in lieu of: Res. 001, I-16; Reaffirmation: A-17

Parental Leave H-405.954
1. Our AMA encourages the study of the health implications among patients if the United States were to modify one or more of the following aspects of the Family and Medical Leave Act (FMLA): a reduction in the number of employees from 50 employees; an increase in the number of covered weeks from 12 weeks; and creating a new benefit of paid parental leave.
2. Our AMA will study the effects of FMLA expansion on physicians in varied practice environments.
3. Our AMA: (a) encourages employers to offer and/or expand paid parental leave policies; (b) encourages state medical associations to work with their state legislatures to establish and promote paid parental leave policies; (c) advocates for improved social and economic support for paid family leave to care for newborns, infants and young children; and (d) advocates for federal tax incentives to support early child care and unpaid child care by extended family members.
Res. 215, I-16; Appended: BOT Rep. 11, A-19

E-9.5.5 Gender Discrimination in Medicine
Inequality of professional status in medicine among individuals based on gender can compromise patient care, undermine trust, and damage the working environment. Physician leaders in medical schools and medical institutions should advocate for increased leadership in medicine among individuals of underrepresented genders and equitable compensation for all physicians.
Collectively, physicians should actively advocate for and develop family-friendly policies that:
(a) Promote fairness in the workplace, including providing for:
(i) retraining or other programs that facilitate re-entry by physicians who take time away from their careers to have a family;
(ii) on-site child care services for dependent children;
(iii) job security for physicians who are temporarily not in practice due to pregnancy or family obligations.
(b) Promote fairness in academic medical settings by:
(i) ensuring that tenure decisions make allowance for family obligations by giving faculty members longer to achieve standards for promotion and tenure;
(ii) establish more reasonable guidelines regarding the quantity and timing of published material needed for promotion or tenure that emphasize quality over quantity and encourage the pursuit of careers based on individual talent rather than tenure standards that undervalue teaching ability and overvalue research;
(iii) fairly distribute teaching, clinical, research, administrative responsibilities, and access to tenure tracks;
(iv) structuring the mentoring process through a fair and visible system.
(c) Take steps to mitigate gender bias in research and publication.
AMA Principles of Medical Ethics: II,VII
The Opinions in this chapter are offered as ethics guidance for physicians and are not intended to establish standards of clinical practice or rules of law.
Issued: 2016

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 007
(November 2020)

Introduced by: Michael M. Miller, MD, Delegate

Subject: Access to Confidential Health Care Services for Physicians and Trainees

Referred to: Reference Committee on Amendments to Constitution and Bylaws

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Whereas, Mental disorders and addictive disorders are serious medical conditions, and can be severe, leading to significant distress and dysfunction; and

Whereas, Despite years of education and advocacy, these conditions remain associated with stigma, and persons with these conditions can face discrimination, including in the workplace; and

Whereas, Physicians and medical students also experience mental disorders and addictive disorders, but they tend to avoid seeking professional help, often due to concerns about the impact of such care-seeking on their professional status and their ability to advance through training without discrimination; and

Whereas, The COVID-19 pandemic has intensified the stresses on practicing physicians, fellows, residents and medical students, with increased rates of anxiety disorders, mood disorders, posttraumatic stress disorder, and substance-related problems; and

Whereas, Physicians and trainees need access to confidential health care services and barriers to care-seeking should be removed for these groups; and

Whereas, Similar stresses and mental and addictive disorders have befallen all licensed independent practitioners (physicians, dentists, podiatrists, optometrists, psychologists), advanced practice practitioners (nurse practitioners, CRNAs, nurse midwives and physician assistants) and other professionals in clinical roles (nurses, mental health therapists, addiction counselors); and

Whereas, Most health professionals have health insurance benefits or coverage via self-insured employers, but in many cases, especially when the health system that employs them has an ownership stake in a health plan, the in-network providers are employed in the same system where the clinician or trainee works or is in training, leading to challenges to maintaining confidentiality and extra hesitancy on the part of those in need of mental health or addiction services to seek help; and

Whereas, Differences in costs of care for in-network vs out-of-network providers can be a deterrent to an individual deciding to seek behavioral health care services or continue in treatment; and

Whereas, Rates of suicide among physicians, especially women physicians, continue to climb, and professions such as medicine should do all they can to assist their peers to have access to high quality and confidential behavioral health care services; and

Whereas, Some health systems recognize these variables, and work closely with health plans to assure that physicians, other licensed independent professionals, advance practice practitioners, nurses, mental health therapists and addiction counselors are able to go out-of-network to see a mental health or addiction professional who does not work in the same health system as the employee, and at in-network rates; and

Whereas, The primary care physician is the first point of contact for many persons with mental disorders and addictive disorders, and the relationship with one's primary care provider may have a level of intimacy that approximates that which a person has with a behavioral health care professional; therefore be it

RESOLVED, That our American Medical Association advocate that employers of physicians, other licensed independent professionals, advance practice practitioners, nurses, mental health therapists and addiction counselors, should encourage them to maintain self-care and to seek professional help from a mental health professional or addiction professional when they have concerns about psychiatric or substance-related symptoms that are not responding to self-care (Directive to Take Action); and be it further

RESOLVED, That our AMA advocate that employers of physicians, other licensed independent professionals, advance practice practitioners, nurses, mental health therapists and addiction counselors should do all they can to reduce stigma, reduce or eliminate discrimination, and remove barriers to treatment entry for those who need professional behavioral health care services (Directive to Take Action); and be it further

RESOLVED, That our AMA advocate that employers in the health care sector including academic medical centers where residents and fellows are trained, as well as medical schools, who offer health benefits to their employees, fellows, residents and medical students, and where there is a defined set of in-network providers, should assure that physicians, other licensed independent professionals, advance practice practitioners, nurses, mental health therapists and addiction counselors are able to go out-of-network to see a mental health or addiction professional who does not work in the same health system as the employee (Directive to Take Action); and be it further

RESOLVED, That our AMA advocate that fellows, residents and medical students be provided access to out-of-network providers when they are seeking to establish care with a primary care provider, so that they are able to use their health insurance benefits while not finding themselves under the care of a past, current or future faculty member, if the original provider network does not contain adequate options for primary care offered by clinicians not on the faculty of the medical school or academic medical center; (Directive to Take Action) and be it further

RESOLVED, That our AMA advocate that contracts should be established by medical schools, academic medical centers, and employers of practicing physicians such that the deductibles, copays, coinsurance, and out-of-pocket maximums for such practicing physicians, fellows, residents and medical students seeing out-of-network providers of mental health, addiction, and primary medical care should be the same as the deductibles, copays, coinsurance, and out-of-pocket maximums for seeing in-network providers. (Directive to Take Action)

Fiscal Note: Moderate - between $5,000 - $10,000

Received: 10/05/20

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 008
(November 2020)

Introduced by: Mississippi, Alabama, Florida, South Carolina, West Virginia, Puerto Rico, Tennessee, New Jersey, Oklahoma, Virginia, Georgia, Louisiana, Kentucky, North Carolina, District of Columbia

Subject: Delegate Apportionment During COVID-19 Pandemic Crisis

Referred to: Reference Committee on Amendments to Constitution and Bylaws

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Whereas, The COVID-19 pandemic has been difficult for our country including the practice of medicine; and

Whereas, Many medical practices and hospitals have had to reduce the number of patients that they see and reduce the number of procedures that they perform. This in turn has reduced many physicians' revenue and, as a consequence, many physicians have elected not to renew their memberships in many organizations including their medical societies and associations; and

Whereas, Because of the COVID-19 pandemic crisis, many medical societies, state medical associations, and specialty associations have not been able to meet in person. As a result, these organizations have not had the usual platform to promote the importance of organized medicine and have seen a drop in membership including AMA membership; and

Whereas, States that have had a significant number of state and national medical associations and/or academies have made accommodations for their membership as a result of the Covid 19 pandemic; therefore be it

RESOLVED, That our American Medical Association extend the current grace period from one year to two years for losing a delegate from a state medical or national medical specialty society until the end of 2022. (Directive to Take Action)

Fiscal Note: Minimal - less than $1,000

Received: 10/13/20

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 009
(November 2020)

Introduced by: Minority Affairs Section

Subject: Support of Learner and Trainee Participation in Peaceful Demonstrations and Other Forms of Public Advocacy

Referred to: Reference Committee on Amendments to Constitution and Bylaws

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1 Whereas, The recent killings of unarmed Black men and women resulted in increased civic,
2 social, and political engagement among learners and trainees through participation in various
3 forms of peaceful demonstrations to bring attention to the historical, structural, and systemic
4 racism experienced by people and communities of color that have led to continued health
5 inequities, including police brutality; and
6
7 Whereas, Learners and trainees have expressed fear or hesitation of engaging in public
8 advocacy due to fear of consequence or perceived impact their participation will have on their
9 academic careers; and
10
11 Whereas, Learners and trainees have reported restrictive institutional policies forbidding their
12 involvement as well as experiences of institutional retaliation because of their participation; and
13
14 Whereas, In July 2020, The Association of American Medical Colleges (AAMC) issued
15 *Guidance on Peaceful Protests by Medical Students and Residents,* highlighting the benefits of
16 learner and trainee participation in their professional development as socially conscious
17 physicians of tomorrow[1]; therefore be it
18
19 RESOLVED, That our American Medical Association issue guidance to protect and support
20 learner and trainee participation in peaceful demonstrations and other forms of public advocacy.
21 (Directive to Take Action)

Fiscal Note: Moderate - between $5,000 - $10,000

Received: 10/13/20

References:
1. AAMC Guidance on Peaceful Protests by Medical Students and Residents https://www.aamc.org/system/files/2020-07/AAMC_Guidance_for_Students_Schools_on%20Peaceful_Protests_07072020.pdf

RELEVANT AMA POLICY

Guiding Principles for Eliminating Racial and Ethic Health Care Disparities D-350.991
Our AMA: (1) in collaboration with the National Medical Association and the National Hispanic Medical Association, will distribute the Guiding Principles document of the Commission to End Health Care Disparities to all members of the federation and encourage them to adopt and use these principles when addressing policies focused on racial and ethnic health care disparities; (2) shall work with the Commission to End Health Care Disparities to develop a national repository of state and specialty society policies, programs and other actions focused on studying, reducing and eliminating racial and ethnic health care disparities; 3) urges medical societies that are not yet members of the Commission to End

Health Care Disparities to join the Commission, and 4) strongly encourages all medical societies to form a Standing Committee to Eliminate Health Care Disparities.
Citation: (Res. 409, A-09; Appended: Res. 416, A-11)

Reducing Discrimination in the Practice of Medicine and Health Care Education D-350.984
Our AMA will pursue avenues to collaborate with the American Public Health Association's National Campaign Against Racism in those areas where AMA's current activities align with the campaign.
Citation: BOT Action in response to referred for decision Res. 602, I-15

Reducing Racial and Ethnic Disparities in Health Care D-350.995
Our AMA's initiative on reducing racial and ethnic disparities in health care will include the following recommendations:
(1) Studying health system opportunities and barriers to eliminating racial and ethnic disparities in health care.
(2) Working with public health and other appropriate agencies to increase medical student, resident physician, and practicing physician awareness of racial and ethnic disparities in health care and the role of professionalism and professional obligations in efforts to reduce health care disparities.
(3) Promoting diversity within the profession by encouraging publication of successful outreach programs that increase minority applicants to medical schools, and take appropriate action to support such programs, for example, by expanding the "Doctors Back to School" program into secondary schools in minority communities.
Citation: BOT Rep. 4, A-03; Reaffirmation A-11; Reaffirmation: A-16; Reaffirmed: CMS Rep. 10, A-19

Racial and Ethnic Disparities in Health Care H-350.974
1. Our AMA recognizes racial and ethnic health disparities as a major public health problem in the United States and as a barrier to effective medical diagnosis and treatment. The AMA maintains a position of zero tolerance toward racially or culturally based disparities in care; encourages individuals to report physicians to local medical societies where racial or ethnic discrimination is suspected; and will continue to support physician cultural awareness initiatives and related consumer education activities. The elimination of racial and ethnic disparities in health care an issue of highest priority for the American Medical Association.
2. The AMA emphasizes three approaches that it believes should be given high priority:
A. Greater access - the need for ensuring that black Americans without adequate health care insurance are given the means for access to necessary health care. In particular, it is urgent that Congress address the need for Medicaid reform.
B. Greater awareness - racial disparities may be occurring despite the lack of any intent or purposeful efforts to treat patients differently on the basis of race. The AMA encourages physicians to examine their own practices to ensure that inappropriate considerations do not affect their clinical judgment. In addition, the profession should help increase the awareness of its members of racial disparities in medical treatment decisions by engaging in open and broad discussions about the issue. Such discussions should take place in medical school curriculum, in medical journals, at professional conferences, and as part of professional peer review activities.
C. Practice parameters - the racial disparities in access to treatment indicate that inappropriate considerations may enter the decisionmaking process. The efforts of the specialty societies, with the coordination and assistance of our AMA, to develop practice parameters, should include criteria that would preclude or diminish racial disparities
3. Our AMA encourages the development of evidence-based performance measures that adequately identify socioeconomic and racial/ethnic disparities in quality. Furthermore, our AMA supports the use of evidence-based guidelines to promote the consistency and equity of care for all persons.
4.Our AMA: (a) actively supports the development and implementation of training regarding implicit bias, diversity and inclusion in all medical schools and residency programs; (b) will identify and publicize effective strategies for educating residents in all specialties about disparities in their fields related to race, ethnicity, and all populations at increased risk, with particular regard to access to care and health outcomes, as well as effective strategies for educating residents about managing the implicit biases of patients and their caregivers; and (c) supports research to identify the most effective strategies for educating physicians on how to eliminate disparities in health outcomes in all at-risk populations.
Citation: CLRPD Rep. 3, I-98; Appended and Reaffirmed: CSA Rep.1, I-02; Reaffirmed: BOT Rep. 4, A-03; Reaffirmed in lieu of Res. 106, A-12; Appended: Res. 952, I-17; Reaffirmed: CMS Rep. 10, A-19

Diversity in Medical Education H-350.970
Our AMA will: (1) request that the AMA Foundation seek ways of supporting innovative programs that strengthen pre-medical and pre-college preparation for minority students; (2) support and work in partnership with local state and specialty medical societies and other relevant groups to provide education on and promote programs aimed at increasing the number of minority medical school admissions; applicants who are admitted; and (3) encourage medical schools to consider the likelihood of service to underserved populations as a medical school admissions criterion.
Citation: (BOT Rep. 15, A-99; Reaffirmed: CME Rep. 2, A-09; Reaffirmed in lieu of Res. 311, A-15)

Fair Process for Employed Physicians H-435.942
1. Our AMA supports whistleblower protections for health care professionals and parties who raise questions that include, but are not limited to, issues of quality, safety, and efficacy of health care and are adversely treated by any health care organization or entity.
2. Our AMA will advocate for protection in medical staff bylaws to minimize negative repercussions for physicians who report problems within their workplace.
Citation: Res. 007, I-16

Race and Ethnicity as Variables in Medical Research H-460.924
Our AMA policy is that: (1) race and ethnicity are valuable research variables when used and interpreted appropriately;
(2) health data be collected on patients, by race and ethnicity, in hospitals, managed care organizations, independent practice associations, and other large insurance organizations;
(3) physicians recognize that race and ethnicity are conceptually distinct;
(4) our AMA supports research into the use of methodologies that allow for multiple racial and ethnic self-designations by research participants;
(5) our AMA encourages investigators to recognize the limitations of all current methods for classifying race and ethnic groups in all medical studies by stating explicitly how race and/or ethnic taxonomies were developed or selected;
(6) our AMA encourages appropriate organizations to apply the results from studies of race-ethnicity and health to the planning and evaluation of health services; and
(7) our AMA continues to monitor developments in the field of racial and ethnic classification so that it can assist physicians in interpreting these findings and their implications for health care for patients.
Citation: CSA Rep. 11, A-98; Appended: Res. 509, A-01; Reaffirmed: CSAPH Rep. 1, A-11)

Racial Housing Segregation as a Determinant of Health and Public Access to Geographic Information Systems (GIS) Data H-350.953
Our AMA will: (1) oppose policies that enable racial housing segregation; and (2) advocate for continued federal funding of publicly-accessible geospatial data on community racial and economic disparities and disparities in access to affordable housing, employment, education, and healthcare, including but not limited to the Department of Housing and Urban Development (HUD) Affirmatively Furthering Fair Housing (AFFH) tool.
Citation: Res. 405, A-18

Research the Effects of Physical or Verbal Violence Between Law Enforcement Officers and Public Citizens on Public Health Outcomes H-515.955
Our AMA:
1. Encourages the National Academies of Sciences, Engineering, and Medicine and other interested parties to study the public health effects of physical or verbal violence between law enforcement officers and public citizens, particularly within ethnic and racial minority communities.
2. Affirms that physical and verbal violence between law enforcement officers and public citizens, particularly within racial and ethnic minority populations, is a social determinant of health.
3. Encourages the Centers for Disease Control and Prevention as well as state and local public health agencies to research the nature and public health implications of violence involving law enforcement.
4. Encourages states to require the reporting of legal intervention deaths and law enforcement officer homicides to public health agencies.
5. Encourages appropriate stakeholders, including, but not limited to the law enforcement and public

health communities, to define serious injuriesfor the purpose of systematically collecting data on law enforcement-related non-fatal injuries among civilians and officers.
Citation: Res. 406, A-16; Modified: BOT Rep. 28, A-18

AMA Initiatives Regarding Minorities H-350.971
The House of Delegates commends the leaders of our AMA and the National Medical Association for having established a successful, mutually rewarding liaison and urges that this relationship be expanded in all areas of mutual interest and concern. Our AMA will develop publications, assessment tools, and a survey instrument to assist physicians and the federation with minority issues. The AMA will continue to strengthen relationships with minority physician organizations, will communicate its policies on the health care needs of minorities, and will monitor and report on progress being made to address racial and ethnic disparities in care. It is the policy of our AMA to establish a mechanism to facilitate the development and implementation of a comprehensive, long-range, coordinated strategy to address issues and concerns affecting minorities, including minority health, minority medical education, and minority membership in the AMA. Such an effort should include the following components:
(1) Development, coordination, and strengthening of AMA resources devoted to minority health issues and recruitment of minorities into medicine;
(2) Increased awareness and representation of minority physician perspectives in the Association's policy development, advocacy, and scientific activities;
(3) Collection, dissemination, and analysis of data on minority physicians and medical students, including AMA membership status, and on the health status of minorities;
(4) Response to inquiries and concerns of minority physicians and medical students; and
(5) Outreach to minority physicians and minority medical students on issues involving minority health status, medical education, and participation in organized medicine.
Citation: CLRPD Rep. 3, I-98; CLRPD Rep. 1, A-08; Reaffirmed: CEJA Rep. 01, A-20

Establishment of State Commission / Task Force to Eliminate Racial and Ethnic Health Care Disparities H-440.869
Our AMA will encourage and assist state and local medical societies to advocate for creation of statewide commissions to eliminate health disparities in each state.
Citation: Res. 914, I-07; Modified: BOT Rep. 22, A-17

Discriminatory Policies that Create Inequities in Health Care H-65.963
Our AMA will: (1) speak against policies that are discriminatory and create even greater health disparities in medicine; and (2) be a voice for our most vulnerable populations, including sexual, gender, racial and ethnic minorities, who will suffer the most under such policies, further widening the gaps that exist in health and wellness in our nation.
Citation: Res. 001, A-18

Support of Human Rights and Freedom H-65.965
Our AMA: (1) continues to support the dignity of the individual, human rights and the sanctity of human life, (2) reaffirms its long-standing policy that there is no basis for the denial to any human being of equal rights, privileges, and responsibilities commensurate with his or her individual capabilities and ethical character because of an individual's sex, sexual orientation, gender, gender identity, or transgender status, race, religion, disability, ethnic origin, national origin, or age; (3) opposes any discrimination based on an individual's sex, sexual orientation, gender identity, race, religion, disability, ethnic origin, national origin or age and any other such reprehensible policies; (4) recognizes that hate crimes pose a significant threat to the public health and social welfare of the citizens of the United States, urges expedient passage of appropriate hate crimes prevention legislation in accordance with our AMA's policy through letters to members of Congress; and registers support for hate crimes prevention legislation, via letter, to the President of the United States.
Citation: CCB/CLRPD Rep. 3, A-14; Reaffirmed in lieu of: Res. 001, I-16; Reaffirmation: A-17

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 010
(November 2020)

Introduced by: Minority Affairs Section

Subject: Racial Essentialism in Medicine

Referred to: Reference Committee on Amendments to Constitution and Bylaws

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Whereas, At the turn of the twentieth century, sociologist and civil rights leader W.E.B. DuBois synthesized sociological and scientific evidence to conclude that race is not a scientific category, and rather that racial health disparities stemmed from social, not biological, inequalities[1]; and

Whereas, "Racial essentialism" is defined as the belief in a genetic or biological essence that defines all members of a racial category[2–4]; and

Whereas, The modern scientific consensus is that race is a social construct based on prevailing societal perceptions of physical characteristics, and that there are no underlying biological traits that unite people of the same racial category[3–15]; and

Whereas, Race as a variable has been inconsistently defined in research literature, clinical practice guidelines, and even U.S. Census categorizations[5,8,12–14,16–22]; and

Whereas, Race is often inappropriately conflated with ethnicity, which led to passage of AMA policy recognizing that race and ethnicity are conceptually distinct (H-460.924)[8,15,16,23]; and

Whereas, Decades of rigorous genetics research has confirmed that genetic and biological variation exists within and among populations across the planet, and groups of individuals can be differentiated by patterns of similarity and difference, but these patterns do not align with socially-defined racial groups (e.g., white, Black) or continentally-defined geographic ancestral clusters (e.g., Africans, Asians, and Europeans)[4,5,7–11,13,16,23]; and

Whereas, Many clinical calculations that "correct for race" were developed under the mistaken belief that race is a useful proxy for intrinsic biological or genetic traits[11,13,14];and

Whereas, Spirometric pulmonary function tests (PFTs) guidelines currently recommending a race-based correction factor despite a 2013 literature review demonstrating that 94% of articles comparing PFTs between white and non-white groups do not assess confounders like socioeconomic status[14,17,18,24]; and

Whereas, Current literature demonstrates that use of race in clinical score calculators is unnecessary, less precise than biological measures, and leads to results that are not reproducible, as evidenced by the use of race in the calculation of estimated glomerular filtration rate (eGFR) based on a 1999 study of 1,628 patients (only 12% of whom self-identified as "Black")[14,19–21,25,26]; and

Whereas, Because the use of race in clinical algorithms reifies racial essentialism and can disproportionately harm Black patients, leading institutions around the country have discarded race-based reporting of eGFR and key stakeholders in the nephrology field are actively working to eliminate this practice in lieu of non-race-based alternatives[13,19–21,27–31]; and

Whereas, Clinical tests and criteria that use race-based factors often do not account for the existence of people from multiracial backgrounds, a population that now makes up 14% of infants born in the US, and other underserved populations including American Indians and Alaskan Natives[13,22,32]; and

Whereas, Current AMA policy supports “research into the use of methodologies that allow for multiple racial and ethnic self-designations” and encourages applying research evidence on race, ethnicity, and health to “the planning and evaluation of health services” (H-460.924); and

Whereas, Perpetuating the incorrect belief that race by itself can explain biological variation contributes to tangible inequities, such as the undertreatment of pain due to wrongly perceived biological differences in pain tolerance, delays in referral for renal transplantation, under-referral for DEXA scans, industry denial of worker’s compensation, and more[11,13,14,21,33–36]; and

Whereas, Although racial essentialism is harmful and has no scientific validity, teaching trainees about and researching race as a sociopolitical construct is useful to understand structural racism as a root cause of health inequity, the lived experiences of patients which contribute to their relationship with the healthcare system, and the day-to-day experiences which affect individual health outcomes[3,10–12,37–42]; and

Whereas, Since race and racism impact multiple structural and social determinants of health, there is no easy replacement risk factor, which highlights the need for directed research to uncover the true causal pathways mitigating racial differences in disease prevalence and health outcomes[10,11,20,21,23,40–43]; and

Whereas, Our AMA denounces practices which exacerbate health disparities, serves as a leading voice for marginalized minority groups, and “encourages investigators to recognize the limitations of current methods for classifying race” (H-65.963, H-460.924), but current policy does not identify or explicitly discourage the inappropriate practice of using race as a proxy for biological risk factors; and

Whereas, In June 2020, our AMA Board of Trustees publicly recognized racism as an urgent threat to public health and resolved to “actively work to dismantle racist and discriminatory policies and practices across all of health care”[44]; and

Whereas, In September 2020, the U.S. House Ways & Means Committee released a series of letters which called upon medical societies, including the AMA, to “describe how racism has influenced the use of race in medicine, science, and research, and call for a new path forward where medicine considers race as a tool to measure racism, not biological differences” letter[45]; and

Whereas, In September 2020, lawmakers requested the Agency for Healthcare Research and Quality to conduct a review of clinical algorithms that correct for race and investigate the impact of structural racism on the health of communities of color to advance data-driven, antiracist health policy[46,47]; therefore be it

RESOLVED, That our American Medical Association recognize that the false conflation of race with inherent biological or genetic traits leads to inadequate examination of true underlying disease risk factors, which exacerbates existing health inequities (New HOD Policy); and be it further

RESOLVED, That our AMA encourage characterizing race as a social construct, rather than an inherent biological trait, and recognizes that when race is described as a risk factor, it is more likely to be a proxy for influences including structural racism than a proxy for genetics (New HOD Policy); and be it further

RESOLVED, That our AMA collaborate with the AAMC, AACOM, NBME, NBOME, ACGME, other appropriate stakeholder organizations, including minority physician organizations and content experts, to identify and address aspects of medical education and board examinations which may be perpetuating the mistaken belief that race is an inherent biologic risk factor for diseases (Directive to Take Action); and be it further

RESOLVED, That our AMA collaborate with appropriate stakeholders and content experts to develop recommendations on how to interpret or improve clinical algorithms that currently include race-based correction factors (Directive to Take Action); and be it further

RESOLVED, That our AMA support research that promotes antiracist strategies to mitigate algorithmic bias in medicine. (Directive to Take Action)

Fiscal Note: Estimated cost of $25,000 to implement resolution.

Received: 10/13/20

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RELEVANT AMA POLICY

Race and Ethnicity as Variables in Medical Research H-460.924
Our AMA policy is that: (1) race and ethnicity are valuable research variables when used and interpreted appropriately;
(2) health data be collected on patients, by race and ethnicity, in hospitals, managed care organizations, independent practice associations, and other large insurance organizations;
(3) physicians recognize that race and ethnicity are conceptually distinct;
(4) our AMA supports research into the use of methodologies that allow for multiple racial and ethnic self-designations by research participants;
(5) our AMA encourages investigators to recognize the limitations of all current methods for classifying race and ethnic groups in all medical studies by stating explicitly how race and/or ethnic taxonomies were developed or selected;
(6) our AMA encourages appropriate organizations to apply the results from studies of race-ethnicity and health to the planning and evaluation of health services; and
(7) our AMA continues to monitor developments in the field of racial and ethnic classification so that it can assist physicians in interpreting these findings and their implications for health care for patients.
Citation: CSA Rep. 11, A-98; Appended: Res. 509, A-01; Reaffirmed: CSAPH Rep. 1, A-11)

Reducing Discrimination in the Practice of Medicine and Health Care Education D-350.984
Our AMA will pursue avenues to collaborate with the American Public Health Association's National Campaign Against Racism in those areas where AMA's current activities align with the campaign.
Citation: BOT Action in response to referred for decision Res. 602, I-15;

Discriminatory Policies that Create Inequities in Health Care H-65.963
Our AMA will: (1) speak against policies that are discriminatory and create even greater health disparities in medicine; and (2) be a voice for our most vulnerable populations, including sexual, gender, racial and ethnic minorities, who will suffer the most under such policies, further widening the gaps that exist in health and wellness in our nation.
Citation: Res. 001, A-18;

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 011
(November 2020)

Introduced by: Minnesota

Subject: Elimination of Race as a Proxy for Ancestry, Genetics, and Biology in Medical Education, Research, and Clinical Practice

Referred to: Reference Committee on Amendments to Constitution and Bylaws

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Whereas, Race is a category often used in medicine--with health statistics often stratified by race, research noting how rates of morbidity and mortality vary by race, and clinicians making treatment and other care-related decisions based on the race of a patient; and

Whereas, Following the completion of the Human Genome Project in 2003[i], leading geneticists concluded that race is neither a rational nor effective representation of real human biological variability; and

Whereas, The Human Genome Project also found that people can have greater genetic similarity to those outside their racial category than to those within their racial category, which demonstrates that genetic variation does not follow along racial lines; and

Whereas, Race is a social construct that is a politically developed classification system based on physical characteristics and geographic ancestry and is not based on science and does not represent shared genetic ancestry; and

Whereas, Using race as a proxy for genetics and genetic ancestry allows for harmful continuations of racial ideology and has the potential to negatively impact patient care, such as attributing higher incidences of certain diseases or conditions seen among certain racial groups that may be due to socioeconomic, environmental, and other nongenetic factors--and not their racial category[ii]; and

Whereas, Since race is not biological, there is no value in attributing racial health disparities to innate biological difference, but there is value in understanding how racism and systemic oppression result in racial health disparities; and

Whereas, Epigenetics is the study of changes in gene expression that are not due to changes in the genetic code itself, and racial trauma, stress, discrimination and systemic racist practices, such as financial and environmental disinvestment in minority communities, have been proposed as an etiology of epigenetic changes; and

Whereas, When we use race as a substitute for genetic ancestry, it limits us from investigating and addressing racism and other racial traumas as the cause of racial health disparities; and

Whereas, The way physicians and other health care workers think and talk about race, racism and racial health disparities affects how we treat our patients; and

Whereas, Existing AMA policy E-8.5, “Disparities in Health Care,” says, in part, “Stereotypes, prejudice, or bias based on gender expectations and other arbitrary evaluations of any individual can manifest in a variety of subtle ways. Differences in treatment that are not directly related to differences in individual patients’ clinical needs or preferences constitute inappropriate variations in health care. Such variations may contribute to health outcomes that are considerably worse in members of some populations than those of members of majority populations.”[iii]; therefore be it

RESOLVED, That our American Medical Association recognize that race is a social construct and is distinct from ethnicity, genetic ancestry, or biology (New HOD Policy); and be it further

RESOLVED, That our AMA support ending the practice of using race as a proxy for biology or genetics in medical education, research, and clinical practice (New HOD Policy); and be it further

RESOLVED, That our AMA encourage undergraduate medical education, graduate medical education, and continuing medical education programs to recognize the harmful effects of presenting race as biology in medical education and that they work to mitigate these effects through curriculum change[iv] that: (1) demonstrates how the category “race” can influence health outcomes; (2) that supports race as a social construct and not a biological determinant and (3) presents race within a socio-ecological model of individual, community and society to explain how racism and systemic oppression result in racial health disparities (New HOD Policy); and be it further

RESOLVED, That our AMA recommend that clinicians and researchers focus on genetics and biology, the experience of racism, and social determinants of health, and not race, when describing risk factors for disease. (Directive to Take Action)

Fiscal Note: Minimal - less than $1,000

Received: 10/11/20

RELEVANT AMA POLICY

8.5 Disparities in Health Care
Stereotypes, prejudice, or bias based on gender expectations and other arbitrary evaluations of any individual can manifest in a variety of subtle ways. Differences in treatment that are not directly related to differences in individual patients’ clinical needs or preferences constitute inappropriate variations in health care. Such variations may contribute to health outcomes that are considerably worse in members of some populations than those of members of majority populations.
This represents a significant challenge for physicians, who ethically are called on to provide the same quality of care to all patients without regard to medically irrelevant personal characteristics.
To fulfill this professional obligation in their individual practices physicians should:
(a) Provide care that meets patient needs and respects patient preferences.
(b) Avoid stereotyping patients.
(c) Examine their own practices to ensure that inappropriate considerations about race, gender identify, sexual orientation, sociodemographic factors, or other nonclinical factors, do not affect clinical judgment.
(d) Work to eliminate biased behavior toward patients by other health care professionals and staff who come into contact with patients.
(e) Encourage shared decision making.
(f) Cultivate effective communication and trust by seeking to better understand factors that can influence patients’ health care decisions, such as cultural traditions, health beliefs and health literacy, language or other barriers to communication and fears or misperceptions about the health care system.
The medical profession has an ethical responsibility to:
(g) Help increase awareness of health care disparities.

(h) Strive to increase the diversity of the physician workforce as a step toward reducing health care disparities.
(i) Support research that examines health care disparities, including research on the unique health needs of all genders, ethnic groups, and medically disadvantaged populations, and the development of quality measures and resources to help reduce disparities.

AMA Principles of Medical Ethics: I,IV,VII,VIII,IX

The Opinions in this chapter are offered as ethics guidance for physicians and are not intended to establish standards of clinical practice or rules of law.

Issued: 2016

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[iv] APA Nieblas-Bedolla, Edwin MPH; Christophers, Briana; Nkinsi, Naomi T.; Schumann, Paul D.; Stein, Elizabeth Changing How Race Is Portrayed in Medical Education, Academic Medicine: May 5, 2020 - Volume Publish Ahead of Print - Issue -doi: 10.1097/ACM.0000000000003496

Reference Committee A

CMS Report(s)

01 Options to Maximize Coverage under the AMA Proposal for Reform
03 Medicare Prescription Drug and Vaccine Coverage and Payment
05 Medicaid Reform
06 Value-Based Management of Drug Formularies
07 Health Plan Initiatives Addressing Social Determinants of Health

Resolution(s)

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REPORT 1 OF THE COUNCIL ON MEDICAL SERVICE (November 2020)
Options to Maximize Coverage under the AMA Proposal for Reform
(Resolution 113-A-19 and Resolution 114-A-19)
(Reference Committee A)

EXECUTIVE SUMMARY

The American Medical Association (AMA) proposal for reform has the potential to make significant strides in covering the remaining uninsured and providing health insurance to millions more Americans. However, the Council sees an opportunity to further maximize coverage rates and improve coverage affordability under the AMA proposal for reform by establishing new policy on a public option, as well as auto-enrollment in health insurance coverage. Of note, both approaches cannot be implemented without safeguards in place to protect patients, as well as physicians and their practices.

The Council is aware of the growing interest within the House of Delegates for our AMA to support a public option. However, the term "public option" has several different meanings, and blanket support for a public option without safeguards in place could have negative consequences for physicians and their practices. If all criteria established by the policy proposed by the Council in this report are met, there is the potential for our AMA to support a public option, as it would provide patients with another choice of health plan. As such, a primary goal of establishing a public option should be to maximize patient choice of health plan and maximize health plan marketplace competition. Importantly, eligibility for premium tax credit and cost-sharing assistance to purchase the public option needs to be restricted to individuals without access to affordable employer-sponsored coverage. Otherwise, physician practice payer mix and revenues could be significantly impacted, especially if payment rates under the public option are tied to or guided by Medicare and/or Medicaid payment rates. Regardless of the public option design, payment rates need to be established through meaningful negotiations and contracts and must not be tied to or guided by Medicare and/or Medicaid rates. Physician freedom of practice needs to also be at the forefront of assessing any public option proposal and, as such, public option proposals should not require provider participation, and/or tie a provider's participation in Medicare, Medicaid and/or any commercial product to participation in the public option.

The Council sees tremendous potential in the use of auto-enrollment to improve the coverage reach of the AMA proposal for reform, especially amid the COVID-19 pandemic. In 2018, 57 percent of the nonelderly uninsured population was eligible for financial assistance – either through Medicaid or the Children's Health Insurance Program, or via premium tax credits to purchase marketplace coverage as provided for under the Affordable Care Act (ACA). Additionally, a substantial percentage of the newly unemployed are eligible for Medicaid or premium tax credits to purchase ACA marketplace coverage. As such, a significant number of uninsured Americans are currently eligible for no- or low-cost coverage but are not enrolled. The Council believes that states and the federal government should seriously consider the use of auto-enrollment to maximize coverage rates, alongside key improvements to the ACA as outlined in the AMA proposal for reform. As such, the Council proposes standards for states and/or the federal government to follow as they pursue auto-enrollment in health insurance coverage. The Council believes that, especially considering the coverage impacts of the COVID-19 pandemic, there needs to be a mechanism in AMA policy to ensure that the AMA proposal for reform can maximize its coverage potential and reach. Physicians have the responsibility to advocate for improving health insurance coverage and health care access so that patients receive timely, high quality care, preventive services, medications and other necessary treatments.

REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 1, November 2020

Subject: Options to Maximize Coverage under the AMA Proposal for Reform (Resolution 113-A-19 and Resolution 114-A-19)

Presented by: Lynda M. Young, MD, Chair

Referred to: Reference Committee A

At the 2019 Annual Meeting, the House of Delegates referred two resolutions jointly sponsored by the Washington and Connecticut Delegations, Resolutions 113 and 114; an alternate resolution offered by Reference Committee A; and an amendment offered by the American College of Physicians during House of Delegates floor consideration of the reference committee report item addressing Resolutions 113 and 114. The Board of Trustees assigned these items to the Council on Medical Service for a report back to the House of Delegates.

Resolution 113-A-19, Ensuring Access to Statewide Commercial Health Plans, asked that our American Medical Association (AMA) study the concept of offering state employee health plans to every state resident, including exchange participants qualifying for federal subsidies, and report back to the House of Delegates this year; and advocate that State Employees Health Benefits Program health insurance plans be subject to all fully insured state law requirements on prompt payment, fairness in contracting, network adequacy, limitations or restrictions against high deductible health plans, retrospective audits and reviews, and medical necessity.

Resolution 114-A-19, Ensuring Access to Nationwide Commercial Health Plans, asked that our AMA advocate that Federal Employees Health Benefits Program (FEHBP) health insurance plans should become available to everyone to purchase at actuarially appropriate premiums as well as be eligible for federal premium tax credits; and advocate that FEHBP health insurance plans be subject to all fully insured state law requirements on prompt payment, fairness in contracting, network adequacy, limitations or restrictions against high deductible health plans, retrospective audits and reviews, and medical necessity.

The alternate resolution proposed by Reference Committee A asked that our AMA study the impacts of various approaches that offer a public option in addition to current sources of coverage, private or public, including but not limited to a Medicare buy-in; a public option offered on health insurance exchanges; and buying into either the FEHBP or a state employee health plan; and reaffirm Policy H-165.838, which states that insurance coverage options offered in a health insurance exchange be self-supporting; have uniform solvency requirements; not receive special advantages from government subsidies; include payment rates established through meaningful negotiations and contracts; not require provider participation; and not restrict enrollees' access to out-of-network physicians.

The amendment offered during the House of Delegates' consideration of this item at the 2019 Annual Meeting asked that our AMA support various approaches that offer a public option in addition to current sources of coverage, private or public, including but not limited to: (a)(i) a Medicare buy-in; (ii) a public option offered on health insurance exchanges; and (iii) buying into

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either the FEHBP or a state employee health plan; and (b) study the options to effectively implement such approaches.

This report provides background on the AMA proposal for reform; summarizes potential approaches to a public option; outlines how the use of auto-enrollment has the potential to maximize coverage rates; and presents policy recommendations.

THE AMA PROPOSAL FOR REFORM

Covering the uninsured and improving health insurance affordability have been long-standing goals of the AMA. Since the enactment of the Affordable Care Act (ACA), the AMA proposal for reform has continued to evolve to ensure that AMA policy is able to address how to best cover the remaining uninsured in the current coverage environment. In 2018, nearly 60 percent of nonelderly Americans (153.8 million) had employer-sponsored health insurance coverage, 22 percent (57.9 million) had Medicaid coverage, and 7 percent (19.4 million) had non-group coverage, while 10.4 percent (27.9 million) remained uninsured.[1]

Under the ACA, eligible individuals and families with incomes between 100 and 400 percent of the federal poverty level (FPL) (between 133 and 400 percent FPL in Medicaid expansion states) are being provided with refundable and advanceable premium credits that are inversely related to income to purchase coverage on health insurance exchanges. Individuals eligible for premium credits include individuals who are offered an employer plan that does not have an actuarial value of at least 60 percent or if the employee share of the premium exceeds 9.78 percent of income in 2020. In addition, individuals and families with incomes between 100 and 250 percent FPL (between 133 and 250 percent FPL in Medicaid expansion states) also qualify for cost-sharing subsidies if they select a silver plan, which reduces their deductibles, out-of-pocket maximums, copayments and other cost-sharing amounts. At the time that this report was written, 38 states and the District of Columbia had adopted the Medicaid expansion provided for in the ACA, which extended Medicaid eligibility to individuals with incomes up to 133 percent FPL.[2]

The AMA proposal for reform focuses on expanding health insurance coverage to four main population targets:

1. Individuals eligible for ACA's premium tax credits who remain uninsured (9.2 million in 2018);
2. Individuals eligible for Medicaid or the Children's Health Insurance Program (CHIP) who remain uninsured (6.7 million in 2018);
3. People that remain uninsured who are ineligible for ACA's premium tax credits due to income or an offer of "affordable" employer-sponsored coverage (5.7 million in 2018); and
4. People with low incomes that remain uninsured and are ineligible for Medicaid (2.3 million in 2018).[3]

By appropriately targeting the provision of coverage to the uninsured population, the AMA proposal for reform as follows has the potential to make significant strides in covering the remaining uninsured and providing health insurance to millions more Americans:

- Premium tax credits would be available to individuals without an offer of "affordable" employer coverage, with no upper income limit (Policy H-165.824).
- Individuals currently caught in the "family glitch" and unable to afford coverage offered through their employers for their families would become eligible for ACA financial assistance based on the premium for family coverage of their employer plan (Policy

H-165.828). Currently, in determining eligibility for premium tax credits, coverage for family members of an employee is considered to be affordable as long as employee-only coverage is affordable. The employee-only definition of affordable coverage pertaining to employer-sponsored coverage, commonly referred to as ACA's "family glitch," does not take into consideration the cost of family-based coverage, which commonly is much more expensive than employee-only coverage. As a result, the "family glitch" leaves many workers and their families ineligible to receive premium and cost-sharing subsidies to purchase coverage on health insurance exchanges, even though in reality they would likely have to pay well over 9.78 percent of their income for family coverage.

- To help employees currently having difficulties affording coverage, the threshold used to determine the affordability of employer coverage would be lowered, which would make more people eligible for ACA financial assistance based on income (Policy H-165.828).
- The generosity of premium tax credits would be increased to improve premium affordability, by tying premium tax credit size to gold-level instead of silver-level plan premiums, and/or lowering the cap on the percentage of income individuals are required to pay for premiums of the benchmark plan (Policy H-165.824).
- Young adults facing high premiums would be eligible for "enhanced" tax credits based on income (Policy H-165.824).
- Eligibility for cost-sharing reductions would be expanded to help more people with the cost-sharing obligations of the plan in which they enroll (Policy H-165.824).
- The size of cost-sharing reductions would be increased to lessen the cost-sharing burdens many individuals with low incomes face, which impact their ability to access and afford the care they need (Policy H-165.824).
- A permanent federal reinsurance program would be established, to address the impact of high-cost patients on premiums (H-165.842).
- State initiatives to expand their Medicaid programs will continue to be supported. To incentivize expansion decisions, states that newly expand Medicaid would still be eligible for three years of full federal funding (Policies D-290.979 and H-290.965).
- To maximize coverage rates, the AMA would continue to support reinstating a federal individual mandate penalty, as well as state efforts to maximize coverage, including individual mandate penalties and auto-enrollment mechanisms (Policies H-165.848 and H-165.824).
- To improve coverage rates of individuals eligible for either ACA financial assistance or Medicaid/CHIP but who remain uninsured, the AMA would support investments in outreach and enrollment assistance activities (Policies H-165.824, H-290.976, H-290.971, H-290.982 and D-290.982).
- States would continue to have the ability to test different innovations to cover the uninsured, provided such experimentations: a) meet or exceed the projected percentage of individuals covered under an individual responsibility requirement while maintaining or improving upon established levels of quality of care; b) ensure and maximize patient choice of physician and private health plan; and c) include reforms that eliminate denials for pre-existing conditions (Policy D-165.942).

APPROACHES TO A PUBLIC OPTION

As evidenced by the House of Delegates' discussion of this item at the 2019 Annual Meeting, the term "public option" can be interpreted to include different proposals to expand public coverage. In general, proposals to expand public coverage can range from creating a public option on health insurance exchanges, to allowing people to buy into Medicare or Medicaid. In addition, proposals have explored leveraging the FEHBP and state employee benefit plans to increase the plan offerings available to individuals seeking exchange coverage.

Public Option on Exchanges

In general, proposals put forward in Congress to establish a public option on the exchanges rely on components of the Medicare program both for structure and to keep plan costs down. The public option would be available to individuals and/or employers eligible to purchase such coverage. Under these proposals, Medicare participating providers could potentially be required to participate in the public option. Proposals differ in their approaches to provider opt-out provisions, and whether providers in Medicaid would also be required to participate in the public option. Most public option proposals would also base provider payment rates on Medicare, either extending Medicare payment rates or using Medicare rates as a guide to establish payment levels. Individuals who qualify for premium tax credits and cost-sharing subsidies could use such subsidies to purchase the public option. All public option proposals would cover essential health benefits as required under the ACA, with some proposals covering more benefits.

State public option proposals vary in their structure and scope, and how they leverage Medicare/Medicaid payment rates, as well as state employee plans. For example, Washington's public option, Cascade Care, which was enacted in 2019, aims to increase coverage options on *Washington Healthplanfinder* by requiring the state health care authority to contract with one or more health insurance carriers to offer a public option plan at the bronze, silver and gold levels by January 1, 2021. At the time that this report was written, five insurance carriers had applied to offer public option plans in a majority of counties across the state.[4] Washington's public option is not a fully public option governed exclusively by the state; rather, it is a blended public-private approach. The state will contract with private insurers to administer the state-sponsored plan but maintain control of the terms to manage cost.

Cascade Care carriers must cap payment of providers and facilities at a maximum of 160 percent of Medicare rates but excluding pharmacy benefits. Payment for critical access hospitals and sole community hospitals may not be less than 101 percent of Medicare's allowable cost. Of note, payment for primary care services provided by physicians in family medicine, general internal medicine, or pediatric medicine may not be less than 135 percent of the amount that Medicare pays for the same or similar services.[5] There is not a defined floor for payment for services provided by specialists outlined in the law.

Importantly, the Council notes that adding a public option to health insurance exchanges may not necessarily achieve significant additional coverage gains, compared to proposals to build upon the ACA. Many of the proposals that aim to cover more people under the ACA are included in the AMA proposal for reform. For example, the Urban Institute in October 2019 modeled the coverage and cost impacts of various health reform options. It found that, after implementing a range of proposals to build upon and improve the ACA – including enhancing and extending subsidies for marketplace coverage, establishing a permanent reinsurance program, restoring the ACA's individual mandate, addressing the Medicaid eligibility gap in non-expansion states, and allowing for limited Medicaid autoenrollment – 21.4 million individuals would be uninsured in 2020. When a public option is added to these ACA improvement provisions, 21.3 million individuals would still be uninsured in 2020. Under this scenario, adding a public option would not achieve meaningful additional coverage gains, as the public option would only lower health insurance premiums for individuals not eligible for subsidies in the nongroup market, which would be a smaller population after the implementation of the aforementioned ACA improvements. That being said, adding a public option was shown to meaningfully lower federal spending on subsidies for marketplace coverage, as lower premiums, premised on lower provider payment rates, would lead to lower premium tax credit amounts.[6]

Similarly, in a March 2020 brief that assessed the impacts of various public option designs, the Urban Institute found that "[a] public option's largest effects are on government and private spending—not on insurance coverage, unless paired with other reforms, such as enhanced premium tax credits and strategies to provide subsidized coverage for more low-income adults in states that have not expanded Medicaid eligibility." As evidence of its finding, Urban Institute estimated that introducing a public option into the nongroup market would cause a small decrease in the number of uninsured Americans – ranging from approximately 155,000 to 230,000 in 2020.[7]

In May 2020, RAND Corporation released a report that assessed the impact of four public option alternatives: 1) coverage offered off of the ACA marketplaces, with provider payment set at 79 percent of commercial rates; 2) coverage offered on the ACA marketplaces, with provider payment set at 79 percent of commercial rates; 3) coverage offered on the ACA marketplaces, with provider payment set at 93 percent of commercial rates; and 4) coverage offered on the ACA marketplaces, with provider payment set at 93 percent of commercial rates, and eligibility for ACA's premium tax credits extended to 500 percent FPL. Overall, the RAND analysis found that changes to the number of the uninsured resulting from the introduction of a public option in scenarios 2, 3 and 4 would be small, with the first alternative having the largest impact on the uninsured. Notably, there was also a shift in enrollment from private individual market plans to public plans, due in large part to the lower premium of the public option, driven by lower provider payment rates. The analysis also showed that the introduction of a public option could reduce premium tax credit amounts and increase premiums for private ACA marketplace plans. As such, while some individuals would be better off with a public option, those who would be worse off would likely be those with lower incomes who would be eligible for smaller premium tax credits as a result.[8]

Broader Availability of a Public Option

Proposals introduced in Congress would also leverage a public option that relies heavily on Medicare and Medicaid payment rates to achieve near-universal coverage. Unlike federal and state legislation that proposes offering a public option on ACA marketplaces, which would be available only to marketplace participants and keep the ACA's eligibility criteria for premium tax credits and cost-sharing subsidies the same, more expansive public option proposals would also open up the public option and eligibility for premium and cost-sharing assistance to individuals who are offered affordable employer-sponsored coverage. As a result, these proposals to establish a public option would be expected to cause crowd-out from employer-sponsored coverage, as well as higher enrollment in the public option, which would impact the payer mix of physician practices. In addition, as employer-sponsored health plans tend to have higher provider payment rates than nongroup health plans, opening up a public option to individuals with employer-sponsored coverage has the potential to significantly reduce provider revenues and cause disruptions in the health care delivery system.[9]

For example, as an alternative to the traditional Medicare-for-All proposals, Representative Rosa DeLauro (D-CT) introduced H.R. 2452, the Medicare for America Act of 2019. Unlike Medicare-for-All, Medicare for America would allow large employers to continue providing health insurance to their employees, if they provide gold-level coverage (i.e., 80 percent of benefits costs covered). Alternatively, employers can direct their contributions for employee coverage toward paying for premiums for Medicare for America. If employers continue to offer health insurance to their employees, employees would have the ability to choose Medicare for America coverage instead of their employer coverage. There would also be premiums and cost-sharing under Medicare for America, but notably, there would be no deductibles. Premiums would be on a sliding scale based on income, with individuals with incomes below 200 percent FPL having no premium, deductible or out-of-pocket costs. Premiums overall would be capped at no more than eight percent of

monthly income. Individuals and families with incomes between 200 and 600 percent FPL would be eligible to receive subsidies to lower their premium contributions, with current Medicare beneficiaries either paying the premium for which they are responsible under Medicare, or that of Medicare for America, whichever is less expensive. Out-of-pocket maximums would also be applied on a sliding scale based on income, with the caps being $3,500 for an individual and $5,000 for families. Provider payment under Medicare for America would be based largely on Medicare and Medicaid rates, with increases in payment for primary care, mental and behavioral health, and cognitive services, and the Secretary being given the authority to establish a rate schedule for services currently not paid for under Medicare. Participating providers under Medicare or Medicaid would be considered to be participating providers under Medicare for America.[10,11]

In addition, former Vice President Joe Biden, the Democratic presidential nominee, in conjunction with Senator Bernie Sanders (I-VT), put forward the Biden-Sanders Unity Task Force recommendations, which included provisions related to a public option. The recommendations called for the establishment of a public option administered by the Centers for Medicare & Medicaid Services that would be available to individuals covered by employer-sponsored coverage (regardless of whether such coverage is affordable), those with individually purchased coverage, and the uninsured. Significantly, uninsured individuals who fall in the coverage gap – not eligible for Medicaid, and not eligible for tax credits because they reside in states that did not expand Medicaid – would be automatically enrolled in a premium-free public option, with the ability to opt out should they choose. The public option would also be a health plan choice for older members of the workforce, along with their employer-sponsored plan, and the ability to enroll in Medicare at the age of 60. The public option would be required to provide at least one plan choice without deductibles, would cover all primary care without any cost-sharing, and would negotiate prices with physicians and hospitals to control costs for other treatments and services, "just like Medicare does on behalf of older people."[12]

The Biden-Sanders Unity Task Force recommendations also called for leveraging a public option in the context of a health emergency, which would include the COVID-19 pandemic. First, when an individual's eligibility for Consolidated Omnibus Budget Reconciliation Act (COBRA) coverage expires, the recommendations call for workers whose incomes would qualify them for a zero-premium public option to be automatically enrolled in the public option, with the ability to opt out. In addition, the recommendations support automatically enrolling in the public option individuals eligible for a zero-premium public option, and individuals enrolled in any social safety net program for low-income Americans, such as the Supplemental Nutrition Assistance Program (SNAP) and Temporary Assistance for Needy Families (TANF).[13]

Medicare Buy-In

Senator Debbie Stabenow (D-MI) introduced S. 470, the Medicare at 50 Act, and Congressman Brian Higgins (D-NY) introduced H.R. 1346, the Medicare Buy-In and Health Care Stabilization Act of 2019, both of which would enable individuals to buy in to Medicare at age 50. Premiums would be based on estimating the average, annual per capita amount for benefits and administrative expenses that would be payable under Parts A, B, and D for the buy-in populations. Notably, individuals enrolled in the buy-in would receive financial assistance similar to that which they would have received had they purchased a qualified health plan through the marketplace.[14,15]

RAND Corporation has modeled various approaches to a Medicare buy-in to assess the impacts of allowing individuals ages 50 to 64 to buy in to the Medicare program, including on total health insurance enrollment. Across all approaches to a Medicare buy-in analyzed by RAND, 2.8 to 7 million older adults would enroll, with 6 million individuals enrolling under RAND's base buy-in

scenario. This rate of take-up of a Medicare buy-in is due to the premiums for the buy-in being less expensive than plans offered on the individual market – the result of factors including the buy-in paying providers at Medicare rates. However, when these older adults exit the individual market, premiums for plans offered on the individual market increase, as the remaining risk pool is smaller, and comprised of less healthy and more expensive individuals considering their ages. Accordingly, the RAND analysis showed that a Medicare buy-in has little to no effect on total health insurance enrollment, as more older adults enrolling in health insurance pursuant to the establishment of the buy-in is countered by more younger adults becoming uninsured.[16]

Medicaid Buy-In

Senator Brian Schatz (D-HI) and Congressman Ben Ray Luján (D-NM) introduced S. 489/H.R. 1277, the State Public Option Act. The legislation would give states the option to establish a Medicaid buy-in plan for residents regardless of income. For individuals ineligible for premium tax credits, their premiums cannot exceed 9.5 percent of household income. However, if these individuals were to enroll in other plans on state ACA marketplaces, their premiums would not be capped as a percentage of their income. In terms of physician payment rates, the State Public Option Act would make permanent a payment increase to Medicare levels for a range of primary care providers.[17,18] Understandably, this approach to a Medicaid buy-in is more likely to be taken up by states that have expanded Medicaid versus states that have not. Urban Institute, in analyzing this approach to a Medicaid buy-in, found that, while it may not have a meaningful impact in states with competitive markets, it could make a difference in states with limited insurer competition and high premiums.[19]

As state Medicaid programs are different, Medicaid buy-in proposals can be expected to vary from state to state. For example, a Medicaid buy-in can be offered on the exchanges (potentially a Medicaid managed care plan), or a Medicaid-like program could be offered off of the exchanges. Such design differences could impact the ability of individuals to use ACA subsidies to purchase Medicaid buy-in coverage. Importantly, Medicaid buy-in proposals strive to not change the existing Medicaid program for those currently eligible and enrolled. Approaches to physician payment can vary as well, from using Medicaid or Medicare rates as a guide, to opening the door to negotiated rates. Several states are considering a Medicaid buy-in approach, including New Mexico, Delaware, Massachusetts and Oregon.

Leveraging the Federal Employees Health Benefits Program (FEHBP) and State Employee Benefit Plans

The FEHBP provides health insurance coverage to federal employees, retirees, and their dependents. By entering into contracts with qualified health insurance carriers, the US Office of Personnel Management (OPM) offers through FEHBP two primary types of plans – fee-for-service (FFS) plans (most of which have a preferred provider organization component) and health management organization (HMO) plans. While FFS plans are offered nationwide to all enrollees, HMO plans offer coverage in certain geographic areas. In reviewing health plans to be offered under FEHBP, OPM considers the ability of plans to provide reasonable access to and choice of primary and specialty medical care throughout the service area.

Leveraging health plan FEHBP participation has been included in a leading proposed solution to prevent bare counties in the marketplaces. A 2017 bipartisan proposal to fix the ACA supported, in the short-term, requiring the two largest FEHBP insurers in any county to offer at least one silver-level plan though the federal exchange in all counties that would otherwise be without coverage as a condition of participation in FEHBP. These plans would be eligible for premium tax credits and

could otherwise charge actuarially appropriate premiums.[20] In addition, last Congress, Representative Darrell Issa (R-CA) introduced legislation to allow individuals who are not federal employees to enroll in FEHBP unless the individual is enrolled, or eligible to enroll, in a different public health insurance program; or is a member of the uniformed services.[21]

Some states are exploring leveraging state employee benefit plans to bolster proposed public options, or to increase exchange plan offerings available. For example, the public option legislation passed in the state of Washington requires the state authority to submit a report to the legislature by December 1, 2022, that addresses the impact on exchange market choices, affordability, and stability of linking a carrier's ability to offer a state-contracted public option with their participation in programs administered by the public employees' benefits board, the school employees' benefits board, or the health care authority; and the impact on the exchange market of requiring providers who participate in the aforementioned programs to participate in public option plan networks.[22] In addition, an option available to potentially increase exchange plan offerings is to require plans that participate in state employee benefit plans to offer plans on the exchange.

Relevant AMA Policy

Policy H-165.838 states that insurance coverage options offered in a health insurance exchange should be self-supporting; have uniform solvency requirements; not receive special advantages from government subsidies; include payment rates established through meaningful negotiations and contracts; not require provider participation; and not restrict enrollees' access to out-of-network physicians. Policy H-165.825 states that the largest two FEHBP insurers in counties that lack a marketplace plan should be required to offer at least one silver-level marketplace plan as a condition of FEHBP participation.

Addressing a Medicare buy-in, Policy H-330.896 states that Medicare's age-eligibility requirements and incentives should be restructured to match the Social Security schedule of benefits. Concerning Medicaid expansion, Policy D-290.979 advocates working with interested states to expand Medicaid eligibility in their states to 133 percent of the federal poverty level.

ACHIEVING HIGHER COVERAGE RATES THROUGH AUTO-ENROLLMENT

In 2018, 27.9 million nonelderly individuals (10.4 percent) were uninsured, an increase from the 27.4 million (10.2 percent) who were uninsured in 2017.[23] Nearly seven million of the nonelderly uninsured were eligible for Medicaid or CHIP. More than nine million nonelderly individuals were eligible for premium tax credits provided for under the ACA.[24] In December 2019, the Kaiser Family Foundation estimated that, of the uninsured who could purchase coverage on health insurance exchanges, 4.7 million are eligible to purchase a zero-premium bronze plan (i.e., 60 percent of benefits costs covered) after subsidies in 2020.[25]

The elimination of the federal individual mandate penalty as a part of tax reform legislation enacted in December 2017, as well as job losses amid the COVID-19 pandemic, raise the need to examine alternative approaches to maximize coverage rates. Resulting from the reality that a significant proportion of the uninsured and newly unemployed are eligible for no- or low-cost coverage provided for under the ACA, auto-enrollment has emerged as a prominent policy option. Federal and/or state auto-enrollment approaches could address auto-enrollment in marketplace coverage, Medicaid/CHIP and employer coverage.

Any auto-enrollment program needs to address four policy challenges:

1. How to obtain eligibility information so uninsured individuals can be identified and matched to coverage for which they are eligible, including Medicaid/CHIP and marketplace coverage, as well as premium tax credits.
2. How to collect premiums, if applicable.
3. How to assign individuals to an insurance plan.
4. How to manage situations where individuals are auto-enrolled into coverage for which they are not eligible, or remain uninsured despite believing they were enrolled in health insurance coverage.[26]

There are multiple approaches to auto-enrollment. First, states and/or the federal government can pursue tax-based auto-enrollment, under which individuals at the time of tax filing would either indicate whether or not they had health insurance coverage, and/or authorize the state or federal entity to determine eligibility for Medicaid/CHIP, or free or low-cost health insurance offered on the marketplaces. Once coverage determinations take place, auto-enrollment can occur that results in coverage for the upcoming year or coverage could be applied retroactively. Under traditional auto-enrollment programs, individuals could either be auto-enrolled in Medicaid/CHIP, as well as no-premium bronze plans if they are eligible; a special enrollment period could be established for individuals who qualify for premium tax credits for marketplace coverage; and/or targeted outreach activities could be implemented to facilitate the health insurance enrollment of those eligible for premium tax credits and Medicaid/CHIP.

For example, the Maryland Easy Enrollment Health Insurance Program, enacted in 2019, is taking steps to use a tax-based approach to auto-enrollment. Under the first phase of the program, individuals check a box on their tax return to indicate any uninsured household members, and then have a choice of providing authorization to the state to share information from their tax return with the state exchange to determine their eligibility for no- or low-cost insurance. If individuals grant the state authorization, the state exchange makes a preliminary eligibility determination and sends out a written notice to the household. While individuals must use traditional channels to sign up for marketplace coverage, they are granted a special enrollment period so they can sign up for coverage after tax filing, versus waiting for the next open enrollment period. In the second phase of implementation, which commences January 2021, the state is striving for real-time eligibility determinations; automatic Medicaid enrollment; and streamlined marketplace plan enrollment, again coupled with the use of a special enrollment period.[27]

Auto-enrollment in health insurance coverage could also be implemented retroactively. For example, individuals uninsured at the time of tax filing could be considered covered by a “backstop plan” for each month of the previous year they were uninsured. As a result, these individuals would pay premiums retroactively for the backstop coverage, which would be income-adjusted. If they accessed health care services during their time of being uninsured and retroactively covered by the backstop plan, the backstop plan would pay their claims.

If disconnected from tax filing, auto-enrollment programs could also leverage existing state systems, such as automobile registration and drivers’ license renewal, or could be implemented in partnership with health care providers, clinics and hospitals. Relevant to the tens of millions of Americans who are projected to lose their employer-sponsored health insurance coverage resulting from the COVID-19 pandemic, state unemployment insurance systems could be leveraged to facilitate enrollment in no- or low-cost health insurance for which the newly unemployed are eligible.

Relevant AMA Policy

Policy H-165.824 encourages state innovation, including considering state-level individual mandates, auto-enrollment and/or reinsurance, to maximize the number of individuals covered and stabilize health insurance premiums without undercutting any existing patient protections. Policy H-165.855 states that, should tax credits be given to Medicaid beneficiaries, that they be given a choice of coverage, and that a mechanism be developed to administer a process by which those who do not choose a health plan will be assigned a plan in their geographic area through auto-enrollment until the next enrollment opportunity. The policy also stipulates that patients who have been auto-enrolled should be permitted to change plans any time within 90 days of their original enrollment.

DISCUSSION

The AMA proposal for reform has the potential to make significant strides in covering the remaining uninsured and providing health insurance to millions more Americans. However, the Council sees an opportunity to further maximize coverage rates and improve coverage affordability under the AMA proposal for reform by establishing new policy on a public option, as well as auto-enrollment in health insurance coverage. The Council stresses that both approaches cannot be implemented without safeguards in place to protect patients, as well as physicians and their practices.

The Council is aware of the growing interest within the House of Delegates for our AMA to support a public option. However, the term "public option" has several different meanings, and blanket support for a public option without safeguards in place could have negative consequences for physicians and their practices. For example, public option proposals that allow individuals with affordable employer coverage to qualify for premium and cost-sharing subsidies and enroll in a public option could significantly change the payer mix of physician practices, especially if payment rates under the public option are tied to or guided by Medicare and/or Medicaid payment rates. Regardless of the public option design, payment rates need to be established through meaningful negotiations and contracts and must not be tied to or guided by Medicare and/or Medicaid rates. Physician freedom of practice needs to also be at the forefront of assessing any public option proposal and, as such, public option proposals should not require provider participation, and/or tie a provider's participation in Medicare, Medicaid and/or any commercial product to participation in the public option. Public options need to be financially self-sustaining and not receive advantageous government subsidies, so they do not place stressors on other funding streams of government health programs, such as the Medicare Trust Fund.

If all criteria established by the policy proposed by the Council in this report are met, there is the potential for the AMA to support a public option, as it would provide patients with another choice of health plan. As such, a primary goal of establishing a public option should be to maximize patient choice of health plan and maximize health plan marketplace competition. The Council recognizes public options could be designed in many ways, and as a result could have various coverage and affordability impacts. Overall, with guardrails in place to protect patients and physicians, the Council underscores that a public option should not be seen as a panacea to cover the uninsured. The Council reiterates that, in the meantime, in the event of bare counties in the ACA marketplaces, Policy H-165.825 supports that the largest two FEHBP insurers in counties that lack a marketplace plan should be required to offer at least one silver-level marketplace plan as a condition of FEHBP participation.

On the other hand, the Council sees tremendous potential in the use of auto-enrollment to improve the coverage reach of the AMA proposal for reform, especially amid the COVID-19 pandemic. In 2018, 57 percent of the nonelderly uninsured was eligible for financial assistance – either through Medicaid/CHIP, or via premium tax credits to purchase marketplace coverage as provided for under the ACA. In addition, a substantial percentage of the newly unemployed are eligible for Medicaid or premium tax credits to purchase ACA marketplace coverage. As such, a significant number of uninsured Americans are currently eligible for no- or low-cost coverage but are not enrolled. The Council believes that states and the federal government should seriously consider the use of auto-enrollment to maximize coverage rates, alongside key improvements to the ACA as outlined in the AMA proposal for reform.

After providing consent to applicable state and/or federal entities to share their health insurance status and tax data, the Council believes that individuals should only be auto-enrolled in health insurance coverage if coverage options are available at no cost to them after any applicable subsidies. As such, candidates for auto-enrollment would be individuals eligible for Medicaid/CHIP or zero-premium marketplace coverage, unless they choose to opt out. Individuals who are auto-enrolled should not be penalized if they are auto-enrolled into coverage for which they are not eligible or remain uninsured despite believing they were enrolled in health insurance coverage via auto-enrollment. Individuals eligible for zero-premium marketplace coverage should be randomly assigned among plans with the highest actuarial value with a zero-dollar premium option, and plans should be incentivized to offer pre-deductible coverage including physician services to maximize the value of zero-premium plans to patients. Individuals enrolled in a zero-premium bronze plan who would otherwise qualify for significant cost-sharing reductions if they enrolled in a silver plan (70 percent of benefits costs covered) should be notified of their eligibility for cost-sharing reductions, and what enrolling in a silver plan would mean in terms of differences in out-of-pocket responsibilities, so they could be appropriately informed in advance of the subsequent open enrollment period. In this scenario, to assist with out-of-pocket responsibilities of the bronze plan into which they are enrolled in the meantime, the Council recommends reaffirmation of Policy H-165.824, which supports these individuals having access to a health savings account (HSA) partially funded by an amount determined to be equivalent to the cost-sharing subsidy.

To facilitate health insurance enrollment of other individuals (eligible for coverage, but with a premium after application of any subsidies), the Council also believes that there should be targeted outreach promoting enrollment. In addition, states and/or the federal government should consider establishing a special enrollment period for these individuals to enroll in the coverage of their choosing so they do not have to wait until the next open enrollment period to get covered.

The Council believes that, in the absence of a federal individual mandate penalty and as millions of Americans have lost their employer-sponsored health insurance coverage resulting from the COVID-19 pandemic, there needs to be a mechanism in AMA policy to ensure that the AMA proposal for reform can maximize its coverage potential and reach. Physicians have the responsibility to advocate for improving health insurance coverage and health care access so that patients receive timely, high quality care, preventive services, medications and other necessary treatments. The Council believes its recommendations address gaps in AMA policy with respect to covering the uninsured and improving affordability, which are necessary to ensure that our patients are able to secure affordable and meaningful coverage, and access the care that they need.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted in lieu of Resolution 113-A-19, Resolution 114-A-19, the alternate resolution proposed by Reference Committee A, and the amendment offered during the House of Delegates' consideration of item 9 of the report of Reference Committee A, and that the remainder of the report be filed.

1. That our American Medical Association (AMA) support that a public option to expand health insurance coverage must meet the following standards:

    a. The primary goals of establishing a public option are to maximize patient choice of health plan and maximize health plan marketplace competition.
    b. Eligibility for premium tax credit and cost-sharing assistance to purchase the public option is restricted to individuals without access to affordable employer-sponsored coverage.
    c. Physician payments under the public option are established through meaningful negotiations and contracts. Physician payments under the public option must not be tied to Medicare and/or Medicaid rates.
    d. Physicians have the freedom to choose whether to participate in the public option. Public option proposals should not require provider participation and/or tie physician participation in Medicare, Medicaid and/or any commercial product to participation in the public option.
    e. The public option is financially self-sustaining and has uniform solvency requirements.
    f. The public option does not receive advantageous government subsidies in comparison to those provided to other health plans. (New HOD Policy)

2. That our AMA support states and/or the federal government pursuing auto-enrollment in health insurance coverage that meets the following standards:

    a. Individuals must provide consent to the applicable state and/or federal entities to share their health insurance status and tax data with the entity with the authority to make coverage determinations.
    b. Individuals should only be auto-enrolled in health insurance coverage if they are eligible for coverage options that would be of no cost to them after the application of any subsidies. Candidates for auto-enrollment would, therefore, include individuals eligible for Medicaid/Children's Health Insurance Program (CHIP) or zero-premium marketplace coverage.
    c. Individuals should have the opportunity to opt out from enrolling in health insurance coverage.
    d. Individuals should not be penalized if they are auto-enrolled into coverage for which they are not eligible or remain uninsured despite believing they were enrolled in health insurance coverage via auto-enrollment.
    e. Individuals eligible for zero-premium marketplace coverage should be randomly assigned among the zero-premium bronze plans with the highest actuarial values.
    f. Health plans should be incentivized to offer pre-deductible coverage including physician services in their bronze plans, to maximize the value of zero-premium plans to plan enrollees.
    g. Individuals enrolled in a zero-premium bronze plan who are eligible for cost-sharing reductions should be notified of the cost-sharing advantages of enrolling in silver plans.

h. There should be targeted outreach and streamlined enrollment mechanisms promoting health insurance enrollment, which could include raising awareness of the availability of premium tax credits and cost-sharing reductions, and establishing a special enrollment period. (New HOD Policy)

3. That our AMA reaffirm Policy H-165.825, which states that the largest two Federal Employees Health Benefits Program (FEHBP) insurers in counties that lack a marketplace plan should be required to offer at least one silver-level marketplace plan as a condition of FEHBP participation. (Reaffirm HOD Policy)

4. That our AMA reaffirm Policy H-165.828, which encourages the development of demonstration projects to allow individuals eligible for cost-sharing subsidies, who forego these subsidies by enrolling in a bronze plan, to have access to a health savings account partially funded by an amount determined to be equivalent to the cost-sharing subsidy. (Reaffirm HOD Policy)

Fiscal Note: Less than $500

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REPORT 3 OF THE COUNCIL ON MEDICAL SERVICE (November 2020)
Medicare Prescription Drug and Vaccine Coverage and Payment
(Resolution 203-A-19)
(Reference Committee A)

EXECUTIVE SUMMARY

At the 2019 Annual Meeting, the House of Delegates referred Resolution 203, "Medicare Part B and Part D Drug Price Negotiation," which was sponsored by the California Delegation. The Board of Trustees assigned this item to the Council on Medical Service for a report back to the House of Delegates at the 2020 Annual Meeting. Resolution 203-A-19 asked:

> That our American Medical Association (AMA): (1) advocate for Medicare to cover all physician-recommended adult vaccines in both the Medicare Part D and the Medicare Part B programs; (2) make it a priority to advocate for a mandate on pharmaceutical manufacturers to negotiate drug prices with the Centers for Medicare & Medicaid Services (CMS) for Medicare Part D and Part B covered drugs; and (3) explore all options with the state and national specialty societies to ensure that physicians have access to reasonable drug prices for the acquisition of Medicare Part B physician-administered drugs and that Medicare reimburse physicians for their actual drug acquisition costs, plus appropriate fees for storage, handling, and administration of the medications, to ensure access to high-quality, cost-effective care in a physician's office.

Over the years, proposals aimed at lowering drug prices in Medicare Part B have also included provisions that would transition reimbursement for the cost of Part B drugs away from the current approach that is tied to average sales price (ASP) plus six percent (which has been reduced to 4.3 percent under the budget sequester). The Council recognizes that there has not yet been consensus among national medical specialty societies, and the house of medicine as a whole, concerning the preferred alternative(s) to using a rate tied to ASP to reimburse physicians and hospitals for the cost of Part B drugs. The Council believes, however, that the time is now for organized medicine to move forward with building consensus on which alternative methods would be preferred to reimburse physicians for the cost of Part B drugs. As a first step, our AMA should build upon past efforts and solicit input from national medical specialty societies and state medical associations for their recommendations to ensure adequate Part B drug reimbursement. Subsequently, the AMA should work with interested national medical specialty societies on alternative methods to reimburse physicians and hospitals for the cost of Part B drugs.

The Council recognizes that coverage and payment policies concerning vaccines under Medicare Parts B and D may be impacting the utilization rates of adult vaccines by Medicare patients, and raises financial risk for patients and physicians. While our AMA has ample, strong policy in this space, which are being recommended for reaffirmation, the Council believes that it is imperative for our AMA to continue to work with interested stakeholders to improve utilization rates of adult vaccines by Medicare beneficiaries. Underscoring the importance of lowering drug prices in Medicare Part D, the Council recommends the reaffirmation of policies that support the elimination of Medicare's prohibition on drug price negotiation; support CMS negotiating pharmaceutical pricing for all applicable medications covered by CMS, and outline safeguards to ensure that international drug price averages are used as a part of drug price negotiations in a way that upholds market-based principles and preserve patient access to necessary medications.

REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 3, November 2020

Subject: Medicare Prescription Drug and Vaccine Coverage and Payment (Resolution 203-A-19)

Presented by: Lynda M. Young, MD, Chair

Referred to: Reference Committee A

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This report provides background on how vaccines are covered and paid for under Medicare Parts B and D; outlines proposals that would allow for drug price negotiation under Medicare Part D; highlights approaches addressing drug prices and associated physician payment under Medicare Part B; and presents policy recommendations.

MEDICARE COVERAGE OF AND PAYMENT FOR VACCINES

Vaccines are covered in Medicare under Parts B and D. Medicare Part B covers the Hepatitis B vaccine for patients at high or intermediate risk; the influenza vaccine; the pneumococcal pneumonia vaccine; and vaccines directly related to treatment of an injury or direct exposure to a disease or condition (e.g., rabies, tetanus). In addition, should a vaccine become available for coronavirus (COVID-19), it will be covered under Medicare Part B, with no cost-sharing for Medicare beneficiaries for the vaccine itself or its administration.[1] At the time this report was written, no COVID-19 vaccine had been approved by the US Food & Drug Administration (FDA). Part D plans generally cover commercially available vaccines that Part B does not cover when they are reasonable and necessary to prevent illness, with required co-insurance rates and copayment amounts varying by plan. Vaccines covered under Part D could range from the shingles vaccine to vaccines for Hepatitis A.

In terms of physician payment for vaccines under Medicare Part B, physicians submit claims to their Medicare Administrative Contractor for the vaccine and its administration. When physicians agree to accept assignment for both the vaccine and its administration, which is common, patients

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do not have to pay copayments or any contribution towards their Part B deductible for the seasonal influenza virus, pneumococcal, and Hepatitis B vaccines. Physicians who are in-network providers of their patient's Medicare Advantage plan submit claims to the plan for payment.

Under Medicare Part D, there are multiple pathways for vaccine payment and administration. Physicians may not be able to directly bill Part D plans for vaccines and their administration. In some cases, patients may need to pay their physicians up front for Part D vaccines, and then submit a claim to their Part D plan for reimbursement. If the physician's charge for the vaccine is greater than the plan's allowable charge, the patient would then be responsible for paying the difference. To limit patient out-of-pocket responsibilities, the physician can receive authorization, via a vaccine-specific notice requested by the physician or Part D plan enrollee. The vaccine-specific notice would provide the physician with instructions on how to receive a coverage authorization for a vaccine and how to submit an out-of-network claim, the plan's vaccine reimbursement rates, and any applicable cost-sharing responsibilities of the patient. In this situation, the physician would agree to accept payment received by the patient's Part D plan as payment in full, and the patient would pay the physician any cost-sharing amount required by their plan.

Alternatively, physicians can administer Part D vaccines and bill a patient's Part D plan through a web-assisted out-of-network billing system. To participate in such a system, the physician would enroll with a company with a portal through which they can electronically submit out-of-network claims for Part D vaccines they administer to their patient, the Part D plan enrollee. In this situation, the physician would also agree to accept payment received by the patient's Part D plan as payment in full, and the patient would pay the physician any cost-sharing amount required by the plan.

In addition, in some instances, prescriptions for Part D vaccines are transmitted to an in-network pharmacy of a patient's Part D plan. After the prescription is transmitted to an in-network pharmacy, there are two potential pathways for vaccine administration: the pharmacist administers the vaccine if permitted under state law; or the pharmacy fills the prescription and distributes it to the prescribing physician's office. In the latter scenario, the pharmacy bills the patient's Part D plan for the vaccine itself, with the pharmacy receiving any cost-sharing amount for the vaccine, and the physician receiving the cost-sharing associated with vaccine administration. Following the administration of the vaccine, the patient can submit the physician prescriber's charge for vaccine administration to their Part D plan for reimbursement.

Under Part D, vaccine administration costs are included as part of the negotiated price for a Part D vaccine. Part D plans can charge a single vaccine administration fee for all vaccines or multiple administration fees based on such factors as vaccine type and complexity of administration.

The complexity of Medicare Part D vaccine physician payment presents challenges and can add administrative burdens and costs to physician practices. Due to the variation in vaccine reimbursement rates of Part D plans, as well as the uncertainty of whether patients will be able to fulfill their out-of-pocket responsibilities, physicians assume risk as they determine how much Part D vaccine to stock, especially considering the need to stock vaccine products for other non-Medicare age groups served by their practices. The mechanisms of payment for vaccines under Part D exacerbate the issues faced by physician practices in having reimbursement not cover the true costs of providing immunizations, which extend beyond the price of the vaccine. These additional issues include the cost of vaccine storage equipment as well as administrative costs including monitoring temperature, ordering, maintaining supply and minimizing waste. The Council recognizes that smaller physician practices often encounter more challenges offering a full array of vaccine products to their patients, due to factors including vaccine acquisition costs and difficulties.

In addition, vaccine utilization rates among adults enrolled in Medicare have historically been, and continue to remain, low.[2] While the Affordable Care Act (ACA) drastically changed the cost-sharing requirements for vaccines under private health plan coverage and Medicaid, the law did not change cost-sharing requirements for vaccines covered under Medicare Part D. As a result, approximately four percent or less of enrollees of either stand-alone or Medicare Advantage prescription drug plans had access to ten vaccines without cost-sharing that are recommended by Advisory Committee on Immunization Practices either generally for adults ages 65 and older, or for adults with certain risk factors.[3] This level of access to these vaccines with no cost-sharing under Medicare Part D remained generally the same from 2015. Of note, no stand-alone Part D plan covered these vaccines with zero cost-sharing between 2015 and 2017.[4]

Relevant AMA Policy

Policy D-440.981 states that our AMA will: (1) continue to work with CMS and provide comment on the Medicare Program payment policy for vaccine services; (2) continue to pursue adequate reimbursement for vaccines and their administration from all public and private payers; (3) encourage health plans to recognize that physicians incur costs associated with the procurement, storage and administration of vaccines that may be beyond the average wholesale price of any one particular vaccine; and (4) advocate that a physician's office can bill Medicare for all vaccines administered to Medicare beneficiaries and that the patient shall only pay the applicable copay to prevent fragmentation of care.

Policy H-440.875 states that our AMA will aggressively petition CMS to include coverage and payment for any vaccinations administered to Medicare patients that are recommended by the Advisory Committee on Immunization Practices, the US Preventive Services Task Force (USPSTF), or based on prevailing preventive clinical health guidelines. Policy H-440.860 supports easing federally imposed immunization burdens by, for example: (i) Providing coverage for Medicare-eligible individuals for all vaccines, including new vaccines, under Medicare Part B; (ii) Creating web-based billing mechanisms for physicians to assess coverage of the patient in real time and handle the claim, eliminating out-of-pocket expenses for the patient; and (iii) Simplifying the reimbursement process to eliminate payment-related barriers to immunization. The policy also states that CMS should raise vaccine administration fees annually, synchronous with the increasing cost of providing vaccinations.

MEDICARE PART D DRUG PRICE NEGOTIATION

The "noninterference clause" in the Medicare Modernization Act of 2003 (MMA) states that the Secretary of Health and Human Services (HHS) "may not interfere with the negotiations between drug manufacturers and pharmacies and [prescription drug plan] PDP sponsors, and may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs." Instead, participating Part D plans compete with each other based on plan premiums, cost-sharing and other features, which provides an incentive to contain prescription drug spending. To contain spending, Part D plans not only establish formularies, implement utilization management measures and encourage beneficiaries to use generic and less-expensive brand-name drugs, but are required under the MMA to provide plan enrollees access to negotiated drug prices. These prices are achieved through direct negotiation with pharmaceutical companies to obtain rebates and other discounts, and with pharmacies to establish pharmacy reimbursement amounts.

In an effort to lower drug prices and patient out-of-pocket costs in Medicare Part D, multiple bills have been introduced in Congress to enable and/or require the Secretary of HHS to negotiate

covered Part D drug prices on behalf of Medicare beneficiaries. However, historically, the Congressional Budget Office (CBO), as well as CMS actuaries, have estimated that providing the Secretary of HHS broad negotiating authority by itself would not have any effect on negotiations taking place between Part D plans and drug manufacturers or the prices that are ultimately paid by Part D.[5,6]

In fact, CBO has previously acknowledged that, in order for the Secretary to have the ability to obtain significant discounts in negotiations with drug manufacturers, the Secretary would also need the "authority to establish a formulary, set prices administratively, or take other regulatory actions against firms failing to offer price reductions. In the absence of such authority, the Secretary's ability to issue credible threats or take other actions in an effort to obtain significant discounts would be limited."[7] CMS actuaries have concurred, stating "the inability to drive market share via the establishment of a formulary or development of a preferred tier significantly undermines the effectiveness of this negotiation. Manufacturers would have little to gain by offering rebates that are not linked to a preferred position of their products, and we assume that they will be unwilling to do so."[8]

Showing the impact of negotiating leverage, the December 10, 2019 CBO cost estimate "Budgetary Effects of HR 3, the Elijah E. Cummings Lower Drug Costs Now Act" stated that Title I of the legislation would reduce federal direct spending for Medicare by $448 billion over the 2020-2029 period.[9] In its October 11, 2019 estimate, CBO estimated that the largest savings would be the result of lower prices for existing drugs that are sold internationally, which would be impacted by the application of the "average international market price" outlined in the bill.[10] Title I of HR 3 would require the Secretary of HHS to directly negotiate with manufacturers to establish a maximum fair price for drugs selected for negotiation, which would be applied to Medicare, with flexibility for Medicare Advantage and Medicare Part D plans to use additional tools to negotiate even lower prices. An "average international market price" would be established to serve as an upper limit for the price reached in any negotiation, if practicable for the drug at hand, defined as no more than 120 percent of the drug's volume-weighted net average price in six countries – Australia, Canada, France, Germany, Japan and the United Kingdom.

Relevant AMA Policy

Policy D-330.954 states that our AMA: (1) will support federal legislation which gives the Secretary of HHS the authority to negotiate contracts with manufacturers of covered Part D drugs; (2) will work toward eliminating Medicare prohibition on drug price negotiation; and (3) will prioritize its support for CMS to negotiate pharmaceutical pricing for all applicable medications covered by CMS.

Addressing the use of international price indices and averages as part of the Secretary of HHS negotiating drug prices in Medicare Part D, Council on Medical Service Report 4-I-19 established Policy H-110.980, which outlines the following policy principles:

a. Any international drug price index or average should exclude countries that have single-payer health systems and use price controls;
b. Any international drug price index or average should not be used to determine or set a drug's price, or determine whether a drug's price is excessive, in isolation;
c. The use of any international drug price index or average should preserve patient access to necessary medications;
d. The use of any international drug price index or average should limit burdens on physician practices; and

e. Any data used to determine an international price index or average to guide prescription drug pricing should be updated regularly.

MEDICARE PART B DRUG PRICES AND PHYSICIAN PAYMENT

Medicare reimburses physicians and hospitals for the cost of Part B drugs at a rate tied to the average sales price (ASP) for all purchasers—including those that receive large discounts for prompt payment and high-volume purchases—plus a percentage of the ASP. Currently, the percentage add-on is six percent, which is then reduced to 4.3 percent under the budget sequester enacted in 2011. Over the years, there have been a number of calls for reductions in the ASP add-on, modifications in the calculation of the ASP, and inflation-related limits on Medicare increases in drug payments.

For example, in 2017, the Medicare Payment Advisory Commission (MedPAC) put forth proposals addressing the ASP payment system. Such proposals included reducing payment rates for new single-source Part B drugs that lack ASP data from 106 percent to 103 percent of wholesale acquisition costs; establishing an ASP inflation rebate; and developing a voluntary alternative, the Drug Value Program (DVP), to the ASP payment system for physicians and outpatient hospitals. Under the proposed DVP, providers would purchase all DVP products at the price negotiated by their selected DVP vendor; Medicare would pay providers the DVP-negotiated price and pay vendors an administrative fee; and Medicare payments under the DVP could not exceed 100 percent of ASP.[11]

Based on a June 2015 MedPAC report to Congress, in 2016, CMS, under the Obama Administration, put forward a proposed rule, *Medicare Program: Part B Drug Payment Model*, to implement a two-phase, multipronged nationwide model that would restructure the way Medicare reimburses physicians for Part B drugs. Under phase 1 of the model, CMS proposed to retain the current rates in some communities and set a reduced rate of ASP+2.5 percent in addition to a $16.80 flat fee in others. After the sequester is factored in, the add-on in the model areas would have been 0.86 percent of ASP plus $16.53. Under phase 2, five additional "value-based" drug payment strategies (test arms) were outlined to be on tap for implementation in specified localities in subsequent years. As a result, Medicare payment policy would have remained unchanged in approximately 25 percent of the country while multiple changes could have been applied to 75 percent of the country.[12] Due to strong opposition from the AMA and other stakeholders, the proposed rule was not implemented and eventually formally withdrawn.

In October of 2018, the Trump Administration released an Advance Notice of Proposed Rulemaking (ANPRM) entitled "International Pricing Index Model for Part B Drugs." The ANPRM did not represent a formal proposal, but rather outlined the Administration's current thinking and sought stakeholder input on a variety of topics and questions related to this new drug pricing model prior to entering formal rulemaking. Under the ANPRM, providers would select vendors from which to receive included drugs but would not be responsible for buying and billing Medicare for the drug product. Instead, providers would continue to be entitled to bill a drug administration fee and would also be entitled to receive a drug add-on fee. While the ANPRM was somewhat short on detail on exactly how this add-on fee would be calculated, it appears the add-on fee would be a flat fee that is based on six percent of the historical average sales price for the drug in question.[13]

In September 2020, an executive order "Lowering Drug Prices by Putting America First" was issued which called for testing of payment models to apply international price benchmarking to Part B and Part D prescription drugs and biological products. For Part B, the executive order

instructed the Secretary of HHS to implement rulemaking to test a payment model under which "Medicare would pay, for certain high-cost prescription drugs and biological products covered by Medicare Part B, no more than the most-favored-nation price." The executive order defined the "most-favored-nation price" as "the lowest price, after adjusting for volume and differences in national gross domestic product, for a pharmaceutical product that the drug manufacturer sells in a member country of the Organization for Economic Co-operation and Development (OECD) that has a comparable per-capita gross domestic product." For Part D, the executive order instructed the Secretary of HHS to develop and implement rulemaking to test a payment model for high-cost Part D drugs, limiting payment to these drugs to the most-favored-nation price, to the extent feasible.[14] At the time that this report was written, no proposed and/or interim final rule had been issued to begin the implementation of the provisions of the executive order, which could also propose changes to Medicare Part B drug reimbursement.

Relevant AMA Advocacy and Policy

In its comments submitted in response to the ANPRM, the AMA stated that "reimbursement models based on an 'add-on' formula are intended to adequately reimburse physicians for the costs of acquisition, proper storage and handling, and other administrative costs associated with providing these treatment options for patients. Many drugs included in this model, such as biological products, are complicated drug products that require special attention to handling and storage to remain stable and viable for administration to patients. Drugs that require specific conditions for shipping, storage, and handling result in significantly higher administrative costs to physician practices than many small molecule-type drugs. Due to the special nature of these products, these costs are fixed, and will not decrease as the price of the drug goes down. Given these fixed administrative costs, the Council is very concerned that, should drug prices decrease as this model predicts, any add-on payment based on an ASP would ultimately decrease with the price of the drug and would no longer be sufficient to cover the administrative costs to the practice. If add-on reimbursement decreases enough that it is no longer sufficient to cover the expenses associated with providing these treatment options, it is likely that practices will no longer be able to offer these options for patients. The Council strongly urges CMS to consider the impact on the add-on as the IPI model over time could reduce this amount below actual clinician cost."

Policy D-330.960 supports efforts to seek legislation to ensure that Medicare payments for drugs fully cover the physician's acquisition, inventory and carrying cost and that Medicare payments for drug administration and related services are adequate to ensure continued patient access to outpatient infusion services. The policy also states that our AMA will continue strong advocacy efforts working with relevant national medical specialty societies to ensure adequate physician payment for Part B drugs and patient access to biologic and pharmacologic agents.

Addressing a Medicare Part B Competitive Acquisition Program (CAP), Policy H-110.983 states that it should provide supplemental payments to reimburse for costs associated with special handling and storage for Part B drugs; and that it must not reduce reimbursement for services related to provision/administration of Part B drugs, and reimbursement should be indexed to an appropriate health care inflation rate.

DISCUSSION

The prices and coverage of, and payment for, prescription drugs and vaccines under Medicare Parts B and D not only impact patients' ability to access the drugs and vaccines they need, but also impact the ability of physician practices to cover their costs associated with acquiring, storing and administering Part B drugs, and Part B and Part D vaccines. Over the years, proposals aimed at

lowering drug prices in Medicare Part B have also included provisions that would transition reimbursement for the cost of Part B drugs away from the current approach that is tied to ASP plus six percent (which has been reduced to 4.3 percent under the budget sequester). The Council recognizes that there has not yet been consensus among national medical specialty societies, and the house of medicine as a whole, concerning the preferred alternative(s) to using a rate tied to ASP to reimburse physicians and hospitals for the cost of Part B drugs. The Council believes, however, that the time is now for organized medicine to move forward with building consensus on which alternative methods would be preferred to reimburse physicians for the cost of Part B drugs. As a first step, our AMA should build upon past efforts and solicit input from national medical specialty societies and state medical associations for their recommendations to ensure adequate Part B drug reimbursement. The Council is hopeful that there will be a high level of participation among members of the Federation, in an effort to work collectively and collaboratively on this issue within the house of medicine. Subsequently, the AMA should work with interested national medical specialty societies on alternative methods to reimburse physicians and hospitals for the cost of Part B drugs.

The Council recognizes that coverage and payment policies concerning vaccines under Medicare Parts B and D may be impacting the utilization rates of adult vaccines by Medicare patients. There is a complicated web guiding coverage and payment for vaccines under Medicare Parts B and D, raising financial risk for patients and physicians. In addition, for some vaccines provided to Medicare beneficiaries, reimbursement to physician practices does not cover the true costs of providing immunizations, which extend beyond the price of the vaccine and also include the cost of vaccine storage equipment as well as administrative costs including monitoring temperature, ordering, maintaining supply and minimizing waste. While our AMA has ample, strong policy in this space, the Council believes that it is imperative for our AMA to continue to work with interested stakeholders to improve utilization rates of adult vaccines by Medicare beneficiaries. In addition, the Council recommends the reaffirmation of Policies D-440.981, H-440.875 and H-440.860, policies that contain strong and innovative approaches to improve the coverage and payment environment for vaccines under Medicare Parts B and D.

Recognizing the importance of lowering drug prices in Medicare Part D, the Council recommends reaffirmation of Policy D-330.954, which states that our AMA supports federal legislation which gives the Secretary of HHS the authority to negotiate contracts with manufacturers of covered Part D drugs; will work toward eliminating Medicare prohibition on drug price negotiation; and will prioritize its support for CMS to negotiate pharmaceutical pricing for all applicable medications covered by CMS. Finally, with the introduction of proposals that would use the average of a drug's price internationally to serve as an upper limit in drug price negotiations, the Council recommends the reaffirmation of Policy H-110.980, which outlines safeguards to ensure that international drug price averages are used as a part of drug price negotiations in a way that upholds market-based principles and preserves patient access to necessary medications.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted in lieu of Resolution 203-A-19, and that the remainder of the report be filed.

1. That our American Medical Association (AMA) continue to solicit input from national medical specialty societies and state medical associations for their recommendations to ensure adequate Medicare Part B drug reimbursement. (Directive to Take Action)

2. That our AMA work with interested national medical specialty societies on alternative methods to reimburse physicians and hospitals for the cost of Part B drugs. (Directive to Take Action)

3. That our AMA continue working with interested stakeholders to improve the utilization rates of adult vaccines by individuals enrolled in Medicare. (Directive to Take Action)

4. That our AMA reaffirm Policy H-440.860, which supports easing federally imposed immunization burdens by, for example, covering all vaccines in Medicare under Part B and simplifying the reimbursement process to eliminate payment-related barriers to immunization; and urges the Centers for Medicare & Medicaid Services (CMS) to raise vaccine administration fees annually, synchronous with the increasing cost of providing vaccinations. (Reaffirm HOD Policy)

5. That our AMA reaffirm Policy D-440.981, which supports adequate reimbursement for vaccines and their administration from all public and private payers; encourages health plans to recognize that physicians incur costs associated with the procurement, storage and administration of vaccines that may be beyond the average wholesale price of any one particular vaccine; and advocates that a physician's office can bill Medicare for all vaccines administered to Medicare beneficiaries and that the patient shall only pay the applicable copay to prevent fragmentation of care. (Reaffirm HOD Policy)

6. That our AMA reaffirm Policy H-440.875, which states that our AMA will aggressively petition CMS to include coverage and payment for any vaccinations administered to Medicare patients that are recommended by the Advisory Committee on Immunization Practices, the US Preventive Services Task Force, or based on prevailing preventive clinical health guidelines. (Reaffirm HOD Policy)

7. That our AMA reaffirm Policy D-330.954, which supports the use of Medicare drug price negotiation. (Reaffirm HOD Policy)

8. That our AMA reaffirm Policy H-110.980, which outlines safeguards to ensure that international drug price averages are used as a part of drug price negotiations in a way that upholds market-based principles and preserve patient access to necessary medications. (Reaffirm HOD Policy)

Fiscal Note: Between $15,000 and $20,000.

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REPORT 5 OF THE COUNCIL ON MEDICAL SERVICE (November 2020)
Medicaid Reform
(Resolution 809-I-19)
(Reference Committee A)

EXECUTIVE SUMMARY

At the 2019 Interim Meeting, the House of Delegates referred Resolution 809, "AMA Principles of Medicaid Reform," which was sponsored by the Utah Delegation. Resolution 809-I-19 asked the American Medical Association (AMA) to support a series of principles and to pursue action to improve the federal requirements for Medicaid programs based on the AMA's Medicaid reform principles. The Council agrees with the intent of the principles proposed in referred Resolution 809-I-19. As demonstrated in the appended crosswalk, the Council analyzed each of the 14 principles and found them to be largely addressed by AMA policy.

AMA Medicaid reform efforts are guided by some 70 AMA policies that have been deliberated over the years by the Council and in the House of Delegates. The Council believes these policies provide the right direction for continued federal and state advocacy efforts and recommends reaffirmation of the following principles:

- Medicaid's role as a safety net must be supported and sustained (Policy H-290.986).
- Medicaid reform should be undertaken within the AMA's broader health insurance reform efforts, which support individually purchased and owned health insurance coverage as the preferred option (Policy H-165.920).
- State efforts to expand Medicaid eligibility as authorized by the Affordable Care Act (ACA) should be supported (Policy D-290.979), and states that newly expand eligibility should receive three years of 100 percent federal funding (Policy H-290.965).
- State waivers should be supported, provided they promote improved access to quality medical care; are properly funded; have sufficient provider payment levels to secure adequate access; and do not coerce physicians into participating (Policy H-290.987).
- Caps on federal Medicaid funding should be opposed (Policies H-290.963 and D-165.966).
- Medicaid should pay physicians a minimum of 100 percent of Medicare rates (Policies H-385.921 and H-290.976).

The Council also considered the need for new policy in the context of the 2019 novel coronavirus (COVID-19) pandemic and the ensuing demands on patients, physicians, and state Medicaid programs. The dual health and economic crises triggered by the pandemic have resulted in unparalleled financial uncertainty for millions of Americans, including physicians serving Medicaid patients. To help safeguard Medicaid funding, the Council recommends new policy supporting increases in states' Federal Medical Assistance Percentage (FMAP) during significant economic downturns to allow state Medicaid programs to continue serving Medicaid patients and cover rising enrollment.

REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 5, November 2020

Subject: Medicaid Reform
(Resolution 809-I-19)

Presented by: Lynda M. Young, MD, Chair

Referred to: Reference Committee A

At the 2019 Interim Meeting, the House of Delegates referred Resolution 809, "AMA Principles of Medicaid Reform," which was sponsored by the Utah Delegation. Resolution 809-I-19 asked the American Medical Association (AMA) to support a series of principles and to pursue action to improve the federal requirements for Medicaid programs based on the AMA's Medicaid reform principles. The Board of Trustees assigned this item to the Council on Medical Service for a report back to the House of Delegates at the 2020 Interim Meeting.

This report provides an overview of Medicaid expansion, waivers and financing; describes the impact of the 2019 novel coronavirus (COVID-19) pandemic; highlights Medicaid's role in addressing disparities in health coverage and access to care; summarizes relevant AMA policy; and makes policy recommendations. A crosswalk comparing each of the 14 principles proposed in Resolution 809-I-19 with current AMA policy is appended.

BACKGROUND

In response to referred Resolution 809-I-19, the Council reviewed approximately 70 AMA policies that guide AMA's federal and state Medicaid advocacy and found that the principles proposed in the resolution are largely addressed by existing policy. At the onset of COVID-19, the Council broadened its analysis to consider the need for new AMA policy in the context of the pandemic and the ensuing demands on physicians, state Medicaid programs, and the health care system.

Medicaid is the largest health insurance program in the US; the leading payer of births, mental health services and long-term care;[1] and an indispensable safety net for low-income and vulnerable populations. As a countercyclical program, Medicaid spending increases during economic downturns as job losses mount, incomes fall, and more people enroll in the program. Enrollment growth occurs just as states, bringing in less tax revenue, experience budget shortfalls that put pressure on state spending, including Medicaid spending. In the current downturn, Medicaid programs are central to state efforts to care for low-income COVID-19 patients and also provide coverage to the newly unemployed and uninsured. Accordingly, the impact of the pandemic on state Medicaid programs could be extraordinary.

In March 2020, Medicaid and Children's Health Insurance Program (CHIP) covered nearly 71 million people (just over 64 million people were enrolled in Medicaid while an additional 6.7 million were enrolled in CHIP) and over half (51 percent) of total enrollees were children.[2] Notably, prior to the pandemic Medicaid provided coverage to more than 20 percent of low-wage workers.[3] As initial unemployment claims surged nationwide, early forecasts predicted that the economic crisis would trigger large-scale Medicaid enrollment increases. A model by Health

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Management Associates, for example, estimated that enrollment could increase by 11 to 23 million people,[4] while the Kaiser Family Foundation projected that over half (12.7 million) of the nearly 27 million individuals who could lose employer-sponsored insurance would become eligible for Medicaid.[5] Three months into the pandemic, the Georgetown University Center for Children and Families found enrollment increases of five percent on average in the 22 states being tracked as well as significant variability across states.[6] National enrollment figures for May 2020, the most recent available at the time this report was written, indicate that 73.5 million individuals were enrolled in Medicaid and CHIP, an increase of approximately 2.5 million from March.[7] The modest increase was at least partially attributed to the ability of furloughed workers to keep employer-sponsored coverage and the fact that, early in the pandemic, fewer people were seeking medical care. The situation is evolving and while enrollment growth over time is uncertain, many states are anticipating and/or already experiencing significant increases in Medicaid applications.

Although Medicaid enrollment and spending increased during the 2002 and 2009 recessions and following Affordable Care Act (ACA) implementation, growth in Medicaid spending per enrollee has generally been less than that of private insurance spending,[8] in part because payment rates are significantly lower than rates paid by Medicare and private insurance for comparable services. Inadequate Medicaid payment rates often do not cover the full cost of patient care and have been associated with lower physician participation in Medicaid, which in turn negatively impacts patient access to care.[9] Delayed payments and administrative burdens also steer some providers away from participating in the program.

The greatest share (almost two-thirds) of all Medicaid spending goes toward the care of elderly and disabled persons, while a far smaller percentage (approximately 14 percent in 2017) pays for the Medicaid expansion population, which is financed primarily with federal dollars.[10] Spending varies by state as do eligibility, coverage and payment policies, so one state's Medicaid program can look very different from another. Notably, disparities in eligibility and coverage are most pronounced between states that have and have not expanded Medicaid under the ACA.

MEDICAID EXPANSION

The Supreme Court ruling—in *National Federation of Independent Business v. Sebelius*—that Medicaid expansion was optional allowed states to decline the opportunity to expand coverage to individuals with incomes up to 133 percent (138 percent including the ACA's five percentage point income disregard) of the federal poverty level (FPL). At the time this report was written, all but 12 states (AL, FL, GA, KS, MS, NC, SC, SD, TN, TX, WI, WY) had chosen to expand Medicaid,[11] although Missouri, Nebraska and Oklahoma had not yet implemented their Medicaid expansions. Wisconsin covers adults up to 100 percent of the FPL, thereby bridging the gap between Medicaid and premium tax credit eligibility without receiving the enhanced federal match. Section 1115 waivers have been used by states to try to customize the scope and structure of expansion plans in ways that would not otherwise be permitted under federal rules. Although a handful of states have sought partial expansions that cover individuals at 100 instead of 133 percent (138 percent including the income disregard) of the FPL and allow them to receive the enhanced federal match associated with full expansion, the Centers for Medicare & Medicaid Services (CMS) has not approved these requests.

Since 2013, more than 14 million people have enrolled in Medicaid under the ACA expansion.[12] Council on Medical Service Report 5-I-14, Medicaid Expansion Options and Alternatives, expressed concern for individuals left in what is known as the coverage gap of earning too much to qualify for Medicaid in their states but too little (less than 100 percent of the FPL) to qualify for premium subsidies to purchase health insurance through ACA marketplaces. Expansion states have

eliminated the coverage gap but, nationally, prior to the pandemic, an estimated 2.3 million uninsured adults fell into the gap in non-expansion states, a number that is sure to grow. Nine out of 10 of these individuals live in southern states, with one third residing in Texas and another 17 percent in Florida.[13]

Policymakers in states that have not expanded Medicaid have voiced concerns about increasing the government's role in health care and are wary of the fiscal impacts associated with expansion (Medicaid expansion was 100 percent federally financed through 2016 and has phased down to 90 percent in 2020). In a 2016 report on Medicaid expansion, the Council expressed concerns about the enormous federal investment in Medicaid expansion, as well as massive enrollment increases which led some states like California to further reduce payment rates to providers. Additionally, the Council noted in its report that initial reviews of the impact of Medicaid expansion on coverage, quality and outcomes were somewhat mixed.

The effects of Medicaid expansion have been widely studied since the Council's last report on the topic in 2016, when data on the impact of the expansion were not yet conclusive. Evidence from a number of studies has since shown that Medicaid expansion is associated with increased access to care, decreased mortality, increased financial well-being, and improved self-reported health.[14,15,16] Enrollees have been found to be more likely to obtain primary and preventive care, be diagnosed and treated for chronic conditions, and have access to prescription medications.[17] Expansion states have experienced greater reductions in their uninsured populations,[18] with coverage gains playing a significant role in addressing the opioid epidemic. Evidence also points to a narrowing of disparities in coverage among people of different races and ethnicities, most notably in expansion states.[19]

Studies of economic measures have also shown that Medicaid expansion may offset costs in other areas (such as uncompensated care) and that it spurs economic activity and may even generate savings for states.[20] Nevertheless, the main arguments against expansion focus on costs and fiscal accountability. Prior to the pandemic, total Medicaid spending had grown to nearly $600 billion[21] with the federal share reaching over $400 billion.[22] Medicaid is the third largest domestic federal program and one of the largest budget items in most states, and has been projected to be a trillion-dollar program by 2026.[23] In 2018, Medicaid accounted for 16.4 percent of national health care spending.[24]

WAIVERS

In states reluctant to expand Medicaid eligibility as designed in the ACA, Section 1115 waivers may provide a workable alternative. Waivers permit states to put aside certain Medicaid requirements to test and evaluate a novel delivery model or provide services not typically covered. Expanding Medicaid is one of the ways that the US Department of Health and Human Services (HHS) has permitted states to employ demonstration waivers. States have also sought waivers that would allow them to charge premiums, require contributions to health savings accounts, require enrollment in private plans, incentivize healthy behaviors, impose work requirements as a condition of eligibility, impose closed prescription formularies, implement lock-out periods, use funds for inpatient substance use and/or mental health services, and use funds for social determinants of health interventions.[25,26] While supportive of state flexibility via Medicaid waivers, AMA policy also underscores the need for safeguards to protect low-income patients and sustain Medicaid's role as an indispensable safety net.

Section 1115 waivers have been around for decades and are frequently used by Administrations to implement domestic priorities. In early 2020, CMS announced the Healthy Adults Opportunity

(HAO) initiative, inviting states to apply for Section 1115 waivers under which states would agree to limited federal financing without being bound to many existing programmatic and oversight requirements.[27] Under the HAO initiative, states agreeing to an aggregate or per-capita cap financing model for adult Medicaid expansion populations would be granted a menu of flexibilities that could be attractive to some states, although state interest in HAO waivers has been limited.

AMA policy opposing caps on federal Medicaid funding was reaffirmed in Council on Medical Service Report 5-I-17. Accordingly, the AMA urged CMS to reject Oklahoma's HAO Section 1115 demonstration application to implement a per capita cap model, the only state application to be submitted under the HAO initiative that has since been withdrawn. The AMA believes that per capita caps artificially limit the growth of Medicaid expenditures, and may hinder a state's ability to address the health care needs of its vulnerable citizens and respond to public health emergencies.

Although waivers imposing work requirements have been encouraged by the current Administration, they have been repeatedly struck down in court. The AMA opposes work requirements as a condition of Medicaid eligibility (Policy H-290.961) because of the potential for continuity of care interruptions when patients subject to the requirements churn in and out of the program, experiencing periods of being uninsured. Work requirements can cause otherwise eligible enrollees to lose coverage, as it did in Arkansas, the only state that has fully implemented such eligibility restrictions. Research has demonstrated that work requirements in Arkansas did not increase rates of employment and that nearly 17,000 people lost coverage in the initial months after the requirements were implemented.[28]

COVID-19 Waivers and Other Temporary Changes

Under guidance issued to state Medicaid directors in March 2020, CMS began considering new COVID-19 Section 1115 waivers. Unlike traditional waivers, CMS is not requiring states to submit budget neutrality calculations for the special waivers, which focus primarily on home and community-based services for the long-term care population. At the time this report was written, six states had CMS-approved Section 1115 waivers to address COVID-19. States can also apply for special Section 1135 waivers that are only authorized during public health emergencies. CMS has approved Section 1135 waivers—focusing on provider enrollment, prior authorizations, appeals, long-term services and supports and state plan processes—for all states.[29]

Temporary changes have also been approved by CMS for 49 states through Medicaid disaster relief state plan amendments (SPAs). At the time this report was written, 31 states had increased state plan payment rates using SPAs, 20 states had waived or extended prescription drug prior authorization requirements, 18 states had expanded coverage for testing and testing-related services to uninsured individuals, and 14 states had eliminated deductibles and other cost-sharing.[30] States have also taken a range of administrative actions in response to COVID-19, including issuing guidance to expand Medicaid telehealth coverage (49 states), instituting payment parity for some telehealth services (43 states), and waiving or lowering telehealth cost-sharing (20 states).[31] The AMA is monitoring Medicaid waivers and state administrative actions and providing assistance to state medical associations upon request.

FEDERAL MEDICAL ASSISTANCE PERCENTAGES (FMAP) INCREASE

Under Medicaid's joint financing model, CMS matches each state's Medicaid expenditures according to the federal medical assistance percentage (FMAP), which varies by state and is inversely related to a state's per capita income. Prior to the pandemic, the 2020 Medicaid FMAP ranged from the minimum 50 percent in 12 states to 77 percent in Mississippi.[32]

A temporary 6.2 percentage point increase in federal Medicaid matching funds was provided to states by the Families First Coronavirus Response Act (PL 116-127) to help them shoulder the costs of increased Medicaid enrollment and services, including COVID-19 testing and treatment. As a condition for receiving these funds, states must provide continuous eligibility through the emergency period and are not permitted to restrict eligibility or make it more difficult to apply for Medicaid.

The temporary 6.2 percentage point increase in the FMAP was an important first step to help states continue serving the tens of millions of Americans enrolled in Medicaid. However, it is unlikely to make up for state budget shortfalls and, at the time this report was written, Medicaid cuts were under consideration in several states. A six percent cut had been made to Nevada's Medicaid program—to be largely taken out of provider payment rates and some optional benefits—and Colorado's Medicaid program had been cut by one percent. Increasing the FMAP is widely recognized as a quick and easy way to provide fiscal relief to states during economic downturns and incentivize them to maintain current Medicaid levels and services. Further enhancements to the 6.2 percentage point increase in the FMAP enjoy broad support from a range of national medical specialty societies and other stakeholders, including the AMA.

NARROWING DISPARITIES IN HEALTH COVERAGE AND ACCESS TO CARE

Although the impact of COVID-19 on our nation, its people and our health care system is continuing to unfold, one feature is unmistakably clear. The pandemic is disproportionately impacting minoritized and marginalized populations, particularly Black, Latino and Native American communities that in many places are testing positive, being hospitalized, and dying from COVID-19 at much higher rates.[33] One in four deaths from the virus have been among Black Americans, who are also more likely than White Americans to have lost income because of the pandemic.[34] COVID-19 has highlighted longstanding health inequities that disproportionately affect many communities of color—including higher rates of chronic diseases, lower access to health care, and lack of or inadequate health insurance. The current crisis underscores the importance of addressing racial and ethnic disparities in health insurance coverage and access to health care and the need to better understand the role of social determinants of health (SDOH), which can negatively affect health outcomes among people of color. Medicaid initiatives addressing SDOH are described in Council on Medical Service Report 11-I-20, Health Insurance Benefits Addressing SDOH. Covering the uninsured and improving health insurance affordability have been long-standing goals of the AMA (see the AMA's Plan to Cover the Uninsured). The AMA recognizes that racism in its systemic, structural, institutional, and interpersonal forms is an urgent threat to public health, the advancement of health equity, and a barrier to excellence in the delivery of medical care.[35]

Studies have shown that coverage expansions implemented under the ACA have reduced racial disparities in both health insurance coverage and access to care but that significant disparities remain.[36,37] The percentage of uninsured Black adults decreased from 24.4 percent in 2013 to 14.4 percent in 2018 while the uninsured rates of Latino adults fell from 40.2 percent to 24.9 percent and uninsured rates of White adults decreased from 14.5 percent to 8.6 percent during the same time period.[38] Notably, coverage disparities narrowed most significantly in states that expanded Medicaid.[39]

Disparities in access to care, as measured by two indicators—foregoing care due to cost and not having a usual source of care—also decreased in all states since 2013, and more so in expansion states.[40] Although Medicaid expansion under the ACA has played a key role in reducing disparities in health insurance coverage and access to care, almost half of Black adults live in states that have

not expanded the program. Black adults in these states who would be eligible for Medicaid if the state had expanded the program are likely to instead fall into the coverage gap. Expansion of Medicaid across the 12 states that have not yet opted to do so may narrow the gaps in coverage and access to care in those states, although disparities will likely remain.

RELEVANT AMA POLICY

AMA policy maintains that Medicaid reform should be undertaken in conjunction with broader health insurance reform (Policy H-290.982) and supports Medicaid's role as a safety net for the nation's most vulnerable populations (Policy H-290.986). AMA policy on covering the uninsured and expanding choice is largely based on recommendations developed by the Council over the years. Although AMA policy supports and advocates that individually purchased and owned health insurance coverage is the preferred option (Policy H-165.920), Policy H-290.974 states that in the absence of private sector reforms that would enable persons with low-incomes to purchase health insurance, the AMA supports eligibility expansions of public sector programs, such as Medicaid/CHIP. Policy D-290.979 states that, at the invitation of state medical societies, the AMA will work with state and specialty medical societies in advocating at the state level to expand Medicaid eligibility as authorized by the ACA (138% FPL including the income disregard). Policy H-290.965, established by Council on Medical Service Report 2-A-16, supports extending to states the three years of 100 percent federal funding for Medicaid expansions that are implemented beyond 2016 and maintaining federal funding for Medicaid expansion populations at 90 percent beyond 2020.

Policy H-165.855 supports states having the option to provide coverage to nonelderly and nondisabled Medicaid populations within the current Medicaid program or using premium tax credits that are refundable, advanceable, inversely related to income, and administratively simple for patients. AMA policy further encourages the development of coverage options, notably through state demonstration waivers, for low-income adults in the coverage gap (Policies H-290.966, D-165.966, and H-290.987). Policy H-290.966 advocates for CMS to exercise broad authority in approving state demonstration waivers, provided that the waivers are consistent with the goals and spirit of expanding health insurance coverage and eliminating the coverage gap for low-income adults. Policy H-290.987 asserts that Section 1115 waivers should meet certain criteria before being approved by HHS, including that the waivers: assist in promoting the Medicaid Act's objective of improving access to quality medical care; are properly funded; have sufficient provider payment levels to secure adequate access; and do not coerce physicians into participating. AMA policy opposes caps on federal Medicaid funding (Policies H-290.963 and D-165.966). AMA policy also opposes lock-out provisions that block Medicaid patients from the program for lengthy periods (Policy H-290.960) and tying work requirements to Medicaid eligibility (Policy H-290.961). Policy H-290.982 supports modest cost-sharing for non-emergent, non-preventive services as a means of expanding coverage to uninsured individuals while Policy H-170.963 advocates that Medicaid and other publicly funded programs incentivize voluntary healthy behaviors.

Policy H-160.913 recognizes the potential value of Medicaid patient-centered medical home models. Streamlined application and enrollment processes are supported by Policy H-290.982, while Policy D-290.985 encourages sufficient federal and state funding for Medicaid/CHIP to support enrollment and the provision of necessary services. Policy H-290.984 opposes mandatory enrollment in managed care plans. The AMA advocates for the same policies for Medicaid managed care that are advocated for private managed care plans, as well as criteria for federal and state oversight of Medicaid managed care plans that are delineated in Policy H-290.985. Network

adequacy elements are outlined in Policy H-285.908, and Policy H-320.908 addresses prior authorization.

Longstanding AMA policy advocates that Medicaid should pay physicians at minimum 100 percent of Medicare rates (Policies H-385.921 and H-290.976). Policy H-290.965 supports: increasing physician payment rates in any redistribution of funds in Medicaid expansion states experiencing budget savings; strict oversight by CMS to ensure that states are setting and maintaining Medicaid rate structures at levels to ensure there is sufficient physician participation; and a mechanism for physicians to challenge payment rates directly to CMS. The AMA opposes cuts in Medicaid and Medicare budgets that may reduce patient access to care and undermine care quality under Policy H-330.932, which also supports expansion of these budgets to adjust for cost of living, population growth, and the cost of new technologies. Policy D-290.979 advocates for increases in Medicaid payments to physicians as well as improvements and innovations in Medicaid that will reduce administrative burdens and deliver health care more effectively. Provider taxes are opposed under Policy H-385.925.

AMA policy supports the creation of basic national standards of uniform eligibility for Medicaid (Policy H-290.997), continuous eligibility (Policy H-165.832), and presumptive assessment of eligibility and retroactive coverage to the time at which an eligible person sought medical care (Policy H-165.855). Principles regarding Basic Health Programs are outlined in Policy H-165.832. AMA policy supports expanded Medicaid coverage for management and treatment of substance abuse disorders (Policy H-290.962) and for twelve months postpartum (Policy D-290.974). Policies H-290.983 and H-440.903 support Medicaid benefits for legal immigrants.

The AMA has several policies focusing on health inequities and reducing racial and ethnic disparities in health care, including Policies D-350.995, D-350.996, H-185.943 and H-65.963. Policy H-350.974 prioritizes the elimination of racial and ethnic disparities in health care through various approaches, including ensuring greater access to health care; encourages the development of measures that identify socioeconomic and racial/ethnic disparities in quality; and supports the use of evidence-based guidelines to promote the consistency and equity of care for all persons. Under Policy H-180.944, health equity is a goal toward which our AMA will work by: advocating for health care access, research and data collection; promoting equity in care; increasing health workforce diversity; influencing determinants of health; and voicing and modeling commitment to health equity. Policies H-65.960, H-160.896 and D-385.952 address SDOH.

AMA ADVOCACY

Because Medicaid patients too often face barriers to care, the AMA works diligently at the state and federal levels to improve Medicaid programs, expand coverage options, and make it easier for physicians to see Medicaid patients. Since the ACA was enacted, AMA advocacy on Medicaid reform has been guided by AMA policy, highlighted in the AMA's Plan to Cover the Uninsured, which seeks to extend the reach of coverage to the remaining uninsured, including individuals eligible for Medicaid/CHIP and adults who fall into the coverage gap. Consistent with AMA policy, the AMA continues to advocate for Medicaid expansion and three years of 100 percent federal funding for states that newly expand. The AMA also supports investments in Medicaid/CHIP outreach and enrollment activities and opposes work requirements. Council on Medical Service Report 1, November 2020, Options to Maximize Coverage under the AMA Proposal for Reform, recommends establishing new AMA policy on auto-enrollment in health insurance as a means of maximizing coverage of the uninsured who are eligible for Medicaid/CHIP or zero-premium marketplace coverage. Importantly, the AMA—along with other

physician organizations—has argued against striking down the ACA (and Medicaid expansion) in an amicus brief filed in the case of *Texas v. California* that is before the US Supreme Court.

The AMA has long encouraged policymakers to work together to identify realistic coverage options for low-income people and believes it is important for states to develop and test new Medicaid models that best meet the needs of low-income and vulnerable populations. AMA advocacy emphasizes that Medicaid reform efforts must ensure that the program remains viable and effective, and that financing changes should not undermine coverage gains that have been made under the ACA. To expand access to care, the AMA works with state-level stakeholders to advocate in favor of fully funding the Medicaid program, increasing participation with policies to streamline enrollment, ensuring fair audit procedures and improving managed care programs. The AMA comments regularly on federal and state proposals regarding Medicaid financing, access to care and managed care, and monitors state actions to expand Medicaid eligibility and seek waivers to Medicaid requirements from CMS.

In response to the COVID-19 pandemic, the AMA has also:

- Successfully sought temporary expansion of Medicaid eligibility to uninsured individuals for COVID-19 testing.
- Urged states to eliminate Medicaid cost-sharing for COVID-19-related care, simplify Medicaid enrollment and renewal processes, and eliminate barriers to Medicaid coverage such as work requirements.
- Called on the Administration to promote health equity by collecting and releasing demographic data to help address any potential race, sex and age disparities during the pandemic.
- Submitted a written statement to Congress on the disproportionate impact of COVID-19 on people of color.
- Urged Congress to enhance federal financing for the Medicaid program by at least 12 percentage points and to keep any increased FMAP in place until states' economic recovery is secure and stable.

Because low Medicaid payment rates have been shown to impact patient access to care, the AMA has for many years advocated at the federal and state levels that physicians be provided fair and adequate Medicaid payment, defined in AMA policy as a minimum of 100 percent of Medicare rates. The AMA has advocated that CMS ensure that states are maintaining Medicaid rate structures at levels that ensure there is sufficient physician participation, so that Medicaid patients can get care in a timely manner. In response to COVID-19, the AMA pressed HHS to distribute funds to assist practices and facilities treating Medicaid patients, which were operating on thin margins even before the pandemic. When initial payments from the Provider Relief Fund were not reaching Medicaid practices, the AMA urged CMS to authorize such payments, warning that without immediate financial assistance, the safety net that these Medicaid practices provide may not survive, endangering a vital part of the health care infrastructure.

DISCUSSION

Because Medicaid is an important—and often the only—source of consistent coverage for low-income children, adults, pregnant women, people with substance use disorders, and the elderly and disabled, the Council recognizes that the roughly 70 policies that provide the foundation for AMA Medicaid advocacy require periodic review. Accordingly, the Council appreciates the compilation of principles proposed in referred Resolution 809-I-19 which were reviewed individually for consistency with AMA policy. As demonstrated in the appended crosswalk, the proposed principles are largely addressed in AMA policy.

The Council points out that the first principle proposed in referred Resolution 809-I-19, which calls for the provision of access to care that is "the most cost-effective and efficient," could be problematic in the context of lower-cost retail clinics. In a 2017 report, the Council expressed concerns that the retail clinic model may have the effect of fragmenting care delivery by potentially undermining the medical home and the patient-physician relationship. Regarding Principle #5 of the resolution, the Council acknowledges that AMA policy does not "establish specialty-specific quality metrics with appropriate remuneration and incentives for clinicians to provide high quality care." After discussing this language, the Council concluded that new policy delineating specific quality metrics is not warranted. On the contrary, the Council is concerned that additional metrics on top of existing quality measures could be detrimental to physicians by exacerbating administrative burdens.

The sponsor of the resolution could not have anticipated that the Council's deliberations would coincide with COVID-19-induced health and economic crises that have placed extraordinary demands on state and federal budgets and state Medicaid programs. The pandemic has had an unparalleled impact on our nation and its people, leading to massive job losses, financial uncertainty, and reduced health care coverage and access. A recent report estimates that half of the nearly 27 million people who could lose their employer-sponsored health insurance will be eligible for Medicaid.[41] Although the totality of Medicaid enrollment growth stemming from the pandemic remains uncertain, many millions of the newly uninsured are likely to turn to Medicaid, especially in expansion states where most low-income adults will be eligible. In non-expansion states, many of the same adults will not be Medicaid eligible and will instead fall into the coverage gap.

Physician practices have also been hit hard by COVID-19 as they struggle to meet the needs of their patients while incurring new costs related to personal protective equipment and supplies and confronting ongoing revenue shortages from deferred patient visits. Practices and facilities serving Medicaid patients operated on thin margins prior to the pandemic and will be particularly vulnerable to state Medicaid cuts. While the FMAP increase provided in the Families First Act was an important first step, it will not be sufficient to overcome projected state budget shortfalls and stave off state Medicaid cuts. To help safeguard Medicaid funding, which will help physicians and patients, the Council recommends new policy supporting increases in states' FMAP or other funding during significant economic downturns to allow state Medicaid programs to continue serving Medicaid patients and cover rising enrollment.

The Council believes that foundational AMA policies supporting various aspects of Medicaid reform remain sound and provide the right direction for continued AMA federal and state advocacy. Accordingly, the Council recommends reaffirming that:

- Medicaid's role as a safety net must be supported and sustained (Policy H-290.986).
- Medicaid reform should be undertaken within the AMA's broader health insurance reform efforts, which support individually purchased and owned health insurance coverage as the preferred option (Policy H-165.920).
- State efforts to expand Medicaid eligibility as authorized by the Affordable Care Act (ACA) should be supported (Policy D-290.979), and states that newly expand eligibility should receive three years of 100 percent federal funding (Policy H-290.965).
- State waivers should be supported, provided they promote improved access to quality medical care; are properly funded; have sufficient provider payment levels to secure adequate access; and do not coerce physicians into participating (Policy H-290.987).
- Caps on federal Medicaid funding should be opposed (Policies H-290.963 and D-165.966).
- Medicaid should pay physicians a minimum of 100 percent of Medicare rates (Policies H-385.921 and H-290.976).

As it has during past deliberations, the Council discussed the potential for bifurcating the Medicaid program which would remove the long-term care function that accounts for two-thirds of the program's spending. Due to concerns regarding the complexity, feasibility, and potential unintended consequences of bifurcation, the Council does not recommend utilizing AMA resources to engage in advocacy on bifurcation. The Council also notes that financing for long-term services and supports was addressed in a 2018 Council report.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted in lieu of Resolution 809-I-19, and that the remainder of the report be filed.

1. That our American Medical Association (AMA) support increases in states' Federal Medical Assistance Percentages or other funding during significant economic downturns to allow state Medicaid programs to continue serving Medicaid patients and cover rising enrollment. (New HOD Policy)

2. That our AMA reaffirm Policy H-290.986, which supports the Medicaid program's role as a safety net for the nation's most vulnerable populations. (Reaffirm HOD Policy)

3. That our AMA reaffirm Policy D-290.979, which states that our AMA, at the invitation of state medical societies, will work with state and specialty medical societies in advocating at the state level to expand Medicaid eligibility to 133 percent [(138 percent federal poverty level (FPL) including the income disregard)] as authorized by the ACA. (Reaffirm HOD Policy)

4. That our AMA reaffirm Policy H-290.965, which supports extending to states the three years of 100 percent federal funding for Medicaid expansions that are implemented beyond 2016 and maintaining federal funding for Medicaid expansion populations at 90 percent beyond 2020. (Reaffirm HOD Policy)

5. That our AMA reaffirm Policy H-290.966, which supports state Medicaid waivers, provided they promote improving access to quality medical care; are properly funded; have sufficient provider payment levels; and do not coerce physicians into participating. (Reaffirm HOD Policy)

6. That our AMA reaffirm Policy H-290.963, which opposes caps on federal Medicaid funding. (Reaffirm HOD Policy)

7. That our AMA reaffirm Policy H-290.976, which affirms the AMA's commitment to advocating that Medicaid should pay physicians at minimum 100 percent of Medicare rates. (Reaffirm HOD Policy)

Fiscal Note: Less than $500.

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Appendix: Crosswalk of Resolution 809-I-19 with AMA Policy

The following table outlines the fourteen principles proposed in Resolution 809-I-19 and relevant AMA policy:

Resolution 809-I-19 Proposed Principle	Relevant AMA Policy and Council Analysis
1. Provide appropriate access to care that is the most cost effective and efficient to our citizens.	Access to care is addressed in numerous policies, including Policies H-290.965 and H-290.997. Policy H-290.989 urges that Medicaid reform be undertaken in conjunction with broader health insurance reform to ensure that the delivery and financing of care results in appropriate access and level of services for low-income patients.
2. Encourage individuals to be enrolled in private insurance supported by Medicaid funding, if possible.	A preference for enrollment in private insurance is embedded throughout policy, including Policies H-165.920, H-165.855 and H-290.982.
3. Create the best coverage at the lowest possible cost.	Policy H-165.846 supports principles for guiding the evaluation and adequacy of health insurance coverage.
4. Incentivize Medicaid patient behavior to improve lifestyle, health, and compliance with appropriate avenues of care and utilization of services.	Policy H-170.963 advocates that Medicaid and other publicly funded health insurance programs incentivize voluntary healthy behaviors among their participants which may decrease the cost of their medical care to the tax-paying public.
5. Establish a set of specialty specific high-quality metrics with appropriate remuneration and incentives for clinicians to provide high quality care.	Policy H-290.982 calls for CMS to develop better measurement, monitoring and accountability systems and indices within Medicaid to assess program effectiveness. Policy D-350.974 encourages the development of measures that identify socioeconomic and racial/ethnic disparities in quality.
6. Seek to establish improved access for Medicaid patients to primary care providers and referrals to specialists for appropriate care.	Policy D-290.977 advocated that the ACA's Medicaid primary care payment increases continue past 2014 in a manner that does not negatively impact payment for any other physicians. Policy H-290.965 advocates for robust access to specialty care.
7. Assure appropriate payment and positive incentives to encourage but not require clinician participation in Medicaid for both face-to-face and non-face-to-face encounters, under appropriate establishment of clinician-patient relationship.	Fair and adequate physician payment by Medicaid that should be a minimum of 100 percent of Medicare rates is supported by Policies H-290.965, H-290.989, H-290.997, H-330.932, and H-385.921. Policy H-480.946 supports coverage of and payment for telemedicine services while Policy D-480.969 supports coverage parity for telemedicine services.

8. Include payment incentives to clinicians for after-hours primary care to assist patients with an inability to access care during normal business hours.	Policy H-290.985 advocates that the availability of off-hours, walk-in primary care and other criteria be used in the oversight and evaluation of Medicaid managed care plans. Policy H-385.940 advocates for fair and equitable payment of services described by CPT codes, including those CPT codes which already exist for off-hour services. Examples of CPT codes for after-hours care include 99050 and 99051.
9. Avoid tactics and processes that inhibit access to care, delay interventions and prevent ongoing maintenance of health.	Parameters related to prior authorization relief in Medicaid plans are outlined in Policy H-320.938. Policy D-320.981 outlines protections related to step therapy.
10. Eliminate current disincentives (e.g., Medicaid spend-down in order to qualify) to patients improving their lives while on Medicaid, to increase successful transition into the private insurance market.	Policy H-280.991 suggests policy directions for the financing of long-term care and encourages private sector coverage. As stated above (under #2), the preference for enrollment in private insurance is embedded throughout policy.
11. Cease any tax, or attempt to tax, any health care profession for the purpose of supporting the cost of Medicaid.	The AMA strongly opposes the use of provider taxes or fees to fund health care programs such as Medicaid (Policy H-385.925).
12. Develop a physician directed clinician oversight board at the state level to insure the proper access, quality and cost of care under the Medicaid program throughout all geographically diverse areas of the states.	Policy H-290.975 supports the creation of state Medicaid Physician Advisory Commissions that would advise states on payment policies, utilization of services, and other relevant policies impacting physicians and patients.
13. Allow clinicians to see patients for more than one procedure in a visit so that patients do not have to return for another service at an extra cost to the Medicaid program and extra time and effort to the Medicaid patient (e.g., if patient comes because they are sick, allow them to have a diabetes check-up at the same time).	Policy H-385.944 supports payment for E&M services and procedures performed on the same day, where consistent with CPT guidelines.
14. Strategically plan to reduce administrative costs and burdens to clinicians, and of the Medicaid program itself, by reducing at least, but not limited to, burdensome documentation requirements, administrative obstacles, and regulatory impediments.	Policy H-320.938 supports prior authorization relief for Medicaid and Medicaid managed care plans and outlines parameters for such relief. The AMA supports improvements in Medicaid that will reduce administrative burdens under Policy D-290.979.

REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 6, November 2020

Subject: Value-Based Management of Drug Formularies (Resolution 814-I-19)

Presented by: Lynda M. Young, MD, Chair

Referred to: Reference Committee A

At the 2019 Interim Meeting, the House of Delegates referred Resolution 814, "PBM Value-Based Framework for Formulary Design," which was sponsored by the American Society of Clinical Oncology (ASCO). The Board of Trustees assigned this item to the Council on Medical Service for a report back to the House of Delegates at the 2020 Interim Meeting. Resolution 814-I-19 asked:

> That our American Medical Association (1) emphasize the importance of physicians' choice of the most appropriate pharmaceutical treatment for their patients in its advocacy; and (2) advocate for pharmacy benefit managers (PBMs) and health plans to use a value-based decision-making framework that is transparent and includes applicable specialty clinical oversight when determining which specialty drugs to give preference on their formularies.

This report provides background regarding the development, use and transparency of prescription drug formularies; outlines mechanisms for the value-based management of formularies; summarizes relevant AMA policy; and presents policy recommendations.

BACKGROUND

Formularies are lists of covered drugs used by health plans and PBMs to direct increased and decreased usage of certain pharmaceuticals. Some formularies attempt to tie the level of coverage of a pharmaceutical to its "value"–its cost as well as clinical effectiveness. At the most basic level, formulary drug tiers signal which pharmaceuticals are preferred or discouraged by payers, with "preferred" drugs requiring lower patient cost-sharing levels than their counterparts. That being said, "preferred" status on a formulary is not solely influenced by a drug's price and effectiveness. For example, drug placement on formularies is also influenced by the number of rebates and discounts PBMs can secure from pharmaceutical manufacturers.

Within formularies, generic drugs are often promoted over their brand counterparts, and therefore typically require much lower patient cost-sharing amounts. However, the dynamic created by rebates and discounts sometimes generates exceptions to this rule. Formulary design is not only tied to patient cost-sharing levels; health plans and PBMs also leverage prior authorization, step therapy and quantity limits in conjunction with their formulary tiers to influence drug selection. For those drugs not covered by formularies, patients and their physicians must pursue a formulary exception to get some level of a drug's cost covered, or patients have to pay the full retail price for a drug.

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An underlying concern of referred Resolution 814-I-19 pertains to the tiering of specialty drugs in formularies. Specialty drugs, which have the highest prices, continue to enter the market, raising questions of how these drugs will be covered by health plans. Spending on specialty drugs is approaching one-half of drug spending.[1] Responding to this financial reality, some private and public payers have taken steps to subdivide the specialty tier of formularies into separate preferred and non-preferred categories, which can further exacerbate the financial burden posed by specialty drugs on patients as well as complicate physician prescribing decisions. For example, a proposed rule released in February 2020 included a proposal to allow Medicare Part D sponsors to establish a second, "preferred" specialty tier that would have lower cost-sharing than the current specialty tier. The proposed rule, if finalized without changes, would also establish a cost-sharing maximum that would be applicable to the higher-cost specialty tier. The proposed rule stipulates that if there are two specialty tiers, one must be a "preferred" tier that has lower cost sharing than the proposed maximum allowable specialty tier cost-sharing, defined as between 25 and 33 percent, which is dependent upon whether a Part D plan includes a deductible.[2] The AMA submitted comments in response to the proposed rule, noting that the creation of a second specialty tier may lead to increased patient copays/cost shares for a chronic medication on which the patient is stabilized. In addition, AMA's comments stressed that in the case of biologic medications, switching to a biosimilar on a lower specialty tier may have negative clinical implications for a patient stabilized on a reference product. As such, the AMA urged the Centers for Medicare & Medicaid Services to consider any Medicare patients currently stabilized on a specialty drug to be exempt from unfavorable coverage changes (e.g., increased patient copays/cost shares) resulting from a secondary specialty tier.[3]

In addition, physicians and patients continue to raise concerns pertaining to the complexity as well as the transparency in the development and administration of formularies, prescription drug cost-sharing requirements, and utilization management requirements. This lack of transparency makes it exceedingly difficult for physicians to determine what treatments are preferred by a particular payer at the point-of-care, what level of cost-sharing their patients will face, and whether medications are subject to any prior authorization, step therapy or other utilization management requirements. For patients, lack of formulary transparency can lead to confusion regarding their plan's utilization management requirements and/or their cost-sharing responsibilities, which could result in delays in accessing necessary prescription medications, impact their ability to afford their prescription medications, and ultimately result in treatment adherence issues. These transparency issues are further exacerbated when formularies are changed mid-year, which can have negative effects on patients and can have a major impact on health care costs. When PBMs choose to remove a medication from a patient's formulary, change its tier within the formulary, or add new restrictions on continued prescription of that medication, sub-optimal outcomes may occur as patients are encouraged to try new medications that may or not be as efficacious for them, or that they have previously failed. These may result in expensive trips to the emergency room and/or hospitalizations, increased out-of-pocket drug costs for the patient, and potentially wasted physician and patient resources used on appeals and attempts to determine an alternative treatment solution.

VALUE-BASED MANAGEMENT OF PRESCRIPTION DRUG FORMULARIES

Various public and private payers have moved forward in implementing initiatives to further incorporate "value" in formulary development and management. However, the term "value" has different meanings to different stakeholders. Policy H-460.909 defines value as "the best balance between benefits and costs, and better value as improved clinical outcomes, quality, and/or patient satisfaction per dollar spent. Improving value in the US health care system will require both clinical and cost information."

Indication-Based Formularies

Under indication-based formulary design, health plans and PBMs can tailor on-formulary drug coverage based on specific indications. The use of indication-based formulary design constitutes a significant transition away from what has been the status quo—a drug's coverage being the same on a formulary, regardless of the indication it is treating. While indication-based formulary design has been promoted as a way to better target drug coverage to individual patient characteristics as well as more closely tie a drug's price to its value, indication-based formularies can make patient selection of a health plan (in Medicare Part D, for example) much more difficult. In addition, it presents new complications for physicians in making the best prescribing decisions for their patients, as drugs could be removed from formularies for indications where they are not deemed as effective. Moreover, the prescription drug formulary and benefit data currently available to physicians in their electronic health records (EHRs) is not sufficiently granular to report differential coverage based on indication, and EHRs typically do not provide sufficient information about the coverage or cost-sharing of a particular drug for a patient, including whether the patient has met his or her deductible. Physicians cannot access basic levels of information, let alone indication-based formulary data in their EHRs at the point of prescribing, which further exacerbates the existing transparency issues surrounding health plan and PBM formulary design. Of note, as of calendar year 2020, indication-based formulary design is allowed in Medicare Part D. Significantly, indication-based formulary design and utilization management are now allowed for new starts in five of the six protected classes in Medicare Part D (excluding antiretroviral medications), which permits Part D plans to exclude a protected class Part D drug for non-protected class indications.

Outcomes-Based Contracts

Payers have also moved forward with initiatives that tie how much they pay for drugs to the health outcomes of patients. Under outcomes-based contracts, a PBM negotiates not only a drug's price, but also measurable outcomes, with a pharmaceutical manufacturer on behalf of a health plan. If the drug delivers its intended outcomes for patients, the original negotiated price remains in place. However, if the drug does not meet the agreed-to outcomes in patients, the drug manufacturer would issue a rebate for part, or all, of the cost. Payers thus far have entered outcomes-based contracts with pharmaceutical companies covering medications for conditions including high cholesterol, diabetes, hepatitis C, multiple sclerosis and chronic heart failure. Outcomes-based contracts have also emerged as a mechanism to address the high costs of new gene therapies. For example, Harvard Pilgrim Health Care entered an outcome-based contract with Spark Therapeutics, the manufacturer of Luxturna, a gene therapy to treat a form of retinal dystrophy. Under the contract, the level of payment for Luxturna is tied to measured improvements in patients after a 30- to 90-day period, and then again at 30 months. If the therapy does not meet the measured outcomes agreed to, Harvard Pilgrim will receive a rebate from Spark Therapeutics.[4]

Leveraging Value-Based Frameworks in Guiding Formulary Placement

Payers are also increasingly using analyses of entities such as the Institute for Clinical and Economic Review (ICER), not only in their drug price negotiations with pharmaceutical companies, but also in their decisions pertaining to formulary inclusions of newly launched drugs. For example, in 2018, CVS Caremark launched a program that would allow its clients to exclude any drug launched at a price of greater than $100,000 per quality adjusted life year (QALY) from their plan. The QALY ratio used by CVS Caremark in this program originated from ICER analyses. CVS Caremark stipulated that breakthrough therapies would be excluded from this program, instead focusing on drugs for which similar effective drug therapies already exist–"me

too" drugs.[5] As of the end of 2019, this plan offering had gained little traction with CVS Caremark clients, with patient advocacy groups raising significant concerns.[6]

The Value Assessment Framework developed by ICER includes two components: a drug's long-term care value and the potential short-term budget impact following a drug's introduction to the marketplace. ICER determines a drug's long-term value by evaluating a drug's comparative clinical effectiveness, incremental cost-effectiveness, other benefits or disadvantages (e.g., methods of administration, public health benefit) and contextual considerations (e.g., future competition in the marketplace). ICER also develops a "health-benefit price benchmark" as part of all of its assessments, which puts forward a price range that is in line with the added benefits of a treatment for patients over their lifetime. Such prices align with long-term cost-effectiveness thresholds, ranging from $100,000 to $150,000 per QALY gained and from $100,000 to $150,000 per Equal Value of a Life Year Gained (evLYG).[7]

American Society of Clinical Oncology

ASCO, the sponsor of referred Resolution 814-I-19, released a conceptual framework in June 2015 to assess the value of cancer treatment options to be used in shared decision-making. Two versions of the framework were developed: one for advanced cancer and one for potentially curative treatment. ASCO then opened up the conceptual value framework to a 60-day public comment period; more than 400 comments were received. Based on the input and feedback received, ASCO released revised versions of the framework for advanced disease and adjuvant settings in May 2016. In both frameworks, points are awarded based on clinical benefit and toxicity, and bonus points can also be applied. Overall, both versions of the framework use points to determine the net health benefit, and have the net health benefit and the cost of the regimen side by side in order to assist physicians and patients to assess value at the point-of-care.[8]

RELEVANT AMA POLICY

Addressing the first resolve of Resolution 814-I-19, Policy H-120.988 strongly supports the autonomous clinical decision-making authority of a physician and that a physician may lawfully use an US Food and Drug Administration approved drug product or medical device for an off-label indication when such use is based upon sound scientific evidence or sound medical opinion; and affirms the position that, when the prescription of a drug or use of a device represents safe and effective therapy, third-party payers, including Medicare, should consider the intervention as clinically appropriate medical care, irrespective of labeling, should fulfill their obligation to their beneficiaries by covering such therapy, and be required to cover appropriate "off-label" uses of drugs on their formulary.

Policy H-125.991 outlines standards for drug formulary systems as well as pharmacy and therapeutics (P&T) committees. Policy H-285.965 states that P&T committee members should include independent physician representatives, and that mechanisms should be established for ongoing peer review of formulary policy as well as for appealing formulary exclusions. Policy D-110.987, established by CMS Report 5-A-19, supports improved transparency of PBM operations, including disclosing P&T committee information, including records describing why a medication is chosen for or removed in the P&T committee's formulary, whether P&T committee members have a financial or other conflict of interest, and decisions related to tiering, prior authorization and step therapy; and formulary information, specifically information as to whether certain drugs are preferred over others and patient cost-sharing responsibilities.

CMS Report 5-I-16 established Policy H-110.986, which supports value-based pricing programs, initiatives and mechanisms for pharmaceuticals that are guided by the following principles: (a) value-based prices of pharmaceuticals should be determined by objective, independent entities; (b) value-based prices of pharmaceuticals should be evidence-based and be the result of valid and reliable inputs and data that incorporate rigorous scientific methods, including clinical trials, clinical data registries, comparative effectiveness research, and robust outcome measures that capture short- and long-term clinical outcomes; (c) processes to determine value-based prices of pharmaceuticals must be transparent, easily accessible to physicians and patients, and provide practicing physicians and researchers a central and significant role; (d) processes to determine value-based prices of pharmaceuticals should limit administrative burdens on physicians and patients; (e) processes to determine value-based prices of pharmaceuticals should incorporate affordability criteria to help assure patient affordability as well as limit system-wide budgetary impact; and (f) value-based pricing of pharmaceuticals should allow for patient variation and physician discretion.

DISCUSSION

Long-standing AMA Policy H-120.988 strongly supports the autonomous clinical decision-making authority of a physician to determine the most appropriate pharmaceutical treatment for their patients. The policy outlines a key AMA position: When the prescription of a drug represents safe and effective therapy, third-party payers, including Medicare, should consider the intervention as clinically appropriate medical care, irrespective of labeling, and should fulfill their obligation to their beneficiaries by covering such therapy. The Council believes that the AMA has historically advocated strongly for its members and the nation's patients in this regard and calls for the reaffirmation of Policy H-120.988 to highlight both the policy and ongoing advocacy of the AMA.

Overall, PBMs and health plans must use a transparent process in formulary development and administration and include practicing network physicians from the appropriate medical specialty when making determinations regarding formulary inclusion or placement for a particular drug class. This builds upon the intent of Policy H-285.965, a policy that also stresses the importance of there being a mechanism to appeal formulary exclusions, providing another avenue for patients to receive the pharmaceutical treatments they need. Overall, physicians and patients need to have access to information relating to how pharmaceuticals are included and/or tiered in formularies, as called for in Policy D-110.987.

As payers continue to move forward in implementing initiatives to further incorporate "value" in formulary development and management, the Council strongly believes there is a need to closely examine these initiatives, to ensure they are in the best interests of patients. Existing Policy H-110.986 took key steps in that direction, but more needs to be done. First, in the event that payers/PBMs enter into an outcomes-based contract with a pharmaceutical manufacturer, and the terms of the contract yield savings to the payer, such savings should be shared with impacted patients. If payers benefit from outcomes-based contracts, so should the patients for whom the pharmaceutical is meant to help. To facilitate the sharing of savings from such refunds and rebates, it is essential that rebate and discount information be made transparent, as called for in Policy D-110.987.

The Council has significant concerns with the increasing use of indication-based formularies. On the patient side of the equation, indication-based formularies can make patient selection of a health plan (in Medicare Part D, for example) much more difficult, as patients would not only have to search for a particular drug, but also confirm that the drug is covered for their particular indication.

And, for newly diagnosed patients already enrolled in a health plan, the drug that may be best to treat their condition may not be covered for their specific indication.

For physicians, indication-based formularies introduce new complications along the chain from a patient's office visit, to a pharmaceutical being dispensed at a pharmacy. Patients' drug coverage is already dependent on and varies according to each individual health plan. Indication-based formularies have the potential to build upon the existing complexity and exacerbate the existing transparency issues surrounding PBM formulary design, as physicians cannot access indication-based formulary data in their EHRs at the point of prescribing. Ultimately, there will be even more variations within and between health plans regarding whether a drug is covered. In addition, drugs could potentially be removed from formularies for indications where they are not deemed as effective. Indication-based formularies could also introduce new administrative burdens for physicians. For example, coverage restrictions will likely not be discovered until after the prescription claim is submitted by the pharmacy and denied by the PBM, which will request the applicable diagnosis code. The pharmacy will need to contact the physician practice for this additional information, and under the best-case scenario, the claim will be resubmitted and paid by the PBM. However, if the PBM does not cover the drug for the reported indication, the pharmacy will contact the physician again and request that an alternate therapy be prescribed. This "prescription rework" and multiple workflow disruptions will further increase physicians' already significant challenges in navigating patients' prescription drug benefits. As such, the Council recommends that indication-based formularies be opposed, in order to protect the ability of patients to access and afford the prescription drugs they need, and physicians to make the best prescribing decisions for their patients.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted in lieu of Resolution 814-I-19, and that the remainder of the report be filed.

1. That our American Medical Association (AMA) reaffirm Policy H-120.988, upholding the ability of patients to access treatments prescribed by their physicians. (Reaffirm HOD Policy)

2. That our AMA reaffirm Policy H-285.965, which states that pharmacy and therapeutics (P&T) committee members should include independent physician representatives, and that mechanisms should be established for ongoing peer review of formulary policy as well as for appealing formulary exclusions. (Reaffirm HOD Policy)

3. That our AMA advocate that pharmacy benefit managers (PBMs) and health plans use a transparent process in formulary development and administration, and include practicing network physicians from the appropriate medical specialty when making determinations regarding formulary inclusion or placement for a particular drug class. (New HOD Policy)

4. That our AMA reaffirm Policy D-110.987, which supports improved transparency of PBM operations, including disclosing rebate and discount information as well as P&T committee information, including records describing why a medication is chosen for or removed in the P&T committee's formulary, whether P&T committee members have a financial or other conflict of interest, and decisions related to tiering, prior authorization and step therapy; and formulary information, specifically information as to whether certain drugs are preferred over others and patient cost-sharing responsibilities. (Reaffirm HOD Policy)

5. That our AMA reaffirm Policy H-110.986, which outlines principles guiding AMA's support for value-based pricing programs, initiatives and mechanisms for pharmaceuticals. (Reaffirm HOD Policy)

6. That our AMA advocate that any refunds or rebates received by a health plan or PBM from a pharmaceutical manufacturer under an outcomes-based contract be shared with impacted patients. (New HOD Policy)

7. That our AMA oppose indication-based formularies in order to protect the ability of patients to access and afford the prescription drugs they need, and physicians to make the best prescribing decisions for their patients. (New HOD Policy)

Fiscal Note: Less than $500.

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REPORT 7 OF THE COUNCIL ON MEDICAL SERVICE (November 2020)
Health Plan Initiatives Addressing Social Determinants of Health
(Reference Committee A)

EXECUTIVE SUMMARY

At recent meetings of the House of Delegates, delegates have adopted policies that have provided the foundation for our American Medical Association's (AMA's) pursuit of greater health equity by identifying and eliminating inequities through advocacy, community leadership and education. AMA Policy H-180.944 states that "health equity," defined as optimal health for all, is a goal toward which our AMA will work by advocating for health care access, research and data collection; promoting equity in care; increasing health workforce diversity; influencing determinants of health; and voicing and modeling commitment to health equity.

In that light, in reviewing AMA policy as well as initiatives across and outside of the health care system addressing social determinants of health, the Council concluded that additional policy is needed to respond to innovative health plan initiatives that incorporate social determinants of health in health insurance benefit design and coverage. The Council recognizes, however, that this represents only a fraction of what needs to be done at the health system level to address health inequities and social determinants of health. The Council underscores that addressing social determinants of health requires an "all hands on deck" approach that is not limited to stakeholders within the health care system. New and continued partnerships among all levels of government, the private sector, philanthropic organizations, and community- and faith-based organizations are critical. While there are avenues to address social determinants of health within the health system, the opportunities outside of the health care system, in non-health sectors, cannot and should not be ignored.

The Council recognizes that health plans have begun to incorporate social determinants of health in their decisions related to benefit design. Some benefit design inclusions of non-medical, yet critical health services are often the result of evidence showing not only improvements in health outcomes, but reductions in hospital admissions and readmissions, emergency department utilization, skilled nursing facility stays and ultimately, health care costs. The Council believes that such efforts should continue, serving as a critical step in addressing social determinants of health among vulnerable populations as well as in promoting health equity. To guide their efforts in this space, it is essential for health plans to examine implicit bias and the role of racism and social determinants of health, including through such mechanisms as professional development and other training.

However, gaps and inconsistencies in data pertaining to social determinants of health remain. These data limitations undercut the ability to use evidence to evaluate health plan interventions addressing social determinants of health and benefit design decisions that incorporate non-medical, yet critical health services. As such, the Council supports mechanisms, including the establishment of incentives, to improve the acquisition of data related to social determinants of health, and believes that Policies D-478.972 and D-478.996 should be reaffirmed. Critically, more research is needed to determine how best to integrate and finance non-medical services as part of health insurance benefit design, and the impact of covering non-medical benefits on health care and societal costs. Coupled with more research in this space, coverage pilots should be pursued to test the impacts of addressing certain non-medical, yet critical health needs, for which sufficient data and evidence are not available, on health outcomes and health care costs.

REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 7, November 2020

Subject: Health Plan Initiatives Addressing Social Determinants of Health

Presented by: Lynda M. Young, MD, Chair

Referred to: Reference Committee A

At recent meetings of the House of Delegates, delegates have adopted policies that have provided the foundation for our American Medical Association's (AMA's) pursuit of greater health equity by identifying and eliminating inequities through advocacy, community leadership and education. AMA Policy H-180.944 states that "health equity," defined as optimal health for all, is a goal toward which our AMA will work by advocating for health care access, research and data collection; promoting equity in care; increasing health workforce diversity; influencing determinants of health; and voicing and modeling commitment to health equity.

In addition, last year, the AMA launched the Center for Health Equity (CHE) with the goal of embedding health equity across the AMA so that it becomes part of the organization's practice, process, action, innovation, and organizational performance and outcomes. The CHE's goals are to: 1) identify and address inequities in how care is delivered; 2) advocate for equitable access to care and research; 3) increase diversity and inclusion in the medical workforce; 4) influence determinants of health; and 5) elevate the AMA as a recognized leader and a model for equity across health care and in our society. The CHE's mission is to strengthen, amplify, and sustain the AMA's work to eliminate health inequities–improving health outcomes and closing disparities gaps–which are rooted in historical and contemporary injustices and discrimination. As part of this work, earlier this year the AMA announced a $2 million investment in a community collaborative focused on improving economic conditions for residents on Chicago's West Side, neighborhoods where life expectancy is far below the national average, and significantly lower than in communities just a few miles away. Through this initiative, called West Side United, the AMA has highlighted that investing in neighborhoods and ensuring improved and equitable distribution of resources can help begin to address social determinants of health and structural root causes of health, and improve the health prospects for individuals and entire communities.

In that light, in reviewing AMA policy as well as initiatives across and outside of the health care system addressing social determinants of health, the Council concluded that additional policy is needed to respond to innovative health plan initiatives that incorporate social determinants of health in health insurance benefit design and coverage. The Council, however, recognizes that this represents only a fraction of what needs to be done at the health system level to address health inequities and social determinants of health. Other necessary activities include increasing health workforce diversity, advocating for equity in health care access, promoting equity in care, ensuring equitable practices and processes in research and data collection, and addressing structural root determinants of health, including structural racism.

As such, this report provides background on social determinants of health as well as their contributions in the 2019 novel coronavirus (COVID-19) pandemic; highlights examples of how the health and non-health sectors are addressing social determinants of health; outlines emerging

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health plan initiatives to address social determinants of health in health insurance benefit design; summarizes relevant AMA policy; and presents policy recommendations.

BACKGROUND

According to Healthy People 2020, the "social determinants of health are conditions in the environment in which people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality of life outcomes and risk."[1] Such social determinants of health include economic stability, neighborhood, education and life opportunities, access to food, quality and safety of housing, community/social support and access to health care.

Social determinants of health directly impact outcomes, including life expectancy.[2] Individual behavior has been estimated to account for 40 percent of health outcomes, with genetics accounting for 30 percent, and social and economic factors accounting for 20 percent.[3] Another estimate shows that various factors have differential impacts on keeping people healthy, with 50 percent being attributed to healthy behaviors, 20 percent to genetics and 20 percent being attributed to the environment.[4] Conversely, social determinants can also negatively affect outcomes, including hospital readmission rates,[5] length of stay and early death. For example, estimates indicate that social determinants of health contribute to early deaths in the United States, with behavioral patterns accounting for 40 percent, genetics 30 percent, social circumstances 15 percent and environmental exposures five percent.[6]

In comparison to the other ten highest-income countries, the United States is below the mean of the group with respect to total social spending (defined as spending on old age, incapacity, labor market, education, family, and housing). The US ranked below the mean of all 11 countries with respect to public social spending, and fourth with respect to private social spending.[7]

Social determinants of health are not experienced equally by all residents of the United States and are often inextricably linked to each other. For example, education and access to transportation can impact employment opportunities, and one's neighborhood can impact access to healthful food options. Social determinants of health serve as an underlying contributor to multiple conditions including obesity, heart disease and diabetes – as well as health care expenditures. These outlined conditions, of note, make individuals significantly more vulnerable to complications and death from COVID-19.

Additional considerations of social determinants of health have also contributed to the disproportionate impact of COVID-19 on marginalized and minoritized communities.[8,9] These communities are more likely to be in poverty, lack access to health care, nutritious food, affordable housing, and accessible transportation; and have a stronger likelihood of living in congregate living with multi-generational family members. In addition, people of color have a greater probability of working in essential jobs that increase their exposure to the virus, such as in meatpacking plants, warehouses, supermarkets, hospitals, and nursing homes.

ADDRESSING SOCIAL DETERMINANTS OF HEALTH: WITHIN AND OUTSIDE OF THE HEALTH CARE SYSTEM

The Council notes that initiatives to address social determinants of health within and outside of the health care system are diverse in nature, both in structure and programmatic aims and goals. Outside of the health care system, the focus of initiatives has been on how to build partnerships and bring non-health sectors into discussions centered on the improvement of health and health equity. Within the health care system, payers on the state and federal levels have implemented payment

and delivery reform initiatives to address social needs, including under the auspices of the Center for Medicare and Medicaid Innovation (CMMI), and state Medicaid programs.

Healthcare Anchor Network

Hospitals, health systems and other health care entities are functioning as anchor institutions, rooted in the communities they serve through invested capital, relationships with employees and community members, and other endeavors. Approximately 50 hospitals and health systems make up the Healthcare Anchor Network, a collaboration aimed at advancing an Anchor Mission within participating institutions, to ensure that health care anchor institutions use their economic stature in partnership with the communities they serve in a way that is mutually beneficial to the community as well as the institution itself. For example, hospitals and health systems, as major employers and purchasers in the community, can work to improve the social and economic opportunities of low-income and underserved residents. As such, the long-term goal of the Healthcare Anchor Network is to "reach a critical mass of health systems adopting as an institutional priority to improve community health and well-being by leveraging all their assets, including hiring, purchasing, and investment for equitable, local economic impact." Advancing toward this goal, the Network members have identified priority areas for their work, and have initiative groups in such areas as effective collaboration with community stakeholders in implementing anchor strategies; developing a shared policy and advocacy agenda around addressing upstream determinants of health; implementing anchor strategies around inclusive, local hiring and internal workforce development, place-based investing and inclusive, local purchasing; and leveraging internal and external philanthropy to catalyze other anchor strategies.[10]

Health in All Policies and the National Prevention Strategy

Health in All Policies (HiAP) recognizes the reality that multiple sectors outside of the traditional health care enterprise affect health. As such, HiAP stipulates that health considerations should be a factor in decision-making across sectors and policy areas, including but not limited to education, transportation, housing and employment. The Council believes that such public-private partnerships envisioned in HiAP are critical to addressing social determinants of health moving forward. At the state and local levels, the HiAP approach is being used to convene stakeholders across agencies and the community to collaborate on and prioritize health and health equity. On the federal level, the National Prevention Strategy, the result of the provision of the Affordable Care Act (ACA) that established the National Prevention Council, highlights the need for and encourages partnerships among all levels of government; business, industry, and other private sector partners; philanthropic organizations; community and faith-based organizations; and the general public to improve health through prevention.[11]

Capturing Data on Patients Impacted by Social Determinants of Health

Stakeholders across the health care spectrum – including physicians, hospitals, health systems and health plans – have taken steps to capture individual patient data to show the impacts of social determinants of health on health status and outcomes. For example, within the ICD-10-CM code set, Z codes can be utilized to capture data pertaining to and quantify the number of patients impacted by social determinants of health. Z codes capture the "factors that influence health status and contact with health services,"[12] with codes Z55-65 specifically being used to identify individuals with potentially hazardous socioeconomic and psychosocial circumstances.[13] However, although such codes are available the Council notes that they are underutilized. For example, within the Medicare fee-for-service, Z codes were used for 467,136 beneficiaries in 2017, amounting to 1.4 percent of total beneficiaries. Among the beneficiaries with Z code claims in

2017, the top chronic conditions included hypertension, depression and hyperlipidemia, with many beneficiaries having more than one chronic condition.[14]

Incorporating Social Determinants of Health in USPSTF Recommendations

The US Preventive Services Task Force (USPSTF) has also taken steps to incorporate social determinants of health in its evidence-based recommendations about clinical preventive services such as screenings, counseling services, and preventive medications. Already, the USPSTF has issued multiple recommendations on social risks impacted by social determinants of health, including interpersonal violence, alcohol use, tobacco use, obesity, adherence to healthy behaviors, and depression. Often, social determinants of health are included as part of the risk assessment in USPSTF recommendation statements, and/or provide the foundation for identifying higher-risk individuals.[15]

Neighborhood and Community Initiatives

With zip code recognized as a strong predictor of quality of health, across the country, in neighborhoods and communities, initiatives are being developed and implemented to coordinate strategies across sectors to address the various and diverse barriers that lead to poor health outcomes and health inequities. For example, Harlem Children's Zone (HCZ) project, which served 27,573 children and adults in 2017, focuses its efforts on a 100-block area in central Harlem that has higher rates of poverty, unemployment, chronic disease and infant mortality than many other sections of New York City. HCZ offers a wide range of health, social service and family-based programs to improve the educational, economic and health outcomes of members of the community. For example, in 2017, the HCZ had 9,000 youth participating in the Healthy Harlem fitness and nutrition program. The same year, 1.2 million healthy, nutritious student meals were prepared by the program.[16]

Accountable Health Communities

In 2016, CMMI announced a new "Accountable Health Communities" model to promote clinical/community collaboration to address health-related social needs. The model aims to promote such collaboration through: "screening of community-dwelling beneficiaries to identify certain unmet health-related social needs; referral of community-dwelling beneficiaries to increase awareness of community services; provision of navigation services to assist high-risk community-dwelling beneficiaries with accessing community services; and encouragement of alignment between clinical and community services to ensure that community services are available and responsive to the needs of community-dwelling beneficiaries." From 2017 to 2022, the model will provide support to community bridge organizations to pilot new and innovative service delivery approaches that have the goal of connecting beneficiaries with community services that address health-related social needs ranging from housing to food to transportation. Currently, 29 organizations are participating in the Accountable Health Communities Model.[17]

Medicaid Accountable Care Organization Initiatives Addressing Social Determinants

As of January 2020, 12 states have adopted Medicaid Accountable Care Organizations (ACOs), nine of which have implemented initiatives addressing social determinants of health. Some of the drivers of Medicaid ACO incorporation of social determinants of health include the potential to contain costs, and the pursuit of health equity. Common strategies to address social determinants of health within Medicaid ACOs include requiring providers to screen for social needs; requiring or incentivizing providers to partner with social service organizations; and including requirements or

incentives for quality metrics associated with social determinants of health. For example, in Oregon, coordinated care organizations are expected to focus their investments on services that address social determinants of health and health equity. From 2020 to 2022, housing services will be prioritized. Significantly, coordinated care organizations within Oregon are required to spend part of any end-of-year surplus on combatting health disparities. The Oregon Health Authority is planning to begin offering bonus payments to coordinated care organizations that meet performance measures on social determinants of health and health equity.[18]

SOCIAL DETERMINANTS OF HEALTH IN HEALTH INSURANCE BENEFIT DESIGN

Resulting from federal regulatory changes and initiatives on the state level, health plans have more flexibility to address social determinants of health, especially in Medicaid and Medicare Advantage. Health plan initiatives that address social determinants of health have the potential to not only improve the health status and outcomes of plan enrollees but can also impact health care costs. For non-medical services that have a strong evidentiary base, including demonstrated impacts on hospital admissions and readmissions and emergency department utilization, health plans generally have more incentive to include coverage of those services as part of their benefit design. For non-medical services for which the evidence base is nascent, pilot coverage of such services has offered an opportunity to grow the evidence base to show impacts on not only health outcomes but also health care costs.

Medicaid State Plan and Waiver Opportunities

Addressing social determinants of health via Medicaid is important as Medicaid patients frequently have unmet social needs, but doing so requires some creativity. Federal law generally requires federal Medicaid dollars to be spent only on direct medical care. There are, however, certain opportunities for states to cover certain non-clinical services under the Medicaid benefit package. States may use the 1915(i) state plan option to cover case management services (such as providing assistance signing up for other social services), the 1915(c) waiver authority to cover home and community based services, and the 1115 demonstration waiver authority to make other changes to Medicaid that would otherwise not be permitted under the state plan, including changes to the benefit package. For example, in Louisiana, the state Department of Health partnered with the Louisiana Housing Authority to establish a Permanent Supportive Housing (PSH) program under the 1915(i) state plan option, aimed at preventing and reducing homelessness as well as unnecessary institutionalization. Under the auspices of the state Medicaid program, tenancy support services are covered, starting from the transition into a PSH unit, ultimately working to ensure that participants can maintain their own housing. Louisiana has reported that the program currently has a 95 percent tenancy rate. Importantly, the program has achieved a 25 percent reduction in Medicaid costs for individuals participating in the PSH program.[19]

Significantly, North Carolina's Medicaid program has taken advantage of Section 1115 waiver authority to cover non-medical services in its Medicaid program. North Carolina's Section 1115 Medicaid demonstration waiver includes a Healthy Opportunities Pilot program that allows the state to use up to $650 million in Medicaid funds over a five-year period for enhanced case management and other services to address beneficiary needs in the arenas of housing, food, transportation, and interpersonal safety. Such pilot services would only be available to certain high-risk enrollees residing in select regions of the state (due to funding limitations) that meet physical or behavioral health and social risk factor criteria. Pilot services that may be covered include housing modifications (e.g., carpet replacement, air conditioner repair) to improve a child's asthma control and reduce emergency department visits and hospitalizations, travel vouchers to a community-based food pantry or a medically-targeted healthy food box for an adult with diabetes

living in a rural food desert, or assistance in securing safe housing and establishing a new phone number for a pregnant woman experiencing interpersonal violence. At the time this report was written, due to the COVID-19 pandemic, North Carolina had suspended the evaluation of the Healthy Opportunities Lead Pilot Entity proposals, and a new award date had not yet been announced.[20,21]

Generally, the predominant way through which state Medicaid programs can implement strategies to address social determinants of health is through managed care contracts. Medicaid managed care plans are increasingly addressing social determinants of health, and some already have relationships and contracts with entities including local social services agencies. Moving forward, states can review and revise their managed care contracts to increasingly incorporate social determinants of health, ranging from the inclusion of requirements to screen and connect beneficiaries to social and economic supports, to the promotion of value-based payments to enable providers to address social determinants of health. In addition, states can require Medicaid managed care organizations to participate in initiatives at the state and local levels with the goal of improving options for affordable housing.[22]

Medicare Advantage

Resulting from the enactment of the Creating High-Quality Results and Outcomes Necessary to Improve Chronic (CHRONIC) Care Act, Medicare Advantage plans now have greater flexibility to offer plan enrollees non-medical benefits, including transportation, healthy food options and housing improvements. The new benefits must have a "reasonable expectation of improving or maintaining the health or overall function of the patient as it relates to their chronic condition or illness."[23] As of 2019, Medicare Advantage plans were able to offer a broader range of benefits to any plan enrollee, including grab bars or wheelchair ramps, as well as in-home personal care attendants and adult day care. Starting this year, plans have the ability to offer special supplemental benefits to chronically ill members who: "1) have at least one complex chronic condition that is life threatening or significantly limits overall health or function, 2) are at high risk of hospitalization or other adverse health outcomes, and 3) require intensive care coordination."[24] Such benefits can include home-delivered meals, nonmedical transportation and minor home repairs. For example, Humana has partnered with Mom's Meals to deliver ten fully-prepared meals after an inpatient stay at a hospital or skilled nursing facility as part of its Well Dine Post Discharge program, and 20 meals to enrollees with certain chronic conditions as part of its Well Dine Chronic Condition Program.[25] Mom's Meals has reported past achievements of up to an 80 percent reduction in inpatient stays 30 days after discharge, and more than a 40 percent reduction in emergency department visits 30 days after discharge.[26] Of note, the coverage of such supplemental benefits by Medicare Advantage plans is still limited, with only 139 of 3052 plans offering Special Supplemental Benefits for the Chronically Ill in 2020. For those plans that do offer such benefits, the most common are pest control, and produce and meal delivery.[27]

Tailoring Benefits for Dual Eligibles Targeting Social Determinants of Health

Health Alliance Plan (HAP), an operating unit of the Henry Ford Health System (HFHS), is a Michigan-based, nonprofit health plan providing health coverage to nearly 500,000 commercial and government program (Medicare, Medicaid, Medicare/Medicaid duals) members. Since 2015, HAP has participated in the Medicare/Medicaid Dual Eligible Demonstration Program, which fully integrates funding from federal Medicare and State of Michigan Medicaid to support the needs of nearly 5,000 vulnerable Medicare/Medicaid beneficiaries in southeast Michigan. Established by Congress in 1981, 1915(c) waivers permit states to seek waivers to provide Home and Community Based Services (HCBS) as Medicaid benefits. The State of Michigan specifically expanded its

HCBS program for the Medicare/Medicaid Dual Demonstration in 2014 as part of the MI Health Link Program to facilitate services to keep vulnerable people safe at home. Since 2015, HAP's MI Health Link HCBS program has focused on identifying dual eligible plan members with significant social determinant risks that exacerbate their underlying clinical conditions and provide non-traditional social supports to reduce unnecessary/preventable emergency room visits, hospitalizations, readmissions, and nursing home stays, while giving them a higher quality of life in their own homes. Through the HCBS program, HAP has provided services in the home including personal emergency response systems to promote home safety, medical and non-medical transportation to facilitate clinical care as well as support social needs (shopping, religious services), home delivered meals to promote effective clinical condition aligned nutrition, personal care/chore services to support daily needs for disabled members, and direct environmental home modifications (chair lifts, wheelchair ramps, bathroom modifications) to keep members safe in the home and avoid injury. These services are provided at no additional cost to the member and are paid directly or through an intermediary by the health plan leveraging integrated Medicare/Medicaid premium dollars.[28]

RELEVANT AMA POLICY

Policy H-65.960 acknowledges that the provision of health care services as well as optimizing the social determinants of health is an ethical obligation of a civil society. Policy H-160.896 supports payment reform policy proposals that incentivize screening for social determinants of health and referral to community support systems.

Addressing housing benefits specifically, Policy H-160.890 supports improved access to housing modification benefits for populations that require modifications in order to mitigate preventable health conditions, including but not limited to the elderly, the disabled and other persons with physical and/or mental disabilities. Policy H-160.903 supports improving the health outcomes and decreasing the health care costs of treating the chronically homeless through clinically proven, high quality, and cost effective approaches that recognize the positive impact of stable and affordable housing coupled with social services; and encourages the collaborative efforts of communities, physicians, hospitals, health systems, insurers, social service organizations, government, and other stakeholders to develop comprehensive homelessness policies and plans that address the healthcare and social needs of homeless patients.

Addressing patient transportation needs, Policy H-130.954 encourages the development of non-emergency patient transportation systems that are affordable to the patient, thereby ensuring cost effective and accessible health care for all patients. Policy H-290.985 states that Medicaid managed care plans should be responsive to cultural, language and transportation barriers to access.

Concerning access to healthful foods, Policy H-150.937 supports efforts to decrease the price gap between calorie-dense, nutrition-poor foods and naturally nutrition-dense foods to improve health in economically disadvantaged populations by encouraging the expansion, through increased funds and increased enrollment, of existing programs that seek to improve nutrition and reduce obesity. Policy H-150.931 recognizes the value of nutrition support team services and their role in positive patient outcomes and supports payment for the provision of their services.

Addressing interpersonal violence, Policy H-515.965 urges hospitals, community mental health agencies, and other helping professions to develop appropriate interventions for all survivors of intimate violence, including individual and group counseling efforts, support groups, and shelters; and stresses that it is critically important that programs be available for survivors and perpetrators of intimate violence.

DISCUSSION

The Council welcomes the growing number of initiatives within and outside of the health care system to address social determinants of health by prioritizing health within non-health sectors and developing and implementing initiatives to address health-related social needs. At the outset, the Council underscores that addressing social determinants of health requires an "all hands on deck" approach that is not limited to stakeholders within the health care system. New and continued partnerships among all levels of government, the private sector, philanthropic organizations, and community- and faith-based organizations are critical. While there are avenues to address social determinants of health within the health system, the opportunities outside of the health care system, in non-health sectors, cannot and should not be ignored.

The Council recognizes that health plans have begun to incorporate social determinants of health in their decisions related to benefit design. Some benefit design inclusions of non-medical, yet critical health services are often the result of evidence showing not only improvements in health outcomes, but reductions in hospital admissions and readmissions, emergency department utilization, skilled nursing facility stays and ultimately, health care costs. The Council believes that such efforts should continue, serving as a critical step in addressing social determinants of health among vulnerable populations as well as in promoting health equity. To guide their efforts in this space, it is essential for health plans to examine implicit bias and the role of racism and social determinants of health, including through such mechanisms as professional development and other training.

However, gaps and inconsistencies in data pertaining to social determinants of health remain. These data limitations undercut the ability to use evidence to evaluate health plan interventions addressing social determinants of health and benefit design decisions that incorporate non-medical, yet critical health services. As such, the Council supports mechanisms, including the establishment of incentives, to improve the acquisition of data related to social determinants of health, and believes that Policies D-478.972 and D-478.996 should be reaffirmed. Critically, more research is needed to determine how best to integrate and finance non-medical services as part of health insurance benefit design, and the impact of covering non-medical benefits on health care and societal costs. Coupled with more research in this space, coverage pilots should be pursued to test the impacts of addressing certain non-medical, yet critical health needs, for which sufficient data and evidence are not available, on health outcomes and health care costs.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted and that the remainder of the report be filed:

1. That our American Medical Association (AMA), recognizing that social determinants of health encompass more than health care, encourage new and continued partnerships among all levels of government, the private sector, philanthropic organizations, and community- and faith-based organizations to address non-medical, yet critical health needs and the underlying social determinants of health. (New HOD Policy)

2. That our AMA support continued efforts by public and private health plans to address social determinants of health in health insurance benefit designs. (New HOD Policy)

3. That our AMA encourage public and private health plans to examine implicit bias and the role of racism and social determinants of health, including through such mechanisms as professional development and other training. (New HOD Policy)

4. That our AMA reaffirm Policies D-478.972 and D-478.996 supporting proactive and practical approaches to promote interoperability at the point of care. (Reaffirm HOD Policy)

5. That our AMA support mechanisms, including the establishment of incentives, to improve the acquisition of data related to social determinants of health. (New HOD Policy)

6. That our AMA support research to determine how best to integrate and finance non-medical services as part of health insurance benefit design, and the impact of covering non-medical benefits on health care and societal costs. (New HOD Policy)

7. That our AMA encourage coverage pilots to test the impacts of addressing certain non-medical, yet critical health needs, for which sufficient data and evidence are not available, on health outcomes and health care costs. (New HOD Policy)

Fiscal Note: Less than $500.

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AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 101
(November 2020)

Introduced by: New York

Subject: End of Life Care Payment

Referred to: Reference Committee A

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1 Whereas, Getting a patient into hospice two days before they expire is a failure but an all too
2 common experience; and
3
4 Whereas, At the end of life a nursing home or an assisted living facility may be a patient's home;
5 and
6
7 Whereas, Hospice benefits do not usually cover the cost of housing a patient in a nursing home
8 or assisted living facility ("room and board"); and
9
10 Whereas, Covering the cost of room and board in a nursing home or assisted living facility is
11 less expensive than hospitalized acute care; therefore be it
12
13 RESOLVED, That our American Medical Association petition the Centers for Medicare &
14 Medicaid Services to allow hospice patients to cover the cost of housing ("room and board") as
15 a patient in a nursing home or assisted living facility (Directive to Take Action); and be it further
16
17 RESOLVED, That our AMA advocate that patients be allowed to use their skilled nursing home
18 benefit while receiving hospice services. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000

Received: 06/18/20

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 102
(November 2020)

Introduced by: New York

Subject: Hospice Recertification for Non-Cancer Diagnosis

Referred to: Reference Committee A

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1 Whereas, The number of Americans ages 65 and older is projected to more than double from 46
2 million today to over 98 million by 2060; and
3
4 Whereas, The rate of dementia and failure to thrive at the end of life for older Americans is
5 increasing because of these demographic shifts; and
6
7 Whereas, The ability to predict the end of life is an art as opposed to a science; and
8
9 Whereas, These patients will need hospice care; therefore be it
10
11 RESOLVED, That our American Medical Association request that the Centers for Medicare &
12 Medicaid Services allow automatic reinstatement for hospice if a patient survives for more than
13 6 months with a non-cancer diagnosis and that prognosis remains terminal. (Directive to Take
14 Action)

Fiscal Note: Modest - between $1,000 - $5,000

Received: 06/18/20

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 103
(November 2020)

Introduced by: Resident and Fellow Section

Subject: Recognizing the Need to Move Beyond Employer-Sponsored Health Insurance

Referred to: Reference Committee A

Whereas, Americans entering the workforce currently have from one quarter to one eighth of the average job tenure as workers now aging into retirement[1]; and

Whereas, Trends such as a higher average worker education level and an increasing share of available jobs in industries with shorter-tenured careers are also contributing to increasing worker mobility, likely more so than any generational differences[1]; and

Whereas, Union membership has been in a prolonged decline, decreasing by 50% in the last 40 years, decreasing the collective bargaining power of today's workers to attain benefits such as quality health insurance[2]; and

Whereas, The number of Americans that have employer-sponsored health insurance has declined steadily over the past 20 years to 66% in 2014, with the greatest decline seen among low- and middle-income families[3]; and

Whereas, Even among those workers with employer-sponsored health insurance, as many as 25% have out-of-pocket costs so high as to be effectively uninsured[4]; and

Whereas, In addition to being increasingly inaccessible and insufficient for workers, reliance on employer-sponsored health insurance results in undesirable effects on the American worker such as "job-lock" (being unable to leave a job because of reliance on its health benefits), medical bankruptcy when a patient changes or loses their job while they or a family member require ongoing medical treatment, and downward pressure on wages[5]; and

Whereas, The predominance of employer-sponsored insurance arose by accident out of an attempt to reduce inflation during WWII by capping wage growth with the Stabilization Act of 1942, and was never intended to become the principal form of health insurance in the United States[6]; and

Whereas, As a result of these and other trends, reliance upon a health insurance system tied to employment is becoming increasingly untenable for large portions of the United States population; therefore be it

RESOLVED, That our American Medical Association recognize the importance of providing avenues for affordable health insurance coverage and health care access to patients who do not have employer-sponsored health insurance, or for whom employer-sponsored health insurance does not meet their needs (New HOD Policy); and be it further

1 RESOLVED, That our AMA recognize that a significant and increasing proportion of patients are
2 unable to meet their health insurance or health care access needs through employer-sponsored
3 health insurance, and that these patients must be considered in the course of ongoing efforts to
4 reform the healthcare system in pursuit of universal health insurance coverage and health care
5 access. (New HOD Policy)

Fiscal Note: Minimal - less than $1,000

Received: 08/25/20

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RELEVANT AMA POLICY:

The Future of Employer-Sponsored Insurance H-165.829

Our AMA: (1) supports requiring state and federally facilitated Small Business Health Options Program (SHOP) exchanges to maximize employee choice of health plan and allow employees to enroll in any plan offered through the SHOP; and (2) encourages the development of state waivers to develop and test different models for transforming employer-provided health insurance coverage, including giving employees a choice between employer-sponsored coverage and individual coverage offered through health insurance exchanges, and allowing employers to purchase or subsidize coverage for their employees on the individual exchanges
Citation: CMS Rep. 6, I-14

Trends in Employer-Sponsored Health Insurance H-165.843

Our AMA encourages employers to:
a) promote greater individual choice and ownership of plans;
b) enhance employee education regarding how to choose health plans that meet their needs;
c) offer information and decision-making tools to assist employees in developing and managing their individual health care choices;
d) support increased fairness and uniformity in the health insurance market; and
e) promote mechanisms that encourage their employees to pre-fund future costs related to retiree health care and long-term care.
Citation: CMS Rep. 4, I-07; Reaffirmed CMS Rep. 1, A-17

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 104
(November 2020)

Introduced by: Georgia

Subject: Reinstatement of Consultation Codes

Referred to: Reference Committee A

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1 Whereas, In 2010, due to a perception of abuse or misuse of consult codes, Medicare
2 eliminated consult codes in what they calculated to be a revenue neutral manner, whereby they
3 increased the value of other evaluation and management (E&M) codes; and
4
5 Whereas, Medicare has proposed re-valuation of E&M codes, effective 2021 if finalized; and
6
7 Whereas, United Health Care (UHC) and Cigna are moving to eliminate consult codes; and
8
9 Whereas, The American Medical Association House of Delegates passed Resolution 819 in
10 2017, which passed without changes but has progressed negatively; and
11
12 Whereas, It appears cognitive care is undervalued; therefore be it
13
14 RESOLVED, That our American Medical Association proactively engage and advocate with any
15 commercial insurance company that discontinues payment for consultation codes or that is
16 proposing to or considering eliminating payment for such codes, requesting that the company
17 reconsider the policy change. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000

Received: 09/28/20

RELEVANT AMA POLICY

Medicare's Proposal to Eliminate Payments for Consultation Service Codes D-70.953
1. Our American Medical Association opposes all public and private payer efforts to eliminate payments for inpatient and outpatient consultation service codes, and supports legislation to overturn recent Center for Medicare & Medicaid Services' (CMS) action to eliminate consultation codes. 2. Our AMA will work with CMS and interested physician groups through the CPT Editorial Panel to address all concerns with billing consultation services either through revision or replacement of the current code sets or by some other means. 3. Our AMA will, at the conclusion of the CPT Editorial Panel's work to address concerns with billing consultation services, work with CMS and interested physician groups to engage in an extensive education campaign regarding appropriate billing for consultation services. 4. Our AMA will: (a) work with the Centers for Medicare & Medicaid Services to consider a two-year moratorium on RAC audit claims based on three-year rule violations for E/M services previously paid for as consultations; and (b) pursue Congressional action through legislation to reinstate payment for consultation codes within the Medicare Program and all other governmental programs. 5. Our AMA will petition the CMS to limit RAC reviews to less than one year from payment of claims.
Citation: Res. 807, I-09; Appended: Sub. Res. 212, I-10; Reaffirmation A-12; Appended: Res. 216, A-12; Modified: CCB/CLRPD Rep. 2, A-14; Reaffirmation: A-17

Consultation Codes and Private Payers D-385.955
1. Our AMA will proactively engage and advocate with any commercial insurance company that discontinues payment for consultation codes or that is proposing to or considering eliminating payment for such codes, requesting that the company reconsider the policy change.
2. Where a reason given by an insurance company for policy change to discontinue payment of consultation codes includes purported coding errors or abuses, our AMA will request the company carry out coding education and outreach to physicians on consultation codes rather than discontinue payment for the codes, and call for release of de-identified data from the company related to purported coding issues in order to help facilitate potential education by physician societies.
Citation: Res. 819, I-17

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 105
(November 2020)

Introduced by: New York

Subject: Access to Medication

Referred to: Reference Committee A

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1 Whereas, Patients have a choice of receiving maintenance prescriptions from either a mail
2 order pharmacy or a brick-and-mortar pharmacy without any financial penalty; and
3
4 Whereas, Insurance plans should be required to fill prescriptions as written up to a 90 day
5 supply for all maintenance medications at a pharmacy or by mail order; and
6
7 Whereas, Pharmacists and their professional organizations should be ensuring the option for
8 patients to have prescriptions dispensed at a local pharmacy; and
9
10 Whereas, When a patient's prescription is initially placed by mail order, the medication cannot
11 also be dispensed by the local pharmacy resulting in a "re-order" delay causing many patients to
12 interrupt or experience an unnecessary delay in their prescribed treatment; therefore be it
13
14 RESOLVED, That our American Medical Association seek regulations on a national level that
15 would prohibit pharmacy benefit plans from limiting patient access to medications because an
16 initial prescription was placed and/or filled by mail-order. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000

Received: 10/08/20

RELEVANT AMA POLICY

Price of Medicine H-110.991
Our AMA: (1) advocates that pharmacies be required to list the full retail price of the prescription on the receipt along with the co-pay that is required in order to better inform our patients of the price of their medications; (2) will pursue legislation requiring pharmacies, pharmacy benefit managers and health plans to inform patients of the actual cash price as well as the formulary price of any medication prior to the purchase of the medication; (3) opposes provisions in pharmacies' contracts with pharmacy benefit managers that prohibit pharmacists from disclosing that a patient's co-pay is higher than the drug's cash price; (4) will disseminate model state legislation to promote drug price and cost transparency and to prohibit "clawbacks"; (5) supports physician education regarding drug price and cost transparency, manufacturers' pricing practices, and challenges patients may encounter at the pharmacy point-of-sale; and (6) work with relevant organizations to advocate for increased transparency through access to meaningful and relevant information about medication price and out-of-pocket costs for prescription medications sold at both retail and mail order/online pharmacies, including but not limited to Medicare's drug-pricing dashboard.
CMS Rep. 6, A-03; Appended: Res. 107, A-07; Reaffirmed in lieu of: Res. 207, A-17; Appended: Alt. Res. 806, I-17; Reaffirmed: BOT Rep. 14, A-18; Appended: CMS Rep. 07, A-18; Reaffirmation: A-19; Appended: Res. 126, A-19

National Mail Order Pharmacy Practices H-120.962
1. The AMA insists that mail-order pharmacy companies respect the prescribing authority of physicians and dispense prescription medications only in the amounts prescribed; and recommends that mail order pharmacy companies charge only a reasonable and small shipping and handling fee per shipment in order not to encourage patients to request amounts of medications greater than those warranted by their physician's best judgment.
2. Our AMA opposes charging patients more than one co-pay for multiple prescriptions of the same or varying doses of a long-term medication within a 90-day period when evidence-based medicine dictates that less than 90-day prescriptions should be written during the initialization and dose stabilization of a newly prescribed long-term medication or during change in dosing of a long-term medication currently being taken.
3. Our AMA will make traditional pharmacies, including national chains, mail-order pharmacies, appropriate insurance carriers, and pharmaceutical benefit management companies aware of its policy opposing the charging of patients more than one co-pay for multiple prescriptions of the same or varying doses of a long-term medication within a 90-day period when evidence-based medicine dictates that less than 90-day prescriptions should be written during the initialization and dose stabilization of a newly prescribed long-term medication or during change in dosing of a long-term medication currently being taken.
Sub. Res. 506, I-96; Reaffirmed: CSAPH Rep. 3, A-06; Appended: Res. 121, A-07; Reaffirmed: BOT Rep. 8, A-11; Reaffirmation A-14

Improve Safety of Mail-Ordered Medication H-120.936
Our AMA supports the establishment of national guidelines for mail-order pharmacies to ensure that medications reach patients in a safe and timely manner with full potency, and that when medication is damaged or loses potency during shipment, it should be replaced by the pharmacy at no cost to the patient.
Res. 917, I-14

Mail Service Pharmacy H-120.989
The AMA believes that: (1) MSP is an established alternative method of distributing drugs in the United States. (2) Controlled studies in the 1970s support the fact that MSPs are less vulnerable to drug diversion than retail pharmacies. Although numerous concerns about lack of safety and drug diversion have been expressed in trade publications and newsletters, documented controlled data regarding these concerns are minimal. There is no evidence of lack of safety in the peer-reviewed controlled-study literature. Presently, the practice of obtaining drugs from mail service pharmacies appears to be relatively safe. (3) Mail service pharmacy for prescription drugs is probably most appropriate for patients who have a well-established diagnosis, who have long-term chronic illnesses, whose disease is relatively stable and in whom the dose and dosage schedule is well regulated, who are isolated because of geographic or personal reasons, who have a drug history profile on record, who have been adequately informed about their medication, and who continue to see their physician regularly. Certainly, MSP is not best utilized for medications that are to be used acutely. Further, there must be assurance that generic substitution occur only by order of the prescribing physician. (4) Any purported price savings from the use of MSP is difficult to assess, since studies are generally limited to regional and limited patient populations. (5) Physicians have the responsibility to prescribe reasonable amounts of prescription medications based on the diagnosis and needs of their patients. Physicians must not be influenced by purely economic reasons, but they must take into account the patient's ability to pay and be aware of the guidelines recommended by particular health benefit programs for drugs.
BOT Rep. I, I-87; Reaffirmed: Sunset Report, I-97; Reaffirmed: CSAPH Rep. 3, A-07; Reaffirmed: BOT Rep. 8, A-11

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 106
(November 2020)

Introduced by: New York

Subject: Bundling Physician Fees with Hospital Fees

Referred to: Reference Committee A

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1 Whereas, There is some thought about bundling the fees of physicians with those of the hospital
2 in which the services are provided; and
3
4 Whereas, Such “bundled” payments will go to the hospital which will then control the
5 payments; and
6
7 Whereas, Such a policy will likely make it not only harder for the physician to get paid, but also
8 much more dependent on the hospitals; and
9
10 Whereas, Hospitals would similarly never agree to bundled payments that went directly to
11 physicians; therefore be it
12
13 RESOLVED, That our American Medical Association oppose bundling of physician payments
14 with hospital payments, unless the physician has agreed to such an arrangement in advance.
15 (New HOD Policy)

Fiscal Note: Minimal - less than $1,000

Received: 10/09/20

RELEVANT AMA POLICY

Health Care Reform Physician Payment Models D-385.963
1. Our AMA will: (a) work with the Centers for Medicare and Medicaid Services and other payers to participate in discussions and identify viable options for bundled payment plans, gain-sharing plans, accountable care organizations, and any other evolving health care delivery programs; (b) develop guidelines for health care delivery payment systems that protect the patient-physician relationship; (c) make available to members access to legal, financial, and ethical information, tools and other resources to enable physicians to play a meaningful role in the governance and clinical decision-making of evolving health care delivery systems; and (d) work with Congre ss and the appropriate governmental agencies to change existing laws and regulations (eg, antitrust and anti-kickback) to facilitate the participation of physicians in new delivery models via a range of affiliations with other physicians and health care providers (not limited to employment) without penalty or hardship to those physicians.
2. Our AMA will: (a) work with third party payers to assure that payment of physicians/healthcare systems includes enough money to assure that patients and their families have access to the care coordination support that they need to assure optimal outcomes; and (b) will work with federal authorities to assure that funding is available to allow the CMMI grant-funded projects that have proven successful in meeting the Triple Aim to continue to provide the information we need to guide decisions that third party payers make in their funding of care coordination services.
3. Our AMA advises physicians to make informed decisions before starting, joining, or affiliating with an ACO. Our AMA will provide information to members regarding AMA vetted legal and financial advisors and will seek discount fees for such services.
4. Our AMA will develop a toolkit that provides physicians best practices for starting and operating an ACO, such as governance structures, organizational relationships, and quality reporting and payment distribution mechanisms. The toolkit will include legal governance models and financial business models to assist physicians in making decisions about potential physician-hospital alignment strategies. The toolkit will also include model contract language for indemnifying physicians from legal and financial liabilities.
5. Our AMA will continue to work with the Federation to identify, publicize and promote physician-led payment and delivery reform programs that can serve as models for others working to improve patient care and lower costs.
6. Our AMA will continue to monitor health care delivery and physician payment reform activities and provide resources to help physicians understand and participate in these initiatives.
7. Our AMA will work with states to: (a) ensure that current state medical liability reform laws apply to ACOs and physicians participating in ACOs; and (b) address any new liability exposure for physicians participating in ACOs or other delivery reform models.
8. Our AMA recommends that state and local medical societies encourage the new Accountable Care Organizations (ACOs) to work with the state health officer and local health officials as they develop the electronic medical records and medical data reporting systems to assure that data needed by Public Health to protect the community against disease are available.
9. Our AMA recommends that ACO leadership, in concert with the state and local directors of public health, work to assure that health risk reduction remains a primary goal of both clinical practice and the efforts of public health.
10. Our AMA encourages state and local medical societies to invite ACO and health department leadership to report annually on the population health status improvement, community health problems, recent successes and continuing problems relating to health risk reduction, and measures of health care quality in the state.
Citation: Sub. Res. 128, A-10; Appended: Res. 819, I-10; Appended: CMS Rep. 8, A-11; Appended: CMS Rep. 1, A-11; Reaffirmation A-11; Modified: BOT Rep. 18, A-12; Reaffirmation: I-12; Appended: Res. 702, A-13; Appended: Res. 827, I-14; Modified: Speakers Rep., I-15; Reaffirmed: CMS Rep. 09, A-16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 107
(November 2020)

Introduced by: New York

Subject: COBRA for College Students

Referred to: Reference Committee A

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1 Whereas, The Consolidated Omnibus Budget Reconciliation Act (COBRA) is a health insurance
2 program that allows an eligible employee and his or her dependents the continued benefits of
3 health insurance coverage in the case that an employee loses his or her job or experiences a
4 reduction of work hours; and
5
6 Whereas, COBRA allows former employees to obtain continued health insurance coverage at
7 group rates that otherwise might be terminated and which are typically less expensive than
8 those associated with individual health insurance plans; and
9
10 Whereas, Such COBRA coverage reduces the disruption, financial and otherwise, that could
11 occur when a person's employment is terminated; and
12
13 Whereas, College students enjoy similar group rate discounts with student health
14 insurance; and
15
16 Whereas, These students, upon graduation or other termination of an enrollment, potentially
17 face similar disruption in their healthcare coverage; therefore be it
18
19 RESOLVED, That our American Medical Association call for legislation similar to COBRA to
20 allow college students to continue their healthcare coverage, at their own expense, for up to
21 18 months after graduation or other termination of enrollment. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000

Received: 10/09/20

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 108
(November 2020)

Introduced by: New York

Subject: Consumer Operated and Oriented Plans (CO-OPs) as a Public Option for Health Care Financing

Referred to: Reference Committee A

Whereas, Consumer Operated and Oriented Plans (CO-OPs) were enacted as a part of the Affordable Care Act (ACA) to improve competition in the health care marketplace; and

Whereas, CO-OPs may improve the cooperation of patients, physicians, and other providers to improve health outcomes while controlling costs; and

Whereas, CO-OPs were anticipated to have at least a 33% failure rate but have exceeded that rate substantially; and

Whereas, CO-OP failures have been due in large part to a combination of premiums that were too low, benefits that were too generous, enrollees who were sicker than anticipated, competition from bigger carriers with larger reserves, changing regulations for risk corridor payments, and restrictions on enrollments from large group markets; and

Whereas, Four of the original 23 CO-OPs have continued to operate despite these challenges; and

Whereas, The remaining CO-OPs have had some success in reducing the cost of premiums, but have limited market share and restrictions on enrollment; and

Whereas, Changing regulations or legislation to allow CO-OPs to more effectively compete in the larger health insurance marketplace, further improve governance, further improve operations, and stabilize the regulatory environment in which they operate may allow CO-OPs to enhance competition in the broader health insurance market; therefore be it

RESOLVED, That Our American Medical Association study options to improve the performance of Consumer Operated and Oriented Plans as a potential public option to improve competition in the health insurance marketplace and to improve the value of healthcare to patients (Directive to Take Action); and be it further

RESOLVED, That our AMA work with the National Alliance of State Health Co-Ops (NASCHCO) to request that Congress and the US Department of Health and Human Services reestablish funding for new health insurance co-operatives. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000

Received: 10/09/20

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 109
(November 2020)

Introduced by: New York

Subject: Health Insurance that Fairly Compensates Physicians

Referred to: Reference Committee A

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1 Whereas, There are increasing numbers of health insurance plans that do not adequately
2 compensate physicians for their services, including Medicaid, Medicare and many private
3 insurance plans; and
4
5 Whereas, Adequate insurance compensation is necessary for the continued independent
6 practice of medicine; and
7
8 Whereas, Hospitals and other groups providing medical goods and services would never accept
9 insurances that do not adequately compensate their services and products; therefore be it
10
11 RESOLVED. That our American Medical Association advocate for insurance plans to
12 adequately compensate physicians so that they are able to remain in practice independent of
13 hospital employment. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000

Received: 10/09/20

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 110
(November 2020)

Introduced by: New York

Subject: Medicaid Tax Benefits

Referred to: Reference Committee A

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1 Whereas, There are many patients with Medicaid or no health insurance that physicians care for
2 routinely for little or no payment; and
3
4 Whereas, It may be politically complicated to rectify this fact directly with improved payments to
5 physicians; and
6
7 Whereas, One way to offset the problem would be to use tax deduction techniques; and
8
9 Whereas, The AMA currently has contrary policy, H-180.965, “Income Tax Credits or
10 Deductions as Compensation for Treating Medically Uninsured or Underinsured,” that opposes
11 providing tax deductions or credits for the provision of care to the medically uninsured and
12 underinsured; therefore be it
13
14 RESOLVED, That our American Medical Association advocate for legislation that would allow
15 physicians who take care of Medicaid or uninsured patients to receive some financial benefit
16 through a tax deduction such as (a) a reduced rate of overall taxation or (b) the ability to use
17 the unpaid charges for such patients as a tax deduction. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000

Received: 10/09/20

RELEVANT AMA POLICY

Income Tax Credits or Deductions as Compensation for Treating Medically Uninsured or Underinsured H-180.965
The AMA will not pursue efforts to have federal laws changed to provide tax deductions or credits for the provision of care to the medically uninsured and underinsured.
Citation: BOT Rep. 49, I-93; Reaffirmed: CMS Rep. 7, A-05; Reaffirmed in lieu of Res. 141, A-07; Reaffirmed: CMS Rep. 01, A-17

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 111
(November 2020)

Introduced by: New York

Subject: Payment for Regadenoson (Lexiscan)

Referred to: Reference Committee A

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1 Whereas, During exercise stress testing in cardiology, many patients are unable to walk on the
2 treadmill due to arthritis of knees and hips, PVD or deconditioning; and
3
4 Whereas, For such patients, a pharmacologic stress test is used to evaluate presence of
5 coronary artery disease using Regadenoson (Lexiscan) which is adenosine related
6 compound; and
7
8 Whereas, Cost of this agent from the supplier is around $248.00 for a single dose; and
9
10 Whereas, No insurance company including Centers for Medicare and Medicaid Services pays
11 the complete amount of $248.00; and
12
13 Whereas, Some HMOs like Fidelis and WellCare pay as little as $135.00, thus expecting the
14 stress test lab to absorb the loss of $110.00 each time such patient is tested; and
15
16 Whereas, This practice of underpaying by HMOs and insurance companies discourages stress
17 test labs to use Regadenoson for these patients due to significant financial loss; and
18
19 Whereas, The costs of other medical agents, such as vaccines and chemotherapy, are also not
20 adequately reimbursed; therefore be it
21
22 RESOLVED, That our American Medical Association petition the Centers for Medicare and
23 Medicaid Services to investigate the disparity between the cost of medical agents and the
24 reimbursement by insurance companies and develop a solution so physicians are not financially
25 harmed when providing medical agents. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000

Received: 10/09/20

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 112
(November 2020)

Introduced by: New York

Subject: Private Payor Payment Integrity

Referred to: Reference Committee A

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1 Whereas, Private for-profit medical insurers often use self-developed payment guidelines to
2 their financial advantage in reducing or denying payment for necessary medical care; and
3
4 Whereas, For-profit private insurers have an unresolvable conflict of interest in denying payment
5 for diagnostic and treatment options approved by the FDA and adopted by CMS, Workers'
6 Compensation, auto liability insurance and other private payers and are considered medically
7 necessary by the patient and treating physician; therefore be it
8
9 RESOLVED, That our American Medical Association advocate for private insurers to require, at
10 a minimum, to pay for diagnosis and treatment options that are covered by government payers
11 such as Medicare (Directive to Take Action); and be it further
12
13 RESOLVED, That our AMA seek to ensure by legislative or regulatory means that private
14 insurers shall not be allowed to deny payment for treatment options as “experimental and/or
15 investigational” when they are covered under the government plans; such coverage shall
16 extend to managed Medicaid, Workers' Compensation plans, and auto liability insurance
17 companies. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000

Received: 10/09/20

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 113
(November 2020)

Introduced by: Association for Clinical Oncology, American Academy of Neurology

Subject: Most Favored Nation Executive Order

Referred to: Reference Committee A

Whereas, On September 13, 2020, President Trump signed a long-promised executive order aimed at reducing the price of drugs. The order grants authority to the Secretary of HHS to implement a demonstration project to test a "most favored nation" (MFN) policy for some drugs or biologicals under Part B and Part D of Medicare;[1] and

Whereas, According to the Administration, it is planning to use the Organization for Economic Co-operation and Development (OECD) to identify countries with a comparable per-capita gross domestic product and, after adjusting for volume and differences in national gross domestic product, to have Medicare pay the lowest price for drugs available in those countries. This policy would enable Medicare to pay the same amount for drugs as other specified developed countries; and

Whereas, It is expected that the Part B demonstration will be the first that the Centers for Medicare and Medicaid Services (CMS) will propose; however, details of the demonstrations have not been released; and

Whereas, CMS has not been transparent about the rulemaking process by which this Executive Order would be implemented; and

Whereas, Our AMA approved H-110.980, "Additional Mechanisms to Address High and Escalating Pharmaceutical Prices," at the 2019 Interim meeting advocating that any use of any international drug price index or average should limit burdens on physician practices; and

Whereas, Our AMA approved D-330.904, "Opposition to the CMS Medicare Part B Drug Payment Model," at the 2016 Annual meeting advocating against policies that are likely to undermine access to the best course of treatment for individual patients and oppose demonstration programs that could lead to lower quality of care and do not contain mechanisms for safeguarding patients; and

Whereas, There are concerns that a hastily developed demonstration could have a negative impact on patient access to critical therapies given that practices and patients are already strained due to the current COVID-19 public health emergency; therefore be it

RESOLVED, That our American Medical Association advocate against the implementation of mandatory demonstration projects testing "Most Favored Nation" policy during the ongoing COVID-19 Public Health Emergency (PHE) to avoid potential further burden on practices (Directive to Take Action); and be it further

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[1] https://www.whitehouse.gov/presidential-actions/executive-order-lowering-drug-prices-putting-america-first/

1 RESOLVED, That our AMA, in the event that a mandatory demonstration project is proposed
2 pursuant to the Most Favored Nation Executive Order during the PHE, oppose the
3 demonstration project's implementation. (New HOD Policy)

Fiscal Note: Modest - between $1,000 - $5,000

Received: 10/14/20

RELEVANT AMA POLICY

Additional Mechanisms to Address High and Escalating Pharmaceutical Prices H-110.980
1. Our AMA will advocate that the use of arbitration in determining the price of prescription drugs meet the following standards to lower the cost of prescription drugs without stifling innovation:
a. The arbitration process should be overseen by objective, independent entities;
b. The objective, independent entity overseeing arbitration should have the authority to select neutral arbitrators or an arbitration panel;
c. All conflicts of interest of arbitrators must be disclosed and safeguards developed to minimize actual and potential conflicts of interest to ensure that they do not undermine the integrity and legitimacy of the arbitration process;
d. The arbitration process should be informed by comparative effectiveness research and cost-effectiveness analysis addressing the drug in question;
e. The arbitration process should include the submission of a value-based price for the drug in question to inform the arbitrator's decision;
f. The arbitrator should be required to choose either the bid of the pharmaceutical manufacturer or the bid of the payer;
g. The arbitration process should be used for pharmaceuticals that have insufficient competition; have high list prices; or have experienced unjustifiable price increases;
h. The arbitration process should include a mechanism for either party to appeal the arbitrator's decision; and
i. The arbitration process should include a mechanism to revisit the arbitrator's decision due to new evidence or data.
2. Our AMA will advocate that any use of international price indices and averages in determining the price of and payment for drugs should abide by the following principles:
a. Any international drug price index or average should exclude countries that have single-payer health systems and use price controls;
b. Any international drug price index or average should not be used to determine or set a drug's price, or determine whether a drug's price is excessive, in isolation;
c. The use of any international drug price index or average should preserve patient access to necessary medications;
d. The use of any international drug price index or average should limit burdens on physician practices; and
e. Any data used to determine an international price index or average to guide prescription drug pricing should be updated regularly.
3. Our AMA supports the use of contingent exclusivity periods for pharmaceuticals, which would tie the length of the exclusivity period of the drug product to its cost-effectiveness at its list price at the time of market introduction.
Citation: CMS Rep. 4, I-19

Most Favored Nation Clause within Insurance Contracts H-385.938
Our AMA opposes the inclusion of "Most Favored Nation Clauses" into insurance contracts that require a physician or other health care provider to give a third party payer his most discounted rate for medical services.
Citation: Res. 712, I-98; Reaffirmed: CMS Rep. 4, A-08; Reaffirmed: CMS Rep. 01, A-18

Opposition to the CMS Medicare Part B Drug Payment Model D-330.904
1. Our AMA will request that the Centers for Medicare & Medicaid Services (CMS) withdraw the proposed Part B Drug Payment Model.
2. Our AMA will support and actively work to advance Congressional action to block the proposed Part B Drug Payment Model if CMS proceeds with the proposal.
3. Our AMA will advocate against policies that are likely to undermine access to the best course of treatment for individual patients and oppose demonstration programs that could lead to lower quality of care and do not contain mechanisms for safeguarding patients.
4. Our AMA will advocate for ensuring that CMS solicits and takes into consideration feedback from patients, physicians, advocates, or other stakeholders in a way that allows for meaningful input on any Medicare coverage or reimbursement policy that impacts patient access to medical therapies, including policies on coverage and reimbursement.
Citation: Res. 241, A-16

Reference Committee B

BOT Report(s)

05 FDA Conflict of Interest

06 Covenants Not to Compete

07 Opposition to Involuntary Civic Commitment for Substance Use Disorder

13 Merit-based Incentive Payment System (MIPS) Update

14 Advocating for the Standardization and Regulation of Outpatient Addiction Rehabilitation Facilities

16 Enabling Methadone Treatment of Opioid Use Disorder in Primary Care Settings

Resolution(s)

201 Permitting the Dispensing of Stock Medications for Post Discharge Patient Use and the Safe Use of Multi-dose Medications for Multiple Patients

202 Cares Act Equity and Loan Forgiveness in the Medicare Accelerated Payment Program

203 COVID-19 Emergency and Expanded Telemedicine Regulations

204 Studying Physician Supervision of Allied Health Professionals Outside of Their Fields of Graduate Medical Education

205 Telehealth Post SARS-COV-2

206 Strengthening the Accountability of Health Care Reviewers

207 AMA Position on All Payer Database Creation

208 Insurance Claims Data

209 Physician Tax Fairness

210 Prohibit Ghost Guns

211 Creating a Congressionally- Mandated Bipartisan Commission to Examine the U.S. Preparations for and Response to the COVID-19 Pandemic to Inform Future Efforts

212 Copay Accumulator Policies

213 Pharmacies to Inform Physicians When Lower Cost Medication Options are on Formulary

214 Increase Advocacy Efforts in Support of the Treat and Reduce Obesity Act

REPORT 5 OF THE BOARD OF TRUSTEES (November 2020)
FDA Conflict of Interest
(Resolution 216-A-18)
(Reference Committee B)

EXECUTIVE SUMMARY

The United States Food and Drug Administration (FDA) utilizes advisory committees to obtain independent expert advice and recommendations on scientific, technical, and policy matters related to FDA-regulated products. There are 50 advisory committees and panels. The FDA's advisory committees are governed by several federal laws and regulations that: (1) establish standards for convening advisory committees; (2) specify criteria for what constitutes a conflict of interest (COI); and (3) outline the requirements for disclosing, assessing, and managing COIs. In addition, the FDA has issued guidance documents interpreting government-wide regulations pertaining to the appearance of COIs as well as guidance related to the public availability of advisor COI disclosures and associated FDA COI waivers.

Despite long-standing federal laws governing COIs and waivers applicable to FDA advisory committee members, there have remained persistent concerns that waivers of COIs negatively impact the trustworthiness and independence of advisory committee recommendations. While there is widespread consensus that COI policies are appropriate and necessary along with a measured approach to granting COI waivers for FDA advisory committee members, there is also concern that an overzealous approach to waivers will undermine the actual or perceived quality of advisory committee recommendations.

The resolve clauses in the resolution generating this report, i.e., Resolution 216-A-18, "[Food and Drug Administration] FDA Conflict of Interest," would have the American Medical Association (AMA) adopt policy that specifies that the FDA should place a greater emphasis on advisory committee member COIs and seek a further reduction in the number of COI waivers granted by the FDA. Existing AMA ethics policy provides a clear set of parameters concerning COIs and waivers regarding clinical practice guidelines development and clinical research that should be utilized to expand upon AMA policy concerning FDA advisory committee member COIs and waivers. Accordingly, the AMA Board of Trustees (Board) recommends extending existing policies to FDA advisory committee member COIs and waivers to underscore the importance of existing FDA laws, regulations, and policies. Since AMA policy does not address concerns that advisory committee members may not be fully disclosing conflicts and independent targeted auditing for sufficiency may be warranted, the Board recommends adopting new policy to that effect.

The Board recognizes that ensuring that COIs do not compromise the integrity of the FDA advisory committee process is paramount. At the same time, the Board understands that there is an on-going, pressing need to fill FDA advisory committee vacancies. Therefore, the Board believes that the AMA should also adopt new policy urging the FDA to streamline the COI process to reduce any unnecessary documentation, administrative barriers, or delays that might hinder the participation of qualified physicians on FDA advisory committees.

Finally, the Board recommends that the AMA adopt new policy stating that the FDA should undertake an evaluation of pay-later conflicts of interest (e.g., where an FDA advisory committee member develops a financial conflict of interest only after his or her initial appointment on the advisory committee has expired) to assess whether these undermine the independence of advisory committee member recommendations and whether policies should be adopted to address this issue.

REPORT OF THE BOARD OF TRUSTEES

B of T Report 5, November 2020

Subject: FDA Conflict of Interest (Resolution 216-A-18)

Presented by: Russ Kridel, MD, Chair

Referred to: Reference Committee B

At the 2018 Annual Meeting of the House of Delegates (HOD), Resolution 216-A-18, "[Food and Drug Administration] FDA Conflict of Interest," was referred for report back at the 2019 Annual Meeting. Resolution 216-A-18, sponsored by the Medical Student Section, asked that:

> Our American Medical Association (AMA) advocate (1) that the Food and Drug Administration [(FDA)] place a greater emphasis on a candidate's conflict of interest when selecting members for advisory committees and (2) for a reduction in conflict of interest waivers granted to Advisory Committee candidates.

There was mixed testimony on Resolution 216 during the reference committee. Testimony was offered that disclosure and transparency into conflicts of interest (COI) are important, but on the other hand challenges may exist to find qualified individuals without COIs. Others offered that the FDA should utilize generally accepted COI policies and should limit waivers of such policies for advisory committees. The HOD referred Resolution 216 to the Board of Trustees (Board) for report back at the 2019 AMA Annual Meeting.

During the 2019 Annual Meeting, the Board presented Report 19-A-19, "FDA Conflict of Interest" to the HOD in response to the HOD's referral of Resolution 216. At the 2019 Annual Meeting, the HOD referred Report 19-A-19 back to the Board for further consideration, because the HOD wanted the report to include in the report's recommendations language urging the FDA to reduce administrative burdens associated with, and otherwise streamlining, its advisory committee COI process to facilitate physician participation on its advisory committees, since participation continues to be a challenge. This report, i.e., Board Report 10-A-20, contains the revisions to Board Report 19-A-19 that the HOD requested, and the Board presents this report for the HOD's further consideration.

FDA AND THE ROLE OF ADVISORY COMMITTEES

The FDA utilizes advisory committees to obtain independent expert advice and recommendations on scientific, technical, and policy matters related to FDA-regulated products. There are 50 advisory committees and panels.[1] The recommendations of advisory committees do not bind the FDA. Although the advisory committees include permanent non-voting members who are FDA employees (typically responsible for administering the meetings), the majority are external experts who are considered special government employees (SGEs) while performing their advisory committee duties. The advisory committees cover a range of products.[2]

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The FDA's advisory committees are governed by several federal laws and regulations that: (1) establish standards for convening advisory committees; (2) specify criteria for what constitutes a COI; and (3) outline the requirements for disclosing, assessing, and managing COIs. In addition, the FDA has issued guidance documents interpreting government-wide regulations pertaining to the appearance of COIs as well as guidance related to the public availability of advisor COI disclosures and associated FDA waivers. For the most part, the federal laws, regulations, and guidance are generally the same whether a committee advisor is a permanent federal employee or SGE with some exceptions as outlined below. For over a decade, the FDA and Congress have implemented reforms to the FDA's process for assessing COIs, managing COIs including waivers, and public disclosure.[3] Members of the FDA's advisory committees are subject to Federal COI laws (18 USC section 208) as well as government-wide standards of ethical conduct regulations (5 CFR section 2635.502). Even where a member has no financial interests that would require the member to refrain from participating in an advisory committee meeting ("recuse") under Federal COI laws, the member may be disqualified from participation under the government-wide Federal regulation at 5 CFR section 2635.502 if the member has interests or relationships that may create the appearance that the member lacks impartiality on the issue before the advisory committee.

As specified in federal law, the FDA has a process for determining whether to grant a waiver for an advisory committee member with an actual financial COI. The FDA also has guidance outlining how the Agency evaluates whether an advisory committee member has potentially disqualifying interests or relationships that fall into the second category of interests: appearance of a COI. (In this latter case, the regulations provide that an authorization to participate would be issued as opposed to issuance of a waiver.) In both cases, the decision to permit voting, permit participation, or recusal will be made by the FDA.

PROHIBITION AGAINST FINANCIAL COI

Unless granted a waiver, a federal employee may not "personally and substantially participate" in an official capacity in any particular matter which, to the employee's knowledge, the employee or a related person or organization (whose interests are imputed to the employee under 18 USC section 208) has a "financial interest" if the particular matter will have a "direct and predictable effect" on that interest (5 CFR section 2640.103(a)). In this analysis, federal employees include FDA advisory committee members who are considered SGEs. A financial interest is defined as the potential for gain or loss as a result of governmental action on the particular matter which includes stock options, a salary, job offer, indebtedness, and similar interests (5 CFR section 2640.103(b)). Under this law, the financial interests of other, related persons and organizations (as defined in law and statute)[4] are imputed to the employee and may disqualify an employee to the same extent as the employee's own interests. Under the law, a COI arises when the employee participates in an official matter and there is a direct and predictable link between the matters in which the federal employee participates and the employee's financial interests. The link cannot be contingent and dependent on other events.

Process for Reviewing Financial COIs and Granting Waivers

The FDA reviews financial COI disclosures made by potential advisory committee members and the member's expertise with respect to the specific product or policy to be evaluated at a particular meeting. Each adviser is required to certify to the truth and completeness of any information provided.[5] The Agency can issue a waiver to permit participation despite a current conflict or one that ended during the 12 months preceding a meeting consistent with applicable law. The FDA is required by law to apply different standards to SGEs (who constitute the majority of advisory

committee members) and permanent government employees in order to determine if an applicable standard for granting a waiver pursuant to 18 USC section 208 is met.

If the individual is a SGE, the FDA's "determination must be based on a certification that the need for the [SGE's] ... services outweighs the potential for a conflict of interest created by the financial interest involved," (5 CFR section 2640.302). The FDA considers a number of factors, including the type of interest that is creating the disqualification, the relationship of the person whose financial interest is involved to the SGE, the uniqueness of the SGE's qualifications, the difficulty of locating a similarly qualified individual without a disqualifying financial interest, the dollar value of the disqualifying financial interest, and the extent to which the disqualifying financial interest could be affected by the actions of the advisory committee.[6] If the individual is a permanent government employee, the FDA determines whether the member's financial interest is not so substantial as to be deemed likely to affect the integrity of the services provided by that individual. In making this determination, the FDA considers a number of factors, including the type of financial interest that is creating the disqualification, the relationship of the person whose financial interest is involved to the member, the dollar value of the disqualifying financial interest, the nature and importance of the employee's role in the matter, and the need for the employee's services in the particular matter.[7] FDA guidance provides that a common factor to be considered for both categories of advisory committee members is the "need" for the individual's services. In deciding whether there is a need, the FDA will consider: (1) the uniqueness of the member's qualifications; (2) the difficulty locating similarly qualified individuals without a disqualifying financial interest; (3) the value and utility of the member's expertise to the matter being addressed by the committee; and (4) the nature and extent of the disqualifying financial interest.

In addition, the FDA must apply one more standard to members serving on drug or biologic advisory committees that provide scientific advice and recommendations regarding a clinical investigation or marketing approval. For these members, the standard for a waiver to permit voting is whether a waiver is "necessary" to afford the committee "essential expertise."[8] Where a financial COI exists, the FDA determines whether the member may: (1) participate as a non-voting member; or (2) not participate in the advisory committee.[9] Individuals with financial COIs are not permitted to vote as a matter of FDA policy. A waiver may not be granted when the member's own scientific work is involved.[10]

The Food and Drug Administration Amendments Act of 2007 included a provision capping the number of COI waivers the FDA could grant in any given year. Subsequently, this cap was rescinded in the Food and Drug Administration Safety and Innovation Act of 2012.[11] A recent analysis of FDA COI waivers found that in fiscal year (FY) 2012, the waiver rate did not exceed one percent and this was less than in earlier years.[12] Additionally, the FDA reports COI waiver rates of less than one percent for FYs 2013, 2014, 2015, and 2016 on its online FDA-TRACK Advisory Committees Dashboard.[13]

Public Disclosure

The FDA publicly discloses[14] on the Agency's website the type, nature, and magnitude of the financial interests of each advisory committee member who has received a waiver under 18 USC section 208. The FDA also provides the reasons for granting each waiver prior to the advisory committee meeting,[15] including, as appropriate, the public health interest in having the expertise of the member with respect to the particular matter.[16]

APPEARANCE OF A CONFLICT OF INTEREST – PERSONAL AND BUSINESS RELATIONSHIPS

Federal law also contains provisions to help ensure that an employee takes appropriate steps to avoid an appearance of loss of impartiality in the performance of his or her official duties. Under 5 CFR section 2635.502 where an agency employee (including FDA advisory committee members), "knows that a particular matter involving specific parties is likely to have a direct and predictable effect on the financial interest of a member" of the employee's household, or knows that a person with whom the employee has a "covered relationship is or represents a party to such matter," and "where the employee determines that the circumstances would cause a reasonable person with knowledge of the relevant facts" to question the employee's impartiality in the matter, the employee should not participate in the matter unless the employee has informed the agency designee of the appearance problem and received authorization from the agency designee. An employee has a "covered relationship" with:

- a person other than a prospective employer with whom the employee has or seeks a business, contractual or other financial relationship that involves other than a routine consumer transaction;
- a person who is a member of the employee's household, or who is a relative with whom the employee has a close personal relationship;
- a person for whom the employee's spouse, parent or dependent child is, to the employee's knowledge, serving or seeking to serve as an officer, director, trustee, general partner, agent, attorney, consultant, contractor or employee; any person for whom the employee has, within the last year, served as officer, director, trustee, general partner, agent, attorney, consultant, contractor or employee; or
- an organization, other than a political party,[17] in which the employee is an "active participant."[18]

Granting a Section 502 Authorization

If the FDA concludes that an appearance issue exists, a determination is made whether the Agency's interest in the member's participation outweighs the concern that a reasonable person may question the integrity of the Agency's programs and operations. If so, the FDA may grant an authorization (i.e., a waiver) before the meeting to allow the member to participate. The FDA may limit authorization or deny authorization. The Agency takes into consideration a number of factors including, but not limited to: (1) the nature of the relationship involved; (2) the effect that resolution of the matter would have upon the financial interests of the person involved in the relationship; (3) the nature and importance of the member's role in the matter, including the extent to which the member is called upon to exercise discretion in the matter; (4) the sensitivity of the matter; (5) the difficulty of reassigning the matter to another expert; and (6) adjustments that may be made in the member's duties that would reduce or eliminate the likelihood that a reasonable person would question her impartiality.

RESEARCH ON COI AND FDA ADVISORY COMMITTEE RECOMMENDATIONS

Despite long-standing federal laws governing COIs and waivers applicable to FDA advisory committee members, there have remained persistent concerns in the general public that waivers of COIs negatively impact the trustworthiness and independence of advisory committee recommendations. However, the research and investigations into this matter have produced mixed results. In a 2014 study of FDA advisory committee member COIs, a researcher found that, where an advisory committee member had an exclusive financial relationship with the manufacturer

(referred to as a sponsor) of the product under review, the member appeared to be biased in support of the product sponsor.[19] No similar bias was found where members had financial ties to both a sponsor and its competitors.[20] The study author noted that "[t]hese findings point to important heterogeneities in financial ties and suggest that policymakers will need to be nuanced in their management of financial relationships of FDA advisory committee members."[21] In another study, the researchers found little significant evidence that advisory committee members vote in their financial interests.[22] The authors also found that the perverse exclusion of "financially-conflicted members resulted in a sharp drop in average member expertise, and an unintended increase in approval voting." The study authors concluded that "[e]liminating conflicts could sharply reduce the level of expertise of the decision makers and lead to unexpected voting tendencies."[23] More recently, an investigation of FDA advisory committee members COIs has called into question: (1) the completeness of COI disclosures submitted by members; (2) whether the FDA does enough to verify the completeness and accuracy of such disclosures; and (3) whether past or current COI assessments are inadequate as pay-later COIs may play a more significant role in influencing a member's deliberations and vote. Specifically, a 2018 investigation found that, at the time of or in the year leading up to the advisory committee meetings under scrutiny, many of the members received payments or other financial support from the sponsoring drug firm or key competitors for consulting, travel, lectures, or research.[24] The investigators concluded that the FDA did not publicly disclose those ties even though this information was disclosed in scholarly journals.[25] In the same investigation, a review was undertaken of compensation records from drug sponsors to advisory committee members who advised the FDA on whether to approve 28 psychopharmacologic, arthritis, and cardiac or renal drugs between 2008 and 2014.[26] The investigators concluded that there were "widespread after-the-fact payments or research support to panel members."[27] As correctly noted by the investigators: "[t]he agency's safeguards against potential conflicts of interest are not designed to prevent such future financial ties."

AMA POLICY

The AMA has policy addressing COIs applicable to FDA advisory committees (Policy H-100.992, "FDA") as well as ethics policy concerning COIs in the areas of research (Ethics Opinion 7.1.4/ AMA Principles of Medical Ethics: II, IV,V, "Conflicts of Interest in Research") and clinical practice guidelines (Policy H-410.953, "Ethical Considerations in the Development of Clinical Practice Guidelines").

DISCUSSION

The resolve clauses in Resolution 216 would have the AMA adopt policy that specifies that the FDA should place a greater emphasis on advisory committee member COIs and seek a further reduction in the number of COI waivers granted by the FDA. While there is widespread consensus that COI policies are appropriate and necessary along with a measured approach to granting COI waivers for FDA advisory committee members, there is also concern that an overzealous approach to waivers will undermine the actual or perceived quality of advisory committee recommendations. The FDA has reduced the number of waivers granted, but there are conflicting reports with regard to the magnitude of the challenge the Agency faces filling advisory committee vacancies. For example, one article reported that in FY 2017, "218 advisory committee positions of the 600-plus on the FDA's 49 advisory committees had not been filled."[28] Yet, data disclosed by FDA indicates that in FY 2017 there were 64 vacancies out of 564[29] and in FY 2018 there were 57 total vacancies out of 547 members.[30] A 10 percent vacancy is substantially lower than a nearly 50 percent vacancy. Nonetheless, the COI waiver rate has remained consistently below one percent. Lowering this percentage further is reasonably likely to increase vacancies which are hovering at 10 percent.

Existing AMA ethics policy provides a clear set of parameters concerning COIs and waivers regarding clinical practice guidelines development and clinical research that should be utilized to expand upon AMA policy concerning FDA advisory committee member COIs and waivers. Our current AMA policy related to advisory committee members provides that a FDA decision to approve a new drug, to withdraw a drug's approval, or to change the indications for use of a drug must be based on sound scientific and medical evidence derived from controlled trials and/or postmarket incident reports as provided by statute and evidence of such should be evaluated by the FDA, in consultation with its advisory committees (Policy H-100.992). The policy also provides that the FDA should not let COIs overrule scientific evidence in making policy decisions. Building on the above policy, our AMA has ethics policy noting how minimizing and mitigating COIs in clinical research is imperative to justify and maintain trust in the medical research community (7.1.4, "Conflicts of Interest in Research"). This is equally true for FDA advisory committee member recommendations. This same policy provides that physicians who engage in research should disclose material ties to companies whose products they are investigating or other ties that create real or perceived COIs. Similarly, AMA ethics policy concerning clinical practice guidelines provides that patients, the public, physicians, and other stakeholders must have confidence that published guidelines are the ethically and scientifically credible product of development processes that are rigorous, independent, transparent, and accountable (Policy H-410.953). Notably, while Policy H-410.953 specifies that published guidelines/updates are to be developed independent of direct financial support from entities that have an interest in the recommendations, it does specify consideration for COIs (actual and perceived) for individuals associated in the development of the guidelines. The policy states: "ideally, all individuals associated with guideline development will be free of conflicts of interest during the development process and will remain so for a defined period following the publication of the guideline." In order to ensure credibility, our AMA policy provides that:

> formal procedures would be adopted to minimize the potential for financial or other interests to influence the process at all key steps (selection of topic, review of evidence, panel deliberations, development and approval of specific recommendations, and dissemination of final product). These should include: a) required disclosure of all potential conflicts of interest by panel members, consultants, staff, and other participants; b) clearly defined criteria for identifying and assessing the seriousness of conflicts of interest; and c) clearly defined strategies for eliminating or mitigating the influence of identified conflicts of interest (such as prohibiting individuals from participating in deliberations, drafting, or voting on recommendations on which they have conflicts) in those limited circumstances when participation by an individual with a conflicting interest cannot be avoided.

The policy provides for a clear statement of methodology, COI policy and procedures, and disclosures of panel members' COIs. The Board recommends extending the foregoing policies to FDA advisory committee member COIs and waivers to underscore the importance of existing FDA laws, regulations, and policies. And since AMA policy does not address concerns that advisory committee members may not be fully disclosing conflicts and independent targeted auditing for sufficiency may be warranted, the Board recommends adopting new policy to that effect.

The Board recognizes that ensuring that COIs do not compromise the integrity of the FDA advisory committee process is paramount. At the same time, the Board understands that there is an ongoing, pressing need to fill FDA advisory committee vacancies. Therefore, the Board believes that, in accordance with the position outlined above, the AMA should also adopt new policy urging the FDA to streamline the COI process to reduce any unnecessary documentation, administrative barriers, or delays that might hinder the participation of qualified physicians on FDA advisory committees.

Finally, existing policy does not address the impact of pay-later COIs (e.g., where a FDA advisory committee member develops a financial COI only after his or her initial appointment on the advisory committee has expired). Since there is limited research on the topic, this is an important area for the FDA and researchers to more fully evaluate and craft appropriate policy.

RECOMMENDATIONS

In light of these considerations, your Board of Trustees recommends that the following be adopted in lieu of Resolution 216-A-18 and the remainder of this report be filed:

1. That our American Medical Association (AMA) reaffirm Policy H-100.992, "FDA," which supports that FDA conflicts of interest should not overrule scientific evidence in making policy decisions and the FDA should include clinical experts on advisory committees. (Reaffirm HOD Policy)

2. That our AMA adopt the following new policy:

   It is the position of the American Medical Association that decisions of the Food and Drug Administration (FDA) must be trustworthy. Patients, the public, physicians, other health care professionals and health administrators, and policymakers must have confidence that FDA decisions and the recommendations of FDA advisory committees are ethically and scientifically credible and derived through a process that is rigorous, independent, transparent, and accountable. Rigorous policies and procedures should be in place to minimize the potential for financial or other interests to influence the process at all key steps. These should include, but not necessarily be limited to: a) required disclosure of all relevant actual or potential conflicts of interest, both financial and personal; b) a mechanism to independently audit disclosures when warranted; c) clearly defined criteria for identifying and assessing the magnitude and materiality of conflicts of interest; and d) clearly defined processes for preventing or terminating the participation of a conflicted member, and mitigating the influence of identified conflicts of interest (such as prohibiting individuals from participating in deliberations, drafting, or voting on recommendations on which they have conflicts) in those limited circumstances when an individual's participation cannot be terminated due to the individual's unique or rare skillset or background that is deemed highly valuable to the process. Further, clear statements of COI policy and procedures, and disclosures of FDA advisory committee members' conflicts of interest relating to specific recommendations, should be published or otherwise made public. Participation on advisory committees should be facilitated through appropriate balancing of the relative scarcity or uniqueness of an individual's expertise and ability to contribute to the process, as compared to the feasibility and effectiveness of mitigation measures. Finally, our AMA urges the FDA to streamline the COI process to the greatest extent possible, thereby eliminating any unnecessary documentation, delays, or administrative barriers to qualified physicians' participation on FDA advisory committees. (New HOD Policy)

3. That our AMA adopt the following new policy:

   It is the position of the American Medical Association that the FDA should undertake an evaluation of pay-later conflicts of interest (e.g., where a FDA advisory committee member develops a financial conflict of interest only after his or her initial appointment on the advisory committee has expired) to assess whether these undermine the independence of advisory

1 committee member recommendations and whether policies should be adopted to address this
2 issue. (New HOD Policy)

Fiscal Note: Less than $500

REFERENCES

[1] FDA Advisory Committees, Accessed on February 25, 2019

[2] Id. Products include blood, vaccines and other biologics; human drugs; food; medical devices; patient engagement; pediatric; radiation-emitting products; risk communication; science board; toxicological research; veterinary; and tobacco.

[3] See, for example, the FDA Amendments Act (FDAA) of 2007 which mandated that by 2012 no more than thirteen percent of committee advisors per year could receive COI waivers. The FDA reduced the maximum size of financial interests eligible for waivers from a combined financial interest of up to $100,000, to a maximum of $50,000. See also Draft Guidance for the Public, FDA Advisory Committee Members, and FDA Staff on Procedures for Determining COI and Eligibility for Participation in FDA Advisory Committees (March 2007); Public Availability of Advisory Committee Members' Financial Interest Information and Waivers-Final Guidance (2014); and, Procedures for Evaluating Appearance Issues and Granting Authorizations for Participation in FDA Advisory Committees (2016).

[4] Related persons and organizations include: the employee's spouse, minor child, or general partner; an organization or entity for which the employee serves as officer, director, trustee, general partner, or employee; and a person with whom the employee is negotiating for, or has an arrangement concerning, prospective employment.

[5] In preparation for advisory committee meetings involving particular matters, SGEs invited to participate in the meetings are required to report to FDA any financial interests related to the subject matter of the advisory committee meeting. 5 CFR § 2634.904(a)(2). Permanent government employees also report financial interests on a yearly basis and/or just prior to the advisory committee meeting they are planning to attend. 5 CFR §§ 2634.202 and 2634.904(a)(1). The FDA reviews not only the financial interests of a potential advisory committee participant and the individual's immediate family, but also the financial interests, of which the individual has knowledge, of the participant's business partners, organizations for which the individual serves as officer, director, trustee, general partner, or employee, and any prospective employer of the member (if there are ongoing employment negotiations or an agreement regarding future employment). See 18 U.S.C. § 208(a).

[6] 5 CFR 2640.302(b)

[7] 5 CFR 2640.301(b)

[8] Food, Drug, and Cosmetic Act section 505 (n)(4) "Each member of a panel shall publicly disclose all conflicts of interest that member may have with the work to be undertaken by the panel. No member of a panel may vote on any matter where the member or the immediate family of such member could gain financially from the advice given to the Secretary. The Secretary may grant a waiver of any conflict of interest requirement upon public disclosure of such conflict of interest if such waiver is necessary to afford the panel essential expertise, except that the Secretary may not grant a waiver for a member of a panel when the member's own scientific work is involved."

[9] Draft Guidance for the Public, FDA Advisory Committee Members, and FDA Staff on Procedures for Determining COI and Eligibility for Participation in FDA Advisory Committees March 2007

[10] Id.

[11] Wood SF, Mador JK. *Science and regulation. Uncapping conflict of interest?* Science (2013)

[12] Lurie P. *Suggestions for Improving Conflict of Interest Processes in the US Food and Drug Administration Advisory Committees—Past Imperfect*. JAMA Intern Med. 2018;178(7):997–998. doi:10.1001/jamainternmed.2018.1324

[13] Report to Congress Food and Drug Administration Safety and Innovation Act, Section 712 (e) of the Federal Food, Drug, and Cosmetic Act, Fiscal Year 2016 Annual Report on FDA Advisory Committee Vacancies and Public Disclosures Accessed on February 27, 2019

[14] The FDA does not publicly disclose financial interest information if it is exempt from disclosure under the Freedom of Information Act or otherwise protected from disclosure by statute or regulation, except if necessary to describe the type, nature, and magnitude of the financial conflict being waived.

[15] This information must be published within specified time frames before advisory committee meetings. Food, Drug, and Cosmetic Act section 712(c).

[16] FDA Guidance on Publication of Financial COI waivers. https://www.fda.gov/RegulatoryInformation/Guidances/ucm391034.htm#_ftn11

[17] Political party as described in 26 U.S.C. 527(e)

[18] Participation is active if, for example, it involves service as an official of the organization or in a capacity similar to that of a committee or subcommittee chairperson or spokesperson, or participation in directing the activities of the organization. In other cases, significant time devoted to promoting specific programs of the organization, including coordination of fundraising efforts, is an indication of active participation. Payment of dues or the donation or solicitation of financial support does not, in itself, constitute active participation.

[19] Pham-Kanter G., Revisiting Financial Conflicts of Interest in FDA Advisory Committees, Milbank Quarterly, September 2014 Volume 92, Issue 3 (pages 446–470), DOI: 10.1111/1468-0009.12073

[20] Id.

[21] Id.

[22] Cooper J., Golec J. Conflicts of Interest on Expert Committees: The Case of FDA Drug Advisory Committees, University of Connecticut School of Business Research Paper No. 17-02, April 2018 Accessed February 24, 2019

[23] Id.

[24] Piller C., You J. Hidden conflicts? Pharma payments to FDA advisers after drug approvals spark ethical concerns, Science Magazine, July 5, 2018 Accessed February 24, 2019

[25] Id.

[26] Id.

[27] Piller C., You J. Hidden conflicts? Pharma payments to FDA advisers after drug approvals spark ethical concerns, Science Magazine, July 5, 2018 Accessed February 24, 2019

[28] Sullivan, T., FDA Conflicts of Interest Rules Means Fewer Experts on Advisory Panels, Policy and Medicine Blog, May 5, 2018 Accessed on February 24, 2019.

[29] FDA website – online Percent of FDA advisory committee member positions vacant at the end of the month Accessed February 27, 2019

[30] FDA website – online Percent of FDA advisory committee member positions vacant at the end of the month Accessed February 27, 2019

APPENDIX: RELEVANT AMA POLICY

Policy H-100.992, "FDA"

(1) Our AMA reaffirms its support for the principles that: (a) an FDA decision to approve a new drug, to withdraw a drug's approval, or to change the indications for use of a drug must be based on sound scientific and medical evidence derived from controlled trials and/or postmarket incident reports as provided by statute; (b) this evidence should be evaluated by the FDA, in consultation with its Advisory Committees and expert extramural advisory bodies; and (c) any risk/benefit analysis or relative safety or efficacy judgments should not be grounds for limiting access to or indications for use of a drug unless the weight of the evidence from clinical trials and postmarket reports shows that the drug is unsafe and/or ineffective for its labeled indications.
(2) The AMA believes that social and economic concerns and disputes per se should not be permitted to play a significant part in the FDA's decision-making process in the course of FDA devising either general or product specific drug regulation.
(3) It is the position of our AMA that the Food and Drug Administration should not permit political considerations or conflicts of interest to overrule scientific evidence in making policy decisions; and our AMA urges the current administration and all future administrations to consider our best and brightest scientists for positions on advisory committees and councils regardless of their political affiliation and voting history.

E-7.1.4, "Conflicts of Interest in Research"

Increasing numbers of physicians, both within and outside academic health centers, are becoming involved in partnerships with industry to conduct biomedical and health research. As they do so, physicians must be mindful of the conflicts such engagement poses to the integrity of the research and the welfare of human participants. In addition to financial conflicts of interest created by incentives to conduct trials and recruit subjects, physicians must be sensitive to the differing roles of clinician and investigator, which may require them to balance dual commitments to participants and science. This conflict of commitment is particularly acute when a physician-investigator has treated or continues to treat a patient who is eligible to enroll as a participant in a clinical trial the physician is conducting.
Minimizing and mitigating conflicts of interest in clinical research is imperative if the medical community is to justify and maintain trust in the medical research community.
Physicians who engage in research should:
(a) Decline financial compensation that awards in excess of the physician's research efforts and does not reflect fair market value. Physicians should not accept payment solely for referring patients to research studies.
(b) Ensure that the research protocol includes provision for funding participants' medical care in the event of complications associated with the research. A physician should not double-bill a third-party payer for additional expenses related to conducting the trial if he or she has already received funds from a sponsor for those expenses.
(c) As part of the informed consent process, disclose to prospective participants the nature and source of funding and financial incentives offered to the investigators. This disclosure should be included in any written consent materials.
(d) Avoid engaging in any research where there is an understanding that limitations can be placed on the presentation or publication of results by the research sponsor.
(e) Refrain from knowingly participating in a financial relationship with a commercial entity with whom they have a research relationship until the research relationship ends and the research results have been published or otherwise disseminated to the public.
(f) Disclose material ties to companies whose products they are investigating or other ties that create real or perceived conflicts of interest to:
(i) institutions where the research will be carried out;
(ii) organizations that are funding the research;
(iii) any journal or publication where the research results are being submitted.
(g) Physicians who have leadership roles in institutions that conduct biomedical and health research as well as the entities that fund research with human participants should promote the development of guidelines on conflicts of interest that clarify physician-investigators responsibilities.

AMA Principles of Medical Ethics: II,IV,V; The Opinions in this chapter are offered as ethics guidance for physicians and are not intended to establish standards of clinical practice or rules of law. Issued: 2016

Policy H-410.953, "Ethical Considerations in the Development of Clinical Practice Guidelines"

Clinical practice guidelines are statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options. Clinical practice guidelines help inform physician judgment and decision making by physicians and patients. Clinical practice guidelines also have significant potential to meaningfully inform efforts to provide care of consistently high quality for all patients and to help shape development of sound public policy in health care. To achieve those ends, clinical practice guidelines must be trustworthy. Patients, the public, physicians, other health care professionals and health administrators, and policymakers must have confidence that published guidelines are the ethically and scientifically credible product of development processes that are rigorous, independent, transparent, and accountable.
To that end, the development or updating of clinical practice guidelines should meet the following expectations:
1. Guidelines/updates are developed independent of direct financial support from entities that have an interest in the recommendations to be developed.
2. Formal, scientifically rigorous methods and explicit standards are adopted for the review and weighting of evidence, the integration of expert judgment, and the strength of clinical recommendations.
3. Guideline panels have access to appropriate expertise among members or consultants, including not only relevantly qualified clinical experts but also appropriately qualified methodologists, representatives of key stakeholders, and, ideally, one or more individuals skilled in facilitating groups.
4. Ideally, all individuals associated with guideline development will be free of conflicts of interest during the development process and will remain so for a defined period following the publication of the guideline.
5. Formal procedures are adopted to minimize the potential for financial or other interests to influence the process at all key steps (selection of topic, review of evidence, panel deliberations, development and approval of specific recommendations, and dissemination of final product). These should include: a) required disclosure of all potential conflicts of interest by panel members, consultants, staff, and other participants; b) clearly defined criteria for identifying and assessing the seriousness of conflicts of interest; and c) clearly defined strategies for eliminating or mitigating the influence of identified conflicts of interest (such as prohibiting individuals from participating in deliberations, drafting, or voting on recommendations on which they have conflicts) in those limited circumstances when participation by an individual with a conflicting interest cannot be avoided.
6. Guidelines are subject to rigorous, independent peer review.
7. Clear statements of methodology, COI policy and procedures, and disclosures of panel members' conflicts of interest relating to specific recommendations are published with any guideline or otherwise made public.
8. Guidelines are in the first instance disseminated independent of support from or participation by individuals or entities that have a direct interest in the recommendations.

REPORT OF THE BOARD OF TRUSTEES

B of T Report 6, November 2020

Subject: Covenants Not to Compete (Resolution 10-A-19)

Presented by: Russ Kridel, MD, Chair

Referred to: Reference Committee B

INTRODUCTION

At the 2019 Annual Meeting, the American Medical Association (AMA) House of Delegates (HOD) considered Resolution 10, "Covenants Not to Compete," introduced by the New Mexico Delegation, which directed:

1. Our American Medical Association consider as the basis for model legislation the New Mexico statute allowing a requirement that liquidated damages be paid when a physician partner who is a part owner in practice is lured away by a competing hospital system.

2. Our AMA ask our Council on Ethical and Judicial Affairs to reconsider their blanket opposition to covenants not to compete in the case of a physician partner who is a part owner of a practice, in light of the protection that liquidated damages can confer to independent physician owned partnerships, and because a requirement to pay liquidated damages does not preclude a physician from continuing to practice in his or her community.

Mixed testimony regarding Resolution 10-A-19 was received by the reference committee. A number of speakers suggested that more information was necessary regarding the issues raised by the resolution and that it should be referred to the Board of Trustees for further study. Testimony also suggested that the Board and not the Council on Ethical and Judicial Affairs (CEJA), was the appropriate entity to study the concerns that prompted the resolution. Individuals testifying also expressed hesitation about both basing model legislation on the New Mexico statute and basing AMA policy on a specific state law. Following the reference committee's recommendation, the HOD referred Resolution 10-A-19 to the Board.

Although Resolution 10-A-19 uses the phrase "Covenants Not to Compete," this report uses "Restrictive Covenants," to be consistent with AMA policy.

Use of the term "partner" or "partners"

While this report uses the terms "partner" or "partners" to refer to physician ownership interests in a group practice, this report's use of these terms should not be interpreted in any way as being limited to physician ownership interests in group practices formed as partnerships. Rather, the term "partner" or "partners" encompasses *any* type of physician ownership interests in a group practice, e.g., as a member in a limited liability corporation, a shareholder in a corporation, a partner in a partnership etc., regardless of the group practice's legal structure.

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DISCUSSION

Concerns about Restrictive Covenants' Potential Negative Effects

There is growing concern among many AMA members regarding the negative impact of restrictive covenants. Some AMA members oppose restrictive covenants, in part because of the negative impact that restrictive covenants may have on them and their families if restrictive covenant enforcement compels a physician to move out of his or her community to continue practicing medicine. Members may also be disturbed about the potential negative effects that restrictive covenants may have on patient choice, patient access and the patient-physician relationship.

An Increase in Employed Physicians

The reason restrictive covenants are becoming more problematic for many AMA members is perhaps due to that fact that, for the first time ever, there are more employed physicians than physician-practice owners.[1] Recent state legislative activity is consistent with this trend, as several states have either enacted or amended restrictive covenant statutes applicable to physicians specifically or to health care generally.

Reasons why AMA members may support reasonable restrictive covenants

Other physicians, e.g., owners of physician practices or physician leaders of integrated health systems, may strongly support reasonable restrictive covenants. A reasonable restrictive covenant may, for example, give a medical practice peace of mind about committing the significant resources needed to help a new physician succeed, without having to fear that the physician will then leave, taking patients to a competitor and/or using sensitive information to gain a competitive advantage over his or her former employer. Further, physician practice owners may view reasonable restrictive covenants as necessary to ensure that all of the owners are mutually committed to the joint investments in the equipment and/or facilities that the entire practice must make in order to meet the agreed-upon business plan. CEJA Ethical Opinion 11.2.3.1, entitled, "Restrictive Covenants," does state, in part, that physicians should not agree to restrictive covenants that are unreasonable with respect to geography or duration and that do not make reasonable accommodation for patients' choice of physician. This report presents the entire text of Ethical Opinion 11.2.3.1 in the discussion concerning the second resolve of the resolution.

New Mexico

The New Mexico statute is a relatively recent development, enacted in 2015 and amended in 2017. The New Mexico law is a legislative compromise between physicians who are practice owners and physicians who are employees, acknowledging that there are physicians on both sides of the restrictive covenant issue.

The statute applies to "health care practitioners,"[2] which includes physicians, and to "agreements," which means "a written contract to which a health care practitioner is a party."[3] The New Mexico law states that a restrictive covenant in an agreement that restricts the right of a health care practitioner to provide clinical health care services is "unenforceable upon the termination of: (1) the agreement; (2) a renewal or extension of the agreement; or (3) a health care practitioner's employment with a party seeking to enforce the agreement."[4] Consequently, under the New Mexico statute, a restrictive covenant in an agreement such as an employment or practice partnership agreement, cannot be enforced against a former employee or partner. The law also states that such a provision in an agreement for clinical health care services is void, unenforceable

and against public policy if the provision: (1) makes the agreement subject to the laws of another state; or (2) requires any litigation arising out of the agreement to be conducted in another state.

Although the New Mexico law precludes restrictive covenant enforcement, the party, e.g., a former employer, retains significant rights. First, if a physician has worked for an employer for an initial period of less than three years and then leaves, the employer may require the physician to repay: (1) a loan; (2) relocation expenses; (3) a signing bonus or other remuneration bonus or other remuneration to induce the health care practitioner to relocate or establish a health care practice in a specified geographic area; or (4) recruiting, education, and training expenses. Second, a party may enforce a nondisclosure provision relating to confidential information and trade secrets. Third, the physician or health care practitioner may be required to comply with a non-solicitation provision with respect to patients and employees of the party seeking to enforce the agreement for a period of one year or less after the last date of employment.

The statute achieves a compromise between physicians who are only employees and practice owners by differentiating between the two when it comes to liquidated damages. As noted above, if a physician was an employee who has worked for an employer for an initial period of less than three years and leaves, the former employer can recover (1)-(4) above. This is the statute's way of protecting the former employer financially by enabling it to recover amounts incurred to bring the employee to the community and to help the physician establish a practice. After the initial three-year period, however, the employer cannot recover (1)-(4) because the statute presumes that the employer has, by then, recovered those costs. Further, since monetary recovery is limited to (1)-(4), the former employer may not obligate the physician to pay liquidated damages. By limiting monetary recovery and prohibiting restrictive covenant enforcement, the statute protects the employed physician who may have entered into an employment agreement with little or no bargaining power.

With respect to physician partners, the statute does not allow the practice to enforce a restrictive covenant against a former partner but does permit the practice to require the former partner to pay reasonable liquidated damages. This disparate treatment of physician owners and employees recognizes that physician partners owe duties to one another that do not apply to employed physicians. Unlike employees, a physician partner has a duty to protect other partners, the partnership itself and the large investment that the physician and the other partners have collectively made in the practice. If a practice makes investments that count on an individual partner's continued financial and other commitments to the practice, the New Mexico statute permits, as a matter of fairness, that the departing physician partner pay the practice reasonable liquidated damages if the partner leaves.

First Resolve of Resolution 10-A-19

The Board does not recommend that the AMA develop state model legislation at this time. The Board fully understands, however, that restrictive covenant issues are of great concern to many AMA members and believes that the AMA should provide members with further guidance and resources than currently exist. Accordingly, this report recommends that the AMA develop a state restrictive covenant legislative template, for reasons described below.

Difference Between a Model Bill and a Legislative Template

The AMA Advocacy Resource Center (ARC), the state legislative and regulatory unit of the AMA, makes model bills and state legislative templates available to state and national medical specialty societies to assist in their respective state legislative and regulatory strategy development and

implementation. Model bills are prescriptive in the sense that they present a single, optimal approach to an issue. A model bill usually has little commentary or explanation concerning the underlying rationale for the bill's specific provisions.

A state legislative template, on the other hand, is not prescriptive. A template is an environmental scan of relevant state law and presents multiple legislative options for addressing a topic that is so diverse and complex across the states that the more one-size-fits-all approach that a model bill represents may not be adequate. The ARC has developed legislative templates for a variety of issues including health courts, scope of practice issues, and medical liability reforms, to name a few.

Reasons Favoring a State Legislative Template

The Board has three reasons for recommending the creation of a state legislative template over a model bill.

First, state restrictive covenant statutes are very diverse, differing in terms of issues addressed, e.g., the role, if any, that liquidated damages may play in restrictive covenant analyses. Further complicating the matter is that many states have restrictive covenant-related legal decisions going back years, regardless of whether the state also has a statute on the books. The wide variation in states' legislative and judicial treatment of restrictive covenants can be particularly present when it comes to physician restrictive covenants. This is especially true where temporal and geographic reasonableness, the legitimacy of business interests involved, patient demographics, physician specialty and public policy considerations like patient choice and patient access may differ greatly from one case to another. The Board is concerned that any model legislation may be too specific to be of much use, since a bill would only present one set of legislative solutions to the myriad restrictive covenant issues. Not drafting a model bill would also avoid concerns expressed by reference committee testimony about basing model legislation on a specific state solution, e.g., the New Mexico statute, and AMA policy, more broadly, on one state law.

A legislative template could, on the other hand, capture at least some of the diversity discussed above and offer several options for legislative language and accompanying rationale. Issues covered could include, but not be limited to: identification of legitimate business interests; reasonableness of geographic scope; reasonableness of duration; damages; consideration given to the impact that restrictive covenant enforcement may have on the individual physician; termination events that trigger a restrictive covenant's application; and differing treatment of physician-owners and employees. The template could, of course, discuss key aspects of the New Mexico statute, and present potential solutions based on that law.

Second, restrictive covenants are a highly sensitive issue for AMA members. Many members have very strong opinions for and against restrictive covenants. The Board is concerned that any AMA-initiated model bill would fail to strike the proper balance between competing points of view, assuming a balance could be achieved across a membership that is diverse in a great many respects, e.g., in terms of specialty, geography, practice environment, etc. The Board notes that Policy H-383.987, "Restrictive Covenants in Physician Contracts," states that, "Our AMA will provide guidance, consultation, and model legislation concerning the application of restrictive covenants to physicians upon request of state medical associations and national medical specialty societies." This policy ensures that the AMA's development of any restrictive covenant model bill is informed by guidance that has been fully vetted at the state medical association or national medical specialty society level to ensure that the bill reflects the likely compromises that the association or society has worked out among its members. A state legislative template is, on the other hand, less likely to

invite division among AMA members, since the template would simply provide an environmental scan of the issues raised above and possible legislative options.

Third, with respect to making revisions and updates, a template is more flexible than a model bill. The AMA Council on Legislation (COL) works with AMA ARC staff to develop the AMA's model state bills. The COL approves the final draft of a model bill during one of its quarterly in-person meetings. The COL then submits that draft to the Board for consideration at the next Board meeting. The model bill is only final if the Board approves the bill. Any significant revisions to a model bill must go through the same process. Creating and revising a legislative template does not involve the more formal process that applies to official AMA model state bills. Again, this is because templates are environmental scans providing varying legislative language options rather than constituting a model bill's more definitive approach. Consequently, the AMA has more flexibility when it comes to timely updating its state legislative templates. This flexibility may be particularly important now given state medical associations', national medical specialty societies' and legislatures' increasing attention to restrictive covenants.

Second Resolve of Resolution 10-A-19

The Board does not recommend that the HOD adopt the second resolve in Resolution 10, since that resolve does not accurately reflect CEJA's position concerning restrictive covenants. Ethical Opinion 11.2.3.1, "Restrictive Covenants," states:

> Competition among physicians is ethically justifiable when it is based on such factors as quality of services, skill, experience, conveniences offered to patients, fees, or credit terms.
>
> Covenants-not-to-compete restrict competition, can disrupt continuity of care, and may limit access to care.
>
> Physicians should not enter into covenants that:
>
> a) Unreasonably restrict the right of a physician to practice medicine for a specified period of time or in a specified geographic area on termination of a contractual relationship; and
>
> b) Do not make reasonable accommodation for patients' choice of physician.
>
> Physicians in training should not be asked to sign covenants not to compete as a condition of entry into any residency or fellowship program.

Ethical Opinion 11.2.3.1 does not express a blanket opposition to restrictive covenant agreements, and does not prohibit physicians from using, or agreeing to, restrictive covenants. Ethical Opinion 11.2.3.1 simply states that physicians should not enter into a restrictive covenant that is unreasonable in terms of duration, geographic scope and does not make a reasonable accommodation for patients' choice of physician. Ethical Opinion 11.2.3.1 is consistent with the majority of states where courts will enforce physician restrictive covenants so long as the covenants protect a legitimate business interest, are reasonable with respect to duration and geography and are not otherwise against public policy, of which patient choice may be a consideration in some jurisdictions.[5] Accordingly, the Board does not recommend adopting the second resolve of the resolution.

Nevertheless, given the importance of restrictive covenants to AMA members, the HOD may have an interest in asking CEJA to incorporate into Ethical Opinion 11.2.3.1 the distinction recognized

by the New Mexico law between physician partners and physicians who are only employed. CEJA could, for example, state that partners in a practice have an ethical obligation to protect the practice, their fellow partners, and partners' investment in the practice. CEJA could further recognize that these mutual obligations apply when a partner chooses to leave the practice, e.g., if he or she chooses to work at a competing hospital, entailing that both the physician and the partners owe one another an ethical obligation to treat one another fairly upon the physician's exit. These duties could, depending on the circumstances, obligate the departing physician to compensate the partnership via the payment of reasonable, liquidated damages. Such an addition to Ethical Opinion 11.2.3.1 could further the opinion's emphasis on accommodating patient choice—ensuring that practices are treated fairly upon a partner's exit and enabling the practice to stay financially viable, thus remaining an option for patient choice.

AMA POLICY

In addition to the CEJA Ethical Opinion 11.2.3.1 and Policy H-383.987, other AMA policies discuss restrictive covenants. Policy H-310.929, "Principles for Graduate Medical Education," states that restrictive covenants must not be required of residents or applicants for residency education; and Policy H-225.950, "AMA Principles for Physician Employment," discourages physicians from entering into agreements that restrict the physician's right to practice medicine for a specified period of time or in a specified area upon termination of employment.

AMA EDUCATIONAL RESOURCES

Finally, as noted above, AMA has many resources that educate medical students, physicians-in-training, and physicians about restrictive covenants. For example:

- The AMA Career Planning Resource webpage has a wealth of information discussing physician employment issues, which includes information and tips regarding restrictive covenants. The AMA Career Planning Resource webpage may be accessed at https://www.ama-assn.org/residents-students/career-planning-resource/understanding-employment-contracts.
- The AMA also has two model employment agreements that discuss restrictive covenants: the Annotated Model Physician-Hospital Employment Agreement, 2011 edition: E-Book, free for AMA members at https://commerce.ama-assn.org/store/ui/catalog/productDetail?product_id=prod1240028&sku_id=sku1240037 and the Annotated Model Physician-Group Practice Employment Agreement: E-Book, free for members at https://commerce.ama-assn.org/store/ui/catalog/productDetail?product_id=prod2530052&sku_id=sku2530104. These resources contain model restrictive covenant language for potential physician employees to consider, which may prove useful in the employment negotiation process.
- Finally, AMA ARC staff work extensively on physician employment issues. AMA members are encouraged to contact the Advocacy Resource Center at arc@ama-assn.org, if they would like to obtain more information and resources concerning restrictive covenants.

RECOMMENDATION

In light of these considerations, the Board recommends that the following be adopted in lieu of Resolution 10-A-19 and the remainder of this report be filed:

Our American Medical Association create a state restrictive covenant legislative template to assist state medical associations, national medical specialty societies and physician members as they navigate the intricacies of restrictive covenant policy at the state level. (Directive to Take Action)

Fiscal Note: Less than $5000

REFERENCES

[1] "Updated Data on Physician Practice Arrangements: For the First Time, Fewer Physicians are Owners Than Employees," American Medical Association, Policy Research Perspectives, Carol Kane, PhD. (2019). This resource can be accessed at https://www.ama-assn.org/system/files/2019-07/prp-fewer-owners-benchmark-survey-2018.pdf.
[2] NMSA 1978, § 24-1I-1(B).
[3] NMSA 1978, § 24-1I-1(A).
[4] NMSA 1978, § 24-1I-2(A).
[5] Some states have enacted statutes prohibiting restrictive covenants, either generally or specifically with respect to physicians. States that more generally prohibit restrictive covenants include California, North Dakota, and Oklahoma. States that prohibit physician restrictive covenants include Colorado, Delaware, Massachusetts, New Hampshire, and Rhode Island. These statutes differ with respect to damages.

REPORT OF THE BOARD OF TRUSTEES

B of T Report 7, November 2020

Subject: Opposition to Involuntary Civil Commitment for Substance Use Disorder (Resolution 22-A-19)

Presented by: Russ Kridel, MD, Chair

Referred to: Reference Committee B

INTRODUCTION

At the 2019 Annual Meeting, the American Medical Association (AMA) House of Delegates (HOD) referred Resolution 22-A-19, "Opposition to Involuntary Civil Commitment," introduced by the delegations from Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island and Vermont, which asked:

> That our American Medical Association oppose involuntary civil commitment without judicial involvement of persons for reasons solely related to substance-use disorder; and
>
> That our AMA work to advance policy and programmatic efforts to address gaps in voluntary substance use treatment services.

Testimony on Resolution 22 was limited and mixed. Some speakers suggested that involuntary civil commitment was sometimes important to help save lives. Other speakers highlighted the positive role that judicial oversight can play for a person with a substance use disorder (SUD). The resolution sponsors noted the role of consent and questionable medical evidence justifying involuntary civil commitment. This report provides an update on the current use of some civil commitment proceedings and a review of relevant AMA policy, and it also makes policy recommendations.

DISCUSSION

Background

Involuntary civil commitment can be broadly described as "a legal intervention by which a judge, or someone acting in a judicial capacity, may order that a person with symptoms of a serious mental disorder, and meeting other specified criteria, be confined in a psychiatric hospital or receive supervised outpatient treatment for some period of time."[1] There are at least three key aspects to consider regarding this definition. First, the fact that an involuntary civil commitment is a legal proceeding that allows the state to intercede into a person's right to liberty for non-criminal reasons. Second, the loss of liberty is predicated on the existence of a mental disorder, and for the purposes of this report, "other specified criteria" includes a SUD. And third, bedrock to the AMA *Code of Medical Ethics* is that "[p]hysicians have civic duties, but medical ethics do not require a physician to carry out civic duties that contradict fundamental principles of medical ethics, such as the duty to avoid doing harm." (*Code of Medical Ethics*. Opinion 9.7.2, Court-Initiated Medical Treatment in Criminal Cases)

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The U.S. Substance Abuse and Mental Health Services Administration (SAMHSA) says that "[s]ubstance use and mental disorders are closely linked." The 2018 National Survey on Drug Use and Health (NSDUH) presented data that "illicit substance use increases risk for other hazardous substance use and mental illness; and that [m]ental illness is a risk factor for illicit substance use."[2] In 2018, 36 percent of those with a serious mental illness (SMI) received no treatment while more than 20 million Americans had a (SUD), but only 10 percent received any treatment—roughly the same percentage of treatment for those with an SUD and SMI.[3] Detailing the scope of why the treatment gap continues is beyond the scope of the report, but among the predominant factors is the lack of access to health care professionals and appropriate medical services.[4]

Involuntary civil commitment

Proponents of involuntary civil commitment policies for the treatment of a SUD focus on the opportunity to help an individual receive treatment because that individual is a threat to him- or herself and/or others.[5] More than 30 states have a variation of law that allows for involuntary civil commitment for a SUD that variously define the nature of the harm and/or threat. This might include severe incapacitation, lack of decisional capacity, danger to property, abusing while pregnant or a repeated pattern of failing to meet social, financial or occupational responsibilities. The length of the involuntary commitment also can vary from up to one month to an indefinite period of time. The Associated Press reports that use of involuntary civil commitments has increased.[6]

Commentators have highlighted multiple concerns with involuntary civil commitment for SUD, including a lack of infrastructure to ensure that persons involuntarily committed are treated in medical facilities. There also is concern that law enforcement—and not a physician—might be able to initiate an involuntary civil commitment before a judge or magistrate.[7] And if a person is involuntarily committed for a SUD, will treatment be forced upon the person, including the taking of medications to treat withdrawal and/or maintenance medications? Or would such medications be denied to a person? The AMA *Code of Medical Ethics* counsels that physicians should: "Participate only if the procedure being mandated is therapeutically efficacious and is therefore undoubtedly not a form of punishment or solely a mechanism of social control." (*Code of Medical Ethics*. Opinion 9.7.2, Court-Initiated Medical Treatment in Criminal Case) In opposition to a bill allowing for involuntary civil commitment for a SUD, the Massachusetts Medical Society raised further concerns that, "There is no research to suggest that this treatment option will save lives. Therefore, more studies are needed before Massachusetts should institute a law with far-reaching consequences."[8]

While testimony before the HOD indicated that there may be benefits for select individuals, and there are news reports of positive individual outcomes, the studies that have been done on the subject note that dangers of involuntary civil commitment are high. A Massachusetts Department of Public Health review found that persons "who received involuntary treatment were 2.2 times as likely to die of opioid-related overdoses and 1.9 times as likely to die of any cause compared to those with a history of voluntary treatment only."[9] A review of nine studies found:

> There is limited scientific literature evaluating compulsory drug treatment. Evidence does not, on the whole, suggest improved outcomes related to compulsory treatment approaches, with some studies suggesting potential harms. Given the potential for human rights abuses within compulsory treatment settings, non-compulsory treatment modalities should be prioritized by policymakers seeking to reduce drug-related harms.[10]

Some of these abuses have ranged from placing persons civilly committed into the general population in a criminal facility, making persons wear prison garb (e.g. an orange jumpsuit) and forcing detoxification. For comparison, American Society of Addiction Medicine (ASAM) placement criteria for persons with a substance use disorder emphasize:

> [s]eparate placement criteria for adolescents and adults to create comprehensive and individualized treatment plans. Adolescent and adult treatment plans are developed through a multidimensional patient assessment over five broad levels of treatment that are based on the degree of direct medical management provided, the structure, safety and security provided, and the intensity of treatment services provided.[11]

This is not to suggest that all facilities where a person subject to involuntary civil commitment might be placed primarily house criminal subjects or provide substandard care. Rather, the juxtaposition is to highlight the need for in-patient care to rely upon medical standards of care. It is questionable whether a criminal facility can accomplish this.

Also, this does not suggest there is no role for involuntary civil commitment, or that jails cannot play a positive role for providing medical care to those incarcerated,[12] but as testified by members of the HOD, legal, ethical and other safeguards need to be put in place if a person is to lose his or her liberty and is civilly committed without his or her consent. As a threshold matter, it is worth noting that, "The availability of effective, comprehensive, community-based systems of care for persons suffering from serious mental illnesses will diminish the need for involuntary commitment and/or court-ordered treatment,"[13] according to the National Alliance of Mental Illness (NAMI). That is, using jails as stand-ins for medically-based treatment centers would not be necessary if there were sufficient public support and resources for community-based care for mental illness and SUDs. And it should be clear that while jails and prisons can and do provide medical care, a correctional facility's core purpose is to imprison, not treat patients.

NAMI's policy position further highlights elements to balance patient autonomy with the proper role of the judicial system when considering involuntary civil commitment. This includes ensuring a person potentially subject to involuntary civil commitment receive an expeditious hearing, medical decisions be made by medical professionals—and not courts—and that, "Involuntary inpatient and outpatient commitment and court-ordered treatment should be used as a last resort and only when it is believed to be in the best interests of the individual." This also includes ensuring the individual has an opportunity to oppose the involuntary commitment.[14]

The patient's right to be a part of the medical decision-making process is central to an effective patient-physician relationship. The ability to make decisions is central to the issues in this report. Among the detailed recommendations put forward by the American Psychiatric Association Council on Psychiatry and Law, "States authorizing involuntary outpatient commitment should provide due process protections equivalent to those afforded patients subject to involuntary hospitalization."[15]

An update on AMA efforts to advance policy and programmatic efforts to address gaps in voluntary substance use treatment services

The AMA, through its ongoing state and federal advocacy as well as its work through the AMA Opioid Task Force, continues its efforts to address gaps in evidence-based treatment for mental health and substance use disorders. At the state level, in the past two years, the AMA has helped advance and enact state laws in more than one dozen states to remove prior authorization for medications to help treat opioid use disorder—commonly referred to as medication assisted

treatment (MAT). The AMA's work in this area has included technical support to state medical societies, development of model state legislation and presentations by AMA leadership and staff to influential stakeholders such as the National Governors Association, National Association of Insurance Commissioners (NAIC), National Academies of Sciences, Engineering and Medicine, as well as the U.S. Congress.[16]

In 2019, the AMA also released with Manatt Health a "National Roadmap on State-Level Efforts to End the Opioid Epidemic," which highlighted best practices from multiple states on areas including reducing the treatment gap. While it is beyond the scope of this report to detail all of the best practices, with respect to reducing the treatment gap, the AMA-Manatt Health report[17] highlighted examples such as:

- The Pennsylvania state insurance commissioner helping forge a voluntary agreement with the Commonwealth's major commercial payers to remove prior authorization for MAT;
- The Colorado Division of Insurance implementing a law establishing an office of the ombudsman to assist state residents in accessing behavioral health care;
- The establishment of Centers of Excellence in Pennsylvania as part of hub-and-spoke models of care to help promote evidence-based care; and
- Community-based collaborative practice models led by the North Carolina Medical Society to enhance access to physicians and other health care professionals.

The AMA also continues its advocacy with partners such as the American Psychiatric Association (APA), ASAM and others in support of mental health and substance use disorder parity oversight and enforcement. In February 2020, after sustained advocacy in partnership with the APA, the NAIC approved a new charge for a newly formed Mental Health Parity and Addiction Equity Act (MHPAEA) Working Group that will continue to raise the importance of parity enforcement in the states. The AMA will continue to work with the NAIC and others as they develop parity-specific recommendations and actions.

With respect to payment reform to support increased access to treatment services, the AMA worked with the ASAM to develop a concept paper for an alternative payment model to support a team-based approach to office-based management of treatment for opioid use disorder (OUD), called "Patient-Centered Opioid Addiction Treatment model" (P-COAT). This model concept provided the foundation for Section 6042 of the SUPPORT Act, which requires the U.S. Centers for Medicare & Medicaid Services to implement a demonstration project supporting treatment of Medicare patients with OUD consistent with the comprehensive biopsychosocial model of care in the P-COAT approach. The P-COAT model also formed the basis for AMA and ASAM advocacy on a new Medicare payment policy that, effective in 2020, provides a bundled payment for office-based treatment of OUD. As AMA and ASAM recommended, the bundled payments include a higher payment for the first month of treatment to cover the cost of developing and getting the patient engaged in a treatment plan and educating the patient about self-management of their condition, and monthly payments of about $367 for as long as the patient remains in treatment. The payments support development of a treatment plan, care coordination, individual and group therapy and counseling for patients with OUD, with the cost of medications used in treatment paid separately.

The AMA has also been working to eliminate the requirement for physicians to get a special waiver from the U.S. Drug Enforcement Administration (DEA) in order to prescribe buprenorphine for the treatment of OUD. The AMA has supported legislation introduced in the U.S. House of Representatives that would eliminate this requirement and has met with senior Administration officials to seek the Administration's support for this policy change.

The AMA was encouraged by the Centers for Disease Control and Prevention's (CDC) recognition that its opioid prescribing guidelines have been misapplied and have had serious unintended consequences. CDC recently embarked on an effort to update its guidelines and the AMA has strongly cautioned the agency to heed the advice of the U.S. Department of Human and Health Services' Pain Management Task Force that patients with painful conditions need to be treated as individuals and that one-size-fits-all approaches must be avoided.

The AMA also has repeatedly urged the DEA to update its rules for electronic prescribing of controlled substances, especially outdated multifactor authentication rules. Regardless, even though federal law required an update in 2019, the DEA has not yet done so. This is important because federal law requires e-prescribing controlled substances starting in 2021.

AMA POLICY

The AMA has both Ethics and HOD policy on the areas covered in this report. The AMA *Code of Medical Ethics (the Code)* makes clear that:

> Informed consent to medical treatment is fundamental in both ethics and law. Patients have the right to receive information and ask questions about recommended treatments so that they can make well-considered decisions about care. Successful communication in the patient-physician relationship fosters trust and supports shared decision making. (*Code of Medical Ethics*. Opinion 2.1.1, Informed Consent)

The Code also covers situations when a patient may lack decision-making capacity. In those situations, the Code reiterates that, "Respect for patient autonomy is central to professional ethics and physicians should involve patients in health care decisions commensurate with the patient's decision-making capacity." (*Code of Medical Ethics*. Opinion 2.1.2, Decisions for Adult Patients Who Lack Capacity) The Code further advises:

> Even when a medical condition or disorder impairs a patient's decision-making capacity, the patient may still be able to participate in some aspects of decision making. Physicians should engage patients whose capacity is impaired in decisions involving their own care to the greatest extent possible, including when the patient has previously designated a surrogate to make decisions on his or her behalf. (*Code of Medical Ethics*. Opinion 2.1.2, Decisions for Adult Patients Who Lack Capacity)

For situations involving children and adolescents, the Code also suggests respect not only for the parent's (or guardian's) responsibility, but also the need to include children in the decision-making process. The Code advises that:

> Respect and shared decision making remain important in the context of decisions for minors. Thus, physicians should evaluate minor patients to determine if they can understand the risks and benefits of proposed treatment and tailor disclosure accordingly. The more mature a minor patient is, the better able to understand what a decision will mean, and the more clearly the child can communicate preferences, the stronger the ethical obligation to seek minor patients' assent to treatment. (*Code of Medical Ethics*. Opinion E-2.2.1, Pediatric Decision Making)

The Code further provides that, "Except when immediate intervention is essential to preserve life or avert serious, irreversible harm, physicians and parents/guardians should respect a child's refusal to assent, and when circumstances permit should explore the child's reason for dissent." (*Code of Medical Ethics*. Opinion E-2.2.1, Pediatric Decision Making)

Finally, the Code provides that, "All individuals have a fundamental right to be free from unreasonable bodily restraint." It further explains that, "At times, however, health conditions may result in behavior that puts patients at risk of harming themselves. In such situations, it may be ethically justifiable for physicians to order the use of chemical or physical restraint to protect the patient." These times must be governed by the physician's professional judgment. The Code goes on to state "In certain limited situations, when a patient poses a significant danger to self or others, it may be appropriate to restrain the patient involuntarily. In such situations, the least restrictive restraint reasonable should be implemented and the restraint should be removed promptly when no longer needed." (*Code of Medical Ethics*. Opinion 1.2.7, Use of Restraints)

AMA policy also is clear on the benefits of shared decision-making, including support for "[p]rotecting the patient-physician relationship by continuing to advocate for: the obligation of physicians to be patient advocates." (Policy H-165.837, "Protecting the Patient-Physician Relationship") AMA policy also emphasizes the need for patients to be active partners in their health care, including support for "[t]he concept of voluntary use of shared decision-making processes and patient decision aids as a way to strengthen the patient-physician relationship and facilitate informed patient engagement in health care decisions." (Policy H-373.997, "Shared Decision-Making")

Finally, as briefly quoted in the body of the report, the Code provides important considerations for physicians' actions in court-initiated medical treatments. While the policy cited above mainly focuses on the rights of prisoners in a criminal setting, the Code provides guidance for physicians who do participate in court-initiated medical treatments. In addition to the discussion above, the Code includes the provision that:

> Physicians who provide care under court order should be able to conclude, in good conscience and to the best of his or her professional judgment, that to the extent possible the patient voluntarily gave his or her informed consent, recognizing that an element of coercion that is inevitably present. When treatment involves in-patient therapy, surgical intervention, or pharmacological treatment, an independent physician or a panel of physicians not responsible to the state should confirm that voluntary consent was given. (*Code of Medical Ethics*. Opinion 9.7.2, Court-initiated Medical Treatment in Criminal Cases)

RECOMMENDATIONS

The Board recommends that Resolution 22-A-19 be amended by addition and deletion and the remainder of the report be filed.

1. That our American Medical Association oppose civil commitment proceedings for patients with a substance use disorder unless: a) A physician or mental health professional determines that civil commitment is in the patient's best interest consistent with the AMA *Code of Medical Ethics*; b) Judicial oversight is present to ensure that the patient can exercise his or her right to oppose the civil commitment; c) The patient will be treated in a medical or other health care facility that is staffed with medical professionals with training in mental illness and addiction, including medications to help with withdrawal and other symptoms as prescribed by his or her physician; and d) The facility is separate and distinct from a correctional facility. (New HOD Policy)

2. That our AMA continue its work to advance policy and programmatic efforts to address gaps in voluntary substance use treatment services. (Directive to Take Action)

Fiscal Note: Less than $500

REFERENCES

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REPORT 13 OF THE BOARD OF TRUSTEES (November 2020)
Merit-based Incentive Payment System (MIPS) Update
(Reference Committee B)

EXECUTIVE SUMMARY

At the 2018 Interim Meeting, the American Medical Association (AMA) House of Delegates (HOD) referred two resolutions, and at the 2019 Annual Meeting, a third resolution was referred, for a combined Board of Trustees (Board) Report at the 2019 Interim Meeting related to the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). Each of the resolutions asks for a repeal or significant change to the Merit-Based Incentive Payment System (MIPS). Our AMA worked closely with Centers for Medicare & Medicaid Services' (CMS) and Congress on implementation of the MIPS program, on necessary technical fixes, and has continued advocacy on MIPS implementation. Despite these efforts, the three resolutions highlight the serious challenges physician practices face under the MIPS program.

Our AMA understands that there is significant frustration with the MIPS program and continues to vigorously advocate that both CMS and Congress make needed changes. Our AMA continues to advocate that Congress provide physicians with positive Medicare payment updates, extend the $500 million positive payment adjustment for exceptional performance in MIPS that is not subject to budget neutrality, and extend alternative payment models (APMs) payments to provide physicians with additional resources to help transition to APMs. The COVID-19 pandemic has only increased the hardship on physician practice and underscores the need for positive payment updates this year.

Our AMA should have the ability to support legislation that would provide physicians with positive payment updates that could shift the budget neutrality dynamic of the current MIPS program. Consistent with existing AMA policy, the new recommendation contained in this report is that our AMA support legislation that ensures Medicare physician payment is sufficient to safeguard beneficiary access to care, replaces or supplements budget neutrality in MIPS with incentive payments, or implements positive annual physician payment updates.

The new recommendation to support replacing or supplementing budget neutrality will allow flexibility to review and consider legislation without being too narrowly defined that we overlook an opportunity to improve the MIPS program in another, impactful way.

REPORT OF THE BOARD OF TRUSTEES

B of T Report 13, November 2020

Subject: Merit-based Incentive Payment System (MIPS) Update

Presented by: Russ Kridel, MD, Chair

Referred to: Reference Committee B

At the 2018 Interim Meeting, the American Medical Association (AMA) House of Delegates (HOD) referred two resolutions, and at the 2019 Annual Meeting, a third resolution was referred, for a combined Board of Trustees (Board) Report at the 2019 Interim Meeting related to the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). The first resolution, Resolution 206-I-18, "Repealing Potential Penalties Associated with MIPS," was introduced by the Florida Delegation and asks that:

> Our American Medical Association advocate to repeal all potential penalties associated with the MIPS program.

The second resolution, Resolution 231-I-18, "Reducing the Regulatory Burden in Health Care," was introduced by the Pennsylvania Delegation and asks that:

> Our American Medical Association work to support the repeal of the Merit-Based Incentive Payment System (MIPS); and that upon repeal of MIPS, our AMA oppose any federal efforts to implement any pay-for-performance programs unless such programs add no significant regulatory or paperwork burdens to the practice of medicine and have been shown, by evidence-based research, to improve the quality of care for those served.

The third resolution, Resolution 243-A-19, "Improving the Quality Payment Program and Preserving Patient Access," was introduced by the Texas Delegation and asks that:

> Our American Medical Association strongly advocate for Congress to make participation in MIPS and alternative payment models (APMs) under the Quality Payment Program (QPP) completely voluntary, that our AMA strongly advocate for Congress to eliminate budget neutrality in MIPS and to finance incentive payments with supplemental funds that do not come from Medicare Part B payment cuts to physicians and other clinicians, and that our AMA call on the Centers for Medicare and Medicaid Services (CMS) to provide a transparent, accurate, and complete Quality Payment Program Experience Report on an annual basis so physicians and medical societies can analyze the data to advocate for additional exemptions, flexibilities, and reductions in reporting burdens, administrative hassles, and costs.

The reference committee heard mixed testimony on Resolutions 206, 231, and 243. Some testified that MIPS should be repealed, as many practices that serve Medicare beneficiaries cannot sustain additional reductions in their Medicare payments. Others testified that our AMA should continue working with Congress and the Administration to ensure that all physician practices, regardless of

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size or specialty, have the opportunity to succeed in the QPP. Also, there was significant testimony that our AMA should continue advocating to simplify and improve the MIPS program and increase the number and variety of APMs available to physicians.

BACKGROUND

Our AMA was supportive when Congress replaced the flawed, target-based sustainable growth rate (SGR) formula with a new payment system under MACRA. Scheduled payment cuts prior to the implementation of MACRA exceeded 20 percent. Those cuts would have had a devastating impact on physician practices and patient access to care. Under MACRA, the SGR formula was replaced with specified payment updates for 2015 through 2019, and for 2026 and beyond. MACRA also created an opportunity to address problems found in existing physician reporting programs, including the chance to earn incentives. In addition, the law sought to promote innovation by encouraging new ways of providing care through APMs.

Our AMA worked closely with CMS and Congress on implementation of the MIPS program, and AMA advocacy efforts resulted in a policy allowing physicians who reported on one measure, one time, for one patient to avoid a penalty in the first year. This transition period allowed many physician practices to be successful in the first performance year of MIPS, with 93 percent of eligible clinicians receiving a modest positive payment adjustment and nearly three-quarters qualifying for an additional exceptional performance bonus. (Notably, the exceptional performance bonus is funded at $500 million annually in the MACRA statute and is not budget neutral.)

Following the first year of the MIPS program, our AMA was also successful in getting Congress to make needed technical changes to MACRA in the Bipartisan Budget Act of 2018. These changes helped many practices avoid penalties that they likely would otherwise have incurred under the MIPS program. Specifically, our AMA worked with Congress to exclude Medicare Part B drug costs from MIPS payment adjustments, as including these additional items and services created significant inequities in the administration of the program. In addition, our AMA helped achieve changes that allow CMS to reweight the Cost performance category to not less than 10 percent for the third, fourth, and fifth years of MIPS, instead of increasing it to 30 percent as the law previously required, and to set the performance threshold for three additional years instead of basing it on the mean or median of previous MIPS scores.

As a result of these efforts, CMS has continued to gradually implement the MIPS program. Based on the second performance period in calendar year 2018, 97 percent of eligible clinicians received a modest positive payment adjustment in 2020 with 84 percent qualifying for an additional exceptional performance bonus.

DISCUSSION

Ongoing AMA Advocacy Efforts

Since the enactment of MACRA, our AMA has worked closely with both Congress and CMS to promote a smooth implementation of the QPP. Despite these efforts, Resolutions 206, 231, and 243 illustrate that the implementation of a new quality and payment program for physicians is a major undertaking and significant improvements to the program are still needed. As is noted in the resolutions, numerous improvements must still be made to the MIPS program, including more accurate risk adjustment for cost and quality measures, timelier program feedback for physicians, and a more cohesive program structure. In addition, physician practices, especially small and rural physician practices, cannot shift to new payment models without adequate resources.

In an effort to address these outstanding issues, our AMA has convened MIPS and APM workgroups made up of representatives from across the physician community, which have developed creative solutions to improve the QPP. Feedback from the MIPS and APM workgroups, as well as other state and specialty medical societies, has led our AMA to focus its efforts to improve the QPP on several key issues: replacing the Medicare physician pay freeze with a stable revenue source that allows physicians to sustain their practice; replacing or supplementing budget neutrality provisions; extending the Advanced APM payments for an additional six years; simplifying the MIPS scoring system and creating a more meaningful MIPS program; expanding exceptions and flexibilities during the COVID-19 pandemic; and ensuring small and rural practices have the opportunity to succeed.

Implement Annual Positive Physician Payment Updates

Resolution 206 notes that many physician practices cannot sustain additional reductions in their Medicare payments. Our AMA agrees, and while MACRA included modest positive payment updates in the Medicare Physician Fee Schedule, it left a gap from 2020 through 2025, during which there are no updates at all. Following this six-year freeze, the law specifies physician payment updates of 0.75 percent or 0.25 percent for physicians participating in APMs or MIPS.

Our AMA recognizes that these payment updates are not sufficient, particularly while physicians are investing resources to shift to new payment models and provide quality patient care during the COVID-19 pandemic. Therefore, our AMA has advocated that Congress pass legislation providing physicians with positive payment updates beginning in 2020. As the COVID-19 pandemic continues to confront the nation, our AMA is calling on Congress to protect patient access to medical care and preserve the viability of physician practices across the country by implementing a positive payment update and providing additional financial assistance to physicians. Our AMA is working on a survey to determine the financial impact the COVID-19 pandemic is having on physician practices and the results are expected in September. We anticipate the results will support our AMA's advocacy for Medicare payment improvements.

Medicare physician payment will also be impacted by budget neutrality requirements in implementation of the AMA Current Procedural Terminology (CPT) Editorial Panel coding framework and AMA Specialty Society Relative Value Scale Update Committee (RUC) recommended values for office and outpatient visits starting January 1, 2021. Our AMA strongly supports implementation of CMS' new office visit policy and believes it will lead to significant administrative burden reduction and better describe and recognize the resources involved in office visits as they are performed today. However, we are deeply concerned that the corresponding budget neutrality cuts are deeply problematic during or immediately after the COVID-19 pandemic, during which physician practices have experienced severe reductions in revenue.

Physicians who do not report office visit codes, including radiologists, pathologists, and hospitalists, face estimated 2021 payment cuts of 8 percent solely due to budget neutrality. Specialties, including general surgeons, critical care physicians, anesthesiologists, and emergency physicians, face estimated cuts ranging from 5 percent to 7 percent. The budget neutrality driven cuts also will reduce the positive impacts of the office visit changes for primary care physicians, oncologists, pediatricians, and other specialties for whom the office visits are a high proportion of their services.

Our AMA, joined more than one hundred national specialty societies and health care professional organizations, in urging the U.S. Department of Health & Human Services (HHS) Secretary to use its authorities and flexibilities under the public health emergency to implement the office visit

increases and waive the requirement for CMS to adjust Medicare physician payments for budget neutrality when it implements the office visit coding and payment changes that it has finalized for 2021. Our AMA is pursuing all avenues for waiving budget neutrality, including Congressional action.

The Board strongly supports advocating for positive payment updates, which are needed to provide physicians a margin to maintain their practices, as well as transition to more efficient models of care delivery and provide relief to physician practices confronting the COVID-19 pandemic.

Extend APM Payments

In addition to providing positive physician payment updates, Congress and the Administration must work to provide physicians with adequate resources to move into new payment models. One goal of MACRA, in addition to the MIPS program, was to provide physicians with a path to transition into new, innovative APMs that could allow physicians to be paid for services that add value to patient care.

To help facilitate this transition, Congress provided a five percent incentive payment for physicians who participate in Advanced APMs during the first six years of the program. Unfortunately, through the first three participation years, very few physicians had the opportunity to earn this incentive payment due to the small number of Advanced APMs approved by CMS. While our AMA is working closely with numerous physician groups, as well as the Center for Medicare & Medicaid Innovation (CMMI), to develop and test physician-led APMs, it will take time to implement the number of APMs needed to allow most physicians a realistic opportunity to participate in these models. Therefore, our AMA is urging Congress to extend the Advanced APM incentive payments to provide support to physicians as they transition to new payment models. The Board strongly supports efforts to ensure there are voluntary APMs available for physicians in all specialties and practices of all sizes.

Impact of Budget Neutrality

The Board strongly supports providing physicians with the resources necessary to improve quality and patient care. The Board is therefore concerned about reports from numerous physicians who have worked diligently to comply with the numerous MIPS requirements, yet have ended up investing more in health information technology and care management processes than they received through their resulting MIPS incentive payment. The negative return on investment from MIPS participation is a serious problem. Also, several witnesses have testified in reference committee that funding positive MIPS incentive payments with penalties imposed on practices that do not score above the MIPS performance threshold exacerbates this problem for smaller practices. The Board supports language in Resolution 243-A-19 noting that physicians need dedicated funding for MIPS incentive payments in order to ensure physicians have the capital they need to move into models that provide patients with the utmost value. Basing positive payment adjustments on penalties also creates uncertainty in the program, which further discourages practices from making the up-front investments needed to transition to value-based payment and care delivery models.

MIPS incentive payments for performance years 2019 through 2022 are based on a combination of budget neutrality and dedicated annual funding. Congress provided $500 million for each of the first six years of MIPS to fund additional adjustments for exceptional performance. The first two years of MIPS payment adjustments (2019 and 2020) were funded largely by the $500 million annual allocation due to the gradual implementation of MIPS which resulted in very few penalties.

One option for supplementing budget neutral incentive payments is to seek an extension of the $500 million pool, which expires after year six of MIPS.

While supporting the elimination of budget neutrality in the MIPS program, the Board also understands that this is a complex issue that would involve some difficult trade-offs. It would be extremely difficult to secure funding from Congress both for positive MIPS incentive payments, which would help practices that participate in MIPS and exceed the MIPS performance threshold, and funding for positive conversion factor updates, which would help all practices that care for fee-for-service Medicare patients, including small practices that are excluded from MIPS, because they are below the low-volume threshold. In addition, physicians in large practices have generally obtained higher MIPS scores than those in smaller practices, so this policy is more likely to help large practices than smaller practices. Partially or fully eliminating MIPS budget neutrality may also make it more difficult to achieve adoption of AMA recommendations to improve the MIPS program, because Congress and the Administration would view any increase in the number of physicians able to succeed in MIPS as increasing federal spending.

Despite these concerns, the Board determined that replacing or supplementing the budget neutrality requirements in MIPS with incentive payments would help support physicians as they continue to work to comply with the program. Therefore, the Board supports MIPS incentive payments not limited by budget neutrality requirements to provide physicians a margin to transition into more efficient models of care delivery.

Simplifying and Streamlining MIPS

Our AMA has repeatedly urged CMS to reduce burden and complexity and make MIPS more clinically relevant for physicians and patients. As noted in Resolution 243, many physicians must report MIPS measures that are not linked to improved clinical care for their patients. Studies suggest the cost of reporting quality metrics is considerable.[1] Our AMA is engaged in a research study to determine the cost to physician practices of creating the infrastructure needed to participate in MIPS and of collecting and reporting data. Through interviews with practice leaders and administrators, our AMA aims to understand the costs (e.g., software, staff, practice leaders, and consultants) associated with MIPS participation for practices of different sizes and specialties and in different regions of the country, as well as practice leader views about MIPS.

Our AMA's MIPS workgroup has developed detailed recommendations that would make the MIPS program more cohesive and allow physicians to select more relevant measures to report. Our AMA has urged CMS to streamline the MIPS program by allowing physicians to focus their participation around a specific episode of care, clinical condition, or public health priority. By allowing physicians to focus on activities that fit into their workflow and address their patient populations' needs, rather than segregated measures divided into four disparate MIPS categories, the program would be more likely to improve quality of care for patients and be more meaningful for physicians.

In the 2020 Medicare Physician Payment Schedule final rule, CMS outlined the MIPS Value Pathways (MVPs) approach, which responds to some of the recommendations made to CMS by the AMA after significant consultation with specialty and state medical societies. Physicians in MVPs would focus their MIPS participation on a set of measures tailored to an episode of care or condition starting in the 2021 performance period. The MVPs framework would also provide enhanced data and feedback to physicians. Our AMA and specialty societies are working with CMS to develop MVPs that are relevant to physicians and their patients and expect more details to be included in future rulemaking. Our AMA continues to work with CMS to ensure MVP

participation is voluntary, less burdensome, and incentivizes physicians to opt into this new framework.

Our AMA has also urged Congress to allow CMS the flexibility to base scoring on multi-category measures to make MIPS more clinically meaningful, reduce silos between each of the four MIPS categories, and create a more unified program. Our AMA's goal is to help the Administration develop an approach that allows physicians to spend less time on reporting and more time with patients and on improving care. The Board strongly supports the efforts to unify MIPS reporting while also making it more meaningful for physicians.

Support for Small and Rural Practices

As noted in Resolution 231, our AMA agrees that small physician practices could be disproportionately impacted by penalties under MIPS. In 2017, the national mean and median scores for all MIPS eligible clinicians were 74.01 and 88.97 points. However, the mean and median scores for small practices were 43.46 and 37.67. In 2018, small practice scores increased, although they remain lower than the national mean and median, which were 86.96 and 99.63. The 2018 mean and median scores for small practices were 65.69 and 81.16. Our AMA agrees that the lower scores achieved by small practices illustrate the need for our AMA to continue advocating for changes to MACRA that will help small practices and solo practitioners.

In order to help small practices become more successful in the MIPS program, our AMA has engaged in advocacy efforts in multiple areas. First, our AMA has been a strong supporter of the low-volume threshold exemption which was increased and now excludes physicians with allowed charges of $90,000 or less, 200 or fewer unique Medicare patients, or 200 or fewer covered professional services to Medicare Part B beneficiaries from the MIPS program. Our AMA has also supported MIPS policies including reduced reporting requirements for small practices in the Quality performance category, hardship exemptions from the Promoting Interoperability performance category for qualifying small practices, bonus points for small practices, and technical assistance grants to help small and rural practices succeed in the program. Finally, our AMA is advocating for a legislative change that would allow CMS to develop separate thresholds for small and large practices, so that small physician practices are compared to practices with similar resources. The Board agrees that additional changes are needed to ensure small and rural practices have the opportunity to succeed in the MIPS program.

Flexibility During the COVID-19 Public Health Emergency

Since the HHS Secretary declared a public health emergency (PHE) due to the 2019 novel coronavirus on Jan. 27, 2020, our AMA has worked constantly with CMS to identify issues and make recommendations to ensure physicians are able to continue to meet the needs of patients while confronting and slowing the spread of the virus. In response to our concerns about relieving MIPS reporting burdens, CMS automatically held harmless from penalties every eligible clinician who did not submit any MIPS data for 2019 and extended the deadline for physicians and groups who wished to opt into MIPS.

CMS recently announced expanded hardship exceptions due to COVID-19 for the 2020 MIPS performance period. Physicians will have the option to opt-out completely or partially from MIPS by completing a hardship exception application through the end of the year. For example, a practice may submit a hardship application and indicate that they do not want to be scored on Cost and Quality and have their score calculated based on just Promoting Interoperability and Improvement

Activities. Alternatively, practices may submit a hardship application and opt-out of all four performance categories and be held harmless from a 2022 payment adjustment.

Our AMA is pleased CMS took our recommendation to create flexible reporting options in 2020 with the option to reweight any or all of the MIPS performance categories. The flexibilities should assist with allowing practices to focus their attention on caring for patients during the pandemic and reduce administrative burden. Our AMA continues to monitor the impact COVID-19 is having on practices and advocate to CMS for the appropriate relief and to ensure CMS liberally grants hardship requests due to the COVID-19 PHE. It is also our understanding that CMS QPP.CMS.GOV website is in the process of being updated with the 2020 policy and should reflect the announcement along with additional educational materials in late summer. The information currently posted on the website is regarding the 2019 MIPS COVID-19 policy. CMS has also indicated that additional information on MIPS COVID-19 policy will be included in upcoming rulemaking. The Board strongly supports efforts to minimize MIPS reporting burdens and allow greater flexibility during this pandemic.

Other Advocacy Efforts

In addition to these major program changes, our AMA also continues to urge CMS and Congress to address more nuanced issues in the QPP such as:

- Stabilizing the performance threshold until program improvements are tested and implemented;
- Revamping the Virtual Group option to encourage small practices to participate;
- Improving risk adjustment methodologies to account for social risk factors;
- Reducing the number of quality measures a physician must report under the Quality performance category;
- Maintaining a minimum point floor for physicians reporting on quality measures that meet the data completeness threshold, regardless of performance on the measure;
- Eliminating the requirement that physicians must report on an outcome or high priority measure and eliminating the requirement to report on all-payer data;
- Developing a phased approach for removing “topped-out” measures from MIPS and improving the benchmark methodology;
- Aligning the MIPS and Physician Compare calculation methodologies;
- Maintaining the Cost performance category weight while new episode-based cost measures are developed and piloted;
- Modifying the threshold levels of APM participation required to be eligible for the APM incentive payments;
- Securing adoption of physician-focused payment models with realistic targets for improving patient health outcomes and generating savings;
- Eliminating the Total Cost of Care and Medicare Spending Per Beneficiary measures within the Cost performance category as improved episode-based cost measures are developed;
- Allowing physicians to attest to their use of Certified Electronic Health Record Technology (CEHRT) in the Promoting Interoperability performance category;
- Reducing the number of measures physicians are required to report in the Promoting Interoperability performance category; and
- Providing credit for the use of health information technology beyond CEHRT.

As illustrated by the list above, our AMA has spent significant staff time working with both Congress and CMS to improve the QPP. Our AMA has specifically been advocating persistently for MIPS to be more meaningful to physicians and less administratively burdensome, and to increase the number of available APMs. Our AMA advocacy team meets regularly with both CMS

officials and Congressional staff to work to improve MIPS and the APM pathway for physicians and will continue to do so going forward.

Among the concerns raised with seeking repeal of the MIPS penalties at this time is that the cost would need to be offset and would potentially come at the expense of bonuses or across the board cuts in physician payments, which would impact physicians who are currently exempt from MIPS, such as small practices. Another concern is that repealing penalties associated with MIPS or repealing the entire program at this time could result in an alternative quality payment program that may be less desirable. Furthermore, such a shift in our AMA's advocacy position would effectively preclude our AMA from continuing our advocacy efforts with state and specialty medical societies in support of the Administration's and Congress' efforts to advance successful, innovative payment models as well as the technologies needed to support such models.

AMA POLICY

Our AMA has numerous existing policies on MACRA including Policies D-395.999, D-395.998, H-390.838, D-390.950, and D-390.949. Together, these policies direct our AMA to work with CMS to advocate for improvements to MIPS, a reduction in MIPS requirements for all physicians, an exemption to MIPS for small practices, a period of stability in the MIPS program to allow for testing and stability and additional flexibilities for fragile practices. AMA policy also supports our advocacy to increase the number and variety of APMs available to physicians, extend the Advanced APM incentive payments to provide support to physicians as they transition to new payment models, and modify the threshold levels of APM participation required to be eligible for the APM incentive payments (Policies H-385.913, H-450.931, and H-385.908).

CONCLUSION

Our AMA understands that there is significant frustration with the MIPS program and continues to vigorously advocate that both CMS and Congress make needed changes. In addition to urging CMS to make additional improvements to the MIPS program, our AMA is joined with many state and specialty medical societies making it a priority to advocate that Congress provide physicians with positive Medicare payment updates, extend the $500 million positive payment adjustment for exceptional performance in MIPS that is not subject to budget neutrality, and extend APM payments to provide physicians with additional resources to help transition to APMs. The Board believes that the lack of positive updates from 2020 to 2025 severely threatens physicians' ability to sustain their practices, especially while at the same time implementing quality improvements. Our AMA will work with due purpose to seek positive updates as we continue to reduce MIPS burdens.

While the Board recognizes that the QPP needs improvement, we also acknowledge that the MIPS program continues to be refined. Detailed results from the 2017 and 2018 performance years reflect MIPS' gradual implementation as most physicians were able to achieve high scores and earn a positive payment adjustment. Results from at least the 2019 and 2020 performance periods will be impacted by the COVID-19 pandemic and hardship exceptions will be in place to provide relief. Implementation of a new quality and payment program is a significant undertaking and requires an iterative process with constant evaluation and improvement.

In addition to our current policy, the Board believes that our AMA should have the ability to support legislation that would provide physicians with positive payment updates that could shift the budget neutrality dynamic of the current MIPS program. The Board understands that eliminating the budget neutrality requirements of the MIPS program is a complex issue and that there are many

ways to achieve that goal. Therefore, we offer a recommendation to support replacing or supplementing budget neutrality, which will allow us flexibility to review and consider legislation without being too narrowly defined that we overlook an opportunity to improve the MIPS program in another way.

Therefore, the Board recommends, consistent with existing AMA policy, that our AMA continue its work with CMS and Congress to improve the MIPS program, increase APM opportunities for physicians, and provide additional resources for physician practices through positive updates and APM payments. Given that the repeal of MACRA could result in a more burdensome quality program with no opportunity to earn incentives and lower payment updates for physicians, we recommend not advocating for the repeal of MIPS penalties or the MIPS program at this time. However, the Board will continue to monitor the QPP's impact and burden on physicians, and if improvements to the program are not sufficient, we will reevaluate our advocacy policies and position in the future.

RECOMMENDATIONS

The Board of Trustees recommends that the following recommendations be adopted in lieu of Resolutions 206-I-18, 231-I-18, and 243-A-19 and that the remainder of the report be filed:

1. That our American Medical Association (AMA) support legislation that ensures Medicare physician payment is sufficient to safeguard beneficiary access to care, replaces or supplements budget neutrality in MIPS with incentive payments, or implements positive annual physician payment updates. (Directive to Take Action)

2. That our AMA reaffirm Policy D-395.999, "Reducing MIPS Reporting Burden," Policy D-395.998, "Opposed Replacement of the Merit-Based Incentive Payment System with the Voluntary Value Program," Policy H-390.838, "MIPS and MACRA Exemption," Policy D-390.950, "Preserving a Period of Stability in Implementation of the Medicare Access and Children's Health Insurance Program (CHIP) Reauthorization Act (MACRA)," Policy D-390.949, "Preserving Patient Access to Small Practices Under MACRA," Policy H-385.913, "Physician-Focused Alternative Payment Models," Policy H-385.913, "Physician-Focused Alternative Payment Models," Policy H-450.931, "Moving to Alternative Payment Models," and Policy H-385.908, "Physician-Focused Alternative Payment Models: Reducing Barriers." (Reaffirm HOD Policy)

Fiscal Note: Less than $500

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EXISTING AMA POLICY

Policy D-395.999, "Reducing MIPS Reporting Burden"
Our AMA will work with the Centers for Medicare and Medicaid Services (CMS) to advocate for improvements to Merit-Based Incentive Payment System (MIPS) that have significant input from practicing physicians and reduce regulatory and paperwork burdens on physicians. In the interim, our AMA will work with CMS to shorten the yearly MIPS data reporting period from one-year to a minimum of 90-days (of the physician's choosing) within the calendar year.

Policy D-395.998, "Opposed Replacement of the Merit-Based Incentive Payment System with the Voluntary Value Program"
1. Our AMA will oppose the replacement of the Merit-Based Incentive Payment System (MIPS) with the Voluntary Value Program (VVP) as currently defined.
2. Our AMA will study the criticisms of the Merit-Based Incentive Payment System (MIPS) program as offered by proponents of the VVP to determine where improvement in the MIPS program needs to be made.
3. Our AMA will continue its advocacy efforts to improve the MIPS program, specifically requesting: (a) true EHR data transparency, as the free flow of information is vital to the development of meaningful outcome measures; (b) safe harbor protections for entities providing clinical data for use in the MIPS program; (c) continued infrastructure support for smaller practices that find participation particularly burdensome; (d) adequate recognition of and adjustments for socioeconomic and demographic factors that contribute to variation in patient outcomes as well as geographic variation; and (e) limiting public reporting of physician performance to those measures used for scoring in the MIPS program.
4. Our AMA will determine if population measures are appropriate and fair for measuring physician performance.

Policy H-390.838, "MIPS and MACRA Exemption"
Our AMA will advocate for an exemption from the Merit-Based Incentive Payment System (MIPS) and Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) for small practices.

Policy D-390.950, "Preserving a Period of Stability in Implementation of the Medicare Access and Children's Health Insurance Program (CHIP) Reauthorization Act (MACRA)"
1. Our AMA will advocate that Centers for Medicare and Medicaid Services (CMS) implement the Merit-Based Payment Incentive Payment System (MIPS) and Alternative Payment Models (APMs) as is consistent with congressional intent when the Medicare Access and Children's Health Insurance Program (CHIP) Reauthorization Act (MACRA) was enacted.
2. Our AMA will advocate that CMS provide for a stable transition period for the implementation of MACRA, which includes assurances that CMS has conducted appropriate testing, including physicians' ability to participate and validation of accuracy of scores or ratings, and has necessary resources to implement provisions regarding MIPS and APMs.
3. Our AMA will advocate that CMS provide for a stable transition period for the implementation of MACRA that includes a suitable reporting period.

Policy D-390.949, "Preserving Patient Access to Small Practices Under MACRA"
1. Our AMA will urge the Centers for Medicare and Medicaid Services to protect access to care by significantly increasing the low volume threshold to expand the MACRA MIPS exemptions for small practices (on a voluntary basis), and to further reduce the MACRA requirements for ALL physicians' practices to provide additional flexibility, reduce the reporting burdens and administrative hassles and costs.
2. Our AMA will advocate for additional exemptions or flexibilities for physicians who practice in health professional shortage areas.
3. Our AMA will determine if there are other fragile practices that are threatened by MACRA and seek additional exemptions or flexibilities for those practices.

Policy H-385.913, "Physician-Focused Alternative Payment Models"
1. Our AMA recognizes that the physician is best suited to assume a leadership role in transitioning to alternative payment models (APMs).
2. Our AMA supports that the following goals be pursued as part of an APM:
A. Be designed by physicians or with significant input and involvement by physicians;
B. Provide flexibility to physicians to deliver the care their patients need;
C. Promote physician-led, team-based care coordination that is collaborative and patient-centered;
D. Reduce burdens of Health Information Technology (HIT) usage in medical practice;
E. Provide adequate and predictable resources to support the services physician practices need to deliver to patients, and should include mechanisms for regularly updating the amounts of payment to ensure they continue to be adequate to support the costs of high-quality care for patients;
F. Limit physician accountability to aspects of spending and quality that they can reasonably influence;
G. Avoid placing physician practices at substantial financial risk;
H. Minimize administrative burdens on physician practices; and
I. Be feasible for physicians in every specialty and for practices of every size to participate in.
3. Our AMA supports the following guidelines to help medical societies and other physician organizations identify and develop feasible APMs for their members:
A. Identify leading health conditions or procedures in a practice;
B. Identify barriers in the current payment system;
C. Identify potential solutions to reduce spending through improved care;
D. Understand the patient population, including non-clinical factors, to identify patients suitable for participation in an APM;
E. Define services to be covered under an APM;
F. Identify measures of the aspects of utilization and spending that physicians can control;
G. Develop a core set of outcomes-focused quality measures including mechanisms for regularly updating quality measures;
H. Obtain and analyze data needed to demonstrate financial feasibility for practice, payers, and patients;
I. Identify mechanisms for ensuring adequacy of payment; and
J. Seek support from other physicians, physician groups, and patients.
4. Our AMA encourages CMS and private payers to support the following types of technical assistance for physician practices that are working to implement successful APMs:
A. Assistance in designing and utilizing a team approach that divides responsibilities among physicians and supporting allied health professionals;
B. Assistance in obtaining the data and analysis needed to monitor and improve performance;
C. Assistance in forming partnerships and alliances to achieve economies of scale and to share tools, resources, and data without the need to consolidate organizationally;

D. Assistance in obtaining the financial resources needed to transition to new payment models and to manage fluctuations in revenues and costs; and
E. Guidance for physician organizations in obtaining deemed status for APMs that are replicable, and in implementing APMs that have deemed status in other practice settings and specialties.
5. Our AMA will continue to work with appropriate organizations, including national medical specialty societies and state medical associations, to educate physicians on alternative payment models and provide educational resources and support that encourage the physician-led development and implementation of alternative payment models.

Policy H-450.931, "Moving to Alternative Payment Models"
1. As physician payment moves to pay-for-value, our American Medical Association will help physician practices with the following: (a) physician practices need support and guidance to optimize the quantity and content of physician work under alternative payment models; (b) address physicians' concerns about the operational details of alternative payment models to improve their effectiveness; (c) to succeed in alternative payment models, physician practices need data and resources for data management and analysis; and (d) harmonize key components of alternative payment models across multiple payers, especially performance measures to help physician practices respond constructively.
2. Our AMA will, in partnership with other appropriate physician organizations, work with the Centers for Medicare & Medicaid Services to establish an appropriate timetable for implementation of pay-for-value models that takes into account the physician community's readiness to assume two-sided risk (up-side and down-side risk).

Policy H-385.908, "Physician-Focused Alternative Payment Models: Reducing Barriers"
1. Our AMA encourages physicians to engage in the development of Physician-Focused Payment Models by seeking guidance and refinement assistance from the Physician-Focused Payment Model Technical Advisory Committee (PTAC).
2. Our AMA will continue to urge CMS to limit financial risk requirements to costs that physicians participating in an APM have the ability to influence or control.
3. Our AMA will continue to advocate for innovative ways of defining financial risk, such as including start-up investments and ongoing costs of participation in the risk calculation that would alleviate the financial barrier to physician participation in APMs.
4. Our AMA will work with CMS, the Office of the National Coordinator for Health Information Technology (ONC), PTAC, interested medical societies, and other organizations to pursue the following to improve the availability and use of health information technology (IT):
a. Continue to expand technical assistance;
b. Develop IT systems that support and streamline clinical participation;
c. Enable health IT to support bi-directional data exchange to provide physicians with useful reports and analyses based on the data provided;
d. Identify methods to reduce the data collection burden; and
e. Begin implementing the 21st Century Cures Act.
5. Our AMA will work with CMS, PTAC, interested medical societies, and other organizations to design risk adjustment systems that:
a. Identify new data sources to enable adequate analyses of clinical and non-clinical factors that contribute to a patient's health and success of treatment, such as disease stage and socio-demographic factors;
b. Account for differences in patient needs, such as functional limitations, changes in medical conditions compared to historical data, and ability to access health care services; and

c. Explore an approach in which the physician managing a patient's care can contribute additional information, such as disease severity, that may not be available in existing risk adjustment methods to more accurately determine the appropriate risk stratification.
6. Our AMA will work with CMS, PTAC, interested medical societies, and other organizations to improve attribution methods through the following actions:
a. Develop methods to assign the costs of care among physicians in proportion to the amount of care they provided and/or controlled within the episode;
b. Distinguish between services ordered by a physician and those delivered by a physician;
c. Develop methods to ensure a physician is not attributed costs they cannot control or costs for patients no longer in their care;
d. Explore implementing a voluntary approach wherein the physician and patient agree that the physician will be responsible for managing the care of a particular condition, potentially even having a contract that articulates the patient's and physician's responsibility for managing the condition; and
e. Provide physicians with lists of attributed patients to improve care coordination.
7. Our AMA will work with CMS, PTAC, interested medical societies, and other organizations to improve performance target setting through the following actions:
a. Analyze and disseminate data on how much is currently being spent on a given condition, how much of that spending is potentially avoidable through an APM, and the potential impact of an APM on costs and spending;
b. Account for costs that are not currently billable but that cost the practice to provide; and
c. Account for lost revenue for providing fewer or less expensive services.

REPORT OF THE BOARD OF TRUSTEES

B of T Report 14, November 2020

Subject: Advocating for the Standardization and Regulation of Outpatient Addiction Rehabilitation Facilities (Resolution 201-I-19)

Presented by: Russ Kridel, MD, Chair

Referred to: Reference Committee B

INTRODUCTION

At the American Medical Association's (AMA) 2019 Interim Meeting, the House of Delegates (HOD) referred Resolution 201-I-19, "Advocating for the Standardization and Regulation of Outpatient Addiction Rehabilitation Facilities," introduced by the Medical Student Section, which asks: "That our American Medical Association advocate for the expansion of federal regulations of outpatient addiction rehabilitation centers in order to provide patient and community protection in line with evidence-based care." Testimony on Resolution 201 was mixed. Testimony was provided that raised significant concerns related to additional federal regulations proffered by Resolution 201. Additional testimony offered several amendments and substitute language proposals to strengthen the resolution. Believing that further study was warranted, the HOD referred Resolution 201. This report recommends new policy and reaffirms existing policy in lieu of the adoption of Resolution 201.

DISCUSSION

Background

Despite sharp reductions in opioid prescriptions, increases in the use of state prescription drug monitoring programs, increases in naloxone, and other signs of progress, the nation is now experiencing a more deadly and complicated drug overdose epidemic. According to the AMA's Opioid Task Force 2020 Progress Report, released July 21, 2020, while physicians have reduced opioid prescriptions by 37 percent between 2014 and 2019, illicitly manufactured fentanyl, fentanyl analogues, and stimulants (e.g., methamphetamine, cocaine) are now killing more Americans than ever. The use of these illicit drugs has surged, and their overdose rate increased by 10.1 percent and 10.8 percent, respectively. The changing landscape of the epidemic poses challenges for the health care system, which must pivot to treat people in danger of overdose from all drugs.

One of the primary challenges in ending the nation's drug overdose epidemic remains the inability of most patients to obtain evidence-based care for a substance use disorder. While the Affordable Care Act (ACA) and the Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) in combination have addressed some of the coverage and access gaps, the National Survey on Drug Use and Health for 2017 and 2018, conducted by the Substance Abuse and Mental Health Services Administration (SAMHSA), has found that over 90 percent of those 12 and older with an illicit drug use disorder did not receive treatment. The number of drug overdoses will continue to rise

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unless more is done to help the more than two million Americans with an untreated substance use disorder.

Resolving the issue of capacity to treat all patients who require it, however, faces several barriers. While network adequacy laws require a sufficient number of addiction medicine and psychiatric physicians in a patient's network, health insurance companies are falling far short of their obligation, and enforcement of these requirements often is lacking. Moreover, many payers are failing to comply with state and federal mental health and substance use disorder parity laws.

Removing the barriers for patients to receive evidence-based treatment is critical to helping end the epidemic. AMA advocacy in this area has been substantial and multipronged, focusing on removing barriers to evidence-based care, encouraging more physicians to become trained to provide buprenorphine in-office to help treat opioid use disorder, and advocating for payers to increase network capacity and demonstrate compliance with mental health and substance use disorder parity laws. The AMA is working at the state and federal levels to strengthen network adequacy requirements and enforcement and promote meaningful oversight and enforcement of mental health and substance use disorder parity laws. In addition, the AMA has advocated against health insurance company tactics to delay and deny access to evidence-based treatment for opioid use disorder through the use of prior authorization requirements and other barriers for medications to treat opioid use disorder (MOUD), the gold standard for treating opioid use disorder. Barriers include the reluctance among some providers and individuals to use MOUD, stigma, administrative obstacles, and lack of sufficient treatment facilities and addiction medicine specialists or physicians who treat patients with an OUD. The AMA has partnered with the American Psychiatric Association, American Society of Addiction Medicine (ASAM), and many other organizations in the Federation to simultaneously address these issues.

Congressional Action

According to SAMHSA, due to the increased demand for opioid treatment, substance use treatment centers are a multi-billion-dollar industry. As noted in Resolution 201, media outlets have reported cases of fraud and abuse in this industry. Multiple federal law enforcement agencies, including the Federal Trade Commission (FTC), the Federal Bureau of Investigation (FBI), and the Department of Labor's Employee Benefits Security Administration (EBSA), have conducted investigations uncovering fraudulent acts regarding substance use treatment services and products, especially involving insurance fraud. Under the Federal Trade Commission Act (15 U.S.C. §§41 et seq.), the FTC has the authority to prohibit false or deceptive claims and may seek a judicial order levying civil penalties on violators. The FDA and FTC have sent joint warning letters to companies illegally marketing unapproved opioid cessation products claiming to treat opioid addiction and withdrawal. In addition, several states, including New York, have cracked down on fraudulent operators and federal prosecutors have brought lawsuits in California and Florida.

In 2018, as part of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (P.L. 115-271—the SUPPORT for Patients and Communities Act, or the SUPPORT Act), Congress took action against fraudulent treatment centers. Sections 8021-8023 of the SUPPORT Act include the Opioid Addiction Recovery Fraud Prevention Act, which prohibits any unfair or deceptive acts regarding substance use disorder treatment services or products. The provision makes these practices unlawful under section 18 of the Federal Trade Commission Act (15 U.S.C. §57a). <u>The provision</u> effectively authorizes the FTC to seek civil penalties against opioid treatment programs and products that make false or deceptive claims regarding their cost, price, efficacy, performance, benefit, risk, or safety. The bill also

authorizes state attorneys general, or other state officials, to bring civil actions for violations. The AMA supported these provisions.

The Board commends the laudable goal underlying Resolution 201. However, in considering the many comments received on this resolution, we find most compelling the many comments by those who testified before the reference committee that the problem is not lack of regulation but lack of enforcement of laws. As noted above, state and federal laws already govern outpatient treatment facilities. Federal regulations can often interfere with evidence-based medicine—e.g., the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain issued by the CDC—and the Board agrees that standardized evidence-based federal regulations are not the right approach. The Board also notes that medical specialties, such as ASAM and the American Psychiatric Association, have guidelines and standards to help ensure the provision of evidence-based care in treatment facilities for in-patient and out-patient care.

The Board has determined that more evaluation of existing programs and outcomes is needed. Billions of dollars have been spent by the federal government in support of state-level grant programs to provide care for those with a substance use disorder or co-occurring mental disorder. Many of these programs are certainly saving lives, but there may be others that are not as effective. The SUPPORT Act took an important step toward ensuring such evaluation in section 7171, which requires the Secretary to review entities that receive federal funding to provide SUD treatment services. The review is required to include certain specified elements about the entity's history, population served, and treatment capacity. The Secretary is required, within two years of enactment, to develop and submit a plan to Congress to direct appropriate resources to entities that provide SUD treatment services in order to address inadequacies in services or funding identified through the required review. When released, this report will help in determining which of the many federally funded programs are working and should be continued and which should either be improved or denied future funding. The AMA looks forward to highlighting those evidence-based, best practices demonstrated to help increase access to treatment for those with an OUD.

Moreover, we remain concerned that relying on short-term grants that depend on the annual appropriations process in Congress does not provide long-term certainty for states in terms of planning for programs and resources or accessibility to treatment and continuity of care for individuals seeking substance use disorder treatment. A short-term grant would not allow most states to recruit, for example, addiction medicine specialists or psychiatrists to underserved areas if there is only a short-term commitment for that medical professional. Recruiting a physician (and his or her family) to relocate with a promise of only a 6- or 12-month commitment is problematic, to say the least. Sustained funding and a comprehensive framework to prevent and treat all substance use disorders is necessary as the epidemic evolves and overdose fatalities involving illicit opioids, stimulants (e.g., methamphetamine), heroin, and cocaine increase.

One such proposal, which the AMA supports, is the "Comprehensive Addiction Resources Emergency (CARE) Act" (S. 1365/H.R. 2569), introduced by Senator Elizabeth Warren (D-MA) and the late Representative Elijah E. Cummings (D-MD). The CARE Act is modeled directly on the Ryan White Comprehensive AIDS Resources Emergency Act, which was passed by Congress in 1990 to provide significant new funding to help state and local governments combat the HIV/AIDS epidemic. The CARE Act is designed to support local decision making and federal research and programs to prevent drug use while funding evidence-based treatments and recovery support services. The bill would provide $100 billion over 10 years, the type of long-term funding that could really help to turn-around the substance-use epidemic. While this bill has not moved forward during this Congressional session, your Board believes it serves as an excellent model for a framework in the future.

AMA POLICY

Our AMA has longstanding and extensive policy on addiction and substance use disorder treatment. Policy D-95.981, "Improving Medical Practice and Patient/Family Education to Reverse the Epidemic of Nonmedical Prescription Drug Use and Addiction," which was reaffirmed by the HOD at the 2019 Interim Meeting, provides in part that our AMA "will: (a) advocate for legislation that eliminates barriers to, increases funding for, and requires access to all appropriate FDA-approved medications or therapies used by licensed drug treatment clinics or facilities; and (b) develop a public awareness campaign to increase awareness that medical treatment of substance use disorder with medication-assisted treatment is a first-line treatment for this chronic medical disease."

Likewise, AMA policy provides that "our AMA (1) will continue to seek and participate in partnerships designed to foster awareness and to promote screening, diagnosis, and appropriate treatment of substance misuse and substance use disorders; (2) will renew efforts to: (a) have substance use disorders addressed across the continuum of medical education; (b) provide tools to assist physicians in screening, diagnosing, intervening, and/or referring patients with substance use disorders so that they have access to treatment; (c) develop partnerships with other organizations to promote national policies to prevent and treat these illnesses, particularly in adolescents and young adults; and (d) assist physicians in becoming valuable resources for the general public, in order to reduce the stigma and enhance knowledge about substance use disorders and to communicate the fact that substance use disorder is a treatable disease; and (3) will support appropriate federal and state legislation that would enhance the prevention, diagnosis, and treatment of substance use disorders." (Policy H-95.922, "Substance Use and Substance Use Disorders").

Current AMA policy also broadly covers parity issues, including support for "health care reform that meets the needs of all Americans, including people with mental illness and substance use/addiction disorders and will advocate for the inclusion of full parity for the treatment of mental illness and substance use/addiction disorders in all national health care reform legislation." (Policy H-165.888, "Evaluating Health System Reform Proposals") (Also see Policy D-180.998, "Insurance Parity for Mental Health and Psychiatry" and Policy H-185.974, "Parity for Mental Illness, Alcoholism, and Related Disorders in Medical Benefits Programs").

With respect to third-party payers, our AMA opposes federal, state, third-party and other laws, policies, rules and procedures, including those imposed by pharmacy benefit managers working for Medicaid, Medicare, TRICARE, and commercial health plans, that would limit a patient's access to medically necessary pharmacological therapies for opioid use disorder, whether administered in an office-based opioid treatment setting or in a federal regulated Opioid Treatment Program, by imposing limitations on the duration of treatment, medication dosage or level of care. (Policy H-95.944, "Third-Party Payer Policies on Opioid Use Disorder Pharmacotherapy").

More generally, with regard to federal drug policy, "our AMA, in an effort to reduce personal and public health risks of drug abuse, urges the formulation of a comprehensive national policy on drug abuse, specifically advising that the federal government and the nation should: (1) acknowledge that federal efforts to address illicit drug use via supply reduction and enforcement have been ineffective; (2) expand the availability and reduce the cost of treatment programs for substance use disorders, including addiction; (3) lead a coordinated approach to adolescent drug education; (4) develop community-based prevention programs for youth at risk; (5) continue to fund the Office of National Drug Control Policy to coordinate federal drug policy; (6) extend greater protection against discrimination in the employment and provision of services to drug abusers; (7) make a long-term commitment to expanded research and data collection; (8) broaden the focus

of national and local policy from drug abuse to substance abuse; and (9) recognize the complexity of the problem of substance abuse and oppose drug legalization." (Policy H-95.981, "Federal Drug Policy in the United States").

RECOMMENDATIONS

The Board of Trustees recommends that the following recommendations be adopted in lieu of Resolution 201-I-19, and that the remainder of the report be filed.

1. That our AMA advocate for the expansion of federal grants in support of treatment for a substance use disorder to states that are conditioned on that state's adoption of law and/or regulation that prohibit drug courts, recovery homes, sober houses, correctional settings, and other similar programs from denying entry or ongoing care if a patient is receiving medication for an opioid use disorder or other chronic medical condition. (Directive to Take Action)

2. That our AMA advocate for sustained funding to states in support of evidence-based treatment for patients with a substance use disorder and/or co-occurring mental disorder, such as that put forward by the American Society of Addiction Medicine, American Academy of Addiction Psychiatry, American Psychiatric Association, American Academy of Child and Adolescent Psychiatry and other professional medical organizations. (Directive to Take Action)

3. That our AMA reaffirm Policy D-95.981, "Improving Medical Practice and Patient/Family Education to Reverse the Epidemic of Nonmedical Prescription Drug Use and Addiction." (Reaffirm HOD Policy)

4. That our AMA reaffirm Policy H-95.922, "Substance Use and Substance Use Disorders." (Reaffirm HOD Policy)

5. That our AMA reaffirm H-95.981, "Policy Federal Drug Policy in the United States." (Reaffirm HOD Policy).

Fiscal Note: Less than $5000

REPORT OF THE BOARD OF TRUSTEES

B of T Report 16, November 2020

Subject: Enabling Methadone Treatment of Opioid Use Disorder in Primary Care Settings, BOT Report 2-I-19

Presented by: Russ Kridel, MD, Chair

Referred to: Reference Committee B

INTRODUCTION

At the 2019 Interim Meeting of the AMA House of Delegates, Board of Trustees (BOT) Report 2, "Enabling Methadone Treatment of Opioid Use Disorder in Primary Care Settings," was considered for adoption.

Board Report 2-I-19 recommended:

> That our American Medical Association (AMA) support further research into how primary care practices can implement MAT into their practices and disseminate such research in coordination with primary care specialties;
>
> That our AMA support efforts to expand primary care services to patients receiving methadone maintenance therapy (MMT) for patients receiving care in an Opioid Treatment Program or via office-based therapy; and
>
> That the AMA Opioid Task Force increase its evidence-based educational resources focused on MMT and publicize those resources to the Federation. (Directive to Take Action)

Testimony on Board Report 2-I-19 generally supported the recommendations, but there was conflicting testimony related to Recommendation 2. Recommendations 1 and 3 were adopted. This report discusses the issues raised by Recommendation 2 and presents additional recommendations.

DISCUSSION

Background

Board Report 2-I-19 discussed the history and efficacy of methadone maintenance treatment (MMT) in great detail, including the increase in Opioid Treatment Programs (OTPs) offering MMT; the medication's efficacy in treating opioid use disorder; and the various state and federal requirements regulating the provision of MMT. Board Report 2-I-19 also reviewed examples of clinical research and practice in providing MMT in primary care settings, "that have demonstrated benefits of having MMT provided in a primary care setting outside of a traditional OTP." BOT Report 2 explained, however, that the examples were, "highly structured and still must comply with state and federal rules (including who can dispense, take-home rules for stable patients, patient monitoring, strict record-keeping, etc.) governing the provision of MMT." It is worth further

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highlighting that testimony pointed out the limited nature of the research, and the studies did not involve large groups of patients. The patients in the studies, moreover, were highly selected; with low acuity; without significant untreated psychiatric comorbidity; and had been stable in treatment for at least one year. In addition, the primary care practices in the studies each had a close ongoing relationship with the community OTP, and there was not the option of the physicians in the primary care setting to provide buprenorphine, which was approved by the U.S. Food and Drug Administration (FDA) for use in treating opioid use disorder in 2002.[1]

The Board provides this additional context to emphasize both the positive nature of the pilot programs but also to make clear that they were provided as examples rather than suggesting the MMT primary care practice pilot programs should be the rule or able to be replicated in all situations. The Board appreciates the opportunity to clarify the issues and present a discussion and recommendations to further support increased access to evidence-based care.

There are other barriers to MMT, including the fact that MMT remains one of the most highly stigmatized forms of treatment to treat opioid use disorder (OUD). Previous studies make clear how patients who receive MMT, "experience prejudice, stereotypes, and discrimination from friends and family, coworkers and employers, healthcare workers, and others."[2] This stigma is one of the root causes why those with an OUD may not seek treatment. In addition, because MMT is highly regulated by multiple layers of state and federal government, patients encounter multiple additional barriers, including a lack of access in rural areas[3] and the common requirement to drive or travel long distances to an OTP.[4] Dosing restrictions/requirements and other administration and/or legal barriers limit the ability of jails, prisons and Federally Qualified Health Centers (FQHCs) to provide MMT to particularly vulnerable and marginalized populations. It is beyond the scope of this report, but important to note that the AMA, American Society of Addiction Medicine (ASAM) and other medical organizations strongly support removing barriers to treatment for OUD in correctional settings.[5] Furthermore, some states place additional restrictions on the number of OTPs allowed to operate in a state or have burdensome requirements for an OTP to open.[6] Each of these barriers—whether stigma, social determinants, statute or rule—potentially limit a patient's ability to receive MMT and could also hinder that patient from receiving any care, including primary care as discussed above. At the same time, the Board recognizes that there is an appropriate role for clinical and other guidance to ensure the safety of patients. The focus of this report is not to delve into every potential barrier but to point out, broadly, that there are opportunities for further advocacy to identify, evaluate and either support or oppose policies that impede the provision of primary care services in an OTP, as well as the provision of MMT itself.

At a minimum, better coordination with primary care and MMT services would help increase access to evidence-based care for an OUD. Better support and training for family physicians, for example, to assess, diagnose and refer patients with an OUD to an OTP for MMT or other appropriate care, is supported by evidence.[7] While beyond the scope of this report, clinical research also is widely available to help primary care physicians with dosing and other clinical issues raised by the use of buprenorphine and/or MMT.[8,9] The AMA also has placed additional resources regarding methadone on the AMA drug overdose epidemic microsite, including information and research from the American Association of Treatment for Opioid Dependence,[10] American Academy of Family Physicians,[11] ASAM,[12] American College of Physicians[13] and the Providers Clinical Support System.[14] The AMA will continue to update the microsite with relevant information as provided by our Federation partners.

Physicians who might be interested to include MMT in primary care practices should be aware, for example, of some of the costs that their practices would incur under current federal requirements to operate an OTP.[15] Practices would need to meet specifications to assure that the stocked methadone

and the practice site are secure. Credentialed staff would need to be present to administer medication. Systems would need to be in place to monitor patients for adherence, ensure stock of medication and keep records with accountability to the U.S. Drug Enforcement Administration (DEA). The Board recognizes that these requirements are not insignificant and may be cost prohibitive. In addition, the Board points out the many different therapeutic and patient safety issues raised during the I-19 Interim Meeting concerning dosing, methadone's narrow therapeutic index, side effects and other issues.[16]

The issue at hand, however, is not whether patients currently receiving MMT, or those who might benefit from MMT, should also receive primary care services. The issue is how to best ensure that patients who are receiving MMT, or would benefit from receiving MMT, *also* receive primary care services. As noted in Board Report 2-I-19 and above, this entails multiple aspects, including removing barriers to MMT. There is no question that patients receiving MMT would benefit from receiving primary care services and the AMA remains committed to supporting efforts for patients receiving care in an OTP to also receive primary care services. This must be an evidence-based approach[17] done in compliance with applicable state and federal regulations. If the evidence demonstrates that patients can safely receive MMT in office-based settings, and the provision of such care is done in accordance with the highest standards of medical evidence and clinical research, the AMA wants to ensure that it supports policies that advance patient care.

It follows that the Board recommends further research into evidence-based initiatives to support the integration of primary care services into OTPs. This includes working with our partners at the American Society of Addiction Medicine, American Psychiatric Association, American Academy of Addiction Psychiatry, American Academy of Family Physicians and other medical societies to better understand and identify examples and best practices of how primary care services have been integrated into OTPs and addiction medicine practices. Additional stakeholders, including the American Association for the Treatment of Opioid Dependence, will likely be able to provide helpful information on evidence-based initiatives—as well as barriers—to integrate primary care services in OTPs and practices providing care for substance use disorders.

As stated above, the Board recognizes that the costs, requirements, etc. may make including MMT in primary care practices challenging and as such, the Board understands that not all primary care practices are able to or would be able to provide MMT. Yet, at a time when more Americans than ever are dying from illicitly manufactured fentanyl, fentanyl analogs and heroin—and prescription opioid-involved mortality remains at more than 11,000 deaths per year—the AMA believes all efforts must be made to increase access to evidence-based care. This is in line with recommendations from the National Academy of Medicine (NAM), which recommends the need for the DEA and U.S. Substance Abuse and Mental Health Services Administration (SAMHSA) to "explore methadone delivery models that can increase access to this lifesaving medication."[18] The NAM authors call for additional use of pilot programs to evaluate best practices as well as the need for health insurance companies, Medicaid, and Medicare to "eliminate policies that disincentivize clinicians from providing medications and limit or delay access to treatment." The call for further research and removal of administrative and financial barriers are items the AMA strongly supports.

The AMA will continue its work to remove utilization management barriers to patients with an OUD from receiving evidence-based care. This includes AMA advocacy to: (1) urge states to include all medications used to treat OUD on the lowest cost-sharing tier of a health insurer's or pharmacy benefit management company formulary;[19] (2) support for state Medicaid agencies to include methadone on the state preferred drug list; (3) support for innovative proposals such as mobile units to provide MMT;[20] and broad support for increased flexibility for OTPs to provide take-home dosing and other policies during the COVID-19 pandemic.[21] It bears repeating that the

AMA believes the focus must be on increasing access to MMT *and* primary care. The AMA does not see the value in debating the specific mechanisms by which physicians can do this effectively so long as they do so safely and in accordance with best clinical practice and medical evidence. This approach will help remove stigma and increase access to MMT and primary care. AMA policy strongly supports physicians exercising the clinical judgment to care for their patients according to the highest standards that the medical profession brings to all other medical conditions. This is true for MMT and any other type of treatment proven effective for a medical disease.

The Board, therefore, recommends that the AMA provide further support for primary care services and MMT, including continued support for clinical research and other evidence to guide safe clinical practice, as well as new recommendations to remove barriers and increase access to evidence-based care.

AMA POLICY

The AMA opposes "the stigma associated with patients suffering from persistent pain and/or substance use disorders, including addiction." (Policy D-95.981, "Improving Medical Practice and Patient/Family Education to Reverse the Epidemic of Nonmedical Prescription Drug Use and Addiction") The AMA broadly supports MMT, the evolving nature of evidence supporting MMT, education on MMT as well as removing barriers to MMT. (Policy H-95.957, "Methadone Maintenance in Private Practice") Specifically, Policy H-95.957 "supports the position that 'medical' methadone maintenance may be an effective treatment for the subset of opioid dependent patients who have attained a degree of behavioral and social stability under standard treatment and thereby an effective measure in controlling the spread of infection with HIV and other blood-borne pathogens but further research is needed; encourages additional research that includes consideration of the cost of 'medical' methadone maintenance relative to the standard maintenance program (for example, the cost of additional office security and other requirements for the private office-based management of methadone patients) and relative to other methods to prevent the spread of blood-borne pathogens among intravenous drug users; supports modification of federal and state laws and regulations to make newly approved anti-addiction medications available to those office-based physicians who are appropriately trained and qualified to treat opiate withdrawal and opiate dependence in accordance with documented clinical indications and consistent with sound medical practice guidelines and protocols; and urges that guidelines and protocols for the use of newly approved anti-addiction medications be developed jointly by appropriate national medical specialty societies in association with relevant federal agencies and that continuing medical education courses on opiate addiction treatment be developed by these specialty societies to help designate those physicians who have the requisite training and qualifications to provide therapy within the broad context of comprehensive addiction treatment and management."

The AMA also broadly supports efforts to increase access to OTPs in areas where they are needed most. (Policy H-95.921, "Exclusive State Control of Methadone Clinics") This includes an ongoing commitment by the AMA to support and promote education relating to MMT. (Policy D-120.985, "Education and Awareness of Opioid Pain Management Treatments, Including Responsible Use of Methadone") The policy includes "how primary care practices can implement medication-assisted treatment (MAT) into their practices and disseminate such research in coordination with primary care specialties." (Policy D-95.968, "Support the Elimination of Barriers to Medication-Assisted Treatment for Substance Use Disorder") AMA policy also supports how "[f]inancial incentives should enhance the provision of high quality, cost-effective medical care." (Policy H-285.951, "Financial Incentives Utilized in the Management of Medical Care") Finally, there is extensive

support in current policy for removing administrative barriers for the provision of evidence-based care. (Policy H-320.939, "Prior Authorization and Utilization Management Reform")

RECOMMENDATIONS

The Board recommends that the following be adopted in lieu of the second recommendation of Board Report 2-I-19, and that the remainder of the report be filed:

1. That our AMA research current best practices and support pilot programs and other evidence-based efforts to expand and integrate primary care services for patients receiving methadone maintenance treatment. (New HOD Policy)

2. That our AMA support further research to help define the population of patients who may be safely treated with methadone maintenance treatment via primary care office-based therapy. (New HOD Policy)

3. That our AMA urge all payers, including health insurance companies, pharmacy benefit management companies, and state and federal agencies, to reduce prior authorization and other administrative burdens and to enhance the provision of primary care, counseling, and other medically necessary services for patients being treated with methadone maintenance treatment. (Directive to Take Action)

Fiscal Note: Less than $500

REFERENCES

[1] "Buprenorphine." U.S. Substance Abuse and Mental Health Services Administration. https://www.samhsa.gov/medication-assisted-treatment/treatment/buprenorphine

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[3] Lack of access in rural areas was cited in testimony by family physician residents at the 2019 meeting of the American Academy of Family Physicians in adopting a resolution to support increased access to MMT. See "Residents Focus Discussions on Training, Patient Care," July 31, 2019. Available at https://www.aafp.org/news/education-professional-development/20190731nc-rescongress.html

[4] Joudrey PJ, Edelman EJ, Wang EA. Drive Times to Opioid Treatment Programs in Urban and Rural Counties in 5 US States. JAMA. 2019;322(13):1310–1312. doi:10.1001/jama.2019.12562

[5] See, for example AMA and Vermont Medical Society strong support for strong support for Senate Bill 166, An act relating to the provision of medication-assisted treatment for inmates. Feb. 21, 2018. Available at https://searchlf.ama-assn.org/undefined/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2018-2-21-AMA-VMS-Letter-in-support-of-VT-SB-166-FINAL.pdf. Also see American Society of Addiction Medicine public policy statement on Treatment of OUD in Correctional Settings. Available at https://www.asam.org/docs/default-source/public-policy-statements/2020-statement-on-treatment-of-oud-in-correctional-settings.pdf?sfvrsn=ff156c2_2

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[7] Opioid Use Disorder: Medical Treatment Options, Am Fam Physician. 2019 Oct 1;100(7):416-425., https://www.aafp.org/afp/2019/1001/p416.html

[8] Salisbury-Afshar E. Buprenorphine Maintenance vs. Methadone Maintenance or Placebo for Opioid Use Disorder. Am Fam Physician. 2015;91(3):165-166.

[9] Mattick RP, Breen C, Kimber J, Davoli M. Buprenorphine maintenance versus placebo or methadone maintenance for opioid dependence. Cochrane Database Syst Rev. 2014;(2):CD002207. Published 2014 Feb 6. doi:10.1002/14651858.CD002207.pub4

[10] American Association of Treatment for Opioid Dependence. Frequently Asked Questions. Available at http://www.aatod.org/opioid-education/frequently-asked-questions/

[11] See https://end-overdose-epidemic.org/resources/?_societies_associations=american-academy-of-family-physicians

[12] See https://end-overdose-epidemic.org/resources/?_societies_associations=american-society-of-addiction-medicine

[13] See https://end-overdose-epidemic.org/resources/?_societies_associations=american-college-of-physicians

[14] See https://end-overdose-epidemic.org/resources/?_other_organizations=pcss

[15] See, broadly, the certification and accreditation requirements for Opioid Treatment Programs. U.S. Substance Abuse and Mental Health Services Administration. Available at https://www.samhsa.gov/medication-assisted-treatment/certification-opioid-treatment-programs

[16] National Center for Biotechnology Information. PubChem Database. Methadone, CID=4095, https://pubchem.ncbi.nlm.nih.gov/compound/Methadone (accessed on July 23, 2020)

[17] See, for example, the ASAM National Practice Guideline for the Treatment of Opioid Use Disorder: 2020 Focused Update. American Society of Addiction Medicine. Available at https://www.asam.org/docs/default-source/quality-science/npg-jam-supplement.pdf?sfvrsn=a00a52c2_2

[18] Madras, B. K., N. J. Ahmad, J. Wen, J. Sharfstein, and the Prevention, Treatment, and Recovery Working Group of the Action Collaborative on Countering the U.S. Opioid Epidemic. NAM Perspectives. Discussion Paper, Washington, DC. https://doi.org/10.31478/202004b

[19] This is one of several recommendations contained in the AMA-Manatt Health publication, *National Roadmap on State-Level Efforts to End the Opioid Epidemic: Leading-edge Practices and Next Steps*. September 2019. Available at https://end-overdose-epidemic.org/wp-content/uploads/2020/05/AMA-Manatt-National-Roadmap-September-2019-FINAL.pdf

[20] AMA letter to Uttam Dhillon, Acting Administrator, Drug Enforcement Administration, U.S. Department of Justice. RE: RIN 1117-AB43/Docket No. DEA-459 Registration Requirements for Narcotic Treatment

Programs with Mobile Components. April 27, 2020. Available at https://searchlf.ama-assn.org/undefined/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2020-4-27-Letter-to-Dhillon-re-NTP-Mobile.pdf

[21] AMA letter to Elinore F. McCance-Katz, MD, PhD, Assistant Secretary for Mental Health and Substance Use, U.S. Department of Health and Human Services. April 13, 2020. Available at https://searchlf.ama-assn.org/undefined/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2020-4-13-Letter-to-McCance-Katz-at-SAMHSA-re-OTP-Telemed-.pdf

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 201
(November 2020)

Introduced by: Illinois

Subject: Permitting the Dispensing of Stock Medications for Post Discharge Patient Use and the Safe Use of Multi-dose Medications for Multiple Patients

Referred to: Reference Committee B

Whereas, A topical stock-item medication is an unlabeled ointment or drop that the hospital operating room (OR), or Emergency Room (ER), or Ambulatory Surgical Treatment Center (ASTC) staff has on stand-by or is retrieved from a dispensing system for a specified patient for use during a procedure or visit; and

Whereas, Topical stock-item agents are charged to the patient, but unused medication often gets discarded when the patient is discharged, even if the medication is recommended for post-discharge care to aid in the patient's healing; and

Whereas, Because regulations governing the ability to dispense the remaining portion of stock-item medications for post-discharge use can be unclear or appear overly burdensome, many facilities do not allow the practice; and

Whereas, Patients may need to purchase duplicate agents for post-discharge use, increasing patient cost and creating medication waste; and

Whereas, Similar issues of cost inefficiencies and medical waste arise with the use of medications such as multiuse eye drops that are only allowed for single-patient use, but could safely be used in multiple patients; and

Whereas, The Joint Commission has previously approved specific policies and procedures implemented by the Utah Valley Regional Medical Center for the use of multidose eye drops in multiple patients; therefore be it

RESOLVED, That our American Medical Association work with the Food and Drug Administration, national specialty societies, state medical societies and/or other interested parties to ensure that legislative and regulatory language permits the practice of dispensing stock-item medications to individual patients upon discharge in accordance with labeling and dispensing protocols that help ensure patient safety, minimize duplicated patient costs, and reduce medication waste. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000

Received: 07/17/20

Reference:

Using multi dose eye drops in a health care setting: a policy and procedural approach to safe and effective treatment of patients. Jensen MK, et al. JAMA Ophthalmology 2014. https://jamanetwork.com/journals/jamaophthalmology/article-abstract/1901216

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 202
(November 2020)

Introduced by: New York

Subject: Cares Act Equity and Loan Forgiveness in the Medicare Accelerated Payment Program

Referred to: Reference Committee B

Whereas, In enacting the CARES Act, Congress established a number of programs to assist physicians, hospitals and other care providers to address the devastating drop in patient revenue during the height of the Covid-19 pandemic; and

Whereas, The CARES Act includes $175 billion in relief funds for hospitals and other healthcare providers who are or have been providing testing and treatment for individuals with possible or actual cases of COVID-19; and

Whereas, The initial distributions from this relief fund have only gone to hospitals, physicians and other healthcare providers who have received Medicare payments; and

Whereas, Some specialty physician practices, because of the nature of their patient population, including some primary care specialties such as pediatrics who certainly may provide testing and treatment for individuals with possible or actual COVID-19, may not receive Medicare payments; and

Whereas, Even where payments were made to physicians from this fund, it was often for minimal amounts compared to funds received by health systems; and

Whereas, According to the Department of Health and Human Services (HHS) website, Rural Distribution payments were made to rural acute care general hospitals and Critical Access Hospitals (CAHs), Rural Health Clinics (RHCs), and Community Health Centers (CHCs) located in rural areas (Hospitals and RHCs will each receive a minimum base payment plus a percent of their annual expenses). The base payment will account for RHCs with no reported Medicare claims, such as pediatric RHCs, and CHCs lacking expense data, by ensuring that all clinical, non-hospital sites receive a minimum level of support no less than $100,000, with additional payment based on operating expenses. Rural acute care general hospitals and CAHs will receive a minimum level of support of no less than $1,000,000, with additional payment based on operating expenses; and

Whereas, The Paycheck Protection Program (PPP) forgivable loan program established in the CARES Act has provided awards to many community physician practices, but concerns remain regarding the limitations on the use of the funds; and

Whereas, The Medicare Advanced Payment Program (MAPP) was suspended by CMS on April 26, despite its use by many physicians and the lifeline it provided for many physician practices during the Covid-19 pandemic; therefore be it

RESOLVED, That our American Medical Association and the federation of medicine work to improve and expand various federal stimulus programs (e.g., the CARES Act and MAPP) in order to assist physicians in response to the Covid-19 pandemic, including:

- Restarting the suspended Medicare Advance payment program, including significantly reducing the re-payment interest rate and lengthening the repayment period;

- Expanding the CARES Act health care provider relief pool and working to ensure that a significant share of the funding from this pool is made available to physicians in need regardless of the type of patients treated by those physicians; and

- Reforming the Paycheck Protection Program, to ensure greater flexibility in how such funds are spent and lengthening the repayment period (Directive to Take Action); and be it further

RESOLVED, That, in the setting of the COVID-19 pandemic, our AMA advocate for additional relief to physicians via loan forgiveness for medical school educational debt. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000

Received: 06/18/20

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 203
(November 2020)

Introduced by: New York

Subject: COVID–19 Emergency and Expanded Telemedicine Regulations

Referred to: Reference Committee B

Whereas, The world is facing a global health crisis through the pandemic spread of the coronavirus COVID-19 and as a consequence the health and safety of the people of the United States are uncertain; and

Whereas, The disease poses a heightened risk to immunocompromised individuals and other vulnerable populations including the elderly, those with chronic lung disease, heart disease, cancer, and/or diabetes; and

Whereas, The COVID–19 pandemic has created situations where persons are instructed NOT to go to their physicians' offices if experiencing cough with fever unless they are in a high risk situation or experiencing shortness of breath and are told to present to the emergency department of a hospital in such cases; and it is the medical community and community health centers which serve a vital role in the maintenance of health and prevention of disease; and

Whereas, On March 4, 2020, Congress voted to approve an emergency coronavirus spending bill of $8.3 billion to address this growing health crisis; and

Whereas, Physicians and other medical providers must be enabled to respond to the growing need for medical services including during mandatory quarantine and voluntary isolation and physicians have adopted and adapted to the use of telemedicine as a tool for caring for their patients; and

Whereas, Technology is available to patients and physicians alike to allow for personalized advice and management through various means including telephonic and video communications (telemedicine), and the utilization of telemedicine for geographic areas where access to physicians and other health care providers is not readily accessible has become increasingly important, indeed many patients find telemedicine to be more convenient and satisfying for some of their healthcare needs; and

Whereas, Since the means are available for patient care in these situations, physicians and others should be paid for their services when using such telemedicine technology; and

Whereas, Telemedicine has become an effective tool in reducing inappropriate use of emergency room and ambulance services for evaluation of acute illness and this is especially true during the Covid-19 pandemic; therefore be it

RESOLVED, That, with the expanded use of telemedicine during the Covid-19 pandemic, our American Medical Association continue to advocate for a continuation of coverage for the full-spectrum of technologies that were made available during the pandemic and that physicians be reimbursed by government and private payers for time and complexity (Directive to Take Action); and be it further

RESOLVED, That our AMA advocate that the current emergency regulations for improved access to and payment for telemedicine services be made permanent with respect to payment parity and use of commonly accessible devices for connecting physicians and patients, without reference to the originating site, while ensuring qualifications of duly licensed physicians to provide such services in a secure environment (Directive to Take Action); and be it further

RESOLVED, That our AMA propose that all insurance carriers provide coverage for telemedicine visits with any physician licensed and registered to practice in the United States. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000

Received: 06/18/20

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 204
(November 2020)

Introduced by: Resident and Fellow Section

Subject: Studying Physician Supervision of Allied Health Professionals Outside of Their Fields of Graduate Medical Education

Referred to: Reference Committee B

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1 Whereas, Advanced practice providers and allied health professionals are required under the
2 laws of many states to be supervised to some degree by a physician; and
3
4 Whereas, News reports and articles note instances of thoracic surgeons and obstetrician/
5 gynecologists supervising social workers in the provision of group therapy[1] and plastic surgeons
6 supervising physician assistants who advertise themselves as "dermatologists"[2]; and
7
8 Whereas, Widely known anecdotal evidence suggests numerous advanced practice providers
9 practicing in various fields while being nominally supervised by physicians not trained in those
10 fields; and
11
12 Whereas, Physicians without appropriate training supervising advanced practice providers
13 outside of their expertise defeats the purpose of scope-of-practice laws and endangers patients;
14 therefore be it
15
16 RESOLVED, That our American Medical Association conduct a systematic study to collect and
17 analyze publicly available physician supervision data from all sources to determine how many
18 allied health professionals are being supervised by physicians in fields which are not a core part
19 of those physicians' completed residencies and fellowships. (Directive to Take Action)

Fiscal Note: Estimated cost of $100,000 to implement resolution.

Received: 08/25/20

References:
1. Ornstein C and ProPublica. Illinois leads Medicare billings for group therapy. Chicago Tribune. 13 Jul 2014. https://www.chicagotribune.com/lifestyles/health/ct-medicare-group-therapy-met-20140713-story.html. Accessed 18 Sep 2019.
2. Al-agba N. The P.A. Problem: Who You See and What You Get. The Healthcare Blog. 24 Nov 2017. https://thehealthcareblog.com/blog/2017/11/24/the-p-a-problem/. Accessed 18 Sep 2019.

RELEVANT AMA POLICY:

Principles Guiding AMA Policy Regarding Supervision of Medical Care Delivered by Advanced Practice Nurses in Integrated Practice H-360.987

Our AMA endorses the following principles: (1) Physicians must retain authority for patient care in any team care arrangement, e.g., integrated practice, to assure patient safety and quality of care. (2) Medical societies should work with legislatures and licensing boards to prevent dilution of the authority of physicians to lead the health care team. (3) Exercising independent medical judgment to select the drug of choice must continue to be the responsibility only of physicians. (4) Physicians should recognize physician assistants and advanced practice nurses under physician leadership, as effective physician extenders and valued members of the health care

team. (5) Physicians should encourage state medical and nursing boards to explore the feasibility of working together to coordinate their regulatory initiatives and activities. (6) Physicians must be responsible and have authority for initiating and implementing quality control programs for nonphysicians delivering medical care in integrated practices.
Citation: BOT Rep. 23, A-96; Reaffirmation A-99; Reaffirmed: Res. 240, and Reaffirmation A-00; Reaffirmed: CMS Rep. 6, A-10; Reaffirmed: BOT Rep. 9, I-11; Reaffirmation A-12; Reaffirmed: BOT Rep. 16, A-13

Practice Agreements Between Physicians and Advance Practice Nurses and the Physician to Advance Practice Nurse Supervisory Ratio H-35.969
Our AMA will: (1) continue to work with the Federation in developing necessary state advocacy resource tools to assist the Federation in: (a) addressing the development of practice agreements between practicing physicians and advance practice nurses, and (b) responding to or developing state legislation or regulations governing these practice agreements, and that the AMA make these tools available on the AMA Advocacy Resource Center Web site; and (2) support the development of methodologically valid research comparing physician-APRN practice agreements and their respective effectiveness.
Citation: BOT Rep. 28, A-09; Reaffirmed: BOT Rep. 09, A-19

Physician Assistants and Nurse Practitioners H-160.947
Our AMA will develop a plan to assist the state and local medical societies in identifying and lobbying against laws that allow advanced practice nurses to provide medical care without the supervision of a physician. The suggested Guidelines for Physician/Physician Assistant Practice are adopted to read as follows (these guidelines shall be used in their entirety):
(1) The physician is responsible for managing the health care of patients in all settings.
(2) Health care services delivered by physicians and physician assistants must be within the scope of each practitioner's authorized practice, as defined by state law.
(3) The physician is ultimately responsible for coordinating and managing the care of patients and, with the appropriate input of the physician assistant, ensuring the quality of health care provided to patients.
(4) The physician is responsible for the supervision of the physician assistant in all settings.
(5) The role of the physician assistant in the delivery of care should be defined through mutually agreed upon guidelines that are developed by the physician and the physician assistant and based on the physician's delegatory style.
(6) The physician must be available for consultation with the physician assistant at all times, either in person or through telecommunication systems or other means.
(7) The extent of the involvement by the physician assistant in the assessment and implementation of treatment will depend on the complexity and acuity of the patient's condition and the training, experience, and preparation of the physician assistant, as adjudged by the physician.
(8) Patients should be made clearly aware at all times whether they are being cared for by a physician or a physician assistant.
(9) The physician and physician assistant together should review all delegated patient services on a regular basis, as well as the mutually agreed upon guidelines for practice.
(10) The physician is responsible for clarifying and familiarizing the physician assistant with his/her supervising methods and style of delegating patient care.
Citation: BOT Rep. 6, A-95; Reaffirmed: Res 240 and Reaffirmation A-00; Reaffirmed: Res. 213, A-02; Modified: CLRPD Rep. 1, A-03; Reaffirmed: BOT Rep. 9, I-11; Reaffirmed: Joint CME-CMS Rep., I-12; Reaffirmed: BOT Rep. 16, A-13

Regulation of Advanced Practice Nurses H-35.964
1. AMA policy is that advanced practice registered nurses (APRNs) should be subject to the jurisdiction of state medical licensing and regulatory boards for regulation of their performance of medical acts.
2. Our AMA will develop model legislation to create a joint regulatory board composed of members of boards of medicine and nursing, with authority over APRNs.
Citation: BOT Action in response to referred for decision Amendment B-3 to Res. 233 A-17

Guidelines for Integrated Practice of Physician and Nurse Practitioner H-160.950
Our AMA endorses the following guidelines and recommends that these guidelines be considered and quoted only in their entirety when referenced in any discussion of the roles and responsibilities of nurse practitioners: (1) The physician is responsible for the supervision of nurse practitioners and other advanced practice nurses in all settings.
(2) The physician is responsible for managing the health care of patients in all practice settings.
(3) Health care services delivered in an integrated practice must be within the scope of each practitioner's professional license, as defined by state law.
(4) In an integrated practice with a nurse practitioner, the physician is responsible for supervising and coordinating care and, with the appropriate input of the nurse practitioner, ensuring the quality of health care provided to patients.
(5) The extent of involvement by the nurse practitioner in initial assessment, and implementation of treatment will depend on the complexity and acuity of the patients' condition, as determined by the supervising/collaborating physician.
(6) The role of the nurse practitioner in the delivery of care in an integrated practice should be defined through mutually agreed upon written practice protocols, job descriptions, and written contracts.
(7) These practice protocols should delineate the appropriate involvement of the two professionals in the care of patients, based on the complexity and acuity of the patients' condition.
(8) At least one physician in the integrated practice must be immediately available at all times for supervision and consultation when needed by the nurse practitioner.
(9) Patients are to be made clearly aware at all times whether they are being cared for by a physician or a nurse practitioner.
(10) In an integrated practice, there should be a professional and courteous relationship between physician and nurse practitioner, with mutual acknowledgment of, and respect for each other's contributions to patient care.
(11) Physicians and nurse practitioners should review and document, on a regular basis, the care of all patients with whom the nurse practitioner is involved. Physicians and nurse practitioners must work closely enough together to become fully conversant with each other's practice patterns.
Citation: CMS Rep. 15 - I-94; BOT Rep. 6, A-95; Reaffirmed: Res. 240, A-00; Reaffirmation A-00; Reaffirmed: BOT Rep. 28, A-09; Reaffirmed: BOT Rep. 9, I-11; Reaffirmed: Joint CME-CMS Rep., I-12; Reaffirmed: BOT Rep. 16, A-13

Health Workforce H-200.994
The AMA endorses the following principle on health manpower: Both physicians and allied health professionals have legal and ethical responsibilities for patient care, even though ultimate responsibility for the individual patient's medical care rests with the physician. To assure quality patient care, the medical profession and allied health professionals should have continuing dialogue on patient care functions that may be delegated to allied health professionals consistent with their education, experience and competency. Citation: (BOT Rep. C, I-81; Reaffirmed: Sunset Report, I-98; Modified: CME Rep. 2, I-03; Reaffirmed: CME Rep. 2, A-13)

Health Care Quality Improvement Act of 1986 Amendments H-275.965
The AMA supports modification of the federal Health Care Quality Improvement Act in order to provide immunity from federal antitrust liability to those medical staffs credentialing and conducting good faith peer review for allied health professionals to the same extent that immunity applies to credentialing of physicians and dentists.
Citation: (Res. 203, A-88; Reaffirmed: Sunset Report, I-98; Reaffirmation A-05; Reaffirmed: BOT Rep. 10, A-15)The AMA supports modification of the federal Health Care Quality Improvement Act in order to provide immunity from federal antitrust liability to those medical staffs credentialing and conducting good faith peer review for allied health professionals to the same extent that immunity applies to credentialing of physicians and dentists. Citation: (Res. 203, A-88; Reaffirmed: Sunset Report, I-98; Reaffirmation A-05; Reaffirmed: BOT Rep. 10, A-15)

Protecting Physician Led Health Care H-35.966
Our American Medical Association will continue to work with state and specialty medical associations and other organizations to collect, analyze and disseminate data on the expanded use of allied health professionals, and of the impact of this practice on healthcare access (including in poor, underserved, and rural communities), quality, and cost in those states that permit independent practice of allied health professionals as compared to those that do not. This analysis should include consideration of practitioner settings and patient risk-adjustment. Citation: Res. 238, A-15; Reaffirmed: BOT Rep. 20, A-17;

Education Programs Offered to, for or by Allied Health Professionals Associated with a Hospital H-35.978
The AMA encourages hospital medical staffs to have a process whereby physicians will have input to and provide review of education programs provided by their hospital for the benefit of allied health professionals working in that hospital, for the education of patients served by that hospital, and for outpatient educational programs provided by that hospital. Citation: (BOT Rep. B, A-93; Adopts Res. 317, A-92; Reaffirmed: CME Rep. 2, A-03; Reaffirmed: CME Rep. 2, A-13)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 205
(November 2020)

Introduced by: Virginia, American Association of Clinical Urologists, West Virginia, North Carolina, New Jersey, South Carolina, Mississippi, Louisiana, American Urological Association, Maryland

Subject: Telehealth Post SARS-COV-2

Referred to: Reference Committee B

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1 Whereas, The Coronavirus Preparedness and Response Supplemental Appropriations Act
2 signed into law March 6, 2020 waives certain Medicare telehealth payment requirements during
3 the Public Health Emergency (PHE) and allows beneficiaries in all areas of the country to
4 receive telehealth services, including at home[1]; and
5
6 Whereas, Telehealth has allowed for the continuation of necessary healthcare in a secure and
7 safe manner during this pandemic; and
8
9 Whereas, Patients, depending on their location, age, and/or socioeconomic status, may face
10 barriers to accessing telehealth services due to inadequate access to technology, unreliable
11 broadband coverage, and/or lack of familiarity with technology[2]; and
12
13 Whereas, Our AMA has enacted policies, such as Policy D-480.965 which support increased
14 coverage and reimbursement for telehealth services; and
15
16 Whereas, Prior to COVID-19, the varied, confusing, and cumbersome rules/regulations made
17 telehealth difficult for the practicing physician to incorporate into their practice; and
18
19 Whereas, Both patients and their physicians now have enthusiastically adopted telehealth
20 services and technology; therefore be it
21
22 RESOLVED, That our American Medical Association advocate to facilitate the widespread
23 adoption of telehealth services in the practice of medicine for physicians or physician-led teams
24 post SARS-COV-2 (Directive to Take Action); and be it further
25
26 RESOLVED, That our AMA encourage the Centers for Medicare and Medicaid Services, health
27 insurance industry, and Federal/State government agencies to adopt uniform, clear regulations
28 as well as equitable coverage and reimbursement mechanisms that promote physician-led
29 telehealth services (New HOD Policy); and be it further
30
31 RESOLVED, That our AMA advocate for equitable access to telehealth services especially for
32 the most at risk and under resourced patient populations and communities. (Directive to Take
33 Action)

Fiscal Note: Modest - between $1,000 - $5,000

Received: 06/08/20

References:
[1] Robeznieks, A. (March 2020). Key Changes Made to Telehealth Guidelines to Boost COVID-10 Care. American Medical Association. Retrieved from https://www.ama-assn.org/delivering-care/public-health/key-changes-made-telehealth-guidelines-boost-covid-19-care
[2] Velasquex, D., & Mehrota, A. (May 2020). Ensuring the Growth of Telehealth During COVID-19 Does Not Exacerbate Disparities in Care. HealthAffairs. Retrieved from https://www.healthaffairs.org/do/10.1377/hblog20200505.591306/full/.

RELEVANT AMA POLICY

Reimbursement for Telehealth D-480.965

Our AMA will work with third-party payers, the Centers for Medicare and Medicaid Services, Congress and interested state medical associations to provide coverage and reimbursement for telehealth to ensure increased access and use of these services by patients and physicians.
Citation: Res. 122, A-19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 206
(November 2020)

Introduced by: Georgia

Subject: Strengthening the Accountability of Health Care Reviewers

Referred to: Reference Committee B

Whereas, Health care insurance companies and pharmacy benefits managers use of prior authorization is a mechanism to manage health care for patients; and

Whereas, The reviewers of these procedures are contracted by these corporations and, thus, may be located in areas throughout the United States; and

Whereas, It is well documented that the standard of care throughout the United States may vary depending on location, facilities, and population amongst many other criteria; and

Whereas, When a physician receives a decision for a proposed test or approval of treatment, there is no information on the person making the decision, including their experience or qualifications, prior to review to ensure a proper evaluation is carried out; and

Whereas, The decision of the reviewer not to approve a procedure or treatment may cause delay in the diagnosis or treatment that could be harmful to the patient; and

Whereas, Any decision rendered by the reviewer is not subject to independent peer review which would make the reviewer accountable for their decisions; and

Whereas, These reviewers are not subject to any investigation by the medical board in the state where the care occurs to explain their medical decision for any untoward event; and

Whereas, Practicing physicians today are always subject to review in this era of value-based care by hospitals, insurance companies, and CMS, yet reviewers are not; therefore be it

RESOLVED, That our American Medical Association advocate for legislation to require physicians contracted by health insurers or pharmacy benefit managers to possess an active license in the states where they review prior authorizations and be subject to the rules, statutes, medical board, and peer review of the state in which the prior authorization request is made (Directive to Take Action); and be it further

RESOLVED, That our AMA advocate for the repeal of the Employee Retirement Income Security Act (ERISA) as it pertains to prior authorization decisions. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000

Received: 09/28/20

RELEVANT AMA POLICY

External Grievance Review Procedures H-320.952
Our AMA establishes an External Grievance procedure for all health plans including those under the Affordable Care Act (ACA) with the following basic components:
(1) It should apply to all health carriers and Accountable Care Organizations;
(2) Grievances involving adverse determinations may be submitted by the policyholder, their representative, or their attending physician;
(3) Issues eligible for external grievance review should include, at a minimum, denials for (a) medical necessity determinations; and (b) determinations by carrier that such care was not covered because it was experimental or investigational;
(4) Internal grievance procedures should generally be exhausted before requesting external review;
(5) An expedited review mechanism should be created for urgent medical conditions;
(6) Independent reviewers practicing in the same state should be used whenever possible;
(7) Patient cost sharing requirements should not preclude the ability of a policyholder to access such external review;
(8) The overall results of external review should be available for public scrutiny with procedures established to safeguard the confidentiality of individual medical information;
(9) External grievance reviewers shall obtain input from physicians involved in the area of practice being reviewed. If the review involves specialty or sub-specialty issues the input shall, whenever possible, be obtained from specialists or sub-specialists in that area of medicine.
Citation: Res. 701, I-98; Reaffirmation I-99; Reaffirmation A-00; Reaffirmed: CMS Rep. 6, A-10; Reaffirmed: Res. 709, A-12; Modified: Res. 712, A-13; Reaffirmed in lieu of: Res. 242, A-17; Reaffirmation: I-17

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 207
(November 2020)

Introduced by: New York

Subject: AMA Position on All Payer Database Creation

Referred to: Reference Committee B

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1 Whereas, Organized medicine worked hard to push for the creation of the FAIRHEALTH
2 database, an independent database of charges; and
3
4 Whereas, Private health insurers are now pushing for legislation to create alternate databases
5 at the state and federal levels known as an All Payer Database; and
6
7 Whereas, The All Payer Database will reflect payments from all payers and as such will be
8 heavily weighted towards poor payments for physicians such as Medicare and Medicaid which
9 are generally lower payments than issued by commercial and self-insured plans; and
10
11 Whereas, Much of this information is already available; and
12
13 Whereas, The private insurers interest in such a database is to use it to replace the
14 FAIRHEALTH database and justify lower payments to physicians; and
15
16 Whereas, Much of the payment data for hospitals is not reliable because hospitals frequently
17 pay employed physicians at a much higher rate than the professional collections; therefore be it
18
19 RESOLVED, That our American Medical Association advocate that any All Payer Database
20 should also provide true payments that hospitals are making to their employed physicians, not
21 just the amount of payment that the insurer is making on the physician's behalf to the hospital.
22 (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000

Received: 10/09/20

RELEVANT AMA POLICY

Price Transparency D-155.987
1. Our AMA encourages physicians to communicate information about the cost of their professional services to individual patients, taking into consideration the insurance status (e.g., self-pay, in-network insured, out-of-network insured) of the patient or other relevant information where possible.
2. Our AMA advocates that health plans provide plan enrollees or their designees with complete information regarding plan benefits and real time cost-sharing information associated with both in-network and out-of-network provider services or other plan designs that may affect patient out-of-pocket costs.
3. Our AMA will actively engage with health plans, public and private entities, and other stakeholder groups in their efforts to facilitate price and quality transparency for patients and physicians, and help ensure that entities promoting price transparency tools have processes in place to ensure the accuracy and relevance of the information they provide.
4. Our AMA will work with states and the federal government to support and strengthen the development of all-payer claims databases.
5. Our AMA encourages electronic health records vendors to include features that assist in facilitating price transparency for physicians and patients.
6. Our AMA encourages efforts to educate patients in health economics literacy, including the development of resources that help patients understand the complexities of health care pricing and encourage them to seek information regarding the cost of health care services they receive or anticipate receiving.
7. Our AMA will request that the Centers for Medicare and Medicaid Services expand its Medicare Physician Fee Schedule Look-up Tool to include hospital outpatient payments.
Citation: CMS Rep. 4, A-15; Reaffirmed in lieu of: Res. 121, A-16; Reaffirmed in lieu of: Res. 213, I-17; Reaffirmed: BOT Rep. 14, A-18; Reaffirmed in lieu of: Res. 112, A-19; Modified: Res. 213, I-19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 208
(November 2020)

Introduced by: New York

Subject: Insurance Claims Data

Referred to: Reference Committee B

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1 Whereas, Insurance company claims data is a repository of public health information, utilization
2 information, practice patterns, and other important information; and
3
4 Whereas, The insurers utilize their claims data in order to develop policy, coverage
5 determinations, and pricing; and
6
7 Whereas, The insurers obtain the data from both at risk plans and plans for which they act in the
8 capacity of Third-Party Administrator (TPA); and
9
10 Whereas, Insurers typically do not share this data, asserting that it is proprietary; and
11
12 Whereas, Asymmetry of information is an impediment to more robust health policy, better and
13 more responsive health policy, more cost-effective policy and new entrants into the insurance
14 marketplace; therefore be it
15
16 RESOLVED, That our American Medical Association seek legislation and regulation to promote
17 open sharing of de-identified health insurance claims data. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000

Received: 10/09/20

RELEVANT AMA POLICY

Work of the Task Force on the Release of Physician Data H-406.990

Release of Claims and Payment Data from Governmental Programs

The AMA encourages the use of physician data to benefit both patients and physicians and to improve the quality of patient care and the efficient use of resources in the delivery of health care services. The AMA supports this use of physician data only when it preserves access to health care and is used to provide accurate physician performance assessments.

Raw claims data used in isolation have significant limitations. The release of such data from government programs must be subject to safeguards to ensure that neither false nor misleading conclusions are derived that could undermine the delivery of appropriate and quality care. If not addressed, the limitations of such data are significant. The foregoing limitations may include, but are not limited to, failure to consider factors that impact care such as specialty, geographic location, patient mix and demographics, plan design, patient compliance, drug and supply costs, hospital and service costs, professional liability coverage, support staff and other practice costs as well as the potential for mistakes and errors in the data or its attribution.

Raw claims and payment data resulting from government health care programs, including, but not limited to, the Medicare and Medicaid programs should only be released:

1. when appropriate patient privacy is preserved via de-identified data aggregation or if written authorization for release of individually identifiable patient data has been obtained from such patient in accordance with the requirements of the Health Insurance Portability and Accountability Act (HIPAA) and applicable regulations;
2. upon request of physicians [or their practice entities] to the extent the data involve services that they have provided;
3. to law enforcement and other regulatory agencies when there is reasonable and credible reason to believe that a specific physician [or practice entity] may have violated a law or regulation, and the data is relevant to the agency's investigation or prosecution of a possible violation;
4. to researchers/policy analysts for bona fide research/policy analysis purposes, provided the data do not identify specific physicians [or their practice entities] unless the researcher or policy analyst has (a) made a specific showing as to why the disclosure of specific identities is essential; and, (b) executed a written agreement to maintain the confidentiality of any data identifying specific physicians [or their practice entities];
5. to other entities only if the data do not identify specific physicians [or their practice entities]; or
6. if a law is enacted that permits the government to release raw physician-specific Medicare and/or Medicaid claims data, or allows the use of such data to construct profiles of identified physicians or physician practices. Such disclosures must meet the following criteria:
(a) the publication or release of this information is deemed imperative to safeguard the public welfare;
(b) the raw data regarding physician claims from governmental healthcare programs is:
(i) published in conjunction with appropriate disclosures and/or explanatory statements as to the limitations of the data that raise the potential for specific misinterpretation of such data. These statements should include disclosure or explanation of factors that influence the provision of care including geographic location, specialty, patient mix and demographics, health plan design, patient compliance, drug and supply costs, hospital and service costs, professional liability coverage, support staff and other practice costs as well as the potential for mistakes and errors in the data or its attribution, in addition to other relevant factors.
(ii) safeguarded to protect against the dissemination of inconsistent, incomplete, invalid or inaccurate physician-specific medical practice data.
(c) any physician profiling which draws upon this raw data acknowledges that the data set is not representative of the physicians' entire patient population and uses a methodology that ensures the following:
(i) the data are used to profile physicians based on quality of care provided - never on utilization of resources alone - and the degree to which profiling is based on utilization of resources is clearly identified.
(ii) data are measured against evidence-based quality of care measures, created by physicians across appropriate specialties.
(iii) the data and methodologies used in profiling physicians, including the use of representative and statistically valid sample sizes, statistically valid risk-adjustment methodologies and statistically valid attribution rules produce verifiably accurate results that reflect the quality and cost of care provided by the physicians.
(d) any governmental healthcare data shall be protected and shared with physicians before it is released or used, to ensure that physicians are provided with an adequate and timely opportunity to review, respond and appeal the accuracy of the raw data (and its attribution to individual physicians) and any physician profiling results derived from the analysis of physician-specific medical practice data to ensure accuracy prior to their use, publication or release.
Citation: BOT Rep. 18, A-09; Reaffirmed: BOT Rep. 09, A-19; Modified: Speakers Rep., A-19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 209
(November 2020)

Introduced by: New York

Subject: Physician Tax Fairness

Referred to: Reference Committee B

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1 Whereas, In 2018, President Trump signed the Tax Cuts and Jobs Act; and
2
3 Whereas, This legislation includes a tax break for owners of certain pass-through entities, many
4 of which include physician practices structured as such and can include S corporations,
5 partnerships and some limited liability companies; and
6
7 Whereas, This may benefit those who earn below the threshold of $207,500 or less for a single
8 filer (where the deduction phases out when taxable income exceeds $157,500) or $415,000 or
9 less for a married couple filing jointly (where the deduction phases out starting at $315,000); and
10
11 Whereas, The new tax law disallows this 20% deduction for taxpayers with income above the
12 threshold in specified service businesses which are defined as those in which the principal asset
13 is the reputation or skill of the owners and which category includes physicians; and
14
15 Whereas, Many physicians, especially those in two physician households, will not qualify under
16 the new tax law, and combined with the decrease in the deductions allowed for state and local
17 taxes, home mortgage, etc., many physicians have been adversely affected and will pay more in
18 taxes; and
19
20 Whereas, The effect of this law will be a continued trend of decreased physician self-
21 employment and thus overall lower physician reimbursement; therefore be it
22
23 RESOLVED, That our American Medical Association lobby that physicians be excluded from
24 being considered a specified service business as defined by the Internal Revenue Service.
25 (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000

Received: 10/09/20

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 210
(November 2020)

Introduced by: New York

Subject: Prohibit Ghost Guns

Referred to: Reference Committee B

Whereas, Homemade, difficult to trace firearms are increasingly turning up at crime scenes; and

Whereas, The most important part of a gun is the lower receiver - the 'chassis' of the weapon, the part housing vital components such as the hammer and trigger; and

Whereas, Under federal law, the lower receiver is considered a firearm - while other gun components do not require a background check for purchase; and

Whereas, Dozens of companies sell what are known as "80%" lower receivers - ones that are 80% finished, lack a serial number and can be used to make a homemade gun; and

Whereas, The Gun Control Act (1968) and the Brady Gun Violence Prevention Act (1993) allow for homemade weapons; and

Whereas, Ghost guns don't have any unique markings and therefore present black holes to police investigators; and

Whereas, Ghost guns provide an easy avenue for people banned from owning guns to obtain them; and

Whereas, According to the Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) 30% of all weapons recovered by the bureau in California were homemade; and

Whereas, These weapons have been connected with mass shootings, police shootouts and arms trafficking; therefore be it

RESOLVED, That our American Medical Association support state and federal legislation and regulation that would subject homemade weapons to the same regulations and licensing requirements as traditional weapons. (New HOD Policy)

Fiscal Note: Minimal - less than $1,000

Received: 10/09/20

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 211
(November 2020)

Introduced by: American Academy of Family Physicians, American College of Obstetricians and Gynecologists, American College of Physicians, Infectious Diseases Society of America, Oregon

Subject: Creating a Congressionally-Mandated Bipartisan Commission to Examine the U.S. Preparations for and Response to the COVID-19 Pandemic to Inform Future Efforts

Referred to: Reference Committee B

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1 Whereas, The United States has been the apparent epicenter of the global COVID-19 pandemic
2 and subsequent concerns arising about the United States' capabilities to mount a strategically
3 formulated and concerted response with regards to: effective testing strategies, timely directives
4 on appropriate utilization of social distancing directives, evidence-supported efforts to maintain
5 strategic stockpiles of Personal Protective Equipment (PPE) and ventilators; and
6
7 Whereas, Due to the complex interplay of local, state, and national agencies in pandemic
8 response, traditional academic institutions may not have the authority or resources to acquire all
9 information needed to effectively study and evaluate the United States' preparedness and
10 immediate response to the COVID-19 pandemic; and
11
12 Whereas, In recent historic national crisis - namely the September 11, 2001 terrorist attacks -
13 congressional leaders established the 9-11 commission which was an independent bipartisan
14 effort to prepare a full and complete account of the circumstances surrounding the
15 September 11, 2001 terrorist attacks, including preparedness for and the immediate response to
16 the attacks; and
17
18 Whereas, Commissioning a similar broad-reaching task force under the direction of
19 The United States Congress to complete a comprehensive review and report on the
20 United States' preparedness and immediate response to the COVID-19 pandemic will inform
21 preparation and response to future pandemics; therefore be it
22
23 RESOLVED, That our American Medical Association advocate for passage of federal legislation
24 to create a congressionally-mandated bipartisan commission composed of scientists, physicians
25 with expertise in pandemic preparedness and response, public health experts, legislators and
26 other stakeholders, which is to examine the U.S. preparations for and response to the
27 COVID-19 pandemic, in order to inform future public policy and health systems preparedness
28 (Directive to Take Action); and be it further
29
30 RESOLVED, That, in advocating for legislation to create a congressionally-mandated bipartisan
31 commission, our AMA seek to ensure key provisions are included, namely that the delivery of a
32 specific end product (i.e., a report) is required by the commission by a certain period of time,
33 and that adequate funding be provided in order for the commission to complete its deliverables.
34 (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000
Received: 10/13/20

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 212
(November 2020)

Introduced by: American College of Rheumatology, American Academy of Dermatology, American Academy of Neurology, American Academy of Ophthalmology, Association for Clinical Oncology, Georgia, Society for Investigative Dermatology, American College of Gastroenterology, New Jersey

Subject: Copay Accumulator Policies

Referred to: Reference Committee B

Whereas, Copay assistance funds are intended to help patients afford and maintain their medication; and

Whereas, Commercial payers have implemented copay accumulator polices that prevent copay assistance funds from being applied towards a patient's deductible; and

Whereas, Copay accumulator policies allow payers to collect the full amount of the copay assistance provided to the patient and also collect the full amount of the deductible directly from the patient to the financial detriment of the patient; and

Whereas, Copay accumulator policies negatively impact a patient's ability to afford the medications that have been prescribed by their physician by depriving them of the intended cost-savings designed to make the medication more affordable for the individual patient; and

Whereas, Copay assistance funds are often exhausted in the middle of a plan year, leaving patients to pay their full deductible out-of-pocket or discontinue their medication; and

Whereas, The largest commercial insurer in the United States will require physicians to report copay assistance data beginning January 1, 2021 for the express purpose of preventing the application of copay funds toward the patient deductible, thereby placing physicians in conflict with the welfare of their patients and violating the *AMA Code of Medical Ethics*; and

Whereas, It is of the highest urgency during this time of economic uncertainty and public health emergency that payers avoid policies that increase out-of-pocket costs so that patients can continue to afford their medication to improve outcomes and reduce associated morbidity and mortality; and

Whereas, In the current public health emergency it is of the highest urgency to ensure that patients can continue to afford their medications to avoid the dangerous and potentially fatal complications that are associated with COVID-19 infections and the presence of uncontrolled, or poorly controlled, comorbidities; and

Whereas, Even in the absence of the current public health emergency payers should not be permitted to collect copay assistance funds and also collect the full deductible to the patient's financial detriment; therefore be it

RESOLVED, That our American Medical Association with all haste directly engage and advocate for the adoption of proposed state legislation or regulation that would ban copay accumulator policies in state regulated health care plans, including Medicaid (Directive to Take Action); and be it further

RESOLVED, That our AMA with all haste directly engage and advocate for the adoption of proposed federal legislation or regulation that would ban copay accumulator policies in federally regulated ERISA plans. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000

Received: 10/14/20

RELEVANT AMA POLICY

Co-Pay Accumulators D-110.986
1. Our AMA will develop model state legislation regarding Co-Pay Accumulators for all pharmaceuticals, biologics, medical devices, and medical equipment.
Citation: Res. 205, I-19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 213
(November 2020)

Introduced by: American College of Allergy, Asthma and Immunology

Subject: Pharmacies to Inform Physicians When Lower Cost Medication Options are on Formulary

Referred to: Reference Committee B

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1 Whereas, Physicians often write prescriptions for medications not knowing that the patient's
2 insurance formulary offers a similar medication in the same class at a lower cost; and
3
4 Whereas, Many patients can't afford their medication because the copay is too high so they
5 leave the pharmacy without picking up the medication; and
6
7 Whereas, Pharmacists are not required to inform the physician of the availability of a lower-cost
8 option when one is available on the formulary; and
9
10 Whereas, Medical offices expend a great deal of time and non-reimbursed expense reviewing
11 formularies for patients and communicating back and forth with physicians, pharmacists, and
12 patients; and
13
14 Whereas, Healthcare costs could be reduced by solving this problem; therefore be it
15
16 RESOLVED, That our American Medical Association support legislation or regulatory action to
17 require that in the event a patient cannot afford the medication prescribed, either because it is
18 not on the formulary or it is priced higher than other medications on the formulary, the
19 pharmacist must communicate to the prescriber a medication option in the same class
20 prescribed with the lowest out-of-pocket cost to the patient. (New HOD Policy)

Fiscal Note: Minimal - less than $1,000

Received: 10/16/20

RELEVANT AMA POLICY

Prescription Drug Plans and Patient Access D-330.910
Our AMA will explore problems with prescription drug plans, including issues related to continuity of care, prior authorization, and formularies, and work with the Centers for Medicare and Medicaid Services and other appropriate organizations to resolve them.
Citation: Res. 135, A-14; Reaffirmed: CMS Rep. 05, A-19

Integration of Drug Price Information into Electronic Medical Records / Barriers to Price Transparency / Bidirectional Communication for EHR Software and Pharmacies / Health Plan, Pharmacy, Electronic Health Records Integration D-478.963
Our AMA will collaborate with other interested stakeholders to: (1) explore (a) current availability and accessibility of EHR, pharmacy and payer functionalities that enable integration of price, insurance coverage, formulary tier and drug utilization management policies, and patient cost information at the point of care, (b) at what levels barriers exist to this functionality or access, and (c) what is currently

being done to address these barriers; and (2) develop and implement a strategic plan for improving the availability and accessibility of real-time prescription cost information at the point of care.
Citation: BOT Rep. 14, A-18

Price of Medicine H-110.991
Our AMA: (1) advocates that pharmacies be required to list the full retail price of the prescription on the receipt along with the co-pay that is required in order to better inform our patients of the price of their medications; (2) will pursue legislation requiring pharmacies, pharmacy benefit managers and health plans to inform patients of the actual cash price as well as the formulary price of any medication prior to the purchase of the medication; (3) opposes provisions in pharmacies' contracts with pharmacy benefit managers that prohibit pharmacists from disclosing that a patient's co-pay is higher than the drug's cash price; (4) will disseminate model state legislation to promote drug price and cost transparency and to prohibit "clawbacks"; (5) supports physician education regarding drug price and cost transparency, manufacturers' pricing practices, and challenges patients may encounter at the pharmacy point-of-sale; and (6) work with relevant organizations to advocate for increased transparency through access to meaningful and relevant information about medication price and out-of-pocket costs for prescription medications sold at both retail and mail order/online pharmacies, including but not limited to Medicare's drug-pricing dashboard.
Citation: CMS Rep. 6, A-03; Appended: Res. 107, A-07; Reaffirmed in lieu of: Res. 207, A-17; Appended: Alt. Res. 806, I-17; Reaffirmed: BOT Rep. 14, A-18; Appended: CMS Rep. 07, A-18; Reaffirmation: A-19; Appended: Res. 126, A-19

Private Health Insurance Formulary Transparency H-125.979
1. Our AMA will work with pharmacy benefit managers, health insurers, and pharmacists to enable physicians to receive accurate, real-time formulary data at the point of prescribing.
2. Our AMA supports legislation or regulation that ensures that private health insurance carriers declare which medications are available on their formularies by October 1 of the preceding year, that formulary information be specific as to generic versus trade name and include copay responsibilities, and that drugs may not be removed from the formulary nor moved to a higher cost tier within the policy term.
3. Our AMA will develop model legislation (a) requiring insurance companies to declare which drugs on their formulary will be covered under trade names versus generic, (b) requiring insurance carriers to make this information available to consumers by October 1 of each year and, (c) forbidding insurance carriers from making formulary deletions within the policy term.
4. Our AMA will promote the following insurer-pharmacy benefits manager - pharmacy (IPBMP) to physician procedural policy: In the event that a specific drug is not or is no longer on the formulary when the prescription is presented, the IPBMP shall provide notice of covered formulary alternatives to the prescriber promptly so that appropriate medication can be provided to the patient within 72 hours.
5. Drugs requiring prior authorization, shall be adjudicated by the IPBMP within 72 hours of receipt of the prescription.
6. Our AMA (a) promotes the value of online access to up-to-date and accurate prescription drug formulary plans from all insurance providers nationwide, and (b) supports state medical societies in advocating for state legislation to ensure online access to up-to-date and accurate prescription drug formularies for all insurance plans.
7. Our AMA will continue its efforts with the National Association of Insurance Commissioners addressing the development and management of pharmacy benefits.
8. Our AMA will develop model state legislation on the development and management of pharmacy benefits.
Citation: Sub. Res. 724, A-14; Appended: Res. 701, A-16; Appended: Alt. Res. 806, I-17; Reaffirmed: CMS Rep. 07, A-18; Reaffirmed: BOT Rep. 20, A-19; Reaffirmed: CMS Rep. 05, A-19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 214
(November 2020)

Introduced by: Obesity Medicine Association

Subject: Increase Advocacy Efforts in Support of the Treat and Reduce Obesity Act

Referred to: Reference Committee B

Whereas, People living with obesity (BMI ≥ 30) are at high risk of suffering adverse health consequences when infected with COVID-19[i]; and

Whereas, The cornerstone of evidence-based obesity treatment is intensive lifestyle intervention (ILI); and

Whereas, Obesity has been recognized by our AMA as a disease[ii]; and

Whereas, Pharmacotherapy for obesity has been proven to safely and effectively double to triple the odds of losing 5-10% body weight, an amount that has been proven to prevent diabetes, improve blood pressure and decrease health care costs[iii]; and

Whereas, Providing people living with obesity these evidence-based tools will lower their risk of severe health consequences should they contract COVID-19; and

Whereas, Medicare does not allow payment for any anti-obesity medication (AOM) due to an out-of-date policy, which prohibits Medicare from covering any “drugs for weight loss or weight gain.”; and

Whereas, There are many evidence-based, effective and safe treatment options for obesity including intensive lifestyle intervention[iv,v,vi], pharmacotherapy[vii], and surgery[viii]; and

Whereas, Medicare restricts payment for ILI to primary care providers in the primary care setting, a setting where it is seldom offered. For this reason, this benefit is scarcely being used; and

Whereas, Our AMA "will work with national specialty and state medical societies to advocate for patient access to and physician payment for the full continuum of evidence-based obesity treatment modalities (such as behavioral, pharmaceutical, psychosocial, nutritional, and surgical interventions);"[ix] and

Whereas, Our AMA has already advocated for the Treat and Reduce Obesity Act (TROA - H.R. 1530, a bipartisan bill)[x] since the 114th Congress, having sent multiple letters in support, legislation that would eliminate the Medicare Part D prohibition on weight loss medications and allow other qualified health care providers such as registered dietitians and social workers to provide behavioral treatment; and

1 Whereas, TROA has been introduced to each Congress since 2012, yet in spite of these
2 advocacy efforts, TROA has not been passed leaving millions of Medicare recipients living with
3 obesity without access to the evidence-based treatments that can lower their Body Mass Index
4 to reduce their risk from obesity and their risk of a deadly health consequence from COVID-19;
5 therefore be it
6
7 RESOLVED, That our American Medical Association increase advocacy efforts towards the
8 passage of the Treat and Reduce Obesity Act. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000

Received: 10/19/20

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[i] https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html
[ii] AMA policy H-440.842
[iii] Milken Institute Report. http://www.milkeninstitute.org/publications/view/833. Accessed 1/15/2018
[iv] https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/obesity-in-adults-screening-and-management, accessed 1/15/2018
[v] Centers for Medicare and Medicaid Services (CMS), November 29th, 2011
[vi] Jensen MD et al. *J Am Coll Cardiol*. 2014;63(25 pt B):2985-3023
NIH / NHLBI, October 2000
[vii] https://doi.org/10.1210/jc.2015-1782, accessed 1/15/2018
[viii] http://www.nejm.org/doi/full/10.1056/NEJMoa066254#t=article, accessed 1/15/2018
[ix] Addressing Obesity D-440.954
[x] https://www.congress.gov/bill/116th-congress/house-bill/1530/text?r=8&s=1

Reference Committee C

CME Report(s)

01 An Update on Continuing Board Certification
02 Graduate Medical Education and the Corporate Practice of Medicine
03 Protection of Resident and Fellow Training in the Case of Hospital or Training Program Closure

Resolution(s)

301 Creating a More Accurate Accounting of Medical Education Financial Costs
302 Student Loan Forgiveness
303 CME for Preceptorship
304 Establishing Minimum Standards for Parental Leave During Graduate Medical Education Training
305 Parental Leave and Planning Resources for Medical Students
306 Retirement of the National Board of Medical Examiners Step 2 Clinical Skills Exam for US Medical Graduates: Call for expedited action by the American Medical Association
307 USMLE Step Examination Failures During the Covid-19 Pandemic
308 ECFMG 2024 Accreditation Requirement for World Federation Medical Education (WFME) Recognition
309* Preserve and Increase Graduate Medical Education Funding

**** contained in the Handbook Addendum***

REPORT 1 OF THE COUNCIL ON MEDICAL EDUCATION (November 2020)
An Update on Continuing Board Certification
(Resolutions 301-A-19 and 308-A-19)
(Reference Committee C)

EXECUTIVE SUMMARY

The Council on Medical Education has monitored continuing board certification (CBC) during the last year. This annual report, mandated by American Medical Association (AMA) Policy D-275.954, "Continuing Board Certification," provides an update on some of the changes that have occurred as a result of AMA efforts with the American Board of Medical Specialties (ABMS), ABMS member boards, and key stakeholders, to improve the CBC process.

In early 2018, the Continuing Board Certification: Vision for the Future Commission was established by the ABMS and charged with reviewing continuing certification within the current context of the medical profession. Later that year, the Council on Medical Education provided comments to strengthen the draft recommendations of the Commission. In February 2019, the Commission completed its final report based on research, testimony, and public feedback from stakeholders throughout the member boards and health care communities. The Commission's report contained 14 recommendations intended to modernize CBC so that it is meaningful, contemporary, and a relevant professional development activity for diplomates who are striving to be up to date in their specialty.[1] The ABMS and ABMS member boards, in collaboration with professional organizations and other stakeholders, agreed, prioritized these recommendations, and developed strategies to implement them. A summary of these strategies is provided in this report.

This report also highlights the following initiatives that are underway to improve CBC:

- The ABMS member boards have signaled their intent to offer alternatives to the high-stakes, 10-year examination. Three-fourths of the boards (75 percent) have completed or are administering longitudinal assessment pilots that combine adult learning principles with state-of-the-art technology, enabling delivery of assessments that promote learning and are less stressful. Appendix B in this report summarizes these new models.
- The ABMS member boards have broadened the range of acceptable activities that meet the Improvement in Medical Practice (IMP) requirements, including those offered at the physician's institution and/or individual practices, to address physician concerns about the relevance, cost, and burden associated with fulfilling the IMP requirements. Appendix B includes a summary of these initiatives.
- Studies published during the last year describe how new assessment models and IMP activities have resulted in improved quality and patient care and physician satisfaction. Appendix C provides a bibliography of recent studies and editorials published in peer-reviewed journals.

The Council on Medical Education is committed to ensuring that CBC supports physicians' ongoing learning and practice improvement and can assure the public that physicians are providing high-quality patient care. The Council will remain actively engaged in the implementation of the Commission's recommendations and continue to identify and suggest improvements to CBC programs.

REPORT OF THE COUNCIL ON MEDICAL EDUCATION

CME Report 1, November 2020

Subject: An Update on Continuing Board Certification (Resolutions 301-A-19 and 308-A-19)

Presented by: Liana Puscas, MD, MHS, Chair

Referred to: Reference Committee C

Resolution 301-A-19, "American Board of Medical Specialties Advertising," introduced by Virginia, the American Association of Clinical Urologists, Louisiana, and Mississippi and referred by the American Medical Association (AMA) House of Delegates (HOD), asks the AMA to oppose the use of any physician fees, dues, etc., for any advertising by the American Board of Medical Specialties or any of their component boards to the general public.

Resolution 308-A-19, "Maintenance of Certification Moratorium," introduced by New York and referred by the AMA HOD, asks the AMA to:

1. Call for an immediate end to the high stakes examination components as well as an end to the Quality Initiative (QI)/Practice Improvement (PI) components of Maintenance of Certification (MOC).
2. Call for retention of continuing medical education (CME) and professionalism components (how physicians carry out their responsibilities safely and ethically) of MOC only.
3. Petition the American Board of Medical Specialties for the restoration of certification status for all diplomates who have lost certification status solely because they have not complied with MOC requirements.

Policy D-275.954(1), "Continuing Board Certification," asks that the AMA continue to monitor the evolution of Continuing Board Certification (CBC), continue its active engagement in discussions regarding their implementation, encourage specialty boards to investigate and/or establish alternative approaches for CBC, and prepare a yearly report to the HOD regarding the CBC process." It should be noted that "CBC" is a new term for the MOC Program being used by the American Board of Medical Specialties (ABMS) Board of Directors and some ABMS member boards (other member boards are still referring to the program as MOC). Policy D-275.954 was revised in 2019 to be consistent with this change.

This report is in response to this policy and the two referenced resolutions noted above.

BACKGROUND

During the 2019 Annual Meeting, testimony before Reference Committee C was mixed regarding Resolution 301-A-19. Testimony noted that hospitals, insurance companies, malpractice insurers, and others often require board certification for a physician to practice medicine and that physicians are essentially required to maintain active certification and pay yearly fees to their specialty boards. Testimony also noted that, although the AMA maintains robust policy on CBC, including policy

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related to the cost of development and administration of the CBC components and transparency of finances of the ABMS and the ABMS member boards, this policy does not attempt to exert control over ABMS policies and procedures. In addition, this resolution is not consistent with AMA policy that supports informing the public about the value of board certification. Although the reference committee recommended that Resolution 301 not be adopted, the HOD voted to refer this resolution for further study.

Reference Committee C also heard mixed testimony regarding Resolution 308-A-19. It was stated that continuing certification has become another element that contributes to stress and burnout, and that many physicians find elements of continuous certification/MOC problematic. So, the Council on Medical Education continues to study the issues raised in this resolution. In addition, the ABMS convened a Stakeholders Council to address the recommendations of the recently released report of the Continuing Board Certification: Vision for the Future Commission that addresses some of these concerns. The AMA also has representation on the ABMS Continuing Certification Committee, which monitors and approves alternative models within the existing components of continuing certification. The committee is considering how to integrate the assessment of standards into everyday practice activities. The reference committee felt that a thorough review and analysis of the issues raised in this item was needed and recommended that Resolution 308 be referred with a report back to the HOD at the 2020 Annual Meeting.

CONTINUING BOARD CERTIFICATION: VISION FOR THE FUTURE COMMISSION

In early 2018, the Continuing Board Certification: Vision for the Future Commission (https://visioninitiative.org/), an independent body of 27 individuals representing diverse stakeholders, was established by the ABMS and charged with reviewing continuing certification within the current context of the medical profession. Later that year, the AMA Council on Medical Education provided comments to strengthen the draft recommendations of the Commission. In February 2019, the Commission completed its final report, which was the culmination of research, testimony, and public feedback from stakeholders throughout the member boards and health care communities. As noted in CME Report 2-A-19, the Commission's report contained 14 recommendations intended to modernize CBC so that it is meaningful, contemporary, and a relevant professional development activity for diplomates who are striving to be up to date in their specialty.[1] The ABMS and ABMS member boards, in collaboration with professional organizations and other stakeholders, agreed, prioritized these recommendations, and developed the following strategies as first steps to implement them:

- Creation of the "Achieving the Vision for Continuing Board Certification" Oversight Committee, charged with directing the implementation strategy.

- Establishment of the following task forces to implement key recommendations outlined by the Commission in its final report.
  - Standards Task Force – will obtain appropriate input from stakeholders including practicing physicians to develop new, integrated continuing certification standards, consistent with the Commission's recommendations, which will be implemented by the ABMS member boards.
  - Advancing Practice Task Force – will engage specialty societies, the Council on Medical Education, continuing professional development communities, and other expert stakeholders to identify practice environment changes necessary to support learning and improvement activities that produce data-driven advances in physicians' clinical practices.
  - Information and Data Sharing Task Force – will make recommendations regarding the processes and infrastructure necessary to facilitate data and information sharing between

ABMS member boards and key stakeholders in order to support development of future educational and assessment programs and activities.

- Professionalism Task Force – will address the aspirational Commission recommendation calling for the ABMS and the ABMS member boards to develop approaches to evaluate professionalism and professional standing and will work with other stakeholder organizations to explore approaches to future assessment of professionalism and enhance consistency in judgments regarding professional standards.
- Remediation Task Force – will define aspects and suggest pathways for remediation of gaps prior to certification loss as well as pathways for regaining eligibility after loss of certification.

- Agreement of all 24 ABMS member boards to commit to longitudinal or other formative assessment strategies and offer alternatives to the highly secure, point-in-time examinations of knowledge.

- Commitment by the ABMS to develop new, integrated standards for continuing certification programs by 2020. The standards will address the Commission recommendations for flexibility in knowledge assessment and advancing practice, feedback to diplomates, and consistency.

Additional information about the progress of the ABMS and member boards is available at: vision.abms.org.

CONTINUING BOARD CERTIFICATION: AN UPDATE

The AMA Council on Medical Education and the HOD have carried out extensive and sustained work in developing policy on CBC (Appendix A), including working with the ABMS and the American Osteopathic Association (AOA) to provide physician feedback to improve the CBC processes, informing our members about progress on CBC through annual reports to the HOD, and developing strategies to address the concerns about the CBC processes raised by physicians. The Council has prepared reports covering CBC (formerly known as Maintenance of Certification and Osteopathic Continuous Certification) for the past 11 years.[1-11] During the last year, Council members, AMA trustees, and AMA staff have participated in the following meetings with the ABMS and its member boards:

- ABMS Committee on Continuing Certification
- ABMS Stakeholder Council
- ABMS 2019 Conference
- ABMS Board of Directors Meeting
- Academic Physicians Section November 2019 Meeting
- AMA/ABMS March 2020 Joint Meeting

ABMS Committee on Continuing Certification

The ABMS Committee on Continuing Certification (3C) is charged with overseeing the review process to CBC programs as well as policies and procedures. During 2018 and 2019, the 3C approved substantive program changes that have been implemented and announced new active pilot programs intended to enhance relevance to practice and improve diplomate satisfaction, while maintaining the rigor of educational, assessment, and improvement components. The 3C and the individual member boards continue to receive input from experts who research physician competence and administer assessment programs to discuss the future development of continuing professional development programs as well as security considerations, performance standards, and

psychometric characteristics of longitudinal assessment programs. Additionally, the 3C is currently addressing issues of importance to multiple certificate holders, holders of co-sponsored certificates, and physicians trained through non-Accreditation Council for Graduate Medical Education-approved pathways.

ABMS Stakeholder Council

Formed in 2018, the Stakeholder Council is an advisory body representing the interests of active diplomate physicians, patients, and the public. It was established to ensure that the decisions of the ABMS Board of Directors are grounded in an understanding of the perspectives, concerns, and interests of the multiple constituents impacted by the ABMS's work. The Stakeholder Council also provides guidance to the Achieving the Vision Oversight Commission as it rolls out the Achieving the Vision implementation plan.

At its May 2019 meeting, the Stakeholder Council discussed how the ABMS and its member boards can effectively communicate the evolving process of continuing certification that better balances learning and assessment, in enhancing its value to physicians while meeting the needs of the public for a meaningful credential. Issues identified as an important part of the Council's charge included sharing research, promoting best practices for new/emerging technologies, developing novel assessment techniques, aligning continuing certification activities with national reporting and licensure requirements, strengthening relationships between boards and specialty societies, and engaging in patient advocacy.

ABMS Accountability and Resolution Committee

In 2018, the ABMS also established the Accountability and Resolution Committee (ARC). The ARC, which is comprised of members of the ABMS Board of Directors on a rotating basis, including the Board's public members, is authorized by the ABMS Board to address and make recommendations regarding complaint resolution and allegations of noncompliance by the member boards, when issues have not been resolved through other mechanisms. The ARC is intended to collectively empower the larger ABMS member board community and promote shared accountability and responsibility.

Academic Physicians Section November 2019 Meeting

The November 2019 Academic Physicians Section featured a CME session, "Update on ABMS Continuing Board Certification," that was cosponsored by the Council on Medical Education and Young Physicians Section. The panel discussed the new paradigm of CBC, which has replaced MOC, the advantages of participation in CBC, and the current position of the AMA and its contributions to improvements in MOC/CBC, based on Council on Medical Education reports and AMA policy.

AMA/ABMS March 2020 Joint Meeting

On March 16, the Council on Medical Education facilitated a joint conference call with the ABMS and representatives from some of the ABMS member boards to hear an update on the work of the ABMS Standards Task Force formed to develop new continuing certification standards consistent with the recommendations of the Vision for the Future Commission. The draft revised Standards for the ABMS Program for Continuing Board Certification were also presented to the Council. The ABMS plans to circulate the revised standards for public comment in late summer. The Council also plans to schedule an additional meeting with the ABMS and the ABMS member boards in

2020 to discuss the work of the other four task forces that are implementing the charges of the Commission.

Update on New Continuing Medical Education Models

The ABMS Continuing Certification Directory™ (https://www.abms.org/initiatives/abms-continuing-certification-directory/) continues to offer physicians access to a comprehensive, centralized, web-based repository of CME activities that have been approved for CBC credit by the ABMS member boards. Users can search practice-relevant activities that have been approved by one or more member boards. During the past year, the directory has increased its inventory and now indexes more than 1,000 open-access accredited CME activities from more than 60 CME providers, including Opioid Prescriber Education Programs, to help diplomates from across specialties meet CBC requirements for Lifelong Learning and Self-Assessment (Part II) and Improvement in Medical Practice (Part IV). Many of the member boards collaborate with specialty societies to develop continuing certification and/or CME activities through which physicians can satisfy CBC requirements.

The following types of activities are currently included in the directory: internet enduring activities, journal-based CME, internet point of care, live activities, and performance improvement CME. All CME activities are qualified to award credit(s) from one or more of the CME credit systems: *AMA PRA Category 1 Credit™,* American Academy of Family Physicians (AAFP) Prescribed Credit, American College of Obstetricians and Gynecologists (ACOG) Cognates, and AOA Category 1-A.

Many member boards also employ technology to personalize assessments that promote greater self-awareness and support participation in CME. For example, the American Board of Anesthesiology (ABA) is now able to link assessment results from its MOCA Minute® program with CME opportunities. More than half (53 percent) of MOCA Minute® questions can be linked to at least one CME activity, and more than 110 accredited CME providers have been able to link a combined total of 3,261 activities to the MOCA content outline.[12] This technology facilitates identification of knowledge gaps and targets learning strategies.

Update on Innovative Knowledge Assessments being Offered as an Option to the Secure, High-Stakes Examination

The ABMS member boards have signaled their intent to offer alternatives to the high-stakes, 10-year examination. Twenty-three ABMS member boards (95.8 percent) have moved away from the secure, high-stakes exam, and more than 90 percent have completed, or will soon be launching assessment pilots that combine adult learning principles with state-of-the-art technology, enabling delivery of assessments that promote learning and are less stressful (Appendix B).

Fourteen member boards have implemented and/or are piloting a longitudinal assessment approach which involves administering shorter assessments of specific content, such as medical knowledge, repeatedly over a period of time. Seven of these boards are using CertLink® a technology platform developed by the ABMS to support the boards in delivering more frequent, practice-relevant, and user-friendly competence assessments to physicians (https://www.abms.org/initiatives/certlink-platform-and-pilot-programs/). This platform provides technology to enable boards to create assessments focused on practice-relevant content; offers convenient access on desktop or mobile device (depending on each board's program); provides immediate, focused feedback and guidance to resources for further study; and provides a personalized dashboard that displays participating physicians' areas of strength and weakness. In a recent ABMS survey, 95 percent of physicians using CertLink® indicated a reduction in test anxiety, 98 percent preferred CertLink® and

longitudinal assessment over the every-10-year exam, and most considered CertLink® as a feasible method for keeping up-to-date with developments and an adequate assessment of fundamental knowledge used in everyday practice.[13] To date, more than 10,000 physicians are active on CertLink® and have answered more than 800,000 questions across the seven member boards.

The transition to new, formative approaches to the assessment of knowledge and clinical judgment has created unique opportunities for ABMS member boards and specialty societies to work together to design the future of continuing board certification. The American Board of Internal Medicine (ABIM), American Board of Obstetrics and Gynecology (ABOG), and American Board of Plastic Surgery are adopting these new approaches.[14]

The ABIM also announced that it anticipates launching a longitudinal assessment option in 2022 in as many specialties as possible.[15] As part of this option, internists will be able to:

- Answer a question at any place or time and receive immediate feedback;
- See the rationale behind the answer, along with links related to educational material;
- Proceed at their preferred pace answering questions during each administration window; and,
- Access all the resources used in practice, such as journals or websites.

The ABIM has invited the internal medicine community to provide suggestions on this new pathway through its Community Insights Network and share feedback through surveys, interviews, user tests, and ABIM's online community ABIM Engage.[15] The ABIM convened a Physician Advisory Panel from members of the Community Insights Network representing a range of practice settings, specialties, and geographies to provide input and feedback throughout the project's development and implementation. The ABIM staff are attending society meetings throughout 2020 to offer physicians individualized guidance and ask for their feedback. ABIM will also work with interested societies to explore ways of linking ABIM assessment content with society educational materials.

Other member board efforts to improve knowledge assessments include more diplomate input into exam content; integrating journal article-based core questions into assessments; modularization of exam content that allows for tailoring of assessments to reflect physicians' actual areas of practice; access during the exam to knowledge resources similar to those used at the point of care; remote proctoring to permit diplomates to be assessed at home or in their office; and performance feedback mechanisms. All boards also provide multiple opportunities for physicians to retake the exam. These program enhancements will significantly reduce the cost diplomates incur to participate in CBC by reducing the need to take time off or travel to a testing center to prepare for the assessment; ensure that the assessment is practice-relevant; emphasize the role of assessment for learning; assure opportunities for remediation of knowledge gaps; and reduce the stress associated with a high-stakes test environment.

Seventeen member boards have retained the traditional secure exam option for reentry purposes and for diplomates who prefer this exam method. The American Board of Urology has customized its traditional secure exam to practice with feedback and assigns CME for areas of substandard performance on the exam.

Progress with Refining Part IV, Improvement in Medical Practice

The ABMS member boards have broadened the range of acceptable activities that meet the Improvement in Medical Practice (IMP) requirements, including those offered at the physician's institution and/or individual practices, to address physician concerns about the relevance, cost, and burden associated with fulfilling the IMP requirements (Appendix B). In addition to improving alignment between national value-based reporting requirements and continuing certification programs, the boards are implementing several activities related to registries, practice audits, and systems-based practice.

Patient registries (also known as clinical data registries) provide information to help physicians improve the quality and safety of patient care—for example, by comparing the effectiveness of different treatments for the same disease. While many member boards allow physicians to earn Part IV credit for participating in externally developed patient registries, the American Board of Ophthalmology, American Board of Otolaryngology-Head and Neck Surgery, and American Board of Family Medicine have designed board-specific initiatives that are supported by registry data.

Several ABMS member boards have developed online practice assessment protocols that allow physicians to assess patient care using evidence-based quality indicators. For example:

- The American Board of Pediatrics (ABP) and American Board of Radiology (ABR) offer free tools to complete an IMP project, including a simplified and flexible template to document small improvements, educational videos, infographics, and enhanced web pages;
- The American Board of Preventive Medicine has partnerships with specialty societies to design quality and performance improvement activities for diplomates with a population-based clinical focus;
- Fourteen boards have successfully integrated patient experience and peer review into several of the boards' IMP requirements (the American Board of Psychiatry and Neurology has aggressively addressed the issue of cost and unnecessary procedures with an audit and feedback program);
- Six boards including the ABA and ABOG, have integrated simulation options; and
- Two boards (the ABP and ABR) have a process for individual physicians to develop their own improvement exercises that address an issue of personal importance, using data from their own practices, built around the basic Plan-Do-Study-Act (PDSA) process.

The ABMS member boards are aligning CBC activities with other organizations' QI efforts to reduce redundancy and physician burden while promoting meaningful participation. Eighteen of the boards encourage participation in organizational QI initiatives through the ABMS Multi-Specialty Portfolio Program™ (described below). Many boards encourage involvement in the development and implementation of safety systems or the investigation and resolution of organizational quality and safety problems. For physicians serving in research or executive roles, some boards have begun to give IMP credit for having manuscripts published, writing peer-reviewed reports, giving presentations, and serving in institutional roles that focus on QI (provided that an explicit PDSA process is used). Physicians who participate in QI projects resulting from morbidity and mortality conferences and laboratory accreditation processes resulting in the identification and resolution of quality and safety issues can also receive IMP credit from some boards.

ABMS Multi-Specialty Portfolio Program

The ABMS Multi-Specialty Portfolio Program (Portfolio Program™) offers health care organizations a way to support physician involvement in their institution's quality and performance improvement initiatives by offering credit for the IMP component of the ABMS Program for MOC (mocportfolioprogram.org). Originally designed as a service for large hospitals, the Portfolio Program™ is extending its reach to physicians whose practices are not primarily in institutions. This includes non-hospital organizations such as academic medical centers, integrated delivery systems, interstate collaboratives, specialty societies, and state medical societies. More than 3,735 types of QI projects have been approved by the Portfolio Program™ in which 18 ABMS member boards participate, focusing on such areas as advanced care planning, cancer screening, cardiovascular disease prevention, depression screening and treatment, provision of immunizations, obesity counseling, patient-physician communication, transitions of care, and patient-safety-related topics including sepsis and central line infection reduction. Many of these projects have had a profound impact on patient care and outcomes. There have been nearly 32,000 instances of physicians receiving IMP credit through participation in the program. Recent additions among the nearly 100 current sponsors include Abt Associates, Lexington Medical Center, Gundersen Health System, Aspirus, and Dayton Children's Hospital.

Update on the Emerging Data and Literature Regarding the Value of CBC

The Council on Medical Education has continued to review published literature and emerging data as part of its ongoing efforts to critically review CBC issues. The annotated bibliography in Appendix C provides a summary of recent studies and editorials published in peer-reviewed journals on the following topics:

- Continuing medical education—A recent article explains new options for completing CME to meet the American Board of Surgery's CBC requirements.

- Knowledge assessments—Recently published articles provide information on the implementation of innovative knowledge assessment programs, such as the longitudinal approach, and describe how physicians prepare for assessments. Several studies show that examination performance correlates with better learning and retention of information and in many instances results in practice changes and better patient care.

- Association between continuous certification and practice related outcomes—Several peer-reviewed studies demonstrate the benefits of participating in a practice improvement program and show that integrating quality and patient safety activities in board-approved continuing certification programs is associated with quality care and improved patient outcomes.

- The impact of continuous certification on medical licensure—Recent studies show that examination performance and level of participation are associated with disciplinary action against medical licensure.

- ABMS and ABMS member board policies and initiatives—Several articles describe the ABMS Vision for the Future Commission's recommendations and the ABMS and ABMS member boards implementation plans.

- Physician satisfaction with continuous certification—Four studies describe physician satisfaction levels with new CBC requirements and longitudinal assessments.

- Concerns about CBC—These editorials discuss the lingering discontent with participation in continuing certification in order to satisfy federal government, insurer, employer, and credentialing requirements. Concerns about the cost, time, value, and relevance to practice are also discussed.

- Challenges and considerations—Two articles review current issues and challenges associated with CBC.

OSTEOPATHIC CONTINUOUS CERTIFICATION: AN UPDATE

The AOA Department of Certifying Board Services assists the osteopathic medical specialty certifying boards with the development and implementation of certification programs and assessments. Under the guidance of the AOA Bureau of Osteopathic Specialists, the specialty certifying boards are committed to enhancing certification services to better serve candidates and diplomates pursing and maintaining AOA certification.

In October 2019, the American Osteopathic Board of Family Physicians established an early entry pathway for initial board certification in family medicine. Physicians who meet eligibility requirements and complete two osteopathic in-service examinations may pursue specialty board certification while still completing residency. Upon passing the Early Entry Initial Certification board certification exam in the final year of residency, diplomates will begin the process of Osteopathic Continuous Certification (OCC).

The American Osteopathic Board of Internal Medicine (AOBIM) will offer an early entry examination for candidates pursuing initial certification beginning in March 2020. The early entry examination provides flexibility and options for completing examination requirements pursuant to certification for internal medicine residents.

The AOA is developing options for future certification and continuous certification pathways in recognition of the uniqueness of the contemporary practice of medicine and the value of flexible and sustainable certification models. In recognition of the osteopathic-centered approach to patient assessment, evaluation, and treatment, the certification pathways will focus on targeting the medical knowledge, skills, and critical thinking of the competent practicing physician.

Leading the charge for innovation and change, the American Osteopathic Board of Radiology implemented a self-assessment module (SAM) to meet the cognitive assessment OCC requirement, replacing the 10-year interval examination. Following suit, the American Osteopathic Board of Anesthesiology and American Osteopathic Board of Obstetrics and Gynecology have recently launched innovative assessment models in fulfillment of the requirement to demonstrate competency in specialty medical subject matter. The new models provide increased flexibility by leveraging technology to deliver content at prescribed intervals, relevant to the specialty board's scope of practice.

Four additional boards—the American Osteopathic Board of Family Physicians, American Osteopathic Board of Emergency Medicine, American Osteopathic Board of Internal Medicine, and the American Osteopathic Board of Surgery—are pursuing changes to their cognitive assessment component of OCC in 2020 to provide a fluid, adaptive process to the diplomates.

The AOA offers board certification in 27 primary specialties and 49 subspecialties (including certifications of added qualifications). Nine of the 49 subspecialties are conjoint certifications

managed by multiple AOA specialty boards. As of May 31, 2019, a total of 34,294 osteopathic physicians held 39,968 active certifications issued by the AOA's specialty certifying boards. During the 2019 membership year, 2,376 new certifications were processed:

- Primary Specialty: 1,925
- Subspecialty: 386
- Certification of Added Qualifications (Family Medicine and Preventive Medicine only): 65

During the 2019 membership year, 1,644 osteopathic continuing certifications were processed.

ABMS ADVERTISING

Resolution 301-A-19, "American Board of Medical Specialties Advertising" asks that the AMA oppose the use of any physician fees, dues, etc., for any advertising by the ABMS or any of their component boards to the general public. The ABMS does not have any public marketing campaigns. However, the ABMS does have "Certification Matters," a public website that provides information on currently certified physicians. The purpose of the site is to provide consumers with a free resource to confirm that a physician they are considering is certified by an ABMS member board. There is some paid promotion of the site to increase awareness of its existence, and the ABMS published articles in two of its newsletters when the website was launched.

In August 2011, the ABMS began to display the CBC participation status of member board-certified physicians online (www.CertificationMatters.org). The information displayed includes the physician's name, certifying board(s), and "yes" or "no" as to whether the physician is meeting CBC standards. The AOA (though not mentioned in the resolution, the AOA maintains a continuous certification program) also provides information about the OCC status of member board-certified physicians upon request through its online DO Directory (www.doprofiles.org).

The ABMS website is being revised due to a request from the AMA adopted at the 2017 Annual Meeting, based on AMA Policy H-275.924 (26), which states, "The initial certification status of time-limited diplomates shall be listed and publicly available on all American Board of Medical Specialties (ABMS) and ABMS Member Boards' websites and physician certification databases. The names and initial certification status of time-limited diplomates shall not be removed from ABMS and ABMS Member Boards' websites or physician certification databases even if the diplomate chooses not to participate in MOC."

It is important to note that board certification assures the public that an independent third party has evaluated a physician's skills and abilities and that a physician conducts his or her practice according to a professional code of ethics and remains current with medical practices and procedures. Studies show that the public values physicians' participation in a board certification program and that the public views board certification as an important marker of trust regarding quality care.

During the past two years, the ABMS has funded research to better understand the public's perception of board certification and a small communication program to promote its value. The research included qualitative (focus groups) and quantitative (National Opinion Research Center at the University of Chicago) survey research. The communication program included posted social media (no costs) and promoted social media (under $25,000). ABMS funding comes from general revenue sources, including dues from ABMS member boards, and non-dues revenue sources, including ABMS' credentials verification service—ABMS Solutions, which serves as a leading method of primary source verification of a physician's board certification status to hospitals, health

systems, and insurers across the county. Through research the ABMS has confirmed that consumers implicitly understand that certification is important and look for information about it when they seek care for themselves and their families. In addition, ABMS board certification is frequently highlighted in consumer media stories which requires no direct costs.

The AMA's "Truth in Advertising" campaign highlights the need to improve transparency, clarity, and reliability of physician credentials for the patient and public. The AMA opposes any action, regardless of intent, that appears likely to confuse the public about the unique credentials of ABMS- or AOA-BOS-board certified physicians in any medical specialty or that takes advantage of the prestige of any medical specialty for purposes contrary to the public good and safety (H-275.926 [1], Maintaining Medical Specialty Board Certification Standard.)

The ABMS currently does not have plans to increase investments in the paid public promotion of board certification. However, it is important for the ABMS to reserve the right to advertise and promote board certification to build awareness and accurately communicate its value to the public. The more than 900,000 ABMS board certified physicians derive value from a trusted and recognized credential.[16] This is especially important considering competitive communications for other professions and credentials, some of which are much less rigorous.

While the AMA maintains robust policy on CBC, including policy related to the cost of development and administration of the CBC components, this policy does not attempt to exert control over ABMS/AOA policies and procedures. Existing AMA Policy H-275.924 (19) states that "the CBC process should be reflective of and consistent with the cost of development and administration of the CBC components, ensure a fair fee structure, and not present a barrier to patient care." Policy D-275.954 (9, 10) also states that our AMA will "encourage the ABMS to ensure that all ABMS member boards provide full transparency related to the costs of preparing, administering, scoring and reporting CBC and certifying examinations" and "encourage the ABMS to ensure that CBC and certifying examinations do not result in substantial financial gain to ABMS member boards, and advocate that the ABMS develop fiduciary standards for its member boards that are consistent with this principle."

CURRENT AMA POLICIES RELATED TO CBC

As noted above, the ABMS Board of Directors and some of the ABMS member boards are currently using a new name, "Continuing Board Certification," for their MOC Program (although some ABMS member boards are still referring to the program as MOC). To be consistent with this change, AMA policy was revised in 2019 to change the terms "Maintenance of Certification" that appeared in HOD Policies H-275.924, "AMA Principles on Maintenance of Certification," and D-275.954, "Maintenance of Certification and Osteopathic Continuous Certification," to "Continuing Board Certification" or "CBC," as shown in Appendix A.

DISCUSSION

The Council on Medical Education is actively engaged in the implementation of the Vision for the Future Commission's recommendations to improve the process for approximately 590,000 physicians who participate in CBC.[13] The member boards are engaging physicians in surveys and focus groups and in their committee appointments. This report highlights the progress the ABMS and ABMS member boards have made to ease the burden and improve the CBC process for physicians.

Resolution 308-A-19, "Maintenance of Certification Moratorium," calls for the immediate end to the high-stakes examination components and the quality initiative/practice improvement components of MOC. However, as noted in this report, the ABMS member boards have moved away from the secure high-stakes secure examination and more than three-fourths of the boards have completed (or soon will be launching) assessment pilots that combine adult learning principles with state-of-the-art technology, enabling delivery of assessments that are a more relevant, less onerous, and cost-efficient process for physicians. Appendix B in this report summarizes these new models. The ABMS member boards have also broadened the range of acceptable activities that meet the IMP requirements, including those offered at the physician's institution and/or individual practices, to address physician concerns about the relevance, cost, and burden associated with fulfilling the IMP requirements. Appendix B also includes a summary of these initiatives.

The second item in Resolution 308-A-19 calls for the retention of CME and professionalism components (how physicians carry out their responsibilities safely and ethically) of MOC only. Existing HOD Policy D-275.954 (32) already states, "Our AMA will…Continue to support the requirement of CME and ongoing, quality assessments of physicians, where such CME is proven to be cost-effective and shown by evidence to improve quality of care for patients." This policy aligns with the AMA *Code of Medical Ethics* which states, "Physicians should strive to further their medical education throughout their careers, to ensure that they serve patients to the best of their abilities and live up to professional standards of excellence. Participating in certified continuing medical education (CME) activities is critical to fulfilling this professional commitment to lifelong learning."[17] The Council on Medical Education is committed to ensuring that CBC programs support physicians' ongoing learning and practice improvement and serve to assure the public that physicians are providing high-quality patient care.

The third item in Resolution 308-A-19, asking that certification status be restored for all diplomates who have lost certification status solely because they have not complied with MOC requirements, will be addressed by the recently established ABMS Remediation Task Force. As noted in this report, the ABMS established the Task Force to address the Vision Commission's eighth recommendation, which reads, "The ABMS Boards must have clearly defined remediation pathways to enable diplomates to meet continuing certification standards in advance of and following any loss of certification." The Task Force will be responsible for defining aspects and suggest pathways for remediation of gaps prior to certification loss as well as pathways for regaining eligibility after loss of certification.

SUMMARY AND RECOMMENDATIONS

Throughout the past year, the Council has continued to monitor the development of continuing board certification programs and to work with the ABMS, ABMS member boards, AOA, and state and specialty medical societies to identify and suggest improvements to these programs. The AMA has also been actively engaged in the implementation of the Continuing Board Certification: Vision for the Future Commission's recommendations for the future continuing board certification process.

The Council on Medical Education therefore recommends that the following recommendation be adopted in lieu of Resolutions 301-A-19 and 308-A-19 and the remainder of the report be filed.

1. That our American Medical Association (AMA), through its Council on Medical Education, continue to work with the American Board of Medical Specialties (ABMS) and ABMS member boards to implement key recommendations outlined by the Continuing Board Certification: Vision for the Future Commission in its final report, including the development of new, integrated standards for continuing certification programs by 2020 that will address the Commission's recommendations for flexibility in knowledge assessment and advancing practice, feedback to diplomates, and consistency. (New HOD Policy)

Fiscal Note: $2,500.

APPENDIX A:
CURRENT HOD POLICIES RELATED TO CONTINUING BOARD CERTIFICATION

H-275.924, "Continuing Board Certification"

AMA Principles on Continuing Board Certification
1. Changes in specialty-board certification requirements for CBC programs should be longitudinally stable in structure, although flexible in content.
2. Implementation of changes in CBC must be reasonable and take into consideration the time needed to develop the proper CBC structures as well as to educate physician diplomates about the requirements for participation.
3. Any changes to the CBC process for a given medical specialty board should occur no more frequently than the intervals used by that specialty board for CBC.
4. Any changes in the CBC process should not result in significantly increased cost or burden to physician participants (such as systems that mandate continuous documentation or require annual milestones).
5. CBC requirements should not reduce the capacity of the overall physician workforce. It is important to retain a structure of CBC programs that permits physicians to complete modules with temporal flexibility, compatible with their practice responsibilities.
6. Patient satisfaction programs such as The Consumer Assessment of Healthcare Providers and Systems (CAHPS) patient survey are neither appropriate nor effective survey tools to assess physician competence in many specialties.
7. Careful consideration should be given to the importance of retaining flexibility in pathways for CBC for physicians with careers that combine clinical patient care with significant leadership, administrative, research and teaching responsibilities.
8. Legal ramifications must be examined, and conflicts resolved, prior to data collection and/or displaying any information collected in the process of CBC. Specifically, careful consideration must be given to the types and format of physician-specific data to be publicly released in conjunction with CBC participation.
9. Our AMA affirms the current language regarding continuing medical education (CME): Each Member Board will document that diplomates are meeting the CME and Self-Assessment requirements for CBC Part II. The content of CME and self-assessment programs receiving credit for CBC will be relevant to advances within the diplomate s scope of practice, and free of commercial bias and direct support from pharmaceutical and device industries. Each diplomate will be required to complete CME credits (AMA PRA Category 1 Credit, American Academy of Family Physicians Prescribed, American College of Obstetricians and Gynecologists, and/or American Osteopathic Association Category 1A).
10. In relation to CBC Part II, our AMA continues to support and promote the AMA Physician s Recognition Award (PRA) Credit system as one of the three major credit systems that comprise the foundation for continuing medical education in the U.S., including the Performance Improvement CME (PICME) format; and continues to develop relationships and agreements that may lead to standards accepted by all U.S. licensing boards, specialty boards, hospital credentialing bodies and other entities requiring evidence of physician CME.
11. CBC is but one component to promote patient safety and quality. Health care is a team effort, and changes to CBC should not create an unrealistic expectation that lapses in patient safety are primarily failures of individual physicians.
12. CBC should be based on evidence and designed to identify performance gaps and unmet needs, providing direction and guidance for improvement in physician performance and delivery of care.
13. The CBC process should be evaluated periodically to measure physician satisfaction, knowledge uptake and intent to maintain or change practice.
14. CBC should be used as a tool for continuous improvement.

15. The CBC program should not be a mandated requirement for licensure, credentialing, recredentialing, privileging, reimbursement, network participation, employment, or insurance panel participation.
16. Actively practicing physicians should be well-represented on specialty boards developing CBC.
17. Our AMA will include early career physicians when nominating individuals to the Boards of Directors for ABMS member boards.
18. CBC activities and measurement should be relevant to clinical practice.
19. The CBC process should be reflective of and consistent with the cost of development and administration of the CBC components, ensure a fair fee structure, and not present a barrier to patient care.
20. Any assessment should be used to guide physicians' self-directed study.
21. Specific content-based feedback after any assessment tests should be provided to physicians in a timely manner.
22. There should be multiple options for how an assessment could be structured to accommodate different learning styles.
23. Physicians with lifetime board certification should not be required to seek recertification.
24. No qualifiers or restrictions should be placed on diplomates with lifetime board certification recognized by the ABMS related to their participation in CBC.
25. Members of our House of Delegates are encouraged to increase their awareness of and participation in the proposed changes to physician self-regulation through their specialty organizations and other professional membership groups.
26. The initial certification status of time-limited diplomates shall be listed and publicly available on all American Board of Medical Specialties (ABMS) and ABMS Member Boards websites and physician certification databases. The names and initial certification status of time-limited diplomates shall not be removed from ABMS and ABMS Member Boards websites or physician certification databases even if the diplomate chooses not to participate in CBC.
27. Our AMA will continue to work with the national medical specialty societies to advocate for the physicians of America to receive value in the services they purchase for Continuing Board Certification from their specialty boards. Value in CBC should include cost effectiveness with full financial transparency, respect for physicians' time and their patient care commitments, alignment of CBC requirements with other regulator and payer requirements, and adherence to an evidence basis for both CBC content and processes.
(Policy Timeline: CME Rep. 16, A-09 Reaffirmed: CME Rep. 11, A-12 Reaffirmed: CME Rep. 10, A-12 Reaffirmed in lieu of Res. 313, A-12 Reaffirmed: CME Rep. 4, A-13 Reaffirmed in lieu of Res. 919, I-13 Appended: Sub. Res. 920, I-14 Reaffirmed: CME Rep. 2, A-15 Appended: Res. 314, A-15 Modified: CME Rep. 2, I-15 Reaffirmation A-16 Reaffirmed: Res. 309, A-16 Modified: Res. 307, I-16 Reaffirmed: BOT Rep. 05, I-16 Appended: Res. 319, A-17 Reaffirmed in lieu of: Res. 322, A-17 Modified: Res. 953, I-17 Reaffirmation: A-19 Modified: CME Rep. 02, A-19)

D-275.954, "Continuing Board Certification"

Our AMA will:
1. Continue to monitor the evolution of Continuing Board Certification (CBC), continue its active engagement in discussions regarding their implementation, encourage specialty boards to investigate and/or establish alternative approaches for CBC, and prepare a yearly report to the House of Delegates regarding the CBC process.
2. Continue to review, through its Council on Medical Education, published literature and emerging data as part of the Council s ongoing efforts to critically review CBC issues.
3. Continue to monitor the progress by the American Board of Medical Specialties (ABMS) and its member boards on implementation of CBC, and encourage the ABMS to report its research findings on the issues surrounding certification and CBC on a periodic basis.

4. Encourage the ABMS and its member boards to continue to explore other ways to measure the ability of physicians to access and apply knowledge to care for patients, and to continue to examine the evidence supporting the value of specialty board certification and CBC.
5. Work with the ABMS to streamline and improve the Cognitive Expertise (Part III) component of CBC, including the exploration of alternative formats, in ways that effectively evaluate acquisition of new knowledge while reducing or eliminating the burden of a high-stakes examination.
6. Work with interested parties to ensure that CBC uses more than one pathway to assess accurately the competence of practicing physicians, to monitor for exam relevance and to ensure that CBC does not lead to unintended economic hardship such as hospital de-credentialing of practicing physicians.
7. Recommend that the ABMS not introduce additional assessment modalities that have not been validated to show improvement in physician performance and/or patient safety.
8. Work with the ABMS to eliminate practice performance assessment modules, as currently written, from CBC requirements.
9. Encourage the ABMS to ensure that all ABMS member boards provide full transparency related to the costs of preparing, administering, scoring and reporting CBC and certifying examinations.
10. Encourage the ABMS to ensure that CBC and certifying examinations do not result in substantial financial gain to ABMS member boards, and advocate that the ABMS develop fiduciary standards for its member boards that are consistent with this principle.
11. Work with the ABMS to lessen the burden of CBC on physicians with multiple board certifications, particularly to ensure that CBC is specifically relevant to the physician s current practice.
12. Work with key stakeholders to (a) support ongoing ABMS member board efforts to allow multiple and diverse physician educational and quality improvement activities to qualify for CBC; (b) support ABMS member board activities in facilitating the use of CBC quality improvement activities to count for other accountability requirements or programs, such as pay for quality/performance or PQRS reimbursement; (c) encourage ABMS member boards to enhance the consistency of quality improvement programs across all boards; and (d) work with specialty societies and ABMS member boards to develop tools and services that help physicians meet CBC requirements.
13. Work with the ABMS and its member boards to collect data on why physicians choose to maintain or discontinue their board certification.
14. Work with the ABMS to study whether CBC is an important factor in a physician s decision to retire and to determine its impact on the US physician workforce.
15. Encourage the ABMS to use data from CBC to track whether physicians are maintaining certification and share this data with the AMA.
16. Encourage AMA members to be proactive in shaping CBC by seeking leadership positions on the ABMS member boards, American Osteopathic Association (AOA) specialty certifying boards, and CBC Committees.
17. Continue to monitor the actions of professional societies regarding recommendations for modification of CBC.
18. Encourage medical specialty societies leadership to work with the ABMS, and its member boards, to identify those specialty organizations that have developed an appropriate and relevant CBC process for its members.
19. Continue to work with the ABMS to ensure that physicians are clearly informed of the CBC requirements for their specific board and the timelines for accomplishing those requirements.
20. Encourage the ABMS and its member boards to develop a system to actively alert physicians of the due dates of the multi-stage requirements of continuous professional development and performance in practice, thereby assisting them with maintaining their board certification.
21. Recommend to the ABMS that all physician members of those boards governing the CBC process be required to participate in CBC.

22. Continue to participate in the National Alliance for Physician Competence forums.
23. Encourage the PCPI Foundation, the ABMS, and the Council of Medical Specialty Societies to work together toward utilizing Consortium performance measures in Part IV of CBC.
24. Continue to assist physicians in practice performance improvement.
25. Encourage all specialty societies to grant certified CME credit for activities that they offer to fulfill requirements of their respective specialty board s CBC and associated processes.
26. Support the American College of Physicians as well as other professional societies in their efforts to work with the American Board of Internal Medicine (ABIM) to improve the CBC program.
27. Oppose those maintenance of certification programs administered by the specialty boards of the ABMS, or of any other similar physician certifying organization, which do not appropriately adhere to the principles codified as AMA Policy on Continuing Board Certification.
28. Ask the ABMS to encourage its member boards to review their maintenance of certification policies regarding the requirements for maintaining underlying primary or initial specialty board certification in addition to subspecialty board certification, if they have not yet done so, to allow physicians the option to focus on continuing board certification activities relevant to their practice.
29. Call for the immediate end of any mandatory, secured recertifying examination by the ABMS or other certifying organizations as part of the recertification process for all those specialties that still require a secure, high-stakes recertification examination.
30. Support a recertification process based on high quality, appropriate Continuing Medical Education (CME) material directed by the AMA recognized specialty societies covering the physician s practice area, in cooperation with other willing stakeholders, that would be completed on a regular basis as determined by the individual medical specialty, to ensure lifelong learning.
31. Continue to work with the ABMS to encourage the development by and the sharing between specialty boards of alternative ways to assess medical knowledge other than by a secure high stakes exam.
32. Continue to support the requirement of CME and ongoing, quality assessments of physicians, where such CME is proven to be cost-effective and shown by evidence to improve quality of care for patients.
33. Through legislative, regulatory, or collaborative efforts, will work with interested state medical societies and other interested parties by creating model state legislation and model medical staff bylaws while advocating that Continuing Board Certification not be a requirement for: (a) medical staff membership, privileging, credentialing, or recredentialing; (b) insurance panel participation; or (c) state medical licensure.
34. Increase its efforts to work with the insurance industry to ensure that continuing board certification does not become a requirement for insurance panel participation.
35. Advocate that physicians who participate in programs related to quality improvement and/or patient safety receive credit for CBC Part IV.
36. Continue to work with the medical societies and the American Board of Medical Specialties (ABMS) member boards that have not yet moved to a process to improve the Part III secure, high-stakes examination to encourage them to do so.
37. Our AMA will, through its Council on Medical Education, continue to work with the American Board of Medical Specialties (ABMS), ABMS Committee on Continuing Certification (3C), and ABMS Stakeholder Council to pursue opportunities to implement the recommendations of the Continuing Board Certification: Vision for the Future Commission and AMA policies related to continuing board certification.
(Policy Timeline: CME Rep. 2, I-15 Appended: Res. 911, I-15 Appended: Res. 309, A-16 Appended: CME Rep. 02, A-16 Appended: Res. 307, I-16 Appended: Res. 310, I-16 Modified: CME Rep. 02, A-17 Reaffirmed: Res. 316, A-17 Reaffirmed in lieu of: Res. 322, A-17 Appended: CME Rep. 02, A-18 Appended: Res. 320, A-18 Appended: Res. 957, I-18 Reaffirmation: A-19 Modified: CME Rep. 02, A-19)

H-275.926, "Medical Specialty Board Certification Standards"

Our AMA:
(1) Opposes any action, regardless of intent, that appears likely to confuse the public about the unique credentials of American Board of Medical Specialties (ABMS) or American Osteopathic Association Bureau of Osteopathic Specialists (AOA-BOS) board certified physicians in any medical specialty, or take advantage of the prestige of any medical specialty for purposes contrary to the public good and safety.
(2) Opposes any action, regardless of intent, by organizations providing board certification for non-physicians that appears likely to confuse the public about the unique credentials of medical specialty board certification or take advantage of the prestige of medical specialty board certification for purposes contrary to the public good and safety.
(3) Continues to work with other medical organizations to educate the profession and the public about the ABMS and AOA-BOS board certification process. It is AMA policy that when the equivalency of board certification must be determined, accepted standards, such as those adopted by state medical boards or the Essentials for Approval of Examining Boards in Medical Specialties, be utilized for that determination.
(4) Opposes discrimination against physicians based solely on lack of ABMS or equivalent AOA-BOS board certification, or where board certification is one of the criteria considered for purposes of measuring quality of care, determining eligibility to contract with managed care entities, eligibility to receive hospital staff or other clinical privileges, ascertaining competence to practice medicine, or for other purposes. Our AMA also opposes discrimination that may occur against physicians involved in the board certification process, including those who are in a clinical practice period for the specified minimum period of time that must be completed prior to taking the board certifying examination.
(5) Advocates for nomenclature to better distinguish those physicians who are in the board certification pathway from those who are not.
(6) Encourages member boards of the ABMS to adopt measures aimed at mitigating the financial burden on residents related to specialty board fees and fee procedures, including shorter preregistration periods, lower fees and easier payment terms.
(Policy Timeline: Res. 318, A-07 Reaffirmation A-11 Modified: CME Rep. 2, I-15 Modified: Res. 215, I-19)

APPENDIX B:
IMPROVEMENTS TO THE AMERICAN BOARD OF MEDICAL SPECIALTIES (ABMS) PART III, ASSESSMENT OF KNOWLEDGE, JUDGMENT, AND SKILLS AND PART IV, IMPROVEMENT IN MEDICAL PRACTICE*

American Board of:	Original Format	New Models/Innovations
Allergy and Immunology (ABAI) abai.org	**Part III:** Computer-based, secure exam was administered at a proctored test center once a year. Diplomates were required to pass the exam once every 10 years. *Traditional secure exam only offered for re-entry.*	**Part III:** In 2018, ABAI-Continuous Assessment Program Pilot was implemented in place of 10-year secure exam: • A 10-year program with two 5-year cycles; • Open-book annual exam with approximately 80 questions; • Customized to practice; • Mostly article-based with some core questions during each 6-month cycle; • Diplomates must answer 3 questions for each of 10 journal articles in each cycle posted in February and August; • Questions can be answered independently for each article; • Diplomate feedback required on each question; • Opportunity to drop the two lowest 6-month cycle scores during each 5-year period to allow for unexpected life events; and • Diplomates can take exam where and when it is convenient and have the ability to complete questions on PCs, laptops, MACs, tablets, and smart phones by using the new diplomate dashboard accessed via the existing ABAI Web Portal page.
	Part IV: ABAI diplomates receive credit for participation in registries.	**Part IV:** In 2018, new Part IV qualifying activities provided credit for a greater range of Improvement in Medical Practice (IMP) activities that physicians complete at their institutions and/or individual practices. A practice assessment/quality improvement (QI) module must be completed once every 5 years.

Anesthesiology (ABA) theaba.org	**Part III:** MOCA 2.0 introduced in 2014 to provide a tool for ongoing low-stakes assessment with more extensive, question-specific feedback. Also provides focused content that could be reviewed periodically to refresh knowledge and document cognitive expertise. *All diplomates with time-limited certification in anesthesiology that expired on or before December 31, 2015 and diplomates whose subspecialty certificates expired on or before December 31, 2016, must complete the traditional MOCA® requirements before they can register for MOCA 2.0®.*	**Part III:** MOCA Minute® replaced the MOCA exam: • Customized to practice; • Diplomates must answer 30 questions per calendar quarter (120 per year), no matter how many certifications they are maintaining; and • Knowledge Assessment Report shows details on the MOCA Minute questions answered incorrectly, peer performance, and links to related CME.
	Part IV[2]: Traditional MOCA requirements include completion of case evaluation and simulation course during the 10-year MOCA cycle. One activity must be completed between Years 1 to 5, and the second between Years 6 to 10. An attestation is due in Year 9.	**Part IV[2]:** ABA added and expanded multiple activities for diplomates to demonstrate that they are participating in evaluations of their clinical practice and are engaging in practice improvement. Diplomates may choose activities that are most relevant to their practice; reporting templates no longer required for self-report activities; and simulation activity not required. An attestation is due in Year 9.
Colon and Rectal Surgery (ABCRS) abcrs.org	**Part III:** Computer-based secure exam administered at a proctored test center once a year (in May). Diplomates must pass the exam once every 10 years. *The secure exam is no longer offered.*	**Part III[1]:** New Continuous Certification Longitudinal Assessment Program (CertLink®) replaced the high-stakes Part III Cognitive Written Exam which was required every 10 years: • Diplomates must complete 12 to 15 questions per quarter through the CertLink® platform. • The fifth year of the cycle can be a year free of questions or used to extend the cycle if life events intervene.
	Part IV: Requires ongoing participation in a local, regional, or national outcomes registry or quality assessment program.	**Part IV:** If there are no hospital-based or other programs available, diplomates can maintain a log of their own cases and morbidity outcomes utilizing the ACS Surgeon Specific Case Log System (with tracking of 30-day complications). Resources are provided to enable completion of QI activities based on the results.

Dermatology (ABD) abderm.org	**Part III:** Computer-based secure modular exam still administered at a proctored test center twice a year or by remote proctoring technology. Diplomates must pass the exam once every 10 years. Test preparation material available 6 months before the exam at no cost. The material includes diagnoses from which the general dermatology clinical images will be drawn and questions that will be used to generate the subspecialty modular exams. Examinees are required to take the general dermatology module, consisting of 100 clinical images to assess diagnostic skills, and can then choose among 50-item subspecialty modules.	**Part III[1]:** ABD completed trials employing remote proctoring technology to monitor exam administration in the diplomates' homes or offices. On January 6, 2020, diplomates can participate in CertLink®: • Diplomates must complete 13 questions per quarter for a total of 52 questions; • Diplomates will receive a mix of visual recognition questions, specialty area questions, and article-based questions; • Written references and online resources are allowed while answering questions; and • Diplomates are permitted to take one quarter off per year without advanced permission or penalty, using the "Time Off" feature (if diplomate opts not to take a quarter off, his/her lowest scoring quarter during that year will be eliminated from scoring).
	Part IV[2]: Tools diplomates can use for Part IV include: • Focused practice improvement modules. • ABD's basal cell carcinoma registry tool. Partnering with specialty society to transfer any MOC-related credit directly to Board.	**Part IV[2]:** ABD developed more than 40 focused practice improvement modules that are simpler to complete and cover a wide range of topics to accommodate different practice types. Peer and patient communication surveys are now optional.
Emergency Medicine (ABEM) abem.org	**Part III:** ABEM's ConCert™, computer-based, secure exam administered at a proctored test center twice a year. Diplomates must pass the exam once every 10 years.	**Part III:** In 2020, a ConCert™ alternative, known as MyEMCert,will be piloted. MyEMCert will consist of: • Short assessment modules, consisting of up to 50 questions each; • Each module addresses a category of common patient presentations in the emergency department; • Eight modules are required in each 10-year certification. (ABEM-diplomates who have less than 10 years remaining on their current certification and who choose to participate in MyEMCert will have less time to complete 8 modules before their certification expires); • Each module includes recent advances in Emergency Medicine (that may or may not be related to

		the category of patient presentation). Participants in MyEMCert do not also have to take LLSAs; • Three attempts are available for each registration; • MyEMCert modules will be available 24/7/365; and • Diplomates can look up information—for example, textbooks or online resources to which they subscribe—while completing a module.
	Part IV[2]: Physicians may complete practice improvement efforts related to any of the measures or activities listed on the ABEM website. Others that are not listed, may be acceptable if they follow the four steps ABEM requirements.	**Part IV[2]:** ABEM is developing a pilot program to incorporate clinical data registry. ABEM diplomates receive credit for improvements they are making in their practice setting. Must complete and attest to two PI activities, one in years one through five of certification, and one in years six through ten.
Family Medicine (ABFM) theabfm.org	**Part III:** One-day Family Medicine Certification Exam. Traditional computer-based secure exam administered at a proctored test center twice a year or by remote proctoring technology. Diplomates must pass the exam once every 10 years. The exam day schedule consists of four 95-minute sections (75 questions each) and 100 minutes of pooled break time available between sections.	**Part III:** In 2018, ABFM launched Family Medicine Certification Longitudinal Assessment (FMCLA), a pilot to study the feasibility and validity of an alternative to the 10-year examination. The FMCLA pilot evaluation will be conducted over several years to collect feedback and data to evaluate the quality, effectiveness, and acceptability to the program. • Limited to Diplomates currently certified and in the tenth year of certification that ended in 2020; • Diplomates must complete 25 questions per quarter; 300 questions over a 4-year time period; • Diplomates receive immediate feedback after each response; • Clinical references similar to those used in practice allowed during the assessment; and • Questions can be completed at the place and time of the diplomate's choice.
	Part IV[2]: IMP Projects include: • Collaborative Projects: Structured projects that involve physician teams	**Part IV[2]:** ABFM developed and launched the national primary care registry (PRIME)

	collaborating across practice sites and/or institutions to implement strategies designed to improve care. • Projects Initiated in the Workplace: These projects are based on identified gaps in quality in a local or small group setting. • Web-based Activities: Self-paced activities that physicians complete within their practice setting (these activities are for physicians, who do not have access to other practice improvement initiatives).	to reduce time and reporting requirements.
Internal Medicine (ABIM) abim.org	**Part III:** Computer-based secure exam administered at a proctored test center. Diplomates must pass the exam once every 10 years. This option includes open-book access (to UpToDate®) that physicians requested. *ABIM introduced grace period for physicians to retry assessments for additional study and preparation if initially unsuccessful.*	**Part III:** In 2020, the Knowledge Check-In, will be an option for diplomates in most specialties: • New 2-year open-book (access to *UpToDate®*) assessment; • Diplomates receive immediate performance feedback; and • Assessments can be taken at the diplomate's home or office, or at a computer testing facility. ABIM anticipates launching a longitudinal assessment option in 2022. *ABIM has developed collaborative pathways with the American College of Cardiology and American Society of Clinical Oncology for physicians to maintain board certification in several subspecialties. ABIM is working with other specialty societies to explore the development of pathways.*
	Part IV[2]: Practice assessment/QI activities include identifying an improvement opportunity in practice, implementing a change to address that opportunity, and measuring the impact of the change. Diplomates can earn MOC points for many practice assessment/QI projects through their medical specialty societies, hospitals, medical groups, clinics, or other health-related organizations.	**Part IV[2]:** Optional; incentive for participation in approved activities. Increasing number of specialty-specific IMP activities recognized for credit (activities that physicians are participating in within local practice and institutions).

Medical Genetics and Genomics (ABMGG) abmgg.org	**Part III:** Computer-based secure exam administered at a proctored test center once a year (August). Diplomates must pass the exam once every 10 years. *The secure exam is no longer offered.*	**Part III[1]:** In 2020, a longitudinal assessment program (CertLink®) will replace the 10-year, Continuing Certification (MOC) high-stakes examination: • Diplomates receive 24 questions every 6 months, regardless of number of specialties in which a diplomate is certified; • Diplomates must answer all questions by the end of each 6-month timeframe (5 minutes allotted per question); • Resources allowed, collaboration with colleagues not allowed; • Realtime feedback and performance provided for each question; and • "Clones" of missed questions will appear in later timeframes to help reinforce learning.
	Part IV[2]: Diplomates can choose from the list of options to complete practice improvement modules in areas consistent with the scope of their practice.	**Part IV[2]:** ABMGG is developing opportunities to allow diplomates to use activities already completed at their workplace to fulfill certain requirements. *Expanding accepted practice improvement activities for laboratorians.*
Neurological Surgery (ABNS) abns.org	**Part III:** The 10-year secure exam can be taken from any computer, i.e., in the diplomate's office or home. Access to reference materials is not restricted; it is an open book exam. On applying to take the exam, a diplomate must assign a person to be his or her proctor. Prior to the exam, that individual will participate in an on-line training session and "certify" the exam computers. *The secure exam is no longer offered.*	**Part III:** In 2018, Core Neurosurgical Knowledge, an annual adaptive cognitive learning tool and modules, replaced the 10-year secure exam: • Open book exam focusing on 30 or so evidence-based practice principles critical to emergency, urgent, or critical care; • Shorter, relevant, and more focused questions than the prior exam; • Diplomates receive immediate feedback for each question and references with links and/or articles are provided; and • Web-based format with 24/7 access from the diplomates' home or office.

	Part IV: Diplomates receive credit for documented participation in an institutional QI project.	**Part IV:** Diplomates are required to participate in a meaningful way in morbidity and morality conferences (local, regional, and/or national). For those diplomates participating in the Pediatric Neurosurgery, CNS-ES, NeuCC focused practice programs, a streamlined case log is required to confirm that their practice continues to be focused and the diplomate is required to complete a learning tool that includes core neurosurgery topics and an additional eight evidence-based concepts critical to providing emergency, urgent, or critical care in their area of focus.
Nuclear Medicine (ABNM) abnm.org	**Part III:** Computer-based secure exam administered at a proctored test center once a year (October). Diplomates must pass the exam once every 10 years.	**Part III[1]:** Diplomates can choose between the 10-year exam or a longitudinal assessment pilot program (CertLink®). • Diplomates receive 9 questions per quarter and up to 4 additional questions that are identical or very similar to questions previously answered (called "clones") and many will have images; • Educational resources can be used; • Diplomates receive immediate feedback with critiques and references; and • Allows for emergencies and qualifying life events.
	Part IV: Diplomates must complete one of the three following requirements each year. 1) Attestation that the diplomate has participated in QI activities as part of routine clinical practice, such as participation in a peer review process, attendance at tumor boards, or membership on a radiation safety committee. 2) Participation in an annual practice survey related to approved clinical guidelines released by the ABNM. The survey has several questions based on review of actual cases. Diplomates receive a summary of the answers provided by other physicians that allows them to compare their practice to peers. 3) Improvement in Medical Practice projects designed by diplomates or provided by professional groups such as	**Part IV:** ABNM recognizes QI activities in which physicians participate in their clinical practice.

	the SNMMI. Project areas may include medical care provided for common/major health conditions, physician behaviors, such as communication and professionalism, as they relate to patient care, and many others. The projects typically follow the model of Plan, Do, Study, Act. The ABNM has developed a few IMP modules for the SNMMI, Alternatively, diplomates may design their own project.	
Obstetrics and Gynecology (ABOG) abog.org	**Part III:** The secure, external assessment is offered in the last year of each ABOG diplomate's 6-year cycle in a modular test format; diplomates can choose two selections that are the most relevant to their current practice. The exam administered at a proctored test center.	**Part III:** ABOG completed a pilot program and integrated the article-based self-assessment (Part II) and external assessment (Part III) requirements, allowing diplomates to continuously demonstrate their knowledge of the specialty. The pilot allowed diplomates to earn an exemption from the current computer-based exam in the sixth year of the program if they reach a threshold of performance during the first 5 years of the self-assessment program. Since 2019, diplomates can choose to take the 6-year exam or participate in Performance Pathway, an article-based self-assessment (with corresponding questions) which showcases new research studies, practice guidelines, recommendations, and up-to-date reviews. Diplomates who participate in Performance Pathway are required to read a total of 180 selected articles and answer 720 questions about the articles over the 6-year MOC cycle.
	Part IV[2]: Diplomates required to participate in one of the available IMP activities yearly in MOC Years 1-5. ABOG will consider structured QI projects (IMP modules, QI efforts, simulation courses) in obstetrics and gynecology for Part IV credit. These projects must demonstrate improvement in care and be based on accepted improvement science and methodology. Newly developed QI projects from organizations with a history of successful QI projects are also eligible for approval.	**Part IV[2]:** ABOG recognizes work with QI registries for credit. ABOG continues to expand the list of approved activities which can be used to complete the Part IV.

Ophthalmology (ABO) abop.org	**Part III:** The Demonstration of Ophthalmic Cognitive Knowledge (DOCK) high-stakes, 10-year exam administered through 2018. *The secure exam is no longer offered.*	**Part III:** In 2019, Quarterly Questions™ replaced the DOCK Examination for all diplomates: • Diplomates receive 50 questions (40 knowledge-based and 10 article-based); • The questions should not require preparation in advance, but a content outline for the questions will be available; • The journal portion will require reading five articles from a list of options key ophthalmic journal articles with questions focused on the application of this information to patient care; • Diplomates receive immediate feedback and recommendations for resources related to gaps in knowledge; and • Questions can be completed remotely at home or office through computer, tablet, or mobile apps.
	Part IV[2]: Diplomates whose certificates expire on or before December 31, 2020 must complete one of the following options; all other diplomates complete two activities: • Read QI articles through Quarterly Questions; • Choose a QI CME activity; • Create an individual IMP activity; or • Participate in the ABMS multi-specialty portfolio program pathway.	**Part IV[2]:** Diplomates can choose to: • Select 3 QI journal articles from ABO's reading list and answer two questions about each article (this activity option may be used only once during each 10-year cycle). • Design a registry-based IMP Project using their AAO IRIS® Registry Data; • Create a customized, self-directed IMP activity; or • Participate in the ABMS multi-specialty portfolio program through their institution.
Orthopaedic Surgery (ABOS) abos.org	**Part III:** Computer-based secure modular exam administered at a proctored test center. Diplomates must pass the exam once every 10 years. The optional oral exam is given in Chicago in July. Diplomates without subspecialty certifications can take practice-profiled exams in orthopaedic sports medicine and surgery of the hand. General orthopaedic questions were eliminated from the practice-profiled exams so diplomates are only tested in areas relevant to their practice.	**Part III:** In 2020, a new longitudinal assessment program (ABOS WLA) the Knowledge Assessment, will be available to all diplomates. This pathway may be chosen instead of an ABOS computer-based or oral recertification 10-year exam: • Diplomates must answer 30 questions (from each Knowledge Source chosen by the diplomate); • The assessment is open-book and diplomates can use the Knowledge Sources, if the questions are answered within the 3-minute window and that the answer

	Detailed blueprints are being produced for all exams to provide additional information for candidates to prepare for and complete the exams. Eight different practice-profiled exams offered to allow assessment in the diplomate's practice area.	represents the diplomate's own work; and • Questions can be answered remotely at home or office through computer, tablet, or mobile apps.
	Part IV: Case lists allow diplomates to review their practice including adhering to accepted standards, patient outcomes, and rate and type of complications. Case list collection begins on January 1st of the calendar year that the diplomate plans to submit their recertification application and is due by December 1. The ABOS recommends that this be done in Year 7 of the 10-year MOC Cycle, but it can be done in Year 8 or 9. A minimum of 35 cases is required for the recertification candidate to sit for the recertification exam of their choice. Diplomates receive a feedback report based on their submitted case list.	**Part IV:** ABOS is streamlining the case list entry process to make it easier to enter cases and classify complications.
Otolaryngology – Head and Neck Surgery (ABOHNS) aboto.org	**Part III:** Computer-based secure modular exam administered at a proctored test center. Diplomates must pass the exam once every 10 years.	**Part III[1]:** ABOHNS is piloting a CertLink®-based longitudinal assessment: • Diplomates receive 10 to 15 questions per quarter; • Immediate, personalized feedback provided regarding the percentage of questions answered correctly; • Questions can be answered at a diplomate's convenience so long as all questions are answered by the end of each quarter; and • Remote access via desktop or laptop computer (some items will contain visuals).
	Part IV[2]: The three components of Part IV include: • A patient survey; • A peer survey; and • A registry that will be the basis for QI activities.	**Part IV[2]:** ABOHNS is partnering with the American Academy of Otolaryngology-Head and Neck Surgery in their development of a RegentSM registry. Selected data will be extracted from RegentSM for use in practice improvement modules that diplomates can use to meet IMP requirements. ABOHNS is working to identify and accept improvement activities that diplomates engage in as part of their practice.

		ABOHNS will roll out the last section of MOC, Part IV, which is still under development. Part IV will consist of three components, a patient survey, a professional survey, and a Performance Improvement Module (PIM).
Pathology (ABPath) abpath.org	**Part III:** Computer-based secure modular exam administered at the ABP Exam Center in Tampa, Florida twice a year (March and August). Remote computer exams can be taken anytime 24/7 that the physician chooses during the assigned 2-week period (spring and fall) from their home or office. Physicians can choose from more than 90 modules, covering numerous practice areas for a practice-relevant assessment. Diplomates must pass the exam once every 10 years.	**Part III[1]:** The ABPath CertLink® pilot program is available for all diplomates: • Customization allows diplomates to select questions from practice (content) areas relevant to their practice. • Diplomates can log in anytime to answer 15 to 25 questions per quarter; • Each question must be answered within 5 minutes; • Resources (e.g. internet, textbooks, journals) can be used; and • Diplomates receive immediate feedback on whether each question is answered correctly or incorrectly, with a short narrative about the topic (critique), and references.
	Part IV[2]: Diplomates must participate in at least one inter-laboratory performance improvement and quality assurance program per year appropriate for the spectrum of anatomic and clinical laboratory procedures performed in that laboratory.	**Part IV[2]:** IMP requirements must be reported as part of a reporting period every 2 years via PATHway. There are three aspects to IMP: • Laboratory Accreditation; • Laboratory Performance Improvement and Quality Assurance; and • Individual Performance Improvement and Quality Assurance.
Pediatrics (ABP) abp.org	**Part III:** Computer-based secure exam administered at a proctored test center. Diplomates must pass the exam once every 10 years.	**Part III:** In 2019, a new testing platform with shorter and more frequent assessments, Maintenance of Certification Assessment for Pediatrics (MOCA-Peds), was implemented: • Allows for questions to be tailored to the pediatrician's practice profile; • A series of questions released through mobile devices or a web browser at regular intervals; • Diplomates receive 20 questions per quarter (may be answered at any time during the quarter);

		• Diplomates receive immediate feedback and references; • Resources (i.e., internet, books) can be used. *Those who wish to continue taking the exam once every 5 years in a secure testing facility will be able to do so.*
	Part IV[2]: Diplomates must earn at least 40 points every 5 years, in one of the following activities: • Local or national QI projects • Diplomates' own project • National Committee for Quality Assurance Patient-Centered Medical Home or Specialty Practice • Institutional QI leadership • Online modules (PIMS)	**Part IV[2]:** ABP is enabling new pathways for pediatricians to claim Part IV QI credit for work they are already doing. These pathways are available to physicians who are engaged in QI projects alone or in groups and include a pathway for institutional leaders in quality to claim credit for their leadership. ABP is also allowing trainees (residents and fellows) to "bank" MOC credit for QI activities in which they participate. The pediatricians supervising these trainees also may claim MOC credit for qualifying projects.
Physical Medicine and Rehabilitation (ABPMR) abpmr.org	**Part III:** Computer-based secure exam administered at a proctored test center. Diplomates must pass the exam once every 10 years. Released MOC 100, a set of free practice questions pulled directly from the ABPMR exam question banks to help physicians prepare for the exam. There is a separate computer-based secure exam administered at a proctored test center that is required to maintain subspecialty certification. *After the last administration of secure exam in 2020, the exam will be replaced with the Longitudinal Assessment for PM&R (LA-PM&R).*	**Part III[1]:** In 2020, the Longitudinal Assessment for PM&R (LA-PM&R) will be available for all diplomates: • Diplomates receive 20 questions per quarter; after that: between 15 and 18 questions depending on performance (higher performance = fewer questions); • Maximum of 2 minutes to answer each question; • Diplomates can customize their question content; • Diplomates receive immediate feedback indicating whether the answer was correct or incorrect, followed by a critique; and • Available from a desktop or tablet (some features may not work on a phone's web browser). The ABPMR is exploring the use of longitudinal assessment for its subspecialty assessment requirement, but these plans, IT infrastructure, customer service support, and item banks take time to develop. More information on longitudinal assessment for subspecialties will be available in the next few years.

	Part IV[2]: Guided practice improvement projects are available through ABPMR. Diplomates must complete: • Clinical module (review of one's own patient charts on a specific topic), or • Feedback module (personal feedback from peers or patients regarding the diplomates clinical performance using questionnaires or surveys). Each Module consists of three steps to complete within a 24-month period: initial assessment, identify and implement improvement, and reassessment.	**Part IV[2]:**ABPMR introduced several free tools to complete an IMP project, including: simplified and flexible template to document small improvements and educational videos, infographic, and enhanced web pages. ABPMR is seeking approval from the National Committee for Quality Assurance Patient-Centered Specialty Practice Recognition for Part IV IMP credit. ABPMR is also working with its specialty society to develop relevant registry-based QI activities.
Plastic Surgery (ABPS) abplasticsurgery.org	**Part III:** Computer-based secure exam administered at a proctored test center once a year (October). Diplomates must pass the exam once every 10 years. Modular exam to ensure relevance to practice. ABPS offers a Part III Study Guide with multiple choice question items derived from the same sources used for the exam.	**Part III:** In April 2020, the continuous certification exam will move to an internet-based testing format: • Diplomate receives 30 questions per year; • Diplomates receive immediate feedback on answers with links to references and educational resources are offered with an opportunity to respond again; and • Available on any computer with an internet connection;
	Part IV: ABPS provides Part IV credit for registry participation. ABPS also allows Part IV credit for IMP activities that a diplomate is engaged in through their hospital or institution. Diplomates are asked to input data from 10 cases from any single index procedure every 3 years, and ABPS provides feedback on diplomate data across five index procedures in four subspecialty areas.	**Part IV:** Allowing MOC credit for IMP activities that a diplomate is engaged in through their hospital or institution. Physician participation in one of four options can satisfy the diplomate's Practice Improvement Activity: • Quality Improvement Publication • Quality Improvement Project • Registry Participation • Tracer Procedure Log
Preventive Medicine (ABPM) theabpm.org	**Part III:** In-person, pencil-and-paper, secure exam administered at secure test facility. MOC exams follow the same content outline as the initial certification exam (without the core portion). *In 2016, new multispecialty subspecialty of Addiction Medicine was established. In 2017, Addiction Medicine subspecialty certification exam was administered to diplomates of any of the 24 ABMS member boards who meet the eligibility requirements.*	**Part III:** In 2019, the ABPM began offering all diplomates remotely-proctored MOC exams: • Must be completed by the examinee in a single sitting; • Given in two 50-question sections with an optional 15-minute break between sections; • Diplomates are not allowed to consult outside resources or notes; • Results available on diplomate's dashboard in the physician portal 4 weeks after the completion of the exam; and

		• Available on smart phone or computer. In 2020, ABPM announced plans to offer a longitudinal assessment program for the Clinical Informatics subspecialty certificate starting in 2011.
	Part IV[2]: Diplomates must complete two IMP activities during each 10-year cycle. One of the activities must be completed through a Preventive Medicine specialty or subspecialty society (ACOEM, ACPM, AMIA, AsMA, or UHMS).	**Part IV[2]:** Partnering with specialty societies to design quality and performance improvement activities for diplomates with population-based clinical focus (i.e. Public Health).
Psychiatry and Neurology (ABPN) abpn.com	**Part III:** Computer-based secure exam administered at a proctored test center. Diplomates must pass the exam once every 10 years. ABPN is developing MOC exams with committees of clinically active diplomates to ensure relevance to practice. ABPN is also enabling diplomates with multiple certificates to take all of their MOC exams at once and for a reduced fee. Grace period so that diplomates can retake the exam.	**Part III:** ABPN is implementing a Part III pilot program through 2021 to allow physicians to select 30-40 lifelong learning articles and demonstrate learning by high performance on the questions accompanying the article, to earn exemption from the 10-year MOC high-stakes exam.
	Part IV[2]: Diplomates satisfy the IMP requirement by completing one of the following: 1) Clinical Module: Review of one's own patient charts on a specific topic (diagnosis, types of treatment, etc.). 2) Feedback Module: Obtain personal feedback from either peers or patients regarding your own clinical performance using questionnaires or surveys.	**Part IV[2]:** ABPN is allowing Part IV credit for IMP and patient safety activities diplomates complete in their own institutions and professional societies, and those completed to fulfill state licensure requirements. Diplomates participating in registries, such as those being developed by the American Academy of Neurology and the American Psychiatric Association, can have 8 hours of required self-assessment CME waived.

Radiology (ABR) theabr.org	**Part III:** Computer-based secure modular exam administered at a proctored test center. Diplomates must pass the exam once every 10 years. *The secure exam is needed only in limited situations.*	**Part III:** An Online Longitudinal Assessment (OLA) model was implemented in place of the 10-year traditional exam. OLA includes modern and more relevant adult learning concepts to provide psychometrically valid sampling of the diplomate's knowledge. • Diplomates must create a practice profile of the subspecialty areas that most closely fit what they do in practice, as they do now for the modular exams; • Diplomates will receive weekly emails with links to questions relevant to their registered practice profile. • Questions may be answered singly or, for a reasonable time, in small batches, in a limited amount of time. • Diplomates receive immediate feedback about questions answered correctly or incorrectly and will be presented with a rationale, critique of the answers and brief educational material. *Those who answer questions incorrectly will receive future questions on the same topic to gauge whether they have learned the material.*
	Part IV[2]: Diplomates must complete at least one practice QI project or participatory QI activity in the previous 3 years at each MOC annual review. A project or activity may be conducted repeatedly or continuously to meet Part IV requirements.	**Part IV[2]:** ABR is automating data feeds from verified sources to minimize physician data reporting. ABR is also providing a template and education about QI to diplomates with solo or group projects.
Surgery (ABS) absurgery.org	**Part III:** Computer-based secure exam administered at a proctored test center. Diplomates must pass the exam once every 10 years. Transparent exam content, with outlines, available on the ABS website and regularly updated. ABS is coordinating with the American College of Surgeons and other organizations to ensure available study materials align with exam content.	**Part III:** In 2018, ABS began offering shorter, more frequent, open-book, modular, lower-stakes assessments required every 2 years in place of the high-stakes exam: • Diplomates will select from four practice-related topics: general surgery, abdomen, alimentary tract, or breast; • More topics based on feedback from diplomates and surgical societies are being planned;

	The secure exam is no longer offered for general surgery, vascular surgery, pediatric surgery, surgical critical care, or complex general surgical oncology.	• Diplomates must answer 40 questions total (20 core surgery, 20 practice-related; • Open book with topics and references provided in advance; • Individual questions are untimed (with 2 weeks to complete); • Diplomate receives immediate feedback and results (two opportunities to answer a question correctly); and • Diplomates can use their own computer at a time and place of their choosing within the assessment window. The new assessment is available for general surgery, vascular surgery, pediatric surgery, or surgical critical care with other ABS specialties launching over the next few years.
	Part IV[2]: ABS allows ongoing participation in a local, regional or national outcomes registry or quality assessment program, either individually or through the Diplomate's institution. Diplomates must describe how they are meeting this requirement—no patient data is collected. The ABS audits a percentage of submitted forms each year.	**Part IV[2]:** ABS allows multiple options for registry participation, including individualized registries, to meet IMP requirements.
Thoracic Surgery (ABTS) abts.org	**Part III:** Remote, secure, computer-based exams can be taken any time (24/7) that the physician chooses during the assigned 2-month period (September-October) from their home or office. Diplomates must pass the exam once every 10 years. Modular exam, based on specialty, and presented in a self-assessment format with critiques and resources made available to diplomates.	**Part III:** ABTS developed a web-based self-assessment tool (SESATS) that includes all exam material, instant access to questions, critiques, abstracts and references.
	Part IV[2]: ABTS diplomates must complete at least one practice QI project within 2 years, prior to their 5-year and 10-year milestones. There are several pathways by which diplomates may meet these requirements: individual, group or institutional. A case summary and patient safety module must also be completed.	**Part IV[2]:** *No changes to report at this time.*

Urology (ABU) abu.org	**Part III:** Computer-based secure exam administered at a proctored test center once a year (October). Diplomates must pass the exam once every 10 years. Clinical management emphasized on the exam. Questions are derived from the American Urological Association (AUA) Self-Assessment Study Program booklets from the past five years, AUA Guidelines, and AUA Updates. Diplomates required to take the 40-question core module on general urology and choose one of four 35-question content specific modules. ABU provides increased feedback to reinforce areas of knowledge deficiency.	**Part III:** ABU will continue the modular format for the Lifelong Learning knowledge assessment. The knowledge assessment portion of the Lifelong Learning program will not be used as a primary single metric that influences certificate status but rather to help the diplomate to identify those areas of strength versus weakness in their medical knowledge that is pertinent to their practice. The knowledge assessment is based on Criterion referencing, thus allowing the identification of two groups, those who unconditionally pass the knowledge assessment and those who are given a conditional pass. The group getting a conditional pass will consist of those individuals who score in the band of one standard error of measurement above the pass point down to the lowest score. That group would be required to complete additional CME in the areas where they demonstrate low scores. After completion of the designated CME activity, they would continue in the Lifelong Learning process and the condition of their pass would be lifted.
	Part IV[2]: Completion of Practice Assessment Protocols. ABU uses diplomate practice logs and diplomate billing code information to identify areas for potential performance or QI.	**Part IV[2]:** ABU allows credit for registry participation (i.e., participation in the MUSIC registry in Michigan, and the AUA AQUA registry). Another avenue to receive credit is participation in the ABMS multi-specialty portfolio program (this is more likely to be used by Diplomates who are part of a large health system, e.g. Kaiser, or those in academic practices).

*The information in this table is sourced from ABMS Member Board websites and is current as of January 31, 2020.

[1]Utilizing CertLink®, an ABMS web-based platform that leverages smart mobile technology to support the design, delivery, and evaluation of longitudinal assessment programs, some of which launched in 2017-2018. More information is available at: https://www.abms.org/initiatives/certlink/member-board-certlink-programs/ (accessed 1-13-20).

[2]Participates in the ABMS Portfolio Program™ which offers an option for organizations to support physician involvement in quality, performance, and process improvement (QI/PI) initiatives at their institution and award physician IMP credit for continuing certification.

APPENDIX C:
ANNOTATED BIBLIOGRAPHY

Continuing Medical Education

Howard-McNatt M, Sabel M, Agnese D, et al. Maintenance of Certification and Continuing Medical Education: Are They Still Required? *Ann Surg Oncol*. 2019;26(12):3820-3823.
The authors believe that many surgeons may find the new recommendations for continuing medical education (CME) and maintenance of certification (MOC) confusing. For example, some wonder if they still need MOC, how much CME currently is required by the American Board of Surgery (ABS), and where MOC and CME credits can be obtained. This article reviews the current MOC and CME requirements and lists options for completion of these requisites available through the Society of Surgical Oncology and its official journal, Annals of Surgical Oncology. The ABS and the Society for Surgical Oncology aim for their members to have lifelong learning, with the goal of improving patient care.

Knowledge Assessments

Vandergrift JL, Gray BM. Physician Clinical Knowledge, Practice Infrastructure, and Quality of Care. *Am J Manag Care*. 2019;25(10):497-503.
A study was conducted to understand if and how one dimension of physician skill, clinical knowledge, as measured by performance on the American Board of Internal Medicine (ABIM) Maintenance of Certification (MOC) exam, moderates the relationship between practice infrastructure and the quality of diabetes or hypertension care among general internists. The study included 1301 physicians who certified in internal medicine between 1991 and 1993 or 2001 and 2003 and took the ABIM's MOC exam and completed ABIM's diabetes or hypertension registry during their 10-year recertification period between 2011 and 2014. The study showed that a physician's exam performance significantly moderated the association between practice infrastructure and care quality, and that physician skill, such as clinical knowledge, is important to translating patient-centered practice infrastructure into better care quality.

O'Neill TR, Newton WP, Brady JE, Spogen D. Using the Family Medicine Certification Longitudinal Assessment to Make Summative Decisions. *JABFM*. 2019;32:951-953.
This article reviews the Family Medicine Certification Longitudinal Assessment 1 (FMCLA) pilot launched by the American Board of Family Medicine (ABFM) on January 4, 2019. The ABFM hopes that FMCLA will provide both summative feedback—assessing whether a candidate has the cognitive expertise to be a board-certified family physician—as well as formative feedback—to help diplomates know more accurately what they do not know and, thus, focus their learning. The authors note that with respect to the formative component, early reports are very positive. Of the eligible diplomates, 71 percent took advantage of the pilot. The technology platform is functioning well. Very few diplomates have withdrawn, and many reported that the tool is helping them learn. Evaluation from this quarter and the next will begin to give the ABFM a better understanding of how FMCLA fits into the other ways diplomates learn, and the ABFM will explore new formats of reports to support diplomates' learning efforts.

Turner AL, Olmsted M, Smith AC, et al. Pediatrician Perspectives on Learning and Practice Change in the MOCA-Peds 2017 Pilot. *Pediatrics*. 2019;144(6). doi: 10.1542/peds.2019-2305.
Researchers found that nearly all (98 percent) of 5,081 pediatricians surveyed reported they "learned, refreshed, or enhanced their medical knowledge" because of MOCA-Peds. Of those participating pediatricians, 62 percent reported a practice change associated with pilot participation,

particularly for practice regarding ear, nose, and throat; well-child and preventive care; and mental and behavioral health.

Robinson, LR, Raddatz MM, Kinney, C. Evaluation of Longitudinal Assessment for use in Maintenance of Certification. *Am J Phys Med Rehabil*. 2019 Dec 5. doi: 10.1097/PHM.0000000000001359
This study evaluates a longitudinal assessment process (LA-PM&R) as a replacement for the American Board of Physical Medicine and Rehabilitation (ABPMR) MOC Examination. Design: In this quality improvement study, randomly selected ABPM&R diplomates were invited to participate in LA-PM&R. Participants' MOC scaled scores were compared to LA-PM&R non-participants. The ABPMR examined the association between LA-PM&R scores and MOC Scaled scores and performance on clone items placed on both examinations. The study showed that the LA-PM&R group scored higher on the MOC examination than the control group ($P < .05$). Performance on the 2 examinations was highly correlated, $r = .50$, $P < .0001$. On clone items, LA-PM&R participants had 74 percent correct on LA-PM&R but 86 percent correct on the MOC Examination ($P < .01$). This study indicates the LA-PM&R program leads to better learning and retention of information than the traditional 10-year summative multiple-choice examination and that it is a superior method of assessment for ongoing ABPMR certification. Based on these results, the ABPMR has adopted the LA-PM&R program to replace its MOC Examination – Part III in the four-part framework for maintenance of certification.

Stratman EJ. Dermatology Continuing Certification changes for the Better. *Dermatology News*. 2020;105(1):14-15.
This article discusses major changes to the American Board of Dermatology's (ABD) continuing board certification examination. On January 6, 2020, the ABD launched its new web-based longitudinal assessment program called CertLink®. This new platform is designed to eventually replace the sit-down, high-stakes, once-every-10-year medical knowledge examination that dermatologists take to remain board certified. With this alternative, every participating dermatologist will receive a batch of 13 web-based questions every quarter that he/she may answer at a convenient time and place. Questions are answered one at a time or in batches, depending on the test taker's preference, and can be completed on home or office computers (and eventually on smartphones). Participating in this type of testing will not require shutting down practice, traveling to a test center, or paying for expensive board review courses. CertLink® is designed to be convenient, affordable, and relevant to an individual's practice.

Rosenkrantz AB, Berland LL, Heitkamp DE, Duszak, Jr. R. Diagnostic Radiologists' Participation in the American Board of Radiology Maintenance of Certification Program. *AJR Am J Roentgenol*. 2019;213(6):1284-1290.
The purpose of this study was to characterize diagnostic radiologists' participation in the American Board of Radiology (ABR) MOC program, the framework for its new Online Longitudinal Assessment program. The study showed that although diagnostic radiologists with time-limited certificates nearly universally participate in MOC, those with lifetime certificates (particularly general radiologists and those in smaller and nonacademic practices) participate infrequently. Low rates of nonmandated participation may reflect diplomate dissatisfaction or negative perceptions about MOC.

Chesluk B, Gray B, Eden A, et al. "That Was Pretty Powerful": A Qualitative Study of What Physicians Learn When Preparing for Their Maintenance-of-Certification Exams. *J Gen Intern Med*. 2019;34(9):1790-1796.
The purpose of this study was to understand how maintenance of certification (MOC) exam preparation can affect knowledge and practice. The study included general physicians certified by

the American Board of Family Medicine (ABFM) and the American Board of Internal Medicine (ABIM) who had recently taken a joint ABFM/ABIM MOC exam. Out of the 80 physicians surveyed, 67 stated that during their MOC preparation they gained knowledge relevant to their practice. Sixty-three physicians gave concrete examples of how this new knowledge positively affected their practice. These examples are summarized in this article.

Chesluk BJ, Eden AR, Hansen ER, et al. How Physicians Prepare for Maintenance of Certification Exams: A Qualitative Study. Academic Medicine. *Acad Med*. 2019;94(12):1931-1938.
This qualitative study explores how physicians experience MOC exam preparation: how they prepare for the exams and decide what to study and how exam preparation compares with what they normally do to keep their medical knowledge current. The study showed that most interviewees studied for their MOC exams by varying from their routines for staying current with medical knowledge, both by engaging with a different scope of information and by adopting different study methods. Physicians described exam preparation as returning to a student/testing mindset, which some welcomed and others experienced negatively or with ambivalence. The authors concluded that what physicians choose to study bounds what they can learn from the MOC exam process and therefore also bounds potential improvements to their patient care. Knowing how physicians actually prepare, and how these preparation activities compare with what they do when not preparing for an exam, may inform debates over the value of requiring such exams, as well as conversations about how physicians, certification boards, and other key stakeholders in physicians' continuing professional development could improve the MOC process.

Gold L. Reflections Prompted by the Maintenance of Certification. *J Am Acad Psythiatry Law*. 2019;47(3):347-349.
In this editorial, the author describes her retreat to Bywater, Virginia to study for the American Board of Psychiatry and Neurology (ABPN) Forensic Psychiatry Maintenance of Certification (MOC) 10-year high-stakes examination. Although the author served on the ABPN Forensic Committee for 11 years, writing test questions for the Certification and MOC examinations, reviewing questions written by other people, helping to assemble tests (not this particular one), and reviewing test and question data, there was still a need to study for the exam to avoid the embarrassment of failing.

Poniatowski PA, Dugosh JW, Baranowski RA, et al. Incorporating Physician Input Into a Maintenance of Certification Examination: A Content Validity Tool. *Acad Med*. 2019 Sep;94(9):1369-1375.
As part of the American Board of Internal Medicine's (ABIM's) continuing effort to update its Maintenance of Certification (MOC) program, a content validity tool was used to conduct structured reviews of the MOC exam blueprints (i.e., tables of test specifications) by the physician community. Results from the Cardiovascular Disease MOC blueprint review are presented in this article as an example of the process ABIM conducted for several internal medicine disciplines. Responses from 441 review participants were analyzed. The blueprint review garnered valuable feedback from the physician community and provided new evidence for the content validity of the Cardiovascular Disease MOC exam.

Fain R, Newton WP, O'Neill TR. Creating a New Blueprint for ABFM Examinations. *Ann Fam Med*. 2019;17:562-564.
This report from the American Board of Family Medicine (ABFM) described efforts underway to develop a new blueprint for its examinations, including the Certification Examination, the In-Training Examination taken by residents, and longitudinal assessments.

Association between Continuous Certification and Practice Related Outcomes

Nyenhuis SM, Akkoyun E, Liu L, et al. Real-world Assessment of Asthma Control and Severity in Children, Adolescents, and Adults with Asthma: Relationships to Care Settings and Comorbidities. *J Allergy Clin Immunol Pract*. 2019 Nov 7. doi: 10.1016/j.jaip.2019.10.032
This article discusses Asthma IQ, developed by the American Academy of Allergy, Asthma, and Immunology, which was used to examine the rates and relative contributions of co-morbidities and care settings in terms of asthma severity and control among pediatric and adolescent/adult patients in a large national sample. This was the first time that patient data collected from Part IV of Maintenance of Certification (MOC) has been utilized to help understand the characteristics of patients in different care settings. The web-based Asthma IQ helps clinicians to: 1) use evidence-based medicine to make treatment decisions; 2) graph and report patients' asthma status over time; 3) analyze statistics for the asthma patients in their practice; and 4) report quality improvement measures for Pay for Performance and MOC.

Scott E, Downs S. Pottenger A, Saysana M. Quality Improvement Learning Collaborative Improves Timely Newborn Follow-Up Appointments. *Jt Comm J Qual Patient Saf*. 2019;45(12):808-813
A project involving 11 practices and 24 physicians with a goal to improve rates of timely newborn follow-up through a nine-month quality improvement learning collaborative (QILC) resulted in continual improvement in all measured newborn scheduling metrics throughout the nine-month learning collaborative, with sustainment of progress over the last three months of the QILC. Timely newborn follow-up was defined as an appointment scheduled within three days of newborn discharge. A valuable lesson learned from the QILC was the importance of tying quality improvement work to Part IV Maintenance of Certification (MOC). When surveyed at the end of the learning collaborative, participating pediatricians cited the availability of MOC Part IV credit from the American Board of Pediatrics as a major driver for participation.

Mathur M, Campbell S. Statewide Pediatric Quality Improvement Collaborative for HPV Vaccine Initiation. *WMJ*. 2019;118(1):42-43.
A study involving pediatricians participating in a quality improvement project, for which they received Maintenance of Certification (MOC) credit from the American Board of Pediatrics, resulted in improved human papillomavirus (HPV) vaccination rates at hospitals across Wisconsin. During the program's two-month intervention, the HPV vaccination initiation rates rose in participating practices from 56.4 percent to 71.2 percent, which exceeds state and national averages. In addition, Tdap vaccine initiation rates increased from 92.9 percent to 97.2 percent, and meningococcal vaccine rates increased from 89.7 percent to 92.8 percent. This study showed that a statewide learning collaborative can be a useful and productive way to improve the quality of care, and it is valued by the participants, particularly when MOC credit is awarded.

Willis TS, Yip T, Brown K, et al. Improved Teamwork and Implementation of Clinical Pathways in a Congenital Heart Surgery. *Pediatr Qual Saf*. 2019;4(e126):1-7.
A project to improve teamwork and decrease variations in care in a pediatric congenital heart surgery population by implementing Integrated Clinical Pathways (ICPs) on a foundation of teamwork training resulted in three of the four units experiencing a significant improvement in teamwork after training and coaching. The area without a significant change was one with high-level teamwork training already in place. ICPs were implemented in two patient subpopulations. There was a detected a decrease in total hours intubated using statistical process control charts in both of the ICP patient populations, but no reduction in length of stay in days. The infrastructure for the program was successfully implemented and remains in place six years later. This project

was approved for the quality improvement portion of Maintenance of Certification through the American Board of Pediatrics and was an incentive for participation.

Tew PW, Yard R. Improving Access to Screening, Brief Intervention, and Referral to Treatment in Primary Care for Adolescents: Implementation Considerations. The Center for Health Care Strategies. Available at: https://www.chcs.org/media/SBIRT-BRIEF-101019.pdf (accessed 1-22-20)
This article discusses how the University of Pittsburgh Medical Center (UPMC) Health Plan created a learning collaborative framework for engaging provider practices to participate in their Screening, Brief Intervention, and Referral to Treatment (SBIRT) initiative. SBIRT can be applied to various segments of the population to screen for risky substance use and provide early intervention when appropriate. Based on "The Model for Improvement," their learning collaborative incorporated Plan-Do-Study-Act principles, which is a tool for documenting change. Two separate cohorts of practices participated in an initial training session, a mid-point, and a final convening. At the end of each cohort, UPMC saw screening rates of more than 95 percent in most practices and high rates of brief interventions for youth who screened positively for high-risk substance use. Providers reported positive feedback on the process and welcomed the support in developing their SBIRT workflow and reinforcing the use of MI. Outcomes of the collaborative included providing continuing medical education and/or maintenance of certification credits. By addressing these professional requirements, providers may be better able to justify the time out of the office. UPMC offered MOCs for their training, which requires a more intensive set-up process, and they determined that it added value beyond the more easily obtainable CMEs for their providers.

The Impact of Continuous Certification on Medical Licensure

Young A, Chaudhry HJ, Pei X, et al. FSMB Census of Licensed Physicians in the United States, 2018. *Journal of Medical Regulation*. 2019;105(2):7-23.
This article provides physician census data compiled by the Federation of State Medical Boards (FSMB). The article notes that there are 985,026 physicians with Doctor of Medicine (MD) and Doctor of Osteopathic Medicine (DO) degrees licensed to practice medicine in the United States and the District of Columbia. These qualified physicians graduated from 2,089 medical schools in 167 countries and are available to serve a U.S. national population of 327,167,434. While the percentage of physicians who are international medical graduates have remained relatively stable over the last eight years, the percentage of physicians who are women, possess a DO degree, have three or more licenses, or are graduates of a medical school in the Caribbean have increased by varying degrees during that same period. This report marks the fifth biennial physician census that the FSMB has published, highlighting key characteristics of the nation's available physician workforce, including numbers of licensees by geographic region and state, type of medical degree, location of medical school, age, gender, specialty certification, and number of active licenses per physician.

Farrell ML. The Effect of State Medical Board Action on ABMS Specialty Board Certification. *Journal of Medical Regulation*. 2019;105(2):33-41.
In this article, the author discusses how state medical board action that is deemed a restriction by an American Board of Medical Specialties (ABMS) member board can result in a loss of board certification, impacting a physician's ability to practice, and frustrating a medical board's efforts to rehabilitate the physician and improve the quality of care provided to patients. State medical boards have difficulty predicting what types of actions constitute a restriction by a specialty board and imposing appropriate discipline because specialty boards use varying criteria to evaluate state medical board action. ABMS member boards experience frustration of their own when attempting

to interpret actions from 70 separate state medical boards, each governed by its own laws and using its own nomenclature. This article summarizes the inconsistency of both specialty boards and state medical boards, describes the efforts to resolve this issue, and proposes a series of steps that will bring a higher degree of predictability to this process and meet the needs of all stakeholders.

Nelson LS, Duhigg LM, Arnold GK, et al. The Association between Maintaining ABEM Certification and State Medical Board Disciplinary Actions. *J Emerg Med*. 2019 Dec;57(6):772-779.
A study was undertaken to determine if maintaining American Board of Emergency Medicine (ABEM) certification was associated with a lower risk of disciplinary action. This study which included 23,002 physicians in the study cohort showed that the absolute incidence of physicians with a disciplinary action was low (3.0 percent), and that maintaining ABEM certification was associated with a lower risk of state medical board disciplinary actions.

Nathan N. Regular Maintenance Is Strongly Recommended: The Road to Board Certification and Beyond. *Anesth Analg*. 2019;129(5):1191.
This infographic summarizes the educational pathway that leads to board certification in anesthesiology.

Zhou Y, Sun H, Macario A, et al. Association Between Participation and Performance in MOCA Minute and Actions Against the Medical Licenses of Anesthesiologists. *Anesth Analg*. 2019;129:1401-7.
A study to examine the association between participation and performance in the Maintenance of Certification in Anesthesiology (MOCA) Minute (the American Board of Anesthesiology's web-based longitudinal assessment) and disciplinary actions against medical licenses of anesthesiologists showed that both timely participation and meeting the performance standard in MOCA Minute are associated with a lower likelihood of being disciplined by a state medical board. Using 2016 data, the study found that the cumulative incidence of license actions was 1.2 percent in anesthesiologists required to register for MOCA Minute. Nonregistration was associated with a 2.93 percent higher incidence of license actions. For the 18,534 (96.2 percent) who registered, later registration (after June 30, 2016) was associated with a higher incidence of license actions.

Jones AT, Kopp JP, Malangoni MA. Recertification Exam Performance in General Surgery is Associated With Subsequent Loss of License Actions. *Ann Surg*. 2019 Apr 23. doi: 10.1097/SLA.0000000000003330
A study to measure associations between first-time performance on the American Board of Surgery (ABS) recertification exam with subsequent state medical licensing board disciplinary actions showed that failing the first recertification exam attempt was associated with a greater rate of subsequent loss-of-license actions.

Kinney CL, Raddatz MM, Sliwa JA, et al. Association of Participation in the American Board of Physicial Medicine and Rehabilitation Maintenance of Certification Program and Physician Disciplinary Actions. *Am J Phys Med Rehabil*. 2019 Oct 18. doi: 10.1097/PHM.0000000000001331.
A study to analyze the relationship between participation in the American Board of Physical Medicine and Rehabilitation (ABPMR) maintenance of certification (MOC) program and the incidence of disciplinary actions by state medical boards over a physician's career showed that physicians in physical medicine and rehabilitation who had a lapse in completing ABPMR's MOC program had a 2.5-fold higher incidence of receiving a disciplinary action and had higher severity violations than physicians whose certificate never lapsed.

ABMS and ABMS Member Board Policies and Initiatives

Colenda CC, Scanlon WJ, Hawkins RE. Vision for the Future of Continuing Board Certification. *JAMA*. 2019 Jun 18;321(23):2279-2280..
This article provides an overview of the Vision Initiative process, the Commission's Final Report recommendations, and the American Board of Medical Specialties and ABMS member boards implementation program.

Bartley GB. The Vision for the Future Commission on Continuing Board Certification: Initial Perspectives from the American Board of Ophthalmology. *Ophthalmology*. 2019;126(7):922-925.
This article reviews the recommendations from the Continuing Board Certification: Vision for the Future Commission and discusses the implications of the Commission's report for the ophthalmic community.

Williams GA, Parke II DW. Continuing Professional Certification: Perspective of the American Academy of Ophthalmology. *Ophthalmology*. 2019;126(7):926-927.
This article reviews the recommendations from the Continuing Board Certification: Vision for the Future Commission and discusses the implications of the Commission's report for the ophthalmic community. The authors also provide background information on why the American Board of Ophthalmology (ABO) was established in 1916 and required certification based on examination at the initiation of clinical practice and subsequently established the continuing medical education (CME) system and the linkage of participation in accredited CME offerings with maintenance of state licensure and organizational credentialing

Newton WP, Baxley E, Lefebvre A. Improving Quality Improvement. *Ann Fam Med*. 2019;17:381-382.
In February 2019, the Vision Committee recommended that the American Board of Medical Specialties chart a new course for Improvement in Medical Practice. Arguing that the Maintenance of Certification requirement for Improvement in Medical Practice had become onerous for some diplomates and challenging to implement for many specialties, the Vision Committee called for the identification of new approaches to advancing practice while recognizing what Diplomates are already doing. This article discusses how the American Board of Family Medicine has begun to develop measures to better capture what is unique to family medicine and primary care, such as continuity, comprehensiveness, and patient centered outcomes.

Grayson MH, Oppenheimer J, Castells M, Nowak-Wegrzyn A. Life-long Learning and the ABAI: Practice Improvement Comes of Age. *Ann Allergy Asthma Immunol*. 2019 Jul;123(1):6-8.
This article discusses how the American Board of Allergy and Immunology (ABAI) developed "Alternatives to Practice Assessment/Quality Improvement Modules" to provide diplomates with opportunities to showcase the continual improvement activities they are involved in that apply to their specific career path.

Bradley J, Theobald M. Preliminary Results of the ABFM/STFM Precepting Performance Improvement Pilot. *Ann Fam Med*. 2019;17:185-186.
This article discusses how the Society of Teachers of Family Medicine and the American Board of Family Medicine completed a pilot program that offered Performance Improvement continuing certification credit (previously Maintenance of Certification Part IV) to ABFM diplomates who provide personal instruction, training, and supervision to a medical student or resident and who participate in a teaching improvement activity. Forty-two academic units (sponsors) were selected

to participate through an application process. Thirty-three completed the requirements of the program and submitted a final report.

Newton WP, Baxley E, Rode K, et al. Improving Continuing Education for Family Physicians: The Role of the American Board of Family Medicine. *JABFM*. 2019;32(5):756-8.
This article touches on the history of the American Board of Family Medicine (ABFM) and looks at the role the ABFM should play in the larger continuing medical education system for family physicians. At its founding, ABFM required reassessment of cognitive expertise every seven years. In the early 2000s, ABFM implemented a maintenance of certification model with requirements to participate in knowledge self-assessments and performance improvement activities every three years The organization also extended time between examinations to every 10 years. Currently, the ABFM is offering an optional national Family Medicine Journal Club. This offering will provide practice changing articles selected for relevance and methodological rigor from 140 clinical journals to expand opportunities for ABFM, its chapters, and CME providers to develop continuing education opportunities to meet the needs of ABFM Diplomates.

Bass EB. Strengthening Our Voice in Public Policy on Medical Education. *Trans Am Clin Climatol Assoc.* 2019;130:156–165.
This article provides an overview of medical education issues that are receiving attention by public policymakers. Many forces contribute to the interest of policymakers in medical education, including public awareness of how policies can affect access to and quality of clinical care. Governmental legislatures are getting more involved in medical education policy, with less acceptance of the profession's autonomy. The author notes that professional societies are not positioned to respond optimally to governmental involvement in medical education policy due to limited resources, poor coordination, and competing concerns. In response to concerns of many physicians about maintenance of certification programs, policymakers at the state level have been asked to consider new policies for regulating the approach to maintenance of certification. At the federal level, policymakers have been asked to consider new ways to support the training of physician-investigators.

Nguyen XV, Adams SJ, Hobbs SK, et al. Radiologist as Lifelong Learner: Strategies for Ongoing Education. *Acad Radiol*. 2019 Aug;26(8):1120-1126.
The Association of University Radiologists-Radiology Research Alliance Lifelong Learning Task Force convened to explore the current status and future directions of lifelong learning in radiology and summarized its findings in this article. The authors review the various learning platforms and resources available to radiologists in their self-motivated and self-directed pursuit of lifelong learning. They also discuss the challenges and perceived barriers to lifelong learning and strategies to mitigate those barriers and optimize learning outcomes. The American Board of Radiology's maintenance of certification (MOC) program demonstrates the board's commitment and support for continuous quality improvement, quality patient care, and professional development. More recently, online longitudinal assessment has been introduced as a progressive online assessment that will replace the requirement of a MOC exam every 10 years.

Kates AM, Morris PB. Highlights of the American College of Cardiology Annual Scientific Sessions 2019. *Circulation*. 2019;139:2793-2795.
The authors provide an overview of the American College of Cardiology's (ACC) new strategic plan and announced the groundbreaking agreement between ACC and the American Board of Internal Medicine, establishing a new pathway for the maintenance of certification through the Collaborative Maintenance Pathway.

Shivraj P, Novak A, Aziz S, et al. The Certification Process Driving Patient Safety. *Obstet Gynecol* Clin N Am. 2019;46:269-280.
In 2016, the American Board of Medical Specialties (ABMS) and the National Patient Safety Foundation issued a joint call encouraging each ABMS member board to integrate patient safety principles and activities into their initial and continuous certification processes. This article describes how the American Board of Obstetrics and Gynecology integrates various aspects of patient safety principles into its initial and continuous certification processes. The authors first describe how they assess patient safety within their initial certification processes. They then describe each component of their maintenance of certification program, and how they intentionally embed patient safety principles within each component.

Physician Satisfaction with Continuous Certification

Peabody MR, Peterson LE, Dai M, et al. Motivation for Participation in the American Board of Family Medicine Certification Program. *FamMed.* 2019;51(9):728-36.
This study involving 7,545 family physicians who provide direct patient care and participate in continuing certification showed that approximately one-fifth (21.4 percent) were motivated to continue their board certification solely by intrinsic factors (e.g., to maintain professional image, personal preference, etc.). Less than one-fifth (17.3 percent) were motivated only by extrinsic factors (e.g., required by employers, for credentialing purposes, etc.), and the majority (61.2 percent) reported mixed motivations for continuing their board certification. Only 38 respondents (0.5 percent) included a negative opinion about the certification process in their open-text responses. Approximately half of family physicians in this sample noted a requirement to continue their certification, suggesting that there has been no significant increase in the requirements from employers, credentialing bodies, or insurers for physicians to continue board certification noted in previously cited work. Furthermore, only 17.5 percent of the physicians in this study reported solely external motivation to continue certification, indicating that real or perceived requirements are not the primary driver for most physicians to maintain certification.

Leslie LK, Turner AL, Smith AC, et al. Pediatrician Perspectives on Feasibility and Acceptability of the MOCA-Peds 2017 Pilot. *Pediatrics*. 2019;144(6). doi: 10.1542/peds.2019-2303.
This study involving 4,238 pediatricians who participated in MOCA-Peds showed that 93 percent considered MOCA-Peds to be a feasible and acceptable alternative to the traditional MOC exam. The pediatricians surveyed participated in a pilot MOCA-Peds program in 2017 and completed two questionnaires. Of the pediatricians who completed the fourth-quarter survey, 82 percent agreed the questions assessed clinical judgment, 82 percent agreed the questions were relevant to the practice of general pediatrics, and 59 percent agreed the questions were relevant to their specific practice setting. Most of them (89 percent) reported feeling less anxious about participating in MOCA-Peds than taking the proctored exam. The majority of general pediatricians and subspecialists (97 percent and 95 percent, respectively) said they planned to participate in MOCA-Peds to maintain their certification.

ABOS Web-Based Longitudinal Assessment (ABOS WLA). American Board of Orthopaedic Surgery. Available at: https://www.abos.org/moc/abos-web-based-longitudinal-assessment-abos-wla/ (accessed 1-15-20)
In 2019, the American Board of Orthopaedic Surgery (ABOS) launched the ABOS Web-Based Longitudinal Assessment (ABOS WLA) Program. Nearly 10,000 Diplomates—about 55 percent of those eligible (diplomates whose certification expires 2019 through 2028)—chose to participate in the inaugural program. As the results of this ABOS survey demonstrate, the majority of ABOS Diplomates who participated in the ABOS WLA thought it was a high-quality program and want to

continue with it next year. Diplomates felt that the Knowledge Sources were relevant to their practice and a more appropriate assessment of their knowledge. ABOS' report of survey results includes a list of changes to next year's ABOS WLA based on diplomate feedback.

Dai M, Hagen M, Eden AR, Peterson LE. Physician opinions about American Board of Family Medicine self-assessment modules (2006 –2016). *J Am Board Fam Med.* 2019;32(1):79-88.
An evaluation of the American Board of Family Medicine (ABFM) diplomate feedback survey data to examine family physician opinions about ABFM self-assessment module (SAM) content (448,408 SAM feedback surveys were completed within the period 2006-2016) showed that family medicine diplomates generally value SAMs. Respondents felt that the SAM content is appropriate, and favorability ratings increased as diplomates engaged in more SAM activities.

Concerns about CBC

Singleton MM. Let's Put the Act in Activism. *Journal of American Physicians and Surgeons*. 2019;24(3):75-76.
In this editorial, the author discusses how the requirements of the federal government, insurers and managed care entities, large health care systems, state medical boards, medical specialty boards, and pharmaceutical companies are placing burdensome demands on physicians. In addition, the author notes that, "to apply for or renew hospital staff privileges, hospitals are demanding Maintenance of Certification (MOC), an expensive process of questionable value. MOC places onerous burdens on physicians and worse, takes away physicians' time with their patients. It is up to us to demand and maintain self-governance at the hospital and in our private practices."

Chazal RA. RESPONSE: Dealing With Multiple Certifications and Recertifications. *JACC*. 2019;73(11):1360-1361.
In this editorial, the author discusses concerns about the cost, time, and efficacy of multiple board certifications (and recertifications) that are widespread among trainees and practicing physicians. Limiting the number of board certifications that an individual pursues would seem logical, but it may be more practical for the practicing clinician than a trainee not yet certain of his or her career path.

Berlin J. Closing a Loophole: Medicine Works to Clarify MOC Law. *Texas Medicine*. Mar 2019. Available at: https://www.texmed.org/Template.aspx?id=49952 (accessed 1-23-20).
This editorial discusses the 2017 Texas legislature's Senate Bill 1148 that prohibits health plans from using maintenance of certification (MOC) as a requirement for contracts; prevents the Texas Medical Board from using it as a condition of licensure or license renewal; and prohibits most hospitals and other health care facilities from using MOC status for credentialing, hiring, or retaining physicians. Exceptions include facilities required to use MOC by law, rule, or certification or accreditation standard; medical schools or comprehensive cancer centers; and entities in which the voting physician members of the medical staff vote to authorize the use of MOC. The Texas Medical Association (TMA) is working with lawmakers after receiving complaints that Memorial Hermann Health System is attempting to work around the law. TMA also supports the recommendations of the Vision for the Future Commission to strengthen the MOC reforms it proposed for the American Board of Medical Specialties (ABMS) and the ABMS member boards.

Challenges and Considerations

Cordovani L, Wong A, Monteiro S. Maintenance of certification for practicing physicians: a review of current challenges and considerations. *Canadian Medical Education Journal*. 2019. Available at: http://www.cmej.ca. Accessed December 16, 2019.
This paper reviews current issues and challenges associated with maintenance of certification (MOC) in medicine, including how to define medical competencies for practicing physicians, assessment, and how best to support physicians' lifelong learning in a continuous and self-motivated way. The authors discuss how the combination of self-monitoring, regular feedback, and peer support could improve self-assessment. They note that effective MOC programs are learner-driven, focused on everyday practice, and incorporate educational principles. They also discuss the importance of MOC to the physicians' actual practice to improve acceptability, the benefits of tailored programs, and decentralization of MOC programs to better characterize the physician's practice. Lastly, they discuss the value of simulation-based medical education in MOC programs. Simulation-based education could be used to practice uncommon complications, life-threatening scenarios, and non-technical skills improvement. This type of education can also be used to become proficient with new technology. As learners find simulation experiences educationally valuable, clinically relevant, and positive, simulation could be a way of increasing physicians' participation in MOC programs.

Gabel J, O'Dell T, Masuda E, et al. Who is treating venous disease in America today? *J Vasc Surg: Venous and Lym Dis*. 2019;7:610-614.
A study to examine the specialty, board certification, and training of physicians who are treating venous disease in the United States showed there are a large number of physicians treating venous disease who do not have an active board certification. This was more common for physicians employed by a large multistate venous corporation. Physicians employed by a corporation were more likely to advertise a board certification from the American Board of Venous and Lymphatic Medicine (a certification not endorsed by the American Board of Medical Specialties).

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REPORT OF THE COUNCIL ON MEDICAL EDUCATION

CME Report 2, November 2020

Subject: Graduate Medical Education and the Corporate Practice of Medicine

Presented by: Liana Puscas, MD, MHS, Chair

Referred to: Reference Committee C

INTRODUCTION

American Medical Association (AMA) Policy H-310.904, "Graduate Medical Education and the Corporate Practice of Medicine," states that our AMA:

> (1) recognizes and supports that the environment for education of residents and fellows must be free of the conflict of interest created between a training site's fiduciary responsibility to shareholders and the educational mission of residency or fellowship training programs;
>
> (2) encourages the Accreditation Council for Graduate Medical Education (ACGME) to update its "Principles to Guide the Relationship between Graduate Medical Education, Industry, and Other Funding Sources for Programs and Sponsoring Institutions Accredited by the ACGME" to include corporate-owned lay entity funding sources; and
>
> (3) will study issues, including waiver of due process requirements, created by corporate-owned lay entity control of graduate medical education sites.

The report describes the corporate practice of medicine doctrine (as developed by the AMA),[1] the increase in the number of physicians as employees, the potential effects of corporate medicine on graduate medical education (GME), and protections provided against undue influence in GME.

BACKGROUND

As a country of innovation and new ideas, the United States is a natural laboratory for the development of corporate-funded sponsorships in medical education. That said, the unintended consequences of a potentially pernicious influence in medical education and interference in training by corporate interests highlights the need for hyper-vigilance by the house of medicine.

The corporate practice of medicine doctrine describes the general principle that limits the practice of medicine to licensed physicians, prohibits corporations from practicing medicine, and protects the practice of medicine from corporations' and other lay entities' overriding desire to generate profits.[1] In some cases, the doctrine may prohibit a corporation from directly employing a physician to provide medical services. The doctrine is based on a number of policy concerns, including the following:

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1. Allowing corporations to practice medicine or employ physicians will result in the commercialization of the practice of medicine;
2. A corporation's obligation to its shareholders may not align with a physician's obligation to patients; and
3. Employment of a physician by a corporation may interfere with the physician's independent medical judgment.

Most states, but not all, have laws that prohibit the corporate practice of medicine, which may address the corporate influence on the practice of medicine in contexts other than physician employment. For example, a state's corporate practice of medicine laws frequently limit or prohibit non-physicians from owning, investing in, or otherwise controlling medical practices.[2] Almost every state, however, provides broad exceptions to various forms of the doctrine. For example, all states allow for professional corporations or associations wholly owned by physicians to provide care. Some states allow nonphysicians or shareholders to hold an ownership interest in a professional corporation, but often limit such ownership to a minority percent. Hospitals are also exempted in many states, as many states permit hospitals to employ physicians. In these situations, it is stipulated that the employer not interfere with or attempt to control the independent medical judgment of physicians on staff.[1,2]

THE CORPORATE PRACTICE OF MEDICINE AND INCREASING PHYSICIAN EMPLOYMENT STATUS

More physicians are now employees rather than owners of their own practices. The year 2018 was the first in which there were fewer patient care physicians with ownership stakes in their practices (45.9 percent) than were employees (47.4 percent). The employee status of physicians varies by specialty. Emergency medicine, the specialty that has been most concerned with the corporate practice of medicine, has the lowest proportion of physicians who are owners (26.2 percent). Emergency medicine also has the highest share of physicians who are independent contractors (27.3 percent) and the highest proportion of physicians who are directly employed by or with a contract with a hospital, at 23.3 percent.[3]

As more physicians become employees, the profession should monitor physician professional autonomy within that employment status. One issue of particular concern, which may be part of a physician's employment contract, is post-employment non-compete clauses. Non-compete clauses may negatively affect a physician's ability to find new employment if current employment should cease. For example, the increasing number of hospital and health system mergers can create a local health care environment with few employers who would not be considered as competition under a non-compete clause.[2]

A second issue is due process. The Fifth Amendment requires that the federal government provide due process protections to its citizens, while the 14th Amendment extends those same requirements to states and to state actors. Due process protections, however, do not necessarily apply to private hospitals or other health care facilities that grant medical staff privileges (non-federal or state actors).[4] Generally, medical staff bylaws describe how termination of a physician's privileges must proceed. Hospitals may require that physicians waive any due process rights contained in the hospital bylaws to maintain a quality medical staff while limiting the number of contentious and costly due process hearings. Contracts with third parties can also allow hospitals to avoid adhering to any applicable due process requirements. If a hospital contracts with a staffing company to hire physicians, the hospital may require that the staffing company's contract with physicians contain a due process waiver. If the staffing company does not agree to the hospital's requests, then the hospital may choose to contract with another group. As it is highly likely that emergency medicine

physicians are either employees of hospitals or under contract with a staffing company that has required a due process waiver as a condition of contracting, due process waivers remain an issue of great concern to the specialty. Legislation has been introduced to eliminate the ability of a third-party contract to waive a physician's due process rights.[2,4]

THE CORPORATE PRACTICE OF MEDICINE AND GRADUATE MEDICAL EDUCATION

Currently, at least 14 emergency medicine residency programs are owned by lay entity corporations (i.e., no physician owner) in 10 different states.[5] The potential of the medical education learning environment being unduly influenced by the interests of a corporation, which is beholden to the concerns of shareholders, is disquieting.

The Resident and Student Association of the American Academy of Emergency Medicine has developed questions related to ownership/sponsorship of a program that students can ask of programs during the application or interview process.[6] These include:

> "Are the faculty employed by the hospital/medical school/a group?
> Which type of group? Do the faculty have incentives built around their teaching scores?
>
> Is there a particular type of post-residency practice you try and direct your graduates to?
> How do they get educated as to the various post-residency options?
>
> What type of position do most residents go to after they complete training?
> If mostly academic, do they go to work for physician-owned groups or large companies?
>
> Is the residency sponsored by any entity other than Medicare?
> If so, by whom? If a large amount is sponsored by an entity other than Medicare, does this sponsor affect my education in any way? Have there been issues with this sponsor in relation to this residency program in the past? Would this entity sponsoring my training bias me in any way?"

One of the largest for-profit hospital companies in the U.S., HCA Healthcare, currently has 19 hospitals sponsoring 162 ACGME-accredited programs in 12 states. HCA Healthcare also operates hospitals that are affiliated with training programs (but are not sponsors). One positive outcome of increased involvement in GME by this and other for-profit entities has been the growth of GME in areas with high-population growth, such as Florida, Georgia, Texas, and Nevada, that have long been stymied in their ability to increase GME positions. As with non-profit training institutions, for-profit sponsors likely benefit from the health care workforce that residents provide, as well as the built-in pool of physician candidates for employment.[7]

At the same time, concerns of physician professional autonomy, due process, and conflict of interest may be more common when there is a fiduciary responsibility to shareholders by the sponsors or affiliates of training programs. Recent incidents in which for-profit corporations have purchased and then unexpectedly closed training hospitals have raised apprehensions regarding the long-term interests of corporations and their disconnect to GME. In 2019, for example, Hahnemann University Hospital (HUH) was abruptly closed shortly after being purchased in 2018 by American Academic Health System, LLC (a private equity-backed company).[8,9] Also in 2019, Ohio Valley Medical Center was closed after being purchased by Alecto Healthcare Services, LLC in 2017.[10] The closure of HUH resulted in the displacement of 570 residents from over 30 residency and fellowship programs; the closure of Ohio Valley displaced 32 residents from two programs. The efforts of many individuals, programs, and organizations to successfully provide continuing

training opportunities for these physicians has been described elsewhere. Currently, the situation created by the closure of HUH is still being litigated; however, attention has been increasing regarding the future of health care delivery, as well as GME, in light of financial pressures on training institutions and affiliated practice sites.[11,12] AMA Policy H-310.943 "Closing of Residency Programs" includes many recommendations resulting from the sudden closure of the HUH residency programs.

REQUIREMENTS PROTECTING GME FROM CONFLICT OF INTEREST AND OTHER CORPORATE INFLUENCE

The ACGME accredits residency and fellowship programs and sets requirements for training programs as well as the institutions in which training occurs. A review of ACGME institutional requirements reveals general concerns about due process, conflict of interest, and competition. For example, IV.D. "Grievances: The Sponsoring Institution must have a policy that outlines the procedures for submitting and processing resident/fellow grievances at the program and institutional level and that minimizes conflicts of interest." The contract of appointment must include a reference to grievance and due process [IV.B.2.e)]. Regarding promotion, appointment renewal and dismissal, the sponsoring institution must have policy that provides residents and fellows with due process for suspension, non-renewal, non-promotion, or dismissal [IV.C.1.b)].

Finally, "Sponsoring Institution[s] must maintain a policy which states that neither the Sponsoring Institution nor any of its ACGME-accredited programs will require a resident/fellow to sign a non-competition guarantee or restrictive covenant." [IV.L.][13]

The ACGME's Common Program Requirements (CPRs) include slightly more specificity. In the Common Program Requirements, it is noted that the program director must:

> II.A.4.a).(10) provide a learning and working environment in which residents have the opportunity to raise concerns and provide feedback in a confidential manner as appropriate, without fear of intimidation or retaliation;
> II.A.4.a).(11) ensure the program's compliance with the Sponsoring Institution's policies and procedures related to grievances and due process;
> II.A.4.a).(12) ensure the program's compliance with the Sponsoring Institution's policies and procedures for due process when action is taken to suspend or dismiss, not to promote, or not to renew the appointment of a resident;
> and
> II.A.4.a).(13).(a) Residents must not be required to sign a noncompetition guarantee or restrictive covenant.

The CPRs do require that the learning environment encourage the development of residents and fellows into ethical and caring professionals, which could forearm trainees from negative, undue influence of corporate medicine. For example, faculty are to "demonstrate commitment to the delivery of safe, quality, cost effective, patient-centered care." [II.B.2.b)] The curriculum is to advance "residents' knowledge of ethical principles foundational to medical professionalism." [IV.A.5.]. As part of the ACGME core competency of professionalism, residents are to demonstrate competence in "responsiveness to patient needs that supersedes self-interest," "accountability to patients, society, and the profession" and "appropriately disclosing and addressing conflict or duality of interest." [IV.B.1.a).(1).(b) (d) and (g)] More generally, the core competency of practice-based learning and improvement requires that physicians investigate and evaluate the care of patients, to appraise and assimilate scientific evidence, and to continuously improve patient care based on constant self-evaluation and lifelong learning. [IV.B.1.d)][14]

The ACGME published in 2012 the "Principles to Guide the Relationship between Graduate Medical Education, Industry, and Other Funding Sources for Programs and Sponsoring Institutions Accredited by the ACGME,"[15] as referenced in H-310.904. Written at a time of growing influence of the pharmaceutical industry via funding graduate and undergraduate medical education by sponsoring educational programs, medical research, and promotional marketing, the Principles state that "The relationship of a company to its shareholders defines values and influences behaviors held by the industry." However, the "industry" of the Principles "includes pharmaceutical companies, manufacturers of medical devices, and biotechnology companies," but does not encompass corporate-owned lay entity funding sources. This absence led to adoption of H-310.904 at the 2019 Annual Meeting of the AMA House of Delegates—in particular: "Our AMA … (2) encourages the Accreditation Council for Graduate Medical Education (ACGME) to update its 'Principles to Guide the Relationship between Graduate Medical Education, Industry, and Other Funding Sources for Programs and Sponsoring Institutions Accredited by the ACGME' to include corporate-owned lay entity funding sources."

CURRENT AMA POLICY

AMA policies related to this topic are listed in the Appendix.

SUMMARY AND RECOMMENDATIONS

Corporate involvement in GME is likely to grow with the increase in mergers and acquisitions involving hospitals, health systems, and physician practice management companies, with resulting disruptions to existing relationships. As much of GME is now taking place outside of major teaching hospitals, adherence to professional and ethical principles may be obscured by organizational stresses due to financial accountability to owners not involved in or knowledgeable of the practice of medicine. Negative impacts to the learning environment through the "hidden curriculum" are an additional concern. Enhanced oversight may be needed to protect residents and fellows from potential conflicts between GME and the fiduciary responsibilities of training programs and their institutions.

The Council on Medical Education therefore recommends that the following recommendations be adopted and the remainder of this report be filed:

1. That Policy H-310.904, "Graduate Medical Education and the Corporate Practice of Medicine," be amended by addition and deletion to read as follows: "Our AMA: … (3) will ~~study~~ <u>continue to monitor</u> issues, including waiver of due process requirements, created by corporate~~-owned lay entity~~ control of graduate medical education sites." (Modify Current HOD Policy)

2. That our AMA reaffirm Policy H-310-904 (2), "Graduate Medical Education and the Corporate Practice of Medicine." (Reaffirm HOD Policy)

Fiscal note: $1,000.

APPENDIX: RELEVANT AMA POLICY

H-255.950, "AMA Principles for Physician Employment"

1. Addressing Conflicts of Interest

a) A physician's paramount responsibility is to his or her patients. Additionally, given that an employed physician occupies a position of significant trust, he or she owes a duty of loyalty to his or her employer. This divided loyalty can create conflicts of interest, such as financial incentives to over- or under-treat patients, which employed physicians should strive to recognize and address.

b) Employed physicians should be free to exercise their personal and professional judgement in voting, speaking and advocating on any manner regarding patient care interests, the profession, health care in the community, and the independent exercise of medical judgment. Employed physicians should not be deemed in breach of their employment agreements, nor be retaliated against by their employers, for asserting these interests. Employed physicians also should enjoy academic freedom to pursue clinical research and other academic pursuits within the ethical principles of the medical profession and the guidelines of the organization.

c) In any situation where the economic or other interests of the employer are in conflict with patient welfare, patient welfare must take priority.

d) Physicians should always make treatment and referral decisions based on the best interests of their patients. Employers and the physicians they employ must assure that agreements or understandings (explicit or implicit) restricting, discouraging, or encouraging particular treatment or referral options are disclosed to patients.

(i) No physician should be required or coerced to perform or assist in any non-emergent procedure that would be contrary to his/her religious beliefs or moral convictions; and

(ii) No physician should be discriminated against in employment, promotion, or the extension of staff or other privileges because he/she either performed or assisted in a lawful, non-emergent procedure, or refused to do so on the grounds that it violates his/her religious beliefs or moral convictions.

e) Assuming a title or position that may remove a physician from direct patient-physician relationships--such as medical director, vice president for medical affairs, etc.--does not override professional ethical obligations. Physicians whose actions serve to override the individual patient care decisions of other physicians are themselves engaged in the practice of medicine and are subject to professional ethical obligations and may be legally responsible for such decisions. Physicians who hold administrative leadership positions should use whatever administrative and governance mechanisms exist within the organization to foster policies that enhance the quality of patient care and the patient care experience.

Refer to the AMA Code of Medical Ethics for further guidance on conflicts of interest.

2. Advocacy for Patients and the Profession

a) Patient advocacy is a fundamental element of the patient-physician relationship that should not be altered by the health care system or setting in which physicians practice, or the methods by which they are compensated.

b) Employed physicians should be free to engage in volunteer work outside of, and which does not interfere with, their duties as employees.

3. Contracting

a) Physicians should be free to enter into mutually satisfactory contractual arrangements, including employment, with hospitals, health care systems, medical groups, insurance plans, and other entities as permitted by law and in accordance with the ethical principles of the medical profession.

b) Physicians should never be coerced into employment with hospitals, health care systems, medical groups, insurance plans, or any other entities. Employment agreements between physicians and their employers should be negotiated in good faith. Both parties are urged to obtain the advice of legal counsel experienced in physician employment matters when negotiating employment contracts.

c) When a physician's compensation is related to the revenue he or she generates, or to similar factors, the employer should make clear to the physician the factors upon which compensation is based.

d) Termination of an employment or contractual relationship between a physician and an entity employing that physician does not necessarily end the patient-physician relationship between the employed physician and persons under his/her care. When a physician's employment status is unilaterally terminated by an employer, the physician and his or her employer should notify the physician's patients that the physician will no longer be working with the employer and should provide them with the physician's new contact information. Patients should be given the choice to continue to be seen by the physician in his or her new practice setting or to be treated by another physician still working with the employer. Records for the physician's patients should be retained for as long as they are necessary for the care of the patients or for addressing legal issues faced by the physician; records should not be destroyed without notice to the former employee. Where physician possession of all medical records of his or her patients is not already required by state law, the employment agreement should specify that the physician is entitled to copies of patient charts and records upon a specific request in writing from any patient, or when such records are necessary for the physician's defense in malpractice actions, administrative investigations, or other proceedings against the physician.

(e) Physician employment agreements should contain provisions to protect a physician's right to due process before termination for cause. When such cause relates to quality, patient safety, or any other matter that could trigger the initiation of disciplinary action by the medical staff, the physician should be afforded full due process under the medical staff bylaws, and the agreement should not be terminated before the governing body has acted on the recommendation of the medical staff. Physician employment agreements should specify whether or not termination of employment is grounds for automatic termination of hospital medical staff membership or clinical privileges. When such cause is non-clinical or not otherwise a concern of the medical staff, the physician should be afforded whatever due process is outlined in the employer's human resources policies and procedures.

(f) Physicians are encouraged to carefully consider the potential benefits and harms of entering into employment agreements containing without cause termination provisions. Employers should never terminate agreements without cause when the underlying reason for the termination relates to quality, patient safety, or any other matter that could trigger the initiation of disciplinary action by the medical staff.

(g) Physicians are discouraged from entering into agreements that restrict the physician's right to practice medicine for a specified period of time or in a specified area upon termination of employment.

(h) Physician employment agreements should contain dispute resolution provisions. If the parties desire an alternative to going to court, such as arbitration, the contract should specify the manner in which disputes will be resolved.

Refer to the AMA Annotated Model Physician-Hospital Employment Agreement and the AMA Annotated Model Physician-Group Practice Employment Agreement for further guidance on physician employment contracts.

4. Hospital Medical Staff Relations

a) Employed physicians should be members of the organized medical staffs of the hospitals or health systems with which they have contractual or financial arrangements, should be subject to the bylaws of those medical staffs, and should conduct their professional activities according to the bylaws, standards, rules, and regulations and policies adopted by those medical staffs.

b) Regardless of the employment status of its individual members, the organized medical staff remains responsible for the provision of quality care and must work collectively to improve patient care and outcomes.

c) Employed physicians who are members of the organized medical staff should be free to exercise their personal and professional judgment in voting, speaking, and advocating on any matter regarding medical staff matters and should not be deemed in breach of their employment agreements, nor be retaliated against by their employers, for asserting these interests.

d) Employers should seek the input of the medical staff prior to the initiation, renewal, or termination of exclusive employment contracts.

Refer to the AMA Conflict of Interest Guidelines for the Organized Medical Staff for further guidance on the relationship between employed physicians and the medical staff organization.

5. Peer Review and Performance Evaluations

a) All physicians should promote and be subject to an effective program of peer review to monitor and evaluate the quality, appropriateness, medical necessity, and efficiency of the patient care services provided within their practice settings.

b) Peer review should follow established procedures that are identical for all physicians practicing within a given health care organization, regardless of their employment status.

c) Peer review of employed physicians should be conducted independently of and without interference from any human resources activities of the employer. Physicians--not lay administrators--should be ultimately responsible for all peer review of medical services provided by employed physicians.

d) Employed physicians should be accorded due process protections, including a fair and objective hearing, in all peer review proceedings. The fundamental aspects of a fair hearing are a listing of specific charges, adequate notice of the right to a hearing, the opportunity to be present and to rebut evidence, and the opportunity to present a defense. Due process protections should extend to any disciplinary action sought by the employer that relates to the employed physician's independent exercise of medical judgment.

e) Employers should provide employed physicians with regular performance evaluations, which should be presented in writing and accompanied by an oral discussion with the employed physician. Physicians should be informed before the beginning of the evaluation period of the general criteria to be considered in their performance evaluations, for example: quality of medical services provided, nature and frequency of patient complaints, employee productivity, employee contribution to the administrative/operational activities of the employer, etc.

(f) Upon termination of employment with or without cause, an employed physician generally should not be required to resign his or her hospital medical staff membership or any of the clinical privileges held during the term of employment, unless an independent action of the medical staff calls for such action, and the physician has been afforded full due process under the medical staff bylaws. Automatic rescission of medical staff membership and/or clinical privileges following termination of an employment agreement is tolerable only if each of the following conditions is met:
i. The agreement is for the provision of services on an exclusive basis; and
ii. Prior to the termination of the exclusive contract, the medical staff holds a hearing, as defined by the medical staff and hospital, to permit interested parties to express their views on the matter, with the medical staff subsequently making a recommendation to the governing body as to whether the contract should be terminated, as outlined in AMA Policy H-225.985; and
iii. The agreement explicitly states that medical staff membership and/or clinical privileges must be resigned upon termination of the agreement.

Refer to the AMA Principles for Incident-Based Peer Review and Disciplining at Health Care Organizations (AMA Policy H-375.965) for further guidance on peer review.

6. Payment Agreements

a) Although they typically assign their billing privileges to their employers, employed physicians or their chosen representatives should be prospectively involved if the employer negotiates agreements for them for professional fees, capitation or global billing, or shared savings. Additionally, employed physicians should be informed about the actual payment amount allocated to the professional fee component of the total payment received by the contractual arrangement.

b) Employed physicians have a responsibility to assure that bills issued for services they provide are accurate and should therefore retain the right to review billing claims as may be necessary to verify that such bills are correct. Employers should indemnify and defend, and save harmless, employed physicians with respect to any violation of law or regulation or breach of contract in connection with the employer's billing for physician services, which violation is not the fault of the employee.

Our AMA will disseminate the AMA Principles for Physician Employment to graduating residents and fellows and will advocate for adoption of these Principles by organizations of physician employers such as, but not limited to, the American Hospital Association and Medical Group Management Association.

11.2.1 Code of Ethics, "Professionalism in Health Care Systems,"

Containing costs, promoting high-quality care for all patients, and sustaining physician professionalism are important goals. Models for financing and organizing the delivery of health care services often aim to promote patient safety and to improve quality and efficiency. However, they can also pose ethical challenges for physicians that could undermine the trust essential to patient-physician relationships.

Payment models and financial incentives can create conflicts of interest among patients, health care organizations, and physicians. They can encourage undertreatment and overtreatment, as well as dictate goals that are not individualized for the particular patient.

Structures that influence where and by whom care is delivered—such as accountable care organizations, group practices, health maintenance organizations, and other entities that may emerge in the future—can affect patients' choices, the patient-physician relationship, and physicians' relationships with fellow health care professionals.

Formularies, clinical practice guidelines, and other tools intended to influence decision making, may impinge on physicians' exercise of professional judgment and ability to advocate effectively for their patients, depending on how they are designed and implemented.

Physicians in leadership positions within health care organizations should ensure that practices for financing and organizing the delivery of care:

(a) Are transparent.

(b) Reflect input from key stakeholders, including physicians and patients.

(c) Recognize that over reliance on financial incentives may undermine physician professionalism.

(d) Ensure ethically acceptable incentives that:

(i) are designed in keeping with sound principles and solid scientific evidence. Financial incentives should be based on appropriate comparison groups and cost data and adjusted to reflect complexity, case mix, and other factors that affect physician practice profiles. Practice guidelines, formularies, and other tools should be based on best available evidence and developed in keeping with ethics guidance;

(ii) are implemented fairly and do not disadvantage identifiable populations of patients or physicians or exacerbate health care disparities;

(iii) are implemented in conjunction with the infrastructure and resources needed to support high-value care and physician professionalism;

(iv) mitigate possible conflicts between physicians' financial interests and patient interests by minimizing the financial impact of patient care decisions and the overall financial risk for individual physicians.

(e) Encourage, rather than discourage, physicians (and others) to:

(i) provide care for patients with difficult to manage medical conditions;

(ii) practice at their full capacity, but not beyond.
(f) Recognize physicians' primary obligation to their patients by enabling physicians to respond to the unique needs of individual patients and providing avenues for meaningful appeal and advocacy on behalf of patients.

(g) Are routinely monitored to:

(i) identify and address adverse consequences;

(ii) identify and encourage dissemination of positive outcomes.

All physicians should:

(h) Hold physician-leaders accountable to meeting conditions for professionalism in health care systems.

(i) Advocate for changes in health care payment and delivery models to promote access to high-quality care for all patients.

H-295.961, "Medicolegal, Political, Ethical and Economic Medical School Course"

(1) The AMA urge every medical school and residency program to teach the legal, political, ethical and economic issues which will affect physicians. (2) The AMA will work with state and county medical societies to identify and provide speakers, information sources, etc., to assist with the courses. (3) An assessment of professional and ethical behavior, such as exemplified in the AMA Principles of Medical Ethics, should be included in internal evaluations during medical school and residency training, and also in evaluations utilized for licensure and certification. (4) The Speaker of the HOD shall determine the most appropriate way for assembled physicians at the opening sessions of the AMA House of Delegates Annual and Interim Meetings to renew their commitment to the standards of conduct which define the essentials of honorable behavior for the physician, by reaffirming or reciting the seven Principles of Medical Ethics which constitute current AMA policy. (5) There should be attention to subject matter related to ethics and to the doctor-patient relationship at all levels of medical education: undergraduate, graduate, and continuing. Role modeling should be a key element in helping medical students and resident physicians to develop and maintain professionalism and high ethical standards. (6) There should be exploration of the feasibility of improving an assessment of ethical qualities in the admissions process to medical school. (7) Our AMA pledges support to the concept that professional attitudes, values, and behaviors should form an integral part of medical education across the continuum of undergraduate, graduate, and continuing medical education.

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REPORT OF THE COUNCIL ON MEDICAL EDUCATION

CME Report 3, November 2020

Subject: Protection of Resident and Fellow Training in the Case of Hospital or Training Program Closure

Presented by: Liana Puscas, MD, MHS, Chair

Referred to: Reference Committee C

INTRODUCTION

Policy H-310.943, (2), "Closing of Residency Programs," directs our AMA to:

> Study and provide recommendations on how the process of assisting displaced residents and fellows could be improved in the case of training hospital or training program closure, including:
>
> A. The current processes by which a displaced resident or fellow may seek and secure an alternative training position; and
>
> B. How the Centers for Medicare and Medicaid Services (CMS) and other additional or supplemental graduate medical education (GME) funding is re-distributed, including but not limited to: (1) the direct or indirect classification of residents and fellows as financial assets and the implications thereof; (2) the transfer of training positions between institutions and the subsequent impact on resident and fellow funding lines in the event of closure; (3) the transfer of full versus partial funding for new training positions; and (4) the transfer of funding for displaced residents and fellows who switch specialties.

Strong testimony in support of this policy's underlying resolution was heard during the 2019 Interim Meeting, due to the fall 2019 closure of Hahnemann University Hospital (HUH) in Philadelphia and the urgent need for AMA action to aid the individuals affected and to develop policies to ensure adequate protections in the future. Concerns were expressed related to the graduate medical education (GME) funding for residents inadvertently displaced, as might occur with a natural disaster (e.g., Hurricane Katrina), versus those who are removed from a residency program due to issues with clinical performance and/or professionalism. This report addresses displacement as a result of program closure.

BACKGROUND

The events preceding and following the abrupt closure of HUH have been well documented in the academic medicine press as well as in the popular press. What follows is a brief summary.

HUH, a large, academic safety-net hospital in Philadelphia, had struggled financially for years. It had been purchased twice by for-profit investors, first in 1998 by Tenet Healthcare Corporation and then in 2018 by American Academic Health System (AAHS). In 2019, AAHS concluded that HUH

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was no longer financially viable; subsequently, in late June 2019, HUH announced its closure and then filed for Chapter 11 bankruptcy in July. AAHS announced on July 24 that it was withdrawing from accreditation its 25 medical residency/fellowship programs. This left more than 550 resident and fellow physicians (referred to as residents in this report), including 140 new residents who had not even started training at the time of the announcement, without a program accredited by the Accreditation Council for Graduate Medical Education (ACGME) in which to continue their medical education.[1,2,3,4].

Withdrawal from accreditation by an entire program "displaces" the residents in the program. At that point, the resident is allowed to pursue training in another program, with allocated funding from the Centers for Medicare & Medicaid Services (CMS).[4] The ACGME has policy, developed after the training disruption of Hurricane Katrina in 2005, to assist residents and fellows with temporary and permanent transfers to other programs.[3] This assistance, and the call to action by the ACGME asking for programs to post availability of positions, enabled all residents displaced by the closure of HUH to secure new positions within 43 days, half of them within a 60-mile radius of Philadelphia.[1,2] Interestingly, the same process came into play only a few months later with the closure of Ohio Valley Medical Center (OVMC) in West Virginia, also for financial reasons. OVMC operated only two ACGME-accredited programs, and therefore substantially fewer residents were displaced.

"ORPHANED" RESIDENT PLACEMENT PROCESS

ACGME

On June 28, 2019, the ACGME invoked its Extraordinary Circumstances Policy in response to the announcement of HUH's closing. The ACGME created a database on its website, accessible to GME leaders and residents at HUH, for programs to post potential training position openings for displaced HUH residents. This database was updated daily, with 1,530 positions offered from 90 sponsoring institutions in 39 states.[3] Program directors and designated institution officials (DIOs) submitted requests to ACGME review committees for complement increases to accept some of the residents. In late July, the ACGME announced that it was accepting applications for new training programs, and eventually accredited 31 new programs in Pennsylvania.[2] Residents started interviewing at other institutions that had offered potential positions, and while GME Resident Displacement Agreements were developed by HUH, CMS funding was in question until the programs were officially unaccredited and residents released. Even then (July 29 for one group of residents, August 6 for another), the CMS funding was complicated by both CMS regulations and the stated intent of AAHS to sell the residency slots as an asset.[2]

CMS

Prior to the passage of the Affordable Care Act (ACA), if a teaching hospital closed, its direct GME and indirect resident cap slots would be "lost," because those slots were associated with the specific hospital's terminated Medicare provider agreement. However, Section 5506 of the ACA addressed this situation by establishing a process that would redistribute slots from closing teaching hospitals to hospitals that met certain criteria, with priority given to hospitals located in the same Core Based Statistical Area (CBSA) or in a contiguous CBSA as the closing hospital. As a result, Section 5506 applies to teaching hospitals that closed on or after March 23, 2008.

Despite Section 5506, residents and receiving hospitals have still found it difficult to receive cap slot adjustments, and the associated funding, due to a CMS rule that requires residents to be "physically present" at a closing hospital to be considered displaced. "Physically present" is

defined as training at a hospital on the day prior to, or the day of, hospital or program closure. This definition creates problems for: 1) residents who leave the program after the closure is publicly announced to start training at another hospital but before the actual closure, 2) residents assigned to and training at planned rotations at other hospitals who cannot return to their rotation at the closing hospital or program, and 3) residents who matched into GME programs at the closing hospital or program but have not yet started training at that hospital or program. As such, CMS regulations regarding the funding of displaced residents are perceived as burdensome and inflexible by residents, program directors, and DIOs. Moreover, CMS regulations added uncertainty about the financial risk that institutions that intended to accept transferring residents could potentially incur.[2]

Additionally, CMS regulations assert that it is at the discretion of the closing hospital or program to allocate whatever amount of full-time equivalent (FTE) cap it deems fit. This has caused uncertainty for residents and receiving hospitals regarding the amount of funding that will travel with the transferring resident. For example, in the case of HUH, residents did not receive a 1.0 FTE and instead were given about 80 percent of their allotted funding, per an arrangement with Thomas Jefferson University Hospital and the University of Pennsylvania.[4]

Finally, there have been discrepancies in the past regarding if residency slots are, or are not, "assets" of the closing hospital or program. When HUH tried to sell its 550 residency slots as "assets" during bankruptcy proceedings, the presiding judge initially allowed bidding on the slots. As a result, a coalition of local hospitals bid $55 million on the slots with the goal of keeping them in the Philadelphia region, while a health care firm in California bid $60 million for the valuable chance to increase the number of funded physicians in its hospitals. However, CMS objected to the judge's ruling and asserted that CMS has sole discretion concerning the allocation of Medicare-funded slots. CMS argued that the auction would set a dangerous precedent, in that struggling hospitals with training positions could be purchased by investors, leaving certain hospitals severely understaffed. As a result, the auction did not go forward.[5,6]

Further Complications: Visa Regulations, Medical Liability Coverage, and Economic Impacts

Among the residents training in HUH programs were 59 individuals on J-1 visas who were required to find a position with another GME program within 30 days of the hospital closing or face deportation from the U.S. The AMA wrote a letter to the U.S. Department of State (DoS) urging the DoS to work with U.S. Citizenship and Immigration Services and the Educational Commission for Foreign Medical Graduates (ECFMG) to waive the 30-day grace period requirement and provide needed support for these individuals to find an appropriate alternative GME program. The DoS agreed to review, on a case-by-case basis, anyone who did not have a position lined up within the 30-day period. The ECFMG was instrumental in assisting these residents as they moved to new programs, including meeting with them in person, providing financial assistance, and waiving ECFMG fees. All residents with J-1 visas found positions.[3,7,8]

After HUH residents had found new positions, it was revealed in December that they would lose long-tail medical liability coverage for claims made after January 10, 2020—this, despite an ACGME institutional requirement that sponsoring institutions must have malpractice insurance covering any claims made while the resident is training or any future claims stemming from the resident's training period. AAHS had intended to purchase the coverage through the sale of the residency slots, which was tied up in court, and ultimately did not go through. In February, AAHS agreed to pay $6.2 million to purchase medical liability insurance for the residents and other medical professionals who had worked at HUH during its ownership.[9] In the meantime, the AMA underwrote the costs of a legal team assisting residents in their fight to obtain medical liability coverage from HUH. The AMA also joined the Philadelphia County Medical Society (PCMS),

Pennsylvania Medical Society (PAMED), ECFMG, ACGME, and Association of American Medical Colleges (AAMC) in urging the institutions that accepted HUH residents to help purchase tail coverage, especially important in the state of Pennsylvania, which requires, as do other states, that all physicians have tail coverage from previous employers.[10]

The extensive disruption to the lives of residents and their families cannot be discounted. Besides suddenly potentially uprooting families to move to locations that may be distant, residents stood to forfeit large deposits on rental housing, while having to make new deposits in the new location.[3] The AMA committed $50,000 to assist the residents affected, and the AMA Foundation committed another $20,000 to help. The American Osteopathic Association, American Board of Medical Specialties, AAMC, Council of Medical Specialty Societies, National Board of Medical Examiners, PAMED, PCMS, and many other organizations financially committed funds to support residents during this difficult transition, with the goal of raising $150,000 all told for the Hahnemann University Displaced Resident Fund. The ECFMG created a fund for residents who had J-1 visas.[11]

CMS CHANGES PROPOSED

As mentioned above, CMS has regulations defining a displaced resident as one who is "physically present" at a hospital on the day prior to, or the day of, hospital or program closure. This significantly hampers the ability of residents to seek and find new positions should a program or institution suddenly close and excludes residents who have matched to the closing program but have not started their residencies. On July 25, 2019, the AMA sent a letter to CMS requesting that CMS: 1) address the physical presence requirement; 2) resolve the question of transitional residents who had matched to HUH programs but were not currently employed by HUH or in a program at the time of closure, and who therefore did not have federal funding that transferred with them, and 3) provide full funding for residents.[12]

While CMS was not able to address these issues in the case of HUH residents, CMS has proposed rule changes that will link Medicare temporary funding for displaced residents to the day program or hospital closures are publicly announced (for example, via a press release or a formal notice to the ACGME). This provides greater flexibility for residents to transfer while the hospital operations or residency programs are winding down, rather than waiting until the last day of hospital or program operation. In addition, CMS has proposed to allow funding to be transferred temporarily for residents who are not physically at the closing hospital or closing program, but had intended to train at (or return to training at, in the case of residents on rotation) the closing hospital or closing program.[13] Thus, two of the concerns raised by the AMA and other stakeholders are likely to be resolved. However, not all of the AMA's concerns have been addressed, and CMS continues to allow the closing hospital or program to allocate whatever amount of FTE cap it deems fit. As such, the AMA will continue to request that CMS fully fund displaced residency slots.

Also not addressed in the proposed changes, but included in AMA Policy H-310.943 (2), is the desire to have CMS ensure transfer of funding for displaced residents who switch specialties. Currently, CMS regulations provide funding of 1.0 FTE for an initial residency period (IRP), which consists of the number of years required for residents to attain board certification in their chosen specialty. However, this value does not change, even if a resident switches to a specialty that requires additional training. On the other hand, if a displaced resident switches to a specialty with the same IRP value, CMS will continue with the resident's 1.0 FTE funding. For any additional years of training, the teaching hospital will only count the resident as 0.5 FTE.[14]

CURRENT AMA POLICY

AMA policies related to this topic are listed in the Appendix.

SUMMARY AND RECOMMENDATIONS

Suggestions have been made to better prepare for a future event similar to the closing of HUH. For example, should financially struggling institutions be required to prepare financial "disaster plans?"[1] The ACGME intends to amplify the voices of residents and to make sure they participate in discussions on how to manage future disruptions to GME that result from instability in the health care system.[3] Should a special Match/SOAP (Supplemental Offer and Acceptance Program) be used to process the application, interview, and offer situation, complete with Match rules (e.g., inappropriate questions about family status/plans)?[3] The experience of Philadelphia-based DIOs informs their suggestion, as described in their article in *Academic Medicine*, that the ACGME, CMS, ECFMG, AAMC, and National Resident Matching Program (NRMP) create a "playbook" to avoid the chaos experienced for HUH and its residents and program directors. They have proposed the following action items.[2]

Recommended Action Items to Improve Relocation of Residents Displaced in Future Teaching Hospital Closures

1. Improve alignment of CMS and ACGME policies regarding closure of programs and teaching hospitals and release of CMS funding linked to individual trainees
2. Increase communication to sponsoring institutions, program directors, and residents regarding the rights and responsibilities of residents when seeking new training positions if displaced
3. Establish procedures and policies allowing the ACGME or the AAMC to serve as a primary source of information, collaboration, and implementation of plans for resident relocation
4. Ensure expedited decisions by ACGME Review Committees regarding temporary complement increases
5. Establish clear guidelines as to whether, and under what circumstances, hospitals can submit applications to the ACGME for accreditation of new programs
6. Set policies in advance regarding granting of automatic NRMP Match waivers
7. Explore a special NRMP-sponsored Match to relocate displaced residents
8. Anticipate and address potential lapses in medical professional liability coverage; require training institutions to provide "tail" coverage for any displaced residents; and consider creation of a national insurance "pool" to provide such coverage if necessary.

The closure of a large, long-standing teaching institution due to the financial decisions of its for-profit owner may have been sudden, and certainly historic, but such closures may become more frequent given the current health care financial environment; as noted, OVMC also closed during 2019, stranding 34 residents. The same environment may make non-profit teaching institutions also vulnerable to sudden closures. The eroding of health care institutions' financial health as a result of the COVID-19 pandemic further exacerbates the current instability of our health care system.

The Council on Medical Education therefore recommends that the following recommendations be adopted and the remainder of this report be filed:

1. That our AMA rescind Policy H-310.943 (2), "Closing of Residency Programs," as having been fulfilled by this report. (Rescind HOD Policy)

2. That our AMA ask the Centers for Medicare & Medicaid Services (CMS) to stipulate in its regulations that residency slots are not assets that belong to the teaching institution. (Directive to Take Action)

3. That our AMA encourage the Association of American Medical Colleges (AAMC) and National Resident Matching Program (NRMP) to develop a process similar to the Supplemental Offer and Acceptance Program (SOAP) that could be used in the event of a sudden teaching institution or program closure. (Directive to Take Action)

4. That our AMA encourage the Accreditation Council for Graduate Medical Education (ACGME) to specify in its Institutional Requirements that sponsoring institutions are to provide residents and residency applicants information regarding the financial health of the institution, such as its credit rating, or if it has recently been part of an acquisition or merger. (Directive to Take Action)

5. That our AMA encourage the Association of American Medical Colleges (AAMC) and the Accreditation Council for Graduate Medical Education (ACGME) to coordinate and collaborate on the communication with sponsoring institutions, residency programs, and resident physicians in the event of a sudden institution or program closure to minimize confusion, reduce misinformation, and increase clarity. (Directive to Take Action)

6. That our AMA encourage the Accreditation Council for Graduate Medical Education (ACGME) to revise its Institutional Requirements, under section IV.E., Professional Liability Insurance, to state that sponsoring institutions must create and maintain a fund that will ensure professional liability coverage for residents in the event of an institution or program closure. (Directive to Take Action)

Fiscal note: $1,000.

APPENDIX: RELEVANT AMA POLICY

D-305.967, "The Preservation, Stability and Expansion of Full Funding for Graduate Medical Education"

1. Our AMA will actively collaborate with appropriate stakeholder organizations, (including Association of American Medical Colleges, American Hospital Association, state medical societies, medical specialty societies/associations) to advocate for the preservation, stability and expansion of full funding for the direct and indirect costs of graduate medical education (GME) positions from all existing sources (e.g. Medicare, Medicaid, Veterans Administration, CDC and others).
2. Our AMA will actively advocate for the stable provision of matching federal funds for state Medicaid programs that fund GME positions.
3. Our AMA will actively seek congressional action to remove the caps on Medicare funding of GME positions for resident physicians that were imposed by the Balanced Budget Amendment of 1997 (BBA-1997).
4. Our AMA will strenuously advocate for increasing the number of GME positions to address the future physician workforce needs of the nation.
5. Our AMA will oppose efforts to move federal funding of GME positions to the annual appropriations process that is subject to instability and uncertainty.
6. Our AMA will oppose regulatory and legislative efforts that reduce funding for GME from the full scope of resident educational activities that are designated by residency programs for accreditation and the board certification of their graduates (e.g. didactic teaching, community service, off-site ambulatory rotations, etc.).
7. Our AMA will actively explore additional sources of GME funding and their potential impact on the quality of residency training and on patient care.
8. Our AMA will vigorously advocate for the continued and expanded contribution by all payers for health care (including the federal government, the states, and local and private sources) to fund both the direct and indirect costs of GME.
9. Our AMA will work, in collaboration with other stakeholders, to improve the awareness of the general public that GME is a public good that provides essential services as part of the training process and serves as a necessary component of physician preparation to provide patient care that is safe, effective and of high quality.
10. Our AMA staff and governance will continuously monitor federal, state and private proposals for health care reform for their potential impact on the preservation, stability and expansion of full funding for the direct and indirect costs of GME.
11. Our AMA: (a) recognizes that funding for and distribution of positions for GME are in crisis in the United States and that meaningful and comprehensive reform is urgently needed; (b) will immediately work with Congress to expand medical residencies in a balanced fashion based on expected specialty needs throughout our nation to produce a geographically distributed and appropriately sized physician workforce; and to make increasing support and funding for GME programs and residencies a top priority of the AMA in its national political agenda; and (c) will continue to work closely with the Accreditation Council for Graduate Medical Education, Association of American Medical Colleges, American Osteopathic Association, and other key stakeholders to raise awareness among policymakers and the public about the importance of expanded GME funding to meet the nation's current and anticipated medical workforce needs.
12. Our AMA will collaborate with other organizations to explore evidence-based approaches to quality and accountability in residency education to support enhanced funding of GME.
13. Our AMA will continue to strongly advocate that Congress fund additional graduate medical education (GME) positions for the most critical workforce needs, especially considering the current and worsening maldistribution of physicians.

14. Our AMA will advocate that the Centers for Medicare and Medicaid Services allow for rural and other underserved rotations in Accreditation Council for Graduate Medical Education (ACGME)-accredited residency programs, in disciplines of particular local/regional need, to occur in the offices of physicians who meet the qualifications for adjunct faculty of the residency program's sponsoring institution.
15. Our AMA encourages the ACGME to reduce barriers to rural and other underserved community experiences for graduate medical education programs that choose to provide such training, by adjusting as needed its program requirements, such as continuity requirements or limitations on time spent away from the primary residency site.
16. Our AMA encourages the ACGME and the American Osteopathic Association (AOA) to continue to develop and disseminate innovative methods of training physicians efficiently that foster the skills and inclinations to practice in a health care system that rewards team-based care and social accountability.
17. Our AMA will work with interested state and national medical specialty societies and other appropriate stakeholders to share and support legislation to increase GME funding, enabling a state to accomplish one or more of the following: (a) train more physicians to meet state and regional workforce needs; (b) train physicians who will practice in physician shortage/underserved areas; or (c) train physicians in undersupplied specialties and subspecialties in the state/region.
18. Our AMA supports the ongoing efforts by states to identify and address changing physician workforce needs within the GME landscape and continue to broadly advocate for innovative pilot programs that will increase the number of positions and create enhanced accountability of GME programs for quality outcomes.
19. Our AMA will continue to work with stakeholders such as Association of American Medical Colleges (AAMC), ACGME, AOA, American Academy of Family Physicians, American College of Physicians, and other specialty organizations to analyze the changing landscape of future physician workforce needs as well as the number and variety of GME positions necessary to provide that workforce.
20. Our AMA will explore innovative funding models for incremental increases in funded residency positions related to quality of resident education and provision of patient care as evaluated by appropriate medical education organizations such as the Accreditation Council for Graduate Medical Education.
21. Our AMA will utilize its resources to share its content expertise with policymakers and the public to ensure greater awareness of the significant societal value of graduate medical education (GME) in terms of patient care, particularly for underserved and at-risk populations, as well as global health, research and education.
22. Our AMA will advocate for the appropriation of Congressional funding in support of the National Healthcare Workforce Commission, established under section 5101 of the Affordable Care Act, to provide data and healthcare workforce policy and advice to the nation and provide data that support the value of GME to the nation.
23. Our AMA supports recommendations to increase the accountability for and transparency of GME funding and continue to monitor data and peer-reviewed studies that contribute to further assess the value of GME.
24. Our AMA will explore various models of all-payer funding for GME, especially as the Institute of Medicine (now a program unit of the National Academy of Medicine) did not examine those options in its 2014 report on GME governance and financing.
25. Our AMA encourages organizations with successful existing models to publicize and share strategies, outcomes and costs.
26. Our AMA encourages insurance payers and foundations to enter into partnerships with state and local agencies as well as academic medical centers and community hospitals seeking to expand GME.

27. Our AMA will develop, along with other interested stakeholders, a national campaign to educate the public on the definition and importance of graduate medical education, student debt and the state of the medical profession today and in the future.
28. Our AMA will collaborate with other stakeholder organizations to evaluate and work to establish consensus regarding the appropriate economic value of resident and fellow services.
29. Our AMA will monitor ongoing pilots and demonstration projects, and explore the feasibility of broader implementation of proposals that show promise as alternative means for funding physician education and training while providing appropriate compensation for residents and fellows.
30. Our AMA will monitor the status of the House Energy and Commerce Committee's response to public comments solicited regarding the 2014 IOM report, Graduate Medical Education That Meets the Nation's Health Needs, as well as results of ongoing studies, including that requested of the GAO, in order to formulate new advocacy strategy for GME funding, and will report back to the House of Delegates regularly on important changes in the landscape of GME funding.
31. Our AMA will advocate to the Centers for Medicare & Medicaid Services to adopt the concept of "Cap-Flexibility" and allow new and current Graduate Medical Education teaching institutions to extend their cap-building window for up to an additional five years beyond the current window (for a total of up to ten years), giving priority to new residency programs in underserved areas and/or economically depressed areas.
32. Our AMA will: (a) encourage all existing and planned allopathic and osteopathic medical schools to thoroughly research match statistics and other career placement metrics when developing career guidance plans; (b) strongly advocate for and work with legislators, private sector partnerships, and existing and planned osteopathic and allopathic medical schools to create and fund graduate medical education (GME) programs that can accommodate the equivalent number of additional medical school graduates consistent with the workforce needs of our nation; and (c) encourage the Liaison Committee on Medical Education (LCME), the Commission on Osteopathic College Accreditation (COCA), and other accrediting bodies, as part of accreditation of allopathic and osteopathic medical schools, to prospectively and retrospectively monitor medical school graduates' rates of placement into GME as well as GME completion.
33. Our AMA encourages the Secretary of the U.S. Department of Health and Human Services to coordinate with federal agencies that fund GME training to identify and collect information needed to effectively evaluate how hospitals, health systems, and health centers with residency programs are utilizing these financial resources to meet the nation's health care workforce needs. This includes information on payment amounts by the type of training programs supported, resident training costs and revenue generation, output or outcomes related to health workforce planning (i.e., percentage of primary care residents that went on to practice in rural or medically underserved areas), and measures related to resident competency and educational quality offered by GME training programs.

H-305.929, "Proposed Revisions to AMA Policy on the Financing of Medical Education Programs"

1. It is AMA policy that:
A. Since quality medical education directly benefits the American people, there should be public support for medical schools and graduate medical education programs and for the teaching institutions in which medical education occurs. Such support is required to ensure that there is a continuing supply of well-educated, competent physicians to care for the American public.
B. Planning to modify health system organization or financing should include consideration of the effects on medical education, with the goal of preserving and enhancing the quality of medical education and the quality of and access to care in teaching institutions are preserved.

C. Adequate and stable funding should be available to support quality undergraduate and graduate medical education programs. Our AMA and the federation should advocate for medical education funding.
D. Diversified sources of funding should be available to support medical schools' multiple missions, including education, research, and clinical service. Reliance on any particular revenue source should not jeopardize the balance among a medical school's missions.
E. All payers for health care, including the federal government, the states, and private payers, benefit from graduate medical education and should directly contribute to its funding.
F. Full Medicare direct medical education funding should be available for the number of years required for initial board certification. For combined residency programs, funding should be available for the longest of the individual programs plus one additional year. There should be opportunities to extend the period of full funding for specialties or subspecialties where there is a documented need, including a physician shortage.
G. Medical schools should develop systems to explicitly document and reimburse faculty teaching activity, so as to facilitate faculty participation in medical student and resident physician education and training.
H. Funding for graduate medical education should support the training of resident physicians in both hospital and non-hospital (ambulatory) settings. Federal and state funding formulas must take into account the resources, including volunteer faculty time and practice expenses, needed for training residents in all specialties in non-hospital, ambulatory settings. Funding for GME should be allocated to the sites where teaching occurs.
I. New funding should be available to support increases in the number of medical school and residency training positions, preferably in or adjacent to physician shortage/underserved areas and in undersupplied specialties.
2. Our AMA endorses the following principles of social accountability and promotes their application to GME funding: (a) Adequate and diverse workforce development; (b) Primary care and specialty practice workforce distribution; (c) Geographic workforce distribution; and (d) Service to the local community and the public at large.
3. Our AMA encourages transparency of GME funding through models that are both feasible and fair for training sites, affiliated medical schools and trainees.
4. Our AMA believes that financial transparency is essential to the sustainable future of GME funding and therefore, regardless of the method or source of payment for GME or the number of funding streams, institutions should publicly report the aggregate value of GME payments received as well as what these payments are used for, including: (a) Resident salary and benefits; (b) Administrative support for graduate medical education; (c) Salary reimbursement for teaching staff; (d) Direct educational costs for residents and fellows; and (e) Institutional overhead.
5. Our AMA supports specialty-specific enhancements to GME funding that neither directly nor indirectly reduce funding levels for any other specialty.

H-310.917, "Securing Funding for Graduate Medical Education"

Our American Medical Association: (1) continues to be vigilant while monitoring pending legislation that may change the financing of medical services (health system reform) and advocate for expanded and broad-based funding for graduate medical education (from federal, state, and commercial entities); (2) continues to advocate for graduate medical education funding that reflects the physician workforce needs of the nation; (3) encourages all funders of GME to adhere to the Accreditation Council for Graduate Medical Education's requirements on restrictive covenants and its principles guiding the relationship between GME, industry and other funding sources, as well as the AMA's Opinion 8.061, and other AMA policy that protects residents and fellows from exploitation, including physicians training in non-ACGME-accredited programs; and (4) encourages entities planning to expand or start GME programs to develop a clear statement of the

benefits of their GME activities to facilitate potential funding from appropriate sources given the goals of their programs.

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AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 301
(November 2020)

Introduced by: Illinois

Subject: Creating a More Accurate Accounting of Medical Education Financial Costs

Referred to: Reference Committee C

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1 Whereas, The usual reference to the cost of medical education typically is the summation of
2 tuition for the period of 4 years of medical education; and
3
4 Whereas, There are 3 years of required postgraduate training prior to a medical school
5 graduate's ability to fully practice medicine, during which time school loans are typically deferred
6 and interest is compounded; and
7
8 Whereas, Matriculation into medical school typically requires completion of a four-year
9 undergraduate degree; and
10
11 Whereas, The demands of medical education typically prohibit students from undertaking
12 simultaneous endeavors that provide remuneration for their work; and
13
14 Whereas, Most postgraduate medical education is performed in large urban settings where
15 cost-of-living consumes much of the stipend paid to interns and residents leaving little for
16 repayment of school loans; and
17
18 Whereas, The frequently publicized cost of medical education underrepresents the actual
19 financial responsibility of the prospective medical student and the general public; therefore be it
20
21 RESOLVED, That our American Medical Association study the costs of medical education,
22 taking into account medical student tuition and accrued loan interest, to come up with a more
23 accurate description of medical education financial costs. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000

Received: 07/17/20

RELEVANT AMA POLICY

D-305.984 - Reduction in Student Loan Interest Rates

…

3. Our AMA will consider the total cost of loans including loan origination fees and benefits of federal loans such as tax deductibility or loan forgiveness when advocating for a reduction in student loan interest rates.

4. Our AMA will advocate for policies which lead to equal or less expensive loans (in terms of loan benefits, origination fees, and interest rates) for Grad-PLUS loans as this would change the status quo of high-borrowers paying higher interest rates and fees in addition to having a higher overall loan burden.

5. Our AMA will work with appropriate organizations, such as the Accreditation Council for Graduate Medical Education and the Association of American Medical Colleges, to collect data and report on student indebtedness that includes total loan costs at completion of graduate medical education training. Res. 316, A-03 Reaffirmed: BOT Rep. 28, A-13 Appended: Res. 302, A-13 Modified and Appended: 301, A-16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 302
(November 2020)

Introduced by: Illinois

Subject: Student Loan Forgiveness

Referred to: Reference Committee C

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1 Whereas, The cost of medical education, all facets included, is a significant burden for resident
2 physicians as well as for young physicians beginning practice; and
3
4 Whereas, Such costs and burdens significantly influence medical specialty and location of
5 practice selection and it is widely thought that this limits the numbers of students selecting
6 primary care specialties; and
7
8 Whereas, The Public Service Loan Forgiveness Program, a federal program, allows payment
9 for 10 years against the loan balance then the application for loan forgiveness of the remaining
10 loan amounts at that point; and
11
12 Whereas, Ninety-eight percent of applications for loan forgiveness under the Public Service
13 Loan Forgiveness Program are denied; therefore be it
14
15 RESOLVED, That our American Medical Association study the cause for the unacceptably high
16 denial rate of applications made to the Public Health Services Student Loan Forgiveness
17 Program, and advocate for improvements in the administration and oversight of the program,
18 including but not limited to increasing transparency of and streamlining program requirements;
19 ensuring consistent and accurate communication between loan services and borrowers; and
20 establishing clear expectations regarding oversight and accountability of the loan servicers
21 responsible for the program. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000

Received: 07/17/20

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https://students-residents.aamc.org/financial-aid/article/public-service-loan-forgiveness-pslf/

https://www.nytimes.com/2019/11/28/us/politics/student-loan-forgiveness.html

RELEVANT AMA POLICY

H-305.925 - Principles of and Actions to Address Medical Education Costs and Student Debt
The costs of medical education should never be a barrier to the pursuit of a career in medicine nor to the decision to practice in a given specialty. To help address this issue, our American Medical Association (AMA) will:
1. Collaborate with members of the Federation and the medical education community, and with other interested organizations, to address the cost of medical education and medical student debt through public- and private-sector advocacy.
2. Vigorously advocate for and support expansion of and adequate funding for federal scholarship and loan repayment programs--such as those from the National Health Service Corps, Indian Health Service, Armed Forces, and Department of Veterans Affairs, and for comparable programs from states and the private sector--to promote practice in underserved areas, the military, and academic medicine or clinical research.

3. Encourage the expansion of National Institutes of Health programs that provide loan repayment in exchange for a commitment to conduct targeted research.
4. Advocate for increased funding for the National Health Service Corps Loan Repayment Program to assure adequate funding of primary care within the National Health Service Corps, as well as to permit: (a) inclusion of all medical specialties in need, and (b) service in clinical settings that care for the underserved but are not necessarily located in health professions shortage areas.
5. Encourage the National Health Service Corps to have repayment policies that are consistent with other federal loan forgiveness programs, thereby decreasing the amount of loans in default and increasing the number of physicians practicing in underserved areas.
6. Work to reinstate the economic hardship deferment qualification criterion known as the “20/220 pathway,” and support alternate mechanisms that better address the financial needs of trainees with educational debt.
7. Advocate for federal legislation to support the creation of student loan savings accounts that allow for pre-tax dollars to be used to pay for student loans.
8. Work with other concerned organizations to advocate for legislation and regulation that would result in favorable terms and conditions for borrowing and for loan repayment, and would permit 100% tax deductibility of interest on student loans and elimination of taxes on aid from service-based programs.
9. Encourage the creation of private-sector financial aid programs with favorable interest rates or service obligations (such as community- or institution-based loan repayment programs or state medical society loan programs).
…
14. Take an active advocacy role during reauthorization of the Higher Education Act and similar legislation, to achieve the following goals: (a) Eliminating the single holder rule; (b) Making the availability of loan deferment more flexible, including broadening the definition of economic hardship and expanding the period for loan deferment to include the entire length of residency and fellowship training; (c) Retaining the option of loan forbearance for residents ineligible for loan deferment; (d) Including, explicitly, dependent care expenses in the definition of the “cost of attendance”; (e) Including room and board expenses in the definition of tax-exempt scholarship income; (f) Continuing the federal Direct Loan Consolidation program, including the ability to “lock in” a fixed interest rate, and giving consideration to grace periods in renewals of federal loan programs; (g) Adding the ability to refinance Federal Consolidation Loans; (h) Eliminating the cap on the student loan interest deduction; (i) Increasing the income limits for taking the interest deduction; (j) Making permanent the education tax incentives that our AMA successfully lobbied for as part of Economic Growth and Tax Relief Reconciliation Act of 2001; (k) Ensuring that loan repayment programs do not place greater burdens upon married couples than for similarly situated couples who are cohabitating; (l) Increasing efforts to collect overdue debts from the present medical student loan programs in a manner that would not interfere with the provision of future loan funds to medical students.
…
20. Related to the Public Service Loan Forgiveness (PSLF) Program, our AMA supports increased medical student and physician benefits the program, and will: (a) Advocate that all resident/fellow physicians have access to PSLF during their training years; (b) Advocate against a monetary cap on PSLF and other federal loan forgiveness programs; (c) Work with the United States Department of Education to ensure that any cap on loan forgiveness under PSLF be at least equal to the principal amount borrowed; (d) Ask the United States Department of Education to include all terms of PSLF in the contractual obligations of the Master Promissory Note; (e) Encourage the Accreditation Council for Graduate Medical Education (ACGME) to require residency/fellowship programs to include within the terms, conditions, and benefits of program appointment information on the PSLF program qualifying status of the employer; (f) Advocate that the profit status of a physicians training institution not be a factor for PSLF eligibility; (g) Encourage medical school financial advisors to counsel wise borrowing by medical students, in the event that the PSLF program is eliminated or severely curtailed; (h) Encourage medical school financial advisors to increase medical student engagement in service-based loan repayment options, and other federal and military programs, as an attractive alternative to the PSLF in terms of financial prospects as well as providing the opportunity to provide care in medically underserved areas; (i) Strongly advocate that the terms of the PSLF that existed at the time of the agreement remain unchanged for any program participant in the event of any future restrictive changes.
21. Advocate for continued funding of programs including Income-Driven Repayment plans for the benefit of reducing medical student load burden.
22. Formulate a task force to look at undergraduate medical education training as it relates to career choice, and develop new polices and novel approaches to prevent debt from influencing specialty and subspecialty choice. CME Report 05, I-18 Appended: Res. 953, I-18 Reaffirmation: A-19 Appended: Res. 316, A-19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 303
(November 2020)

Introduced by: Oklahoma

Subject: CME for Preceptorship

Referred to: Reference Committee C

Whereas, Continuing Medical Education (CME) credits are vital to all physicians; and

Whereas, Being a "preceptor" for medical students, residents, and fellows requires countless hours of reading and self-study; and

Whereas, Currently only the American Osteopathic Association (AOA) offers category 1B credit for participation in the Osteopathic Medicine Didactic and Preceptor Program; and

Whereas, Sixty AOA category 1B credits may be applied to the required 120 hours of CME for Osteopathic physicians; and

Whereas, The American Medical Association gives no credit for any amount of AOA credits for being a preceptor; and

Whereas, Recognizing such teaching efforts would encourage more practicing, private physicians to be involved in preceptor programs, which in turn would expose more students to the world of private practice and the practice of medicine in rural and underserved areas; therefore be it

RESOLVED, That our American Medical Association study awarding Category 1 credit to physicians serving as preceptors for medical students, residents, and fellows training at Liaison Committee on Medical Education (LCME) accredited medical schools. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000

Received: 08/17/20

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 304
(November 2020)

Introduced by: Resident and Fellow Section

Subject: Establishing Minimum Standards for Parental Leave During Graduate Medical Education Training

Referred to: Reference Committee C

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1 Whereas, A substantial number of trainees become parents during their training as a resident or
2 fellow; and
3
4 Whereas, PGY-1 trainees will not meet eligibility for the Family Medical Leave Act, which has a
5 12-month employment eligibility threshold; and
6
7 Whereas, Unlike other industries, such as technology and law, "there is no standardized
8 approach to parental leave across GME programs" [1]; and
9
10 Whereas, The Accreditation Council for Graduate Medical Education does not establish
11 minimum standards for duration of parental leave for trainees; and
12
13 Whereas, A lack of minimum national standards may result in some trainees receiving
14 substandard resources and benefits[2]; and
15
16 Whereas, Current AMA policy (H-405.960) encourages residency programs, among other
17 stakeholders, to incorporate a "six-week minimum leave allowance;" therefore be it
18
19 RESOLVED, That our American Medical Association support current efforts by the Accreditation
20 Council for Graduate Medical Education (ACGME), the American Board of Medical Specialties
21 (ABMS), and other relevant stakeholders to develop and align minimum requirements for
22 parental leave during residency and fellowship training and urge these bodies to adopt minimum
23 requirements in accordance with AMA Policy H-405.960 (New HOD Policy); and be it further
24
25 RESOLVED, That our AMA petition the ACGME to recommend strategies to prevent undue
26 burden on trainees related to parental leave (Directive to Take Action); and be it further
27
28 RESOLVED, That our AMA petition the ACGME, ABMS, and other relevant stakeholders to
29 develop specialty specific pathways for residents and fellows in good standing, who take
30 maximum allowable parental leave, to complete their training within the original time frame.
31 (Directive to Take Action)

Fiscal Note: Minimal - less than $1,000

Received: 08/25/20

References:
1. Vassallo P, Jeremiah J, Forman L, et al. Parental Leave in Graduate Medical Education: Recommendations for Reform. Am J Med. 2019;132(3):385-389. doi:10.1016/j.amjmed.2018.11.006
2. Baril N. Parenting during Graduate Medical Training — Practical Policy. 2019:995-997. doi:10.1056/NEJMp1902966

RELEVANT AMA POLICY:

Principles for Graduate Medical Education H-310.929
Our AMA urges the Accreditation Council for Graduate Medical Education (ACGME) to incorporate these principles in its Institutional Requirements, if they are not already present.
(1) PURPOSE OF GRADUATE MEDICAL EDUCATION AND ITS RELATIONSHIP TO PATIENT CARE. There must be objectives for residency education in each specialty that promote the development of the knowledge, skills, attitudes, and behavior necessary to become a competent practitioner in a recognized medical specialty.
Exemplary patient care is a vital component for any residency/fellowship program. Graduate medical education enhances the quality of patient care in the institution sponsoring an accredited program. Graduate medical education must never compromise the quality of patient care. Institutions sponsoring residency programs and the director of each program must assure the highest quality of care for patients and the attainment of the program's educational objectives for the residents.
(2) RELATION OF ACCREDITATION TO THE PURPOSE OF RESIDENCY TRAINING. Accreditation requirements should relate to the stated purpose of a residency program and to the knowledge, skills, attitudes, and behaviors that a resident physician should have on completing residency education.
(3) EDUCATION IN THE BROAD FIELD OF MEDICINE. GME should provide a resident physician with broad clinical experiences that address the general competencies and professionalism expected of all physicians, adding depth as well as breadth to the competencies introduced in medical school.
(4) SCHOLARLY ACTIVITIES FOR RESIDENTS. Graduate medical education should always occur in a milieu that includes scholarship. Resident physicians should learn to appreciate the importance of scholarly activities and should be knowledgeable about scientific method. However, the accreditation requirements, the structure, and the content of graduate medical education should be directed toward preparing physicians to practice in a medical specialty. Individual educational opportunities beyond the residency program should be provided for resident physicians who have an interest in, and show an aptitude for, academic and research pursuits. The continued development of evidence-based medicine in the graduate medical education curriculum reinforces the integrity of the scientific method in the everyday practice of clinical medicine.
(5) FACULTY SCHOLARSHIP. All residency faculty members must engage in scholarly activities and/or scientific inquiry. Suitable examples of this work must not be limited to basic biomedical research. Faculty can comply with this principle through participation in scholarly meetings, journal club, lectures, and similar academic pursuits.
(6) INSTITUTIONAL RESPONSIBILITY FOR PROGRAMS. Specialty-specific GME must operate under a system of institutional governance responsible for the development and implementation of policies regarding the following; the initial authorization of programs, the appointment of program directors, compliance with the accreditation requirements of the ACGME, the advancement of resident physicians, the disciplining of resident physicians when this is appropriate, the maintenance of permanent records, and the credentialing of resident physicians who successfully complete the program. If an institution closes or has to reduce the size of a residency program, the institution must inform the residents as soon as possible. Institutions must make every effort to allow residents already in the program to complete their education in the affected program. When this is not possible, institutions must assist residents to enroll in another program in which they can continue their education. Programs must also make arrangements, when necessary, for the disposition of program files so that future confirmation of the completion of residency education is possible. Institutions should allow residents to form housestaff organizations, or similar organizations, to address patient care and resident work environment concerns. Institutional committees should include resident members.

(7) COMPENSATION OF RESIDENT PHYSICIANS. All residents should be compensated. Residents should receive fringe benefits, including, but not limited to, health, disability, and professional liability insurance and parental leave and should have access to other benefits offered by the institution. Residents must be informed of employment policies and fringe benefits, and their access to them. Restrictive covenants must not be required of residents or applicants for residency education.
(8) LENGTH OF TRAINING. The usual duration of an accredited residency in a specialty should be defined in the "Program Requirements." The required minimum duration should be the same for all programs in a specialty and should be sufficient to meet the stated objectives of residency education for the specialty and to cover the course content specified in the Program Requirements. The time required for an individual resident physician's education might be modified depending on the aptitude of the resident physician and the availability of required clinical experiences.
(9) PROVISION OF FORMAL EDUCATIONAL EXPERIENCES. Graduate medical education must include a formal educational component in addition to supervised clinical experience. This component should assist resident physicians in acquiring the knowledge and skill base required for practice in the specialty. The assignment of clinical responsibility to resident physicians must permit time for study of the basic sciences and clinical pathophysiology related to the specialty.
(10) INNOVATION OF GRADUATE MEDICAL EDUCATION. The requirements for accreditation of residency training should encourage educational innovation and continual improvement. New topic areas such as continuous quality improvement (CQI), outcome management, informatics and information systems, and population-based medicine should be included as appropriate to the specialty.
(11) THE ENVIRONMENT OF GRADUATE MEDICAL EDUCATION. Sponsoring organizations and other GME programs must create an environment that is conducive to learning. There must be an appropriate balance between education and service. Resident physicians must be treated as colleagues.
(12) SUPERVISION OF RESIDENT PHYSICIANS. Program directors must supervise and evaluate the clinical performance of resident physicians. The policies of the sponsoring institution, as enforced by the program director, and specified in the ACGME Institutional Requirements and related accreditation documents, must ensure that the clinical activities of each resident physician are supervised to a degree that reflects the ability of the resident physician and the level of responsibility for the care of patients that may be safely delegated to the resident. The sponsoring institution's GME Committee must monitor programs' supervision of residents and ensure that supervision is consistent with: (A) Provision of safe and effective patient care; (B) Educational needs of residents; (C) Progressive responsibility appropriate to residents' level of education, competence, and experience; and (D) Other applicable Common and specialty/subspecialty specific Program Requirements. The program director, in cooperation with the institution, is responsible for maintaining work schedules for each resident based on the intensity and variability of assignments in conformity with ACGME Review Committee recommendations, and in compliance with the ACGME clinical and educational work hour standards. Integral to resident supervision is the necessity for frequent evaluation of residents by faculty, with discussion between faculty and resident. It is a cardinal principle that responsibility for the treatment of each patient and the education of resident and fellow physicians lies with the physician/faculty to whom the patient is assigned and who supervises all care rendered to the patient by residents and fellows. Each patient's attending physician must decide, within guidelines established by the program director, the extent to which responsibility may be delegated to the resident, and the appropriate degree of supervision of the resident's participation in the care of the patient. The attending physician, or designate, must be available to the resident for consultation at all times.
(13) EVALUATION OF RESIDENTS AND SPECIALTY BOARD CERTIFICATION. Residency program directors and faculty are responsible for evaluating and documenting the continuing

development and competency of residents, as well as the readiness of residents to enter independent clinical practice upon completion of training. Program directors should also document any deficiency or concern that could interfere with the practice of medicine and which requires remediation, treatment, or removal from training. Inherent within the concept of specialty board certification is the necessity for the residency program to attest and affirm to the competence of the residents completing their training program and being recommended to the specialty board as candidates for examination. This attestation of competency should be accepted by specialty boards as fulfilling the educational and training requirements allowing candidates to sit for the certifying examination of each member board of the ABMS.
(14) GRADUATE MEDICAL EDUCATION IN THE AMBULATORY SETTING. Graduate medical education programs must provide educational experiences to residents in the broadest possible range of educational sites, so that residents are trained in the same types of sites in which they may practice after completing GME. It should include experiences in a variety of ambulatory settings, in addition to the traditional inpatient experience. The amount and types of ambulatory training is a function of the given specialty.
(15) VERIFICATION OF RESIDENT PHYSICIAN EXPERIENCE. The program director must document a resident physician's specific experiences and demonstrated knowledge, skills, attitudes, and behavior, and a record must be maintained within the institution.
Citation: CME Rep. 9, A-99; Reaffirmed: CME Rep. 2, A-09; Reaffirmed: CME Rep. 14, A-09; Modified: CME Rep. 06, I-18

Policies for Parental, Family and Medical Necessity Leave H-405.960
AMA adopts as policy the following guidelines for, and encourages the implementation of, Parental, Family and Medical Necessity Leave for Medical Students and Physicians:
1. Our AMA urges medical schools, residency training programs, medical specialty boards, the Accreditation Council for Graduate Medical Education, and medical group practices to incorporate and/or encourage development of leave policies, including parental, family, and medical leave policies, as part of the physician's standard benefit agreement.
2. Recommended components of parental leave policies for medical students and physicians include: (a) duration of leave allowed before and after delivery; (b) category of leave credited; (c) whether leave is paid or unpaid; (d) whether provision is made for continuation of insurance benefits during leave, and who pays the premium; (e) whether sick leave and vacation time may be accrued from year to year or used in advance; (f) how much time must be made up in order to be considered board eligible; (g) whether make-up time will be paid; (h) whether schedule accommodations are allowed; and (i) leave policy for adoption.
3. AMA policy is expanded to include physicians in practice, reading as follows: (a) residency program directors and group practice administrators should review federal law concerning maternity leave for guidance in developing policies to assure that pregnant physicians are allowed the same sick leave or disability benefits as those physicians who are ill or disabled; (b) staffing levels and scheduling are encouraged to be flexible enough to allow for coverage without creating intolerable increases in other physicians' workloads, particularly in residency programs; and (c) physicians should be able to return to their practices or training programs after taking parental leave without the loss of status.
4. Our AMA encourages residency programs, specialty boards, and medical group practices to incorporate into their parental leave policies a six-week minimum leave allowance, with the understanding that no parent should be required to take a minimum leave.
5. Residency program directors should review federal and state law for guidance in developing policies for parental, family, and medical leave.
6. Medical students and physicians who are unable to work because of pregnancy, childbirth, and other related medical conditions should be entitled to such leave and other benefits on the same basis as other physicians who are temporarily unable to work for other medical reasons.

7. Residency programs should develop written policies on parental leave, family leave, and medical leave for physicians. Such written policies should include the following elements: (a) leave policy for birth or adoption; (b) duration of leave allowed before and after delivery; (c) category of leave credited (e.g., sick, vacation, parental, unpaid leave, short term disability); (d) whether leave is paid or unpaid; (e) whether provision is made for continuation of insurance benefits during leave and who pays for premiums; (f) whether sick leave and vacation time may be accrued from year to year or used in advance; (g) extended leave for resident physicians with extraordinary and long-term personal or family medical tragedies for periods of up to one year, without loss of previously accepted residency positions, for devastating conditions such as terminal illness, permanent disability, or complications of pregnancy that threaten maternal or fetal life; (h) how time can be made up in order for a resident physician to be considered board eligible; (i) what period of leave would result in a resident physician being required to complete an extra or delayed year of training; (j) whether time spent in making up a leave will be paid; and (k) whether schedule accommodations are allowed, such as reduced hours, no night call, modified rotation schedules, and permanent part-time scheduling.
8. Our AMA endorses the concept of equal parental leave for birth and adoption as a benefit for resident physicians, medical students, and physicians in practice regardless of gender or gender identity.
9. Staffing levels and scheduling are encouraged to be flexible enough to allow for coverage without creating intolerable increases in the workloads of other physicians, particularly those in residency programs.
10. Physicians should be able to return to their practices or training programs after taking parental leave, family leave, or medical leave without the loss of status.
11. Residency program directors must assist residents in identifying their specific requirements (for example, the number of months to be made up) because of leave for eligibility for board certification and must notify residents on leave if they are in danger of falling below minimal requirements for board eligibility. Program directors must give these residents a complete list of requirements to be completed in order to retain board eligibility.
12. Our AMA encourages flexibility in residency training programs, incorporating parental leave and alternative schedules for pregnant house staff.
13. In order to accommodate leave protected by the federal Family and Medical Leave Act, our AMA encourages all specialties within the American Board of Medical Specialties to allow graduating residents to extend training up to 12 weeks after the traditional residency completion date while still maintaining board eligibility in that year.
14. These policies as above should be freely available online and in writing to all applicants to medical school, residency or fellowship. Citation: CCB/CLRPD Rep. 4, A-13; Modified: Res. 305, A-14; Modified: Res. 904, I-14

Parental Leave H-405.954
1. Our AMA encourages the study of the health implications among patients if the United States were to modify one or more of the following aspects of the Family and Medical Leave Act (FMLA): a reduction in the number of employees from 50 employees; an increase in the number of covered weeks from 12 weeks; and creating a new benefit of paid parental leave.
2. Our AMA will study the effects of FMLA expansion on physicians in varied practice environments.
3. Our AMA: (a) encourages employers to offer and/or expand paid parental leave policies; (b) encourages state medical associations to work with their state legislatures to establish and promote paid parental leave policies; (c) advocates for improved social and economic support for paid family leave to care for newborns, infants and young children; and (d) advocates for federal tax incentives to support early child care and unpaid child care by extended family members. Citation: Res. 215, I-16; Appended: BOT Rep. 11, A-19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 305
(November 2020)

Introduced by: Illinois

Subject: Parental Leave and Planning Resources for Medical Students

Referred to: Reference Committee C

Whereas, The number of women enrolled as first year medical students has recently risen to the majority of 51.6% in 2018[1]; and

Whereas, The average age of matriculated first year medical students is 24[2]; the average amount of time specialized physicians spend in post high school training is 14 years[3], and the average age of mothers at first birth in the United States is 26.8 years[4]; and

Whereas, 9.2% of medical students are parents by graduation[5], and thus it is essential to address the potential of pregnancy and parenthood during the course of medical education; and

Whereas, The rate of attrition for premedical females who ultimately attend medical school is significantly higher than expected due to social factors including policies regarding parental leave, which influence students to opt for a more accommodative career[6]; and

Whereas, The perceived higher compatibility of maintaining a family life with a career as a physician assistant rather than a physician has led to an increase in female physician assistant students at a rate higher than the rate of increase of female medical students[7]; and

Whereas, A survey of students from the South Dakota Sanford School of Medicine shows that medical students of all genders largely want schools to provide “clear, well-defined guidelines, scheduling flexibility and administrators who are approachable and understanding of their individual circumstances” regarding pregnancy and parenthood[5]; and

Whereas, Amongst the barriers that have been identified by female faculty physicians that prevent the advancement of qualified women in academic medicine are workplace policies that do not allow for women to maintain a balanced lifestyle in fear of not advancing in their careers[8]; and

Whereas, A survey across 11 academic medical institutions of residents in internal medicine, family practice, pediatrics, medicine–pediatrics, surgery, and obstetrics–gynecology, found that women residents were more likely than their male counterparts to intentionally postpone pregnancy because of perceived threats to their careers[9]; and

Whereas, Though there is limited research on medical student family planning, research focusing on residents and physicians, summarized above, suggests that early-career professionals of all genders express a desire for well-defined guidelines and policies promoting work-life harmony without effects on career opportunities. It is reasonable to assume that the opinions of residents, in conjunction with the data from South Dakota Sanford School of Medicine, can be extrapolated to medical students; and

Whereas, The Family and Medical Leave Act (FMLA) requires qualifying employers to give up to 12 weeks of unpaid leave to bond with a newborn or newly adopted child and the ability to apply other paid leave time towards FMLA-protected parental leave[10]; and

Whereas, The FMLA does not have protections for students, and thus schools are not required by law to accommodate parental leave[10]; and

Whereas, Current AMA, LCME and COCA policy does not require medical schools to help medical students in family planning or lay out clear policy addressing how assignments and/or classes can be made up in a way that would be amenable to family planning, and thus many schools do not provide resources outside of individual consultation; and

Whereas, The average proportion of medical students who are parents nearly triples between matriculation (3.0%)[11] and graduation (8.9%)[12]; and

Whereas, Medical students from every medical school have anecdotally expressed difficulties regarding family planning in medical school; and

Whereas, A majority of female physicians surveyed have regrets about family planning decisions and career decision-making, and if given the chance would have made decisions such as attempting conception earlier (28.6%), choosing a different specialty (17.1%), or using cryopreservation to extend fertility (7%)[13]; and

Whereas, 68.2% of medical students whose first pregnancy was in medical school and 88.6% of those whose first pregnancies occurred in training perceived substantial workplace support, indicating a lack of policy and support at medical schools comparative to residency training programs[14]; and

Whereas, It is unrealistic and inappropriate to expect trainees to delay childbearing or to forgo spending critical time with their infants, indicating the necessity of alternative solutions to improve family leave in undergraduate medical education; and

Whereas, There is little to no literature on medical students who are fathers, but they should also be allowed to spend critical time with their newborns; and

Whereas, A study addressing, “the common personal and professional challenges that medical students who are also parents face during their undergraduate medical education” found that by addressing the following: lack of career advisory and support networks for parents/expecting parents, unaccommodating schedules requiring formal leaves of absence, and childcare facilitated by the institution and challenges of breastfeeding support, medical schools can support the health and promote the education of their students[15]; and

Whereas, Students who take leaves for family planning may be negatively impacted during their training and the residency application process due to the opinions of faculty evaluators regarding leave, and residency programs’ negative perception of gaps in medical training[16]; and

Whereas, There are clear burdens and stress on medical students, particularly female medical students, and medical school administrators do not counsel and provide trainees with clear information about the impact of childbearing and family leave on coursework; and

Whereas, Medical educators should have established resources and policies that are as accommodating as possible; and

Whereas, Requesting information is often a barrier to access of knowledge, and this information is not freely and publicly available to students; therefore be it

RESOLVED, That our American Medical Association encourage medical schools to create comprehensive informative resources that promote a culture that is supportive of their students who are parents, including information and policies on parental leave and relevant make up work, options to preserve fertility, breastfeeding, accommodations during pregnancy, and resources for childcare that span the institution and the surrounding area (New HOD Policy); and be it further

RESOLVED, That our AMA encourage medical schools to give students a minimum of 6 weeks of parental leave without academic or disciplinary penalties that would delay anticipated graduation based on time of matriculation (New HOD Policy); and be it further

RESOLVED, That our AMA encourage that medical schools formulate, and make readily available, plans for each year of schooling such that parental leave may be flexibly incorporated into the curriculum (New HOD Policy); and be it further

RESOLVED, That our AMA urge medical schools to adopt policy that will prevent parties involved in medical training (including but not limited to residency programs, administration, fellowships, away rotations, physician evaluators, and research opportunities) from discriminating against students who take family/parental leave (Directive to Take Action); and be it further

RESOLVED, That our AMA advocate for medical schools to make resources and policies regarding family leave and parenthood transparent and openly accessible to prospective and current students. (Directive to Take Action)

Fiscal Note: Minimal - less than $1,000

Received: 10/07/20

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RELEVANT AMA POLICY

Policies for Parental, Family and Medical Necessity Leave H-405.960
AMA adopts as policy the following guidelines for, and encourages the implementation of, Parental, Family and Medical Necessity Leave for Medical Students and Physicians:
1. Our AMA urges medical schools, residency training programs, medical specialty boards, the Accreditation Council for Graduate Medical Education, and medical group practices to incorporate and/or encourage development of leave policies, including parental, family, and medical leave policies, as part of the physician's standard benefit agreement.
2. Recommended components of parental leave policies for medical students and physicians include: (a) duration of leave allowed before and after delivery; (b) category of leave credited; (c) whether leave is paid or unpaid; (d) whether provision is made for continuation of insurance benefits during leave, and who pays the premium; (e) whether sick leave and vacation time may be accrued from year to year or used in advance; (f) how much time must be made up in order to be considered board eligible; (g) whether make-up time will be paid; (h) whether schedule accommodations are allowed; and (i) leave policy for adoption.
3. AMA policy is expanded to include physicians in practice, reading as follows: (a) residency program directors and group practice administrators should review federal law concerning maternity leave for guidance in developing policies to assure that pregnant physicians are allowed the same sick leave or disability benefits as those physicians who are ill or disabled; (b) staffing levels and scheduling are encouraged to be flexible enough to allow for coverage without creating intolerable increases in other physicians' workloads, particularly in residency programs; and (c) physicians should be able to return to their practices or training programs after taking parental leave without the loss of status.
4. Our AMA encourages residency programs, specialty boards, and medical group practices to incorporate into their parental leave policies a six-week minimum leave allowance, with the understanding that no parent should be required to take a minimum leave.
5. Residency program directors should review federal and state law for guidance in developing policies for parental, family, and medical leave.
6. Medical students and physicians who are unable to work because of pregnancy, childbirth, and other related medical conditions should be entitled to such leave and other benefits on the same basis as other physicians who are temporarily unable to work for other medical reasons.
7. Residency programs should develop written policies on parental leave, family leave, and medical leave for physicians. Such written policies should include the following elements: (a) leave policy for birth or adoption; (b) duration of leave allowed before and after delivery; (c) category of leave credited (e.g., sick, vacation, parental, unpaid leave, short term disability); (d) whether leave is paid or unpaid; (e) whether provision is made for continuation of insurance benefits during leave and who pays for premiums; (f) whether sick leave and vacation time may

be accrued from year to year or used in advance; (g) extended leave for resident physicians with extraordinary and long-term personal or family medical tragedies for periods of up to one year, without loss of previously accepted residency positions, for devastating conditions such as terminal illness, permanent disability, or complications of pregnancy that threaten maternal or fetal life; (h) how time can be made up in order for a resident physician to be considered board eligible; (i) what period of leave would result in a resident physician being required to complete an extra or delayed year of training; (j) whether time spent in making up a leave will be paid; and (k) whether schedule accommodations are allowed, such as reduced hours, no night call, modified rotation schedules, and permanent part-time scheduling.

8. Our AMA endorses the concept of equal parental leave for birth and adoption as a benefit for resident physicians, medical students, and physicians in practice regardless of gender or gender identity.

9. Staffing levels and scheduling are encouraged to be flexible enough to allow for coverage without creating intolerable increases in the workloads of other physicians, particularly those in residency programs.

10. Physicians should be able to return to their practices or training programs after taking parental leave, family leave, or medical leave without the loss of status.

11. Residency program directors must assist residents in identifying their specific requirements (for example, the number of months to be made up) because of leave for eligibility for board certification and must notify residents on leave if they are in danger of falling below minimal requirements for board eligibility. Program directors must give these residents a complete list of requirements to be completed in order to retain board eligibility.

12. Our AMA encourages flexibility in residency training programs, incorporating parental leave and alternative schedules for pregnant house staff.

13. In order to accommodate leave protected by the federal Family and Medical Leave Act, our AMA encourages all specialties within the American Board of Medical Specialties to allow graduating residents to extend training up to 12 weeks after the traditional residency completion date while still maintaining board eligibility in that year.

14. These policies as above should be freely available online and in writing to all applicants to medical school, residency or fellowship.

CCB/CLRPD Rep. 4, A-13; Modified: Res. 305, A-14; Modified: Res. 904, I-14

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 306
(November 2020)

Introduced by: North Dakota, South Dakota, Iowa

Subject: Retirement of the National Board of Medical Examiners Step 2 Clinical Skills Exam for US Medical Graduates: Call for Expedited Action by the American Medical Association

Referred to: Reference Committee C

Whereas, The teaching of clinical skills in history taking, physical examination, documentation and communication with patients has been the foundation of the education of new physicians; and

Whereas, Perceived inadequacies in the teaching of these skills to medical students in medical schools both in the United States and elsewhere led to the implementation of a clinical skills examination component of the certification processes of the United States Medical Licensing Exam (USMLE Step 2 CS) and National Board of Osteopathic Medical Examiners (COMLEX Level 2 PE) in 2004; and

Whereas, Concurrent improvements since that date in the teaching of clinical skills to medical students utilizing case-based learning, clinical simulation techniques and intensified testing protocols have greatly enhanced the emphasis given to clinical skills acquisition by those students; and

Whereas, Increased emphasis on the teaching of clinical skills by the Liaison Committee on Medical Education (LCME), the accrediting organization for allopathic medical schools and the Commission on Osteopathic College Accreditation (COCA), the accrediting organization for osteopathic medical schools, has produced an environment where the documentation and enhancement of clinical skills teaching and assessment is now firmly embedded in medical school curricula; and

Whereas, In 2019, the overall pass rate of USMLE Step 2 CS and COMLEX Level 2-CE for first-time test takers are greater than 95% and 92% respectively suggesting that students who have failed to acquire satisfactory clinical skills during their medical school training are rarely encountered; and

Whereas, It has been estimated that the cost to identify one inadequate trainee using the clinical skills exams may be in excess of $1 million dollars, suggesting a very low value proposition for medical students and medical schools. (NEJM 2013; 368:889-891 DOI 10.1056/ NEJMp1213760); and

Whereas, The USMLE Step 2 CS Exam is only offered in 5 sites, and the COMLEX Level 2-CE at 2 sites in the US, requiring all medical students desiring state medical licensure to spend up to 3 days travelling to these sites which further adds to their educational debt beyond the test fees themselves; and

Whereas, Validation of the exam's long-term effectiveness on individual physician's clinical skill effectiveness has not been demonstrated; and

Whereas, Previous AMA policy, most recently updated at I-19, has called for transition from and replacement for this examination with a more accessible, locally available examination which would be offered as a replacement for the present USMLE and COMLEX formats; and

Whereas, A replacement examination could also be used on a contract basis to credential international medical graduates as part of the ECFMG credentialing process; and

Whereas, The ongoing COVID-19 pandemic has forced USMLE to cancel all Step 2 CS exams for the indefinite future, which places tremendous stress on students and their ability to complete USMLE in a timely fashion for medical school graduation as well as temporary/permanent licensure, therefore be it

RESOLVED, That our American Medical Association take immediate, expedited action to encourage the NBME, FSMB and COCA to eliminate centralized clinical skills examinations used as a part of state licensure, including the USMLE Step 2 CS Exam and the COMLEX Level 2 PE Exam (Directive to Take Action); and be it further

RESOLVED, That our AMA advocate that a replacement examination process be administered within the medical schools that verifies each medical student's competence in key clinical skills required to be a physician (Directive to Take Action); and be it further

RESOLVED, That our AMA advocate that an equivalent examination process as those offered at US medical schools be made available on a contract basis to foreign medical graduates (Directive to Take Action); and be it further

RESOLVED, That our AMA strongly encourage all state delegations in the AMA House of Delegates and other interested member organizations of the AMA to engage their respective state medical licensing boards, the Federation of State Medical Boards, their medical schools and other interested credentialling bodies to encourage the elimination of these centralized, costly and low-value exams (Directive to Take Action); and be it further

RESOLVED, That our AMA advocate that any replacement examination mechanisms be instituted immediately in lieu of resuming existing USMLE Step 2-CS and COMLEX Level 2-PE examinations when the COVID-19 restrictions subside. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000

Received: 10/13/20

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 307
(November 2020)

Introduced by: Alma B. Littles, MD, Delegate

Subject: USMLE Step Examination Failures During the COVID-19 Pandemic

Referred to: Reference Committee C

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1 Whereas, Students at allopathic schools of medicine in the United States are required to achieve
2 a passing score on all three United States Medical Licensing Examination (USMLE) Step
3 Examinations, conducted under the auspices of the National Board of Medical Examiners
4 (NBME), in order to obtain a license to practice medicine in every state of the United States[1]; and
5
6 Whereas, Fifteen of the 50 states will not permit physicians to obtain a license to practice
7 medicine in that state if they have had two or three failures of any of the individual USMLE Step
8 examinations[1] (while other states have varied but less stringent requirements); and
9
10 Whereas, Many medical students and resident physicians arrange their schedules to permit a
11 study period of several days or weeks before taking these examinations, especially Step 1 and
12 Step 2-CK (Clinical Knowledge); and
13
14 Whereas, During the early months of the SARS-CoV-2 pandemic in the United States, from
15 approximately March 1 through September 30, 2020, scheduled USMLE Step 1 and Step 2-CK
16 examination appointments were delayed or postponed, due to factors beyond students' control,
17 such as pandemic-related closure of available testing sites, resulting in a large backlog of
18 potential examinees awaiting their opportunity to sit for the examination[4]; and
19
20 Whereas, The time period applicable for this resolution therefore begins on March 1, 2020 and
21 ends on September 30 (as testing centers have been newly opened, including some newly
22 opened at medical schools, to enable medical students to take USMLE examinations where
23 they attend medical school); and
24
25 Whereas, The disruption of the testing schedule prevented many medical students from being
26 able to sit for these examinations at times during which they had reserved the opportunity to
27 prepare, which caused various forms of turmoil for these students[5,6,7]; and
28
29 Whereas, In a number of instances, students had subsequently received conflicting information
30 regarding when their examination would be scheduled, as reflected in Internet forum
31 discussions of a "chaotic" process[5,7,8]; and
32
33 Whereas, The delay and disruption around the scheduling of USMLE examinations likely
34 caused some students and residents to be forced to take or re-take these examinations at
35 inconvenient times, during which their ability to prepare appropriately was impaired by other
36 educational obligations; and

Whereas, Some students also encountered added obligations of travel to other cities to access an available testing center[8], and further may have had their testing opportunity postponed after they began to travel to the reassigned examination site[9];, leading to extra financial expenses due to last-minute changes in travel; and

Whereas, These circumstances are likely to have negatively impacted examinees' USMLE Step exam passing score rates while adding avoidable expense to these examinees' fees and expenses; and

Whereas: Although the impact of these circumstances would have been large to an individual medical student's budget, the overall failure rates for these examinations appear to have remained relatively low on a nation-wide basis, such that any financial impact of this proposal upon the National Board of Medical Examiners would be minimal to that Board; and

Whereas, Failure to pass any Step examinations typically must be revealed by applicants when applying for state medical licensure or for privileges to practice medicine at and/or admit patients to hospitals in the United States[10,11]; therefore be it

RESOLVED, That our American Medical Association advocate to the National Board of Medical Examiners (NBME) that students at allopathic schools of medicine who failed the United States Medical Licensing Examination (USMLE) Step 1 Examination or the USMLE Step 2-CK Examination that was scheduled between March 1, 2020 and September 30, 2020 be allowed the opportunity to be re-examined one time at no additional examination fee charged to the student (Directive to Take Action); and be it further

RESOLVED, That our AMA ask that the various state and territorial medical boards, through outreach to the NBME and Federation of State Medical Boards (FSMB), not require students who failed any USMLE Step 1 or USMLE Step 2 CK examination, between March 1 and September 30, 2020 to reveal this information to state medical licensure boards during the processes of obtaining or renewing state licensure (Directive to Take Action); and be it further

RESOLVED, That our AMA advocate to the NBME and FSMB that such failures not count toward the total number of exam attempts by a potential licensee (Directive to Take Action); and be it further

RESOLVED, That our AMA advocate to hospital accreditation organizations such as, but not limited to, The Joint Commission and American Hospital Association, that those who have failed any USMLE Step 1 or USMLE Step 2-CK examination between March 1 and September 30, 2020 not be required to disclose this information to hospital boards and other accrediting bodies that determine a physician's fitness to practice at or admit patients to hospitals in the United States. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000

Received: 10/14/20

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2. https://www.usmle.org/step-1/. Accessed Sept 19, 2020.
3. https://usmle.org/step-2-ck/. Accessed October 2, 2020.
4. https://covid.usmle.org/announcements/preparations-event-testing. Accessed September 19, 2020.
5. https://www.ama-assn.org/residents-students/usmle/delays-miscommunications-add-even-more-stress-usmle-step-exams. Accessed September 19, 2020.
6. https://www.medpagetoday.com/infectiousdisease/covid19/86059. Accessed September 19, 2020.
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8. https://www.ama-assn.org/residents-students/usmle/delays-miscommunications-add-even-more-stress-usmle-step-exams. Accessed September 19, 2020.
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10. https://www.sos.mo.gov/cmsimages/adrules/csr/current/20csr/20c2150-2.pdf Page 4. Accessed September 19, 2020.
11. https://www.barnesjewish.org/About-Us. Accessed September 20, 2020.

RELEVANT AMA POLICY

H-275.934, "Alternatives to the Federation of State Medical Boards Recommendations on Licensure"

Our AMA adopts the following, principles:(1) Ideally, all medical students should successfully complete Steps 1 and 2 of the United States Medical Licensing Examination (USMLE) or Levels 1 and 2 of the Comprehensive Osteopathic Medical Licensing Examination (COMLEX USA) prior to entry into residency training. At a minimum, individuals entering residency training must have successfully completed Step 1 of the USMLE or Level 1 of COMLEX USA. There should be provision made for students who have not completed Step 2 of the USMLE or Level 2 of the COMLEX USA to do so during the first year of residency training. (2) All applicants for full and unrestricted licensure, whether graduates of U.S. medical schools or international medical graduates, must have completed one year of accredited graduate medical education (GME) in the U.S., have passed all licensing examinations (USMLE or COMLEX USA), and must be certified by their residency program director as ready to advance to the next year of GME and to obtain a full and unrestricted license to practice medicine. The candidate for licensure should have had education that provided exposure to general medical content. (3) There should be a training permit/educational license for all resident physicians who do not yet have a full and unrestricted license to practice medicine. To be eligible for an initial training permit/educational license, the resident must have completed Step 1 of the USMLE or Level 1 of COMLEX USA. (4) Residency program directors shall report only those actions to state medical licensing boards that are reported for all licensed physicians. (5) Residency program directors should receive training to ensure that they understand the process for taking disciplinary action against resident physicians, and are aware of procedures for dismissal of residents and for due process. This requirement for residency program directors should be enforced through Accreditation Council for Graduate Medical Education accreditation requirements. (6) There should be no reporting of actions against medical students to state medical licensing boards. (7) Medical schools are responsible for identifying and remediating and/or disciplining medical student unprofessional behavior, problems with substance abuse, and other behavioral problems. as well as gaps in student knowledge and skills. (8) The Dean's Letter of Evaluation should be strengthened and standardized, to serve as a better source of information to residency programs about applicants.
(CME Rep. 8, A-99; Reaffirmed: CME Rep. 4, I-01; Reaffirmed: CME Rep. 2, A-11; Modified: CME Rep. 2, A-12)

H-275.953, "The Grading Policy for Medical Licensure Examinations"

1. Our AMA's representatives to the ACGME are instructed to promote the principle that selection of residents should be based on a broad variety of evaluative criteria, and to propose that the ACGME General Requirements state clearly that residency program directors must not use NBME or USMLE ranked passing scores as a screening criterion for residency selection.
2. Our AMA adopts the following policy on NBME or USMLE examination scoring: (a) Students receive "pass/fail" scores as soon as they are available. (If students fail the examinations, they may request their numerical scores immediately.) (b) Numerical scores are reported to the state licensing authorities upon request by the applicant for licensure. At this time, the applicant may request a copy

of his or her numerical scores. (c) Scores are reported in pass/fail format for each student to the medical school. The school also receives a frequency distribution of numerical scores for the aggregate of their students.
3. Our AMA will co-convene the appropriate stakeholders to study possible mechanisms for transitioning scoring of the USMLE and COMLEX exams to a Pass/Fail system in order to avoid the inappropriate use of USMLE and COMLEX scores for screening residency applicants while still affording program directors adequate information to meaningfully and efficiently assess medical student applications, and that the recommendations of this study be made available by the 2019 Interim Meeting of the AMA House of Delegates.
4. Our AMA will: (a) promote equal acceptance of the USMLE and COMLEX at all United States residency programs; (b) work with appropriate stakeholders including but not limited to the National Board of Medical Examiners, Association of American Medical Colleges, National Board of Osteopathic Medical Examiners, Accreditation Council for Graduate Medical Education and American Osteopathic Association to educate Residency Program Directors on how to interpret and use COMLEX scores; and (c) work with Residency Program Directors to promote higher COMLEX utilization with residency program matches in light of the new single accreditation system.
(CME Rep. G, I-90; Reaffirmed by Res. 310, A-98; Reaffirmed: CME Rep. 3, A-04; Reaffirmed: CME Rep. 2, A-14; Appended: Res. 309, A-17; Modified: Res. 318, A-18; Appended: Res. 955, I-18)

D-295.988, "Clinical Skills Assessment During Medical School"
1. Our AMA will encourage its representatives to the Liaison Committee on Medical Education (LCME) to ask the LCME to determine and disseminate to medical schools a description of what constitutes appropriate compliance with the accreditation standard that schools should "develop a system of assessment" to assure that students have acquired and can demonstrate core clinical skills.
2. Our AMA will work with the Federation of State Medical Boards, National Board of Medical Examiners, state medical societies, state medical boards, and other key stakeholders to pursue the transition from and replacement for the current United States Medical Licensing Examination (USMLE) Step 2 Clinical Skills (CS) examination and the Comprehensive Osteopathic Medical Licensing Examination (COMLEX) Level 2-Performance Examination (PE) with a requirement to pass a Liaison Committee on Medical Education-accredited or Commission on Osteopathic College Accreditation-accredited medical school-administered, clinical skills examination.
3. Our AMA will work to: (a) ensure rapid yet carefully considered changes to the current examination process to reduce costs, including travel expenses, as well as time away from educational pursuits, through immediate steps by the Federation of State Medical Boards and National Board of Medical Examiners; (b) encourage a significant and expeditious increase in the number of available testing sites; (c) allow international students and graduates to take the same examination at any available testing site; (d) engage in a transparent evaluation of basing this examination within our nation's medical schools, rather than administered by an external organization; and (e) include active participation by faculty leaders and assessment experts from U.S. medical schools, as they work to develop new and improved methods of assessing medical student competence for advancement into residency.
4. Our AMA is committed to assuring that all medical school graduates entering graduate medical education programs have demonstrated competence in clinical skills.
5. Our AMA will continue to work with appropriate stakeholders to assure the processes for assessing clinical skills are evidence-based and most efficiently use the time and financial resources of those being assessed.
6. Our AMA encourages development of a post-examination feedback system for all USMLE test-takers that would: (a) identify areas of satisfactory or better performance; (b) identify areas of suboptimal performance; and (c) give students who fail the exam insight into the areas of unsatisfactory performance on the examination.
7. Our AMA, through the Council on Medical Education, will continue to monitor relevant data and engage with stakeholders as necessary should updates to this policy become necessary.
(CME Rep. 7, I-99; Reaffirmed: CME Rep. 2, A-09; Appended: Alt. Res. 311, A-16; Appended: CME Rep. 9, A-17; Reaffirmation: I-19)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 308
(November 2020)

Introduced by: International Medical Graduates Section

Subject: ECFMG 2024 Accreditation Requirement for World Federation for Medical Education (WFME) Recognition

Referred to: Reference Committee C

Whereas, The exponential growth of the private sector medical schools, their varying quality of medical education, clinical rotations, and accreditation requirements have become a severe concern to ECFMG; and

Whereas, A standard global accreditation process would help ensure patient safety, good quality clinical outcomes, and professional accountability; and

Whereas, There has always been a need for a transparent and rigorous method of accreditation of medical schools, worldwide, to meet an internationally accepted standard; and

Whereas, After the international task force meeting in 2005, The World Health Organization (WHO) and the World Federation for Medical Education (WFME) jointly published Guidelines for Accreditation of Basic Medical Education[1,] which formed the basis of the 2013 WHO policy briefing on medical accreditation and the 2016 International Association Medical Regulatory Authorities (IAMRA) statement on accreditation of medical education programs[2]; and

Whereas, In 2010, ECFMG stated that effective in 2023, applicants for ECFMG Certification would be required to be a student or graduate of a medical school accredited by a WFME-recognized accrediting agency[3]; and

Whereas, During the last ten years, of the 130 - 147 countries whose medical students apply for ECFMG certification, only 23 countries have obtained WFME recognition status, and only 13 more have applied[4]; and

Whereas, Because of the COVID-19 pandemic, the current deadline for implementing the WFME based accreditation standards has been extended to 2024[5]. Given the time constraints, it is unlikely that most countries will have their accrediting bodies obtain the WFME recognition status by 2024; and

Whereas, One in four physicians in the U.S. is a graduate of an international medical school who fills 54.6% of primary care specialty positions[6,7] and fills in the physician workforce gaps that would remain vacant; and

Whereas, IMG physicians have provided ongoing primary health care services to the American people of equivalent quality to those who have completed medical school in the U.S.; and

Whereas, There is a predicted shortage of 21,400 to 55,200 primary care physicians and a total physician shortfall of 54,100 to 139,000 by 2033, and the new prerequisites for WFME based certification requirements will significantly limit the applicant pool for primary healthcare positions, thus negatively impacting the health care of the nation; therefore be it

RESOLVED, That our American Medical Association work with the state and specialty medical associations and other stakeholders to apprise them of the ECFMG requirements and the foreseeable shortage of IMG physicians in underserved populations and primary health care settings to be prepared with alternative options (Directive to Take Action); and be it further

RESOLVED, That our AMA work with the Federation of State Medical Boards and ECFMG to develop more robust communication channels with participating medical schools and explore reasons for the low rate of accreditation and possible ways to address those barriers in meeting accreditation requirements. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000

Received: 10/19/20

1.WHO/WFME Guidelines for Accreditation of Basic Medical Education https://bit.ly/3j03bVB, Accessed on September 19, 2020.
2. Policy Brief on Accreditation of Institutions for Health Professional Education World Health organization 2013; https://bit.ly/32Unf6n, Accessed on September 19, 2020.
3. 2023 Medical School Accreditation Requirement https://www.ecfmg.org/accreditation/, Accessed on September 12, 2020.
4. WFME Agencies with Recognition Status and applying https://bit.ly/330jE6K, Accessed on September 12, 2020.
5. ECFMG Medical School Accreditation Requirement Moved to 2024, https://bit.ly/3429jqq, Accessed on September 11, 2020.
6. Inside the numbers behind the record-setting 2019 Match; https://bit.ly/364GyM4, Accessed on September 20, 2020.
7. Press Release: Thousands of Resident Applicants Celebrate NRMP Match Results https://bit.ly/3i7XqEp, Accessed on September 15, 2020.
8. The Complexities of Physician Supply and Demand: Projections From 2018 to 2033, https://bit.ly/2FW7RO9, Accessed on September 23, 2020.

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 309
(November 2020)

Introduced by: Michigan

Subject: Preserve and Increase Graduate Medical Education Funding

Referred to: Reference Committee C

Whereas, The U.S. General Accountability Office (GAO) recently announced their fiscal year budget; and

Whereas, Their announcement included information about potential changes in graduate medical education (GME) funding; and

Whereas, The GAO released a report in December 2019, entitled, "Views on Expanding Medicare Graduate Medical Education Funding to Nurse Practitioners and Physician Assistants"; and

Whereas, This report contains potential errors that may adversely influence legislative decisions; and

Whereas, GME funding, direct and indirect funding, has been earmarked for resident physicians to support their education and training in teaching hospitals; and

Whereas, Advanced practice professionals, such as nurse practitioners or physician assistants, have a shorter training period with an associated lower overall cost for the trainee and no requirement for a residency; and

Whereas, The number of residency slots has not been increased for most residency programs since 1997 due to the restrictions imposed by the Balanced Budget Act; and

Whereas, Teaching hospitals rely on GME funding to offset the increased cost of providing care that may occur in a teaching hospital setting due to the presence of additional health care personnel who are trainees; and

Whereas, An increase in GME funding has been an ongoing request to our legislators for the past few years due to concerns about the rising expenses of providing education coupled with the stagnation of GME funding; and

Whereas, The United States is facing a significant and severe physician shortage based on current predictors and estimates; and

Whereas, The diversion of GME funding to non-physicians will only make this situation worse with potential serious consequences for the health of our nation due to lack of physician access; therefore be it

1 RESOLVED, That our American Medical Association work with the Liaison Committee on
2 Medical Education, the Accreditation Council for Graduate Medical Education, and other
3 interested stakeholders to encourage the U.S. Government Accountability Office to oppose and
4 refrain from further consideration of the diversion of direct and indirect graduate medical
5 education funding to non-physicians. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000

Received: 10/27/20

Sources:
1. U.S. Government Accountability Office Report to Congressional Committees December 2019 HEALTH CARE WORKFORCE "Views on Expanding Medicare Graduate Medical Education Funding to Nurse Practitioners and Physician Assistants"
2. "Residency: The Bottleneck in Physician Training" Physicians for Patient Protection/PPP Response to GAO Report, on-line resource, accessed February 10, 2020.

RELEVANT AMA POLICY

Funding to Support Training of the Health Care Workforce H-310.916
1. Our American Medical Association will insist that any new GME funding to support graduate medical education positions be available only to Accreditation Council for Graduate Medical Education (ACGME) and/or American Osteopathic Association (AOA) accredited residency programs, and believes that funding made available to support the training of health care providers not be made at the expense of ACGME and/or AOA accredited residency programs.
2. Our AMA strongly advocates that: (A) there be no decreases in the current funding of MD and DO graduate medical education while there is a concurrent increase in funding of graduate medical education (GME) in other professions; and (B) there be at least proportional increases in the current funding of MD and DO graduate medical education similar to increases in funding of GME in other professions.
Citation: (Sub. Res. 913, I-09; Appended: Res. 917, I-15)

Securing Funding for Graduate Medical Education H-310.917
Our American Medical Association: (1) continues to be vigilant while monitoring pending legislation that may change the financing of medical services (health system reform) and advocate for expanded and broad-based funding for graduate medical education (from federal, state, and commercial entities); (2) continues to advocate for graduate medical education funding that reflects the physician workforce needs of the nation; (3) encourages all funders of GME to adhere to the Accreditation Council for Graduate Medical Education's requirements on restrictive covenants and its principles guiding the relationship between GME, industry and other funding sources, as well as the AMA's Opinion 8.061, and other AMA policy that protects residents and fellows from exploitation, including physicians training in non-ACGME-accredited programs; and (4) encourages entities planning to expand or start GME programs to develop a clear statement of the benefits of their GME activities to facilitate potential funding from appropriate sources given the goals of their programs.
Citation: (CME Rep. 3, I-09; Modified: CME Rep. 15, A-10; Reaffirmed in lieu of Res. 324, A-12; Reaffirmed: CME Rep. 5, A-13; Appended: CME Rep. 1, I-15)

The Preservation, Stability and Expansion of Full Funding for Graduate Medical Education D-305.967
1. Our AMA will actively collaborate with appropriate stakeholder organizations, (including Association of American Medical Colleges, American Hospital Association, state medical societies, medical specialty societies/associations) to advocate for the preservation, stability and expansion of full funding for the direct and indirect costs of graduate medical education (GME) positions from all existing sources (e.g. Medicare, Medicaid, Veterans Administration, CDC and others).
2. Our AMA will actively advocate for the stable provision of matching federal funds for state Medicaid programs that fund GME positions.
3. Our AMA will actively seek congressional action to remove the caps on Medicare funding of GME positions for resident physicians that were imposed by the Balanced Budget Amendment of 1997 (BBA-1997).
4. Our AMA will strenuously advocate for increasing the number of GME positions to address the future physician workforce needs of the nation.
5. Our AMA will oppose efforts to move federal funding of GME positions to the annual appropriations process that is subject to instability and uncertainty.

6. Our AMA will oppose regulatory and legislative efforts that reduce funding for GME from the full scope of resident educational activities that are designated by residency programs for accreditation and the board certification of their graduates (e.g. didactic teaching, community service, off-site ambulatory rotations, etc.).
7. Our AMA will actively explore additional sources of GME funding and their potential impact on the quality of residency training and on patient care.
8. Our AMA will vigorously advocate for the continued and expanded contribution by all payers for health care (including the federal government, the states, and local and private sources) to fund both the direct and indirect costs of GME.
9. Our AMA will work, in collaboration with other stakeholders, to improve the awareness of the general public that GME is a public good that provides essential services as part of the training process and serves as a necessary component of physician preparation to provide patient care that is safe, effective and of high quality.
10. Our AMA staff and governance will continuously monitor federal, state and private proposals for health care reform for their potential impact on the preservation, stability and expansion of full funding for the direct and indirect costs of GME.
11. Our AMA: (a) recognizes that funding for and distribution of positions for GME are in crisis in the United States and that meaningful and comprehensive reform is urgently needed; (b) will immediately work with Congress to expand medical residencies in a balanced fashion based on expected specialty needs throughout our nation to produce a geographically distributed and appropriately sized physician workforce; and to make increasing support and funding for GME programs and residencies a top priority of the AMA in its national political agenda; and (c) will continue to work closely with the Accreditation Council for Graduate Medical Education, Association of American Medical Colleges, American Osteopathic Association, and other key stakeholders to raise awareness among policymakers and the public about the importance of expanded GME funding to meet the nation's current and anticipated medical workforce needs.
12. Our AMA will collaborate with other organizations to explore evidence-based approaches to quality and accountability in residency education to support enhanced funding of GME.
13. Our AMA will continue to strongly advocate that Congress fund additional graduate medical education (GME) positions for the most critical workforce needs, especially considering the current and worsening maldistribution of physicians.
14. Our AMA will advocate that the Centers for Medicare and Medicaid Services allow for rural and other underserved rotations in Accreditation Council for Graduate Medical Education (ACGME)-accredited residency programs, in disciplines of particular local/regional need, to occur in the offices of physicians who meet the qualifications for adjunct faculty of the residency program's sponsoring institution.
15. Our AMA encourages the ACGME to reduce barriers to rural and other underserved community experiences for graduate medical education programs that choose to provide such training, by adjusting as needed its program requirements, such as continuity requirements or limitations on time spent away from the primary residency site.
16. Our AMA encourages the ACGME and the American Osteopathic Association (AOA) to continue to develop and disseminate innovative methods of training physicians efficiently that foster the skills and inclinations to practice in a health care system that rewards team-based care and social accountability.
17. Our AMA will work with interested state and national medical specialty societies and other appropriate stakeholders to share and support legislation to increase GME funding, enabling a state to accomplish one or more of the following: (a) train more physicians to meet state and regional workforce needs; (b) train physicians who will practice in physician shortage/underserved areas; or (c) train physicians in undersupplied specialties and subspecialties in the state/region.
18. Our AMA supports the ongoing efforts by states to identify and address changing physician workforce needs within the GME landscape and continue to broadly advocate for innovative pilot programs that will increase the number of positions and create enhanced accountability of GME programs for quality outcomes.
19. Our AMA will continue to work with stakeholders such as Association of American Medical Colleges (AAMC), ACGME, AOA, American Academy of Family Physicians, American College of Physicians, and other specialty organizations to analyze the changing landscape of future physician workforce needs as well as the number and variety of GME positions necessary to provide that workforce.
20. Our AMA will explore innovative funding models for incremental increases in funded residency positions related to quality of resident education and provision of patient care as evaluated by appropriate medical education organizations such as the Accreditation Council for Graduate Medical Education.
21. Our AMA will utilize its resources to share its content expertise with policymakers and the public to ensure greater awareness of the significant societal value of graduate medical education (GME) in terms of patient care, particularly for underserved and at-risk populations, as well as global health, research and education.
22. Our AMA will advocate for the appropriation of Congressional funding in support of the National Healthcare Workforce Commission, established under section 5101 of the Affordable Care Act, to provide data and healthcare workforce policy and advice to the nation and provide data that support the value of GME to the nation.

23. Our AMA supports recommendations to increase the accountability for and transparency of GME funding and continue to monitor data and peer-reviewed studies that contribute to further assess the value of GME.
24. Our AMA will explore various models of all-payer funding for GME, especially as the Institute of Medicine (now a program unit of the National Academy of Medicine) did not examine those options in its 2014 report on GME governance and financing.
25. Our AMA encourages organizations with successful existing models to publicize and share strategies, outcomes and costs.
26. Our AMA encourages insurance payers and foundations to enter into partnerships with state and local agencies as well as academic medical centers and community hospitals seeking to expand GME.
27. Our AMA will develop, along with other interested stakeholders, a national campaign to educate the public on the definition and importance of graduate medical education, student debt and the state of the medical profession today and in the future.
28. Our AMA will collaborate with other stakeholder organizations to evaluate and work to establish consensus regarding the appropriate economic value of resident and fellow services.
29. Our AMA will monitor ongoing pilots and demonstration projects, and explore the feasibility of broader implementation of proposals that show promise as alternative means for funding physician education and training while providing appropriate compensation for residents and fellows.
30. Our AMA will monitor the status of the House Energy and Commerce Committee's response to public comments solicited regarding the 2014 IOM report, Graduate Medical Education That Meets the Nation's Health Needs, as well as results of ongoing studies, including that requested of the GAO, in order to formulate new advocacy strategy for GME funding, and will report back to the House of Delegates regularly on important changes in the landscape of GME funding.
31. Our AMA will advocate to the Centers for Medicare & Medicaid Services to adopt the concept of “Cap-Flexibility” and allow new and current Graduate Medical Education teaching institutions to extend their cap-building window for up to an additional five years beyond the current window (for a total of up to ten years), giving priority to new residency programs in underserved areas and/or economically depressed areas.
32. Our AMA will: (a) encourage all existing and planned allopathic and osteopathic medical schools to thoroughly research match statistics and other career placement metrics when developing career guidance plans; (b) strongly advocate for and work with legislators, private sector partnerships, and existing and planned osteopathic and allopathic medical schools to create and fund graduate medical education (GME) programs that can accommodate the equivalent number of additional medical school graduates consistent with the workforce needs of our nation; and (c) encourage the Liaison Committee on Medical Education (LCME), the Commission on Osteopathic College Accreditation (COCA), and other accrediting bodies, as part of accreditation of allopathic and osteopathic medical schools, to prospectively and retrospectively monitor medical school graduates’ rates of placement into GME as well as GME completion.
33. Our AMA encourages the Secretary of the U.S. Department of Health and Human Services to coordinate with federal agencies that fund GME training to identify and collect information needed to effectively evaluate how hospitals, health systems, and health centers with residency programs are utilizing these financial resources to meet the nation’s health care workforce needs. This includes information on payment amounts by the type of training programs supported, resident training costs and revenue generation, output or outcomes related to health workforce planning (i.e., percentage of primary care residents that went on to practice in rural or medically underserved areas), and measures related to resident competency and educational quality offered by GME training programs.
Citation: Sub. Res. 314, A-07; Reaffirmation I-07; Reaffirmed: CME Rep. 4, I-08; Reaffirmed: Sub. Res. 314, A-09; Reaffirmed: CME Rep. 3, I-09; Reaffirmation A-11; Appended: Res. 910, I-11; Reaffirmed in lieu of Res. 303, A-12; Reaffirmed in lieu of Res. 324, A-12; Reaffirmation: I-12; Reaffirmation A-13; Appended: Res. 320, A-13; Appended: CME Rep. 5, A-13; Appended: CME Rep. 7, A-14; Appended: Res. 304, A-14; Modified: CME Rep. 9, A-15; Appended: CME Rep, 1, I-15; Appended: Res. 902, I-15; Reaffirmed: CME Rep. 3, A-16; Appended: Res. 320, A-16; Appended: CME Rep. 04, A-16; Appended: CME Rep. 05, A-16; Reaffirmation A-16; Appended: Res. 323, A-17; Appended: CME Rep. 03, A-18; Appended: Res. 319, A-18; Reaffirmed in lieu of: Res. 960, I-18; Modified: Res. 233, A-19; Modified: BOT Rep. 25, A-19

Reference Committee D

BOT Report(s)

09 Bullying in the Practice of Medicine
10 Compassionate Release for Incarcerated Patients

Resolution(s)

401 Fatigue Mitigation Respite for Faculty and Residents
402 Air Quality and the Protection of Citizen Health
403 Support for Impairment Research
404 Early Vaccination for Correctional Workers and Incarcerated Persons
405 Attacking Disparities in COVID-19 Underlying Health Conditions
406 Face Masking in Hospitals During Flu Season
407* Full Commitment by our AMA to the Betterment and Strengthening of Public Health Systems

**** contained in the Handbook Addendum***

REPORT 9 OF THE BOARD OF TRUSTEES (November 2020)
Bullying in the Practice of Medicine
(Reference Committee D)

EXECUTIVE SUMMARY

At the 2019 Annual Meeting Resolution 402-A-19, "Bullying in the Practice of Medicine," was introduced by the Young Physicians Section and referred by the House of Delegates (HOD) for report back at the 2020 Annual Meeting. The resolution asks the American Medical Association (AMA) to help (1) establish a clear definition of professional bullying, (2) establish prevalence and impact of professional bullying, and (3) establish guidelines for prevention of professional bullying. This report provides statistics and other information about the prevalence and impact of professional bullying in the practice of medicine, and makes recommendations for the adoption of a formal definition and guidelines for establishing policies and strategies for preventing and addressing incidents of bullying among the health care staff.

Bullying in the practice of medicine for physicians can begin in medical school and can endure throughout a physician's career. Bullying is not limited to physicians and can happen among other members of the health care team. Bullying has many definitions, all commonly referring to the repeated abuse of a target by a perpetrator in a work setting. Bullying occurs at different levels within the practice of medicine, and affects the victim as well as their patients, care teams, organizations, and families. Nationally recognized organizations have established guidelines on which health care employers can base their internal policies, and many organizations have implemented anti-bullying or anti-violence policies. Bullying in medicine needs to be stopped and prevented for the sake of patients and care quality, the well-being of the physician workforce, and the integrity of the medical profession.

REPORT OF THE BOARD OF TRUSTEES

B of T Report 9, November 2020

Subject: Bullying in the Practice of Medicine (Resolution 402-A-19)

Presented by: Russ Kridel, MD, Chair

Referred to: Reference Committee D

INTRODUCTION

At the 2019 Annual Meeting Resolution 402-A-19, "Bullying in the Practice of Medicine," was introduced by the Young Physicians Section and referred by the House of Delegates (HOD) for report back at the 2020 Annual Meeting. The resolution asks the American Medical Association (AMA) to: (1) help establish a clear definition of professional bullying; (2) establish prevalence and impact of professional bullying; and (3) establish guidelines for prevention of professional bullying.

This report provides statistics and other information about the causes, prevalence, and impact of bullying in the practice of medicine, and makes recommendations for the adoption of a formal definition and guidelines for establishing policies and strategies for preventing and addressing incidents of bullying among the health care staff.

BACKGROUND

Bullying in the medical profession is a well-documented issue involving the abuse of power or control over a person and repeated offensive, intimidating, malicious, or insulting behavior.[1-6] A 2017 Workplace Bullying Institute (WBI) survey showed 63 percent of workers are aware of bullying in their workplace.[7] Bullying in the workplace is more common than sexual harassment and is initiated by both men and women.[8] This report focuses on bullying among medical students, residents/fellows, and practicing physicians. However, it is important to note that other health care workers such as nurses, medical assistants, and pharmacists, as well as workers in other industries, can also be victims and perpetrators of workplace bullying. Organizational and health system factors may also contribute to the overall workplace climate or culture that allows unprofessional behavior, such as bullying, to persist. This report will discuss some of those factors and the importance of addressing bullying at the individual and organizational levels.

The effects of bullying in medicine can reach beyond the target to the patients, care teams, organizations, and the families of the patients and victims. The effects of bullying on the organizational culture and professional attitudes of the medical staff are significant and lasting, emphasizing the importance of changing the culture to address the problem.[9]

Calls for change in medical education to stop the abuse and harassment of medical students by their teachers have been vocalized for decades.[10] Yet, the unprofessional behavior exercised by some physicians, and the persistence of organizational cultures that enable the behavior, continue to degrade the medical profession. When patient safety, quality of care, and the overall health care industry are under increasingly high scrutiny, it is imperative that physicians, whose professional

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aims include caring for others and as a unified group following a code of ethics, stop the cycle of bullying. Physicians and organizations together need to foster an educational and workplace culture that is respectful, supportive, and conducive to learning and providing high-quality care.

AMA POLICY

The AMA encourages all health care facilities to adopt policies to assess and manage reported workplace violence and abuse, and policies to reduce and prevent all forms of workplace violence and abuse. The AMA recommends that organizations develop a reporting tool that is easy for workers to find and complete and make training courses on workplace violence prevention available to employees and consultants (Policy H-515.966, "Violence and Abuse").

The AMA recommends that all medical education institutions have a widely disseminated policy that: (1) sets forth the expected standards of behavior of the teacher and the learner; (2) delineates procedures for dealing with breaches of that standard, including: (a) avenues for complaints, (b) procedures for investigation, (c) protection and confidentiality, (d) sanctions; and (3) outlines a mechanism for prevention and education. The AMA urges all medical education programs to regard the following Code of Behavior as a guide in developing standards of behavior for both teachers and learners in their own institutions, with appropriate provisions for grievance procedures, investigative methods, and maintenance of confidentiality.

Code of Behavior

The teacher-learner relationship should be based on mutual trust, respect, and responsibility. This relationship should be carried out in a professional manner, in a learning environment that places strong focus on education, high quality patient care, and ethical conduct.

A number of factors place demand on medical school faculty to devote a greater proportion of their time to revenue-generating activity. Greater severity of illness among inpatients also places heavy demands on residents and fellows. In the face of sometimes conflicting demands on their time, educators must work to preserve the priority of education and place appropriate emphasis on the critical role of teacher.

In the teacher-learner relationship, each party has certain legitimate expectations of the other. For example, the learner can expect that the teacher will provide instruction, guidance, inspiration, and leadership in learning. The teacher expects the learner to make an appropriate professional investment of energy and intellect to acquire the knowledge and skills necessary to become an effective physician. Both parties can expect the other to prepare appropriately for the educational interaction and to discharge their responsibilities in the educational relationship with unfailing honesty.

Certain behaviors are inherently destructive to the teacher-learner relationship. Behaviors such as violence, sexual harassment, and inappropriate discrimination based on personal characteristics must never be tolerated. Other behavior can also be inappropriate if the effect interferes with professional development. Behavior patterns such as making habitual demeaning or derogatory remarks, belittling comments, or destructive criticism fall into this category. On the behavioral level, abuse may be operationally defined as behavior by medical school faculty, residents, or students which is consensually disapproved by society and by the academic community as either exploitive or punishing. Examples of inappropriate behavior are: physical punishment or physical threats; sexual harassment; discrimination based on race, religion, ethnicity, sex, age, sexual orientation, gender identity, and physical disabilities;

> repeated episodes of psychological punishment of a student by a particular superior (e.g., public humiliation, threats and intimidation, removal of privileges); grading used to punish a student rather than to evaluate objective performance; assigning tasks for punishment rather than educational purposes; requiring the performance of personal services; taking credit for another individual's work; intentional neglect or intentional lack of communication.
>
> On the institutional level, abuse may be defined as policies, regulations, or procedures that are socially disapproved as a violation of individuals' rights. Examples of institutional abuse are: policies, regulations, or procedures that are discriminatory based on race, religion, ethnicity, sex, age, sexual orientation, gender identity, and physical disabilities; and requiring individuals to perform unpleasant tasks that are entirely irrelevant to their education as physicians.
>
> While criticism is part of the learning process, in order to be effective and constructive, it should be handled in a way to promote learning. Negative feedback is generally more useful when delivered in a private setting that fosters discussion and behavior modification. Feedback should focus on behavior rather than personal characteristics and should avoid pejorative labeling.
>
> Because people's opinions will differ on whether specific behavior is acceptable, teaching programs should encourage discussion and exchange among teacher and learner to promote effective educational strategies. People in the teaching role (including faculty, residents, and students) need guidance to carry out their educational responsibilities effectively.
>
> Medical schools are urged to develop innovative ways of preparing students for their roles as educators of other students as well as patients (Policy H-295.955, “Teacher-Learner Relationship In Medical Education”).

AMA policy also states that the AMA: (1) supports the efforts of the International Association for Healthcare Security and Safety, the AHA, and The Joint Commission to develop guidelines or standards regarding hospital security issues and recognizes these groups' collective expertise in this area. As standards are developed, the AMA will ensure that physicians are advised; and (2) encourages physicians to: work with their hospital safety committees to address the security issues within particular hospitals; become aware of and familiar with their own institution's policies and procedures; participate in training to prevent and respond to workplace violence threats; report all incidents of workplace violence; and promote a culture of safety within their workplace (Policy H-215.978, “Workplace Violence Prevention”).

DISCUSSION

Definitions of bullying

Several definitions of “bullying” are offered throughout existing literature. Various types of bullying have been studied, offering multiple bases on which to define the construct. The variation in definitions may hamper the ability to consistently identify and address the issue. An article in the *International Journal of Environmental Research and Public Health* states “bullying is commonly defined by its social manifestations, which are clearly classifiable under the same umbrella as aggressive behavior that generally occurs during interpersonal interactions in work settings. Similarly, there seems to be a consensus that bullying can be defined in terms of intentionality, frequency (e.g., weekly) or duration (e.g., approximately six months), the targets’ reaction(s), perceived imbalance and misuse of power between the perpetrator and target, inadequate support, and the target’s inability to defend himself from such aggression, as well as having to cope with

negative and constant social interactions, physical or verbal badgering, insulting remarks, and intense pressure."[11]

One study identified five categories of workplace violence:[12]

1. Threat to professional status (public humiliation)
2. Threat to personal standing (name calling, insults, teasing)
3. Isolation (withholding information)
4. Overwork (impossible deadlines)
5. Destabilization (failing to give credit where credit is due)

McAvoy et al. defined bullying as "persistent, offensive, abusive, intimidating, malicious, or insulting behavior; abuse of power; or unfair penal sanctions…that make the recipient feel upset, threatened, humiliated, or vulnerable, undermine their self-confidence and may cause them to suffer stress."[1] Bullying has also been referred to as disruptive, disrespectful, or aggressive behavior. The WBI, a U.S.-based organization dedicated to the eradication of workplace bullying, defines it as repeated, health-harming mistreatment of one or more persons by one or more perpetrators. This definition is also used by The Joint Commission. It includes abusive conduct that is threatening, humiliating, or intimidating, as well as work interference and verbal abuse. The WBI also establishes that workplace bullying:[13]

- Is driven by perpetrators' need to control the targeted individual(s).
- Is initiated by bullies who choose their targets, timing, location, and methods.
- Is a set of acts of commission (doing things to others) or omission (withholding resources from others).
- Requires consequences for the targeted individual.
- Escalates to involve others who side with the bully, either voluntarily or through coercion.
- Undermines legitimate business interests when bullies' personal agendas take precedence over work itself.
- Is akin to domestic violence at work, where the abuser is on the payroll.

Workplace bullying has also been defined as "harassing, offending, or socially excluding someone or negatively affecting someone's work. In order for the label bullying…to be applied to a particular activity, interaction, or process, the bullying behavior has to occur repeatedly and regularly and over a period of time."[14]

A study published in *Innovations in Clinical Neuroscience* defines workplace bullying as "the repetitive and systematic engagement of interpersonally abusive behaviors that negatively affect both the targeted individual and the work organization."[15]

The Advisory, Conciliation and Arbitration Service describes bullying as "offensive, intimidating, malicious or insulting behavior, an abuse or misuse of power through means intended to undermine, humiliate, denigrate or injure the recipient. Bullying or harassment may be by an individual against an individual (perhaps by someone in a position of authority such as a manager or supervisor) or involve groups of people. It may be obvious or it may be insidious. Whatever form it takes, it is unwarranted and unwelcome to the individual."

Harassment, while very similar to bullying and sometimes included in the definitions of bullying, should be distinguished for the purposes of this report. Workplace harassment has a legal definition and is prohibited by law in the context of certain protected classes. Harassment refers to cases in which enduring certain offensive conduct becomes a condition of continued employment, or cases

in which unwanted, unwelcomed and uninvited behavior is severe or pervasive enough to create a work environment that a reasonable person would consider intimidating, hostile, or abusive. The law prohibits harassment based on race, sex, gender, ethnicity, disability, religion or sexual orientation.[16] Conversely, bullying has no legal definition and is not prohibited by law.

Considering the lack of legal definition, the number and variety of definitions in use, and the continued need for more universally accepted policies to prevent bullying in the workplace, the AMA Board of Trustees recommends the establishment of this inclusive, universal definition:

> Bullying is repeated, emotionally or physically abusive, disrespectful, disruptive, inappropriate, insulting, intimidating, and/or threatening behavior targeted at a specific individual or a group of individuals that manifests from a real or perceived power imbalance and is often, but not always, intended to control, embarrass, threaten, undermine, or otherwise harm the target.

Causes and prevalence of bullying in health care professions

Research suggests that bullying results from a combination of individual (e.g., gender, age, and psychological characteristics), organizational (e.g., structure, job characteristics, team setting, etc.), and contextual (service-oriented roles, bureaucracy, public vs. private sector) factors.[11] The inherent desire of physicians to perform at a high level and gain the approval of their superiors, the stressful nature of the physician's role, and the organizational hierarchy in which they practice may create a perfect environment for workplace bullying.

Factors that contribute to workplace bullying include the following:[12]

- A bullying culture
- Poor staffing levels
- Excessive workloads
- Power imbalances
- Poor management skills
- Role conflict or ambiguity
- Stress
- Lack of autonomy

For physicians, bullying in the practice of medicine can begin in medical school. The majority of medical students report experiencing harassment or discrimination during their medical training.[2, 3] Medical students report being harassed or belittled by other students, residents, clinical professors, attending physicians, or patients.[2, 4, 17] Residents also report being bullied during their training, although the reports vary widely depending on the level of training and the country in which the study was completed.[5, 6] The most recent data shows nearly 14 percent of residents have experienced some type of bullying, defined broadly as "harassment that occurs repeatedly (more than once) by an individual in a position of greater power," since the beginning of their training.[6] Studies of practicing physicians in several countries demonstrate that bullying among physicians is a global issue.[11, 18-21]

Physicians and physician trainees are not the only perpetrators and victims of bullying in health care practices. Multiple studies show nurses also observe and experience bullying in their workplaces[22, 23], further pointing to organizational culture as a prime enabler of this type of conduct.

Effects of bullying in the workplace

Bullying in the workplace can have harsh and lasting effects on the victims, their colleagues and co-workers, and the organizations in which they work. Bullying can lead to negative personal or professional consequences including diminished professional satisfaction, unsatisfactory grades, decreased peer respect, social exclusion, distress, depression, anxiety, and burnout.[15] Physical and medical effects of bullying in the workplace include neck pain,[24] acute pain,[25] musculoskeletal complaints,[26] fibromyalgia,[27] and cardiovascular disease.[28] Studies also suggest workplace bullying is associated with subsequent suicidal ideation.[29, 30]

In the health care setting, individuals who reported being bullied experienced the following effects:[6]

- Feeling burned out—57 percent
- Worsened performance—39 percent
- Depression—27 percent
- Change in weight—15 percent
- Alcohol use—6 percent
- Improved performance—6 percent
- Left program—2 percent
- Illicit drug use—1 percent

Bullying among health care workers can also lead to numerous adverse effects for the organization.[11] The risk of adverse effects on patients is the subject of a 2008 Joint Commission alert that warns intimidating and disruptive behavior can result in medical error, poor patient satisfaction and preventable adverse outcomes.[31] Bullying can increase absenteeism[32], reduce overall quality and safety of care[23], and undermine an organization's attempts to foster a culture of respect and safety.[8, 31] Bullying in the health care workplace can threaten patient safety by diverting the worker's attention away from the patient and affecting the worker's ability to think clearly, making unsafe acts and errors more likely.[23] Furthermore, increased absenteeism, reduced quality and safety of care, reputational damage, legal costs, and employee turnover resulting from bullying can all have significant financial effects for an organization.[33]

Less discussed, but just as important, are the effects of workplace bullying on the physicians' family, which can involve withdrawal from family activities, emotional detachment from spouses and children, and sometimes domestic violence.[34]

Addressing bullying in medicine

In the United States bullying is not against the law and there are no universal protections in place for victims of bullying unless there is physical harm involved or if the victim is a member of a protected class, such as people of color or individuals with disabilities. The Healthy Workplace Bill, first introduced in California in 2003, is the product of a grassroots campaign that organized to end workplace bullying. To date, 30 state legislatures and two territories have introduced the bill or some form of it. Only three states have enacted laws similar to the Healthy Workplace Bill, 21 legislatures have considered but ultimately voted down similar bills, and six states currently have bills under review.[35] The bill in its original form protects employers from vicarious liability risk by requiring plaintiffs to provide proof of health harm and providing sufficient reason to terminate or sanction offenders. The bill also provides employees an avenue for legal redress, allows victims to sue the offender as an individual and seek restoration of lost wages and benefits, and holds the employer accountable, compelling them to prevent future instances.[35] The bill has been criticized

for overburdening employers with liability and opening the gates for frivolous complaints which would bog organizations down in expensive litigation.

The Occupational Safety and Health Administration (OSHA), part of the U.S. Department of Labor, ensures safe and healthful working conditions for U.S. workers by setting and enforcing standards and by providing training, outreach, education and assistance. OSHA provides guidance for employers in preventing and controlling workplace violence, which by their definition includes bullying, intimidation, and verbally abusive behaviors. OSHA does not have enforced standards for workplace violence; however, OSHA's "Guidelines for Preventing Workplace Violence for Healthcare and Social Service Workers" provides a foundation for employers to build a workplace violence prevention program. The basic elements of a program should include:

1. Management commitment and employee participation
2. Worksite analysis
3. Hazard prevention and control
4. Safety and health training
5. Recordkeeping and program evaluation

OSHA's guidelines are comprehensive and should be considered integral in an organization's efforts to implement policies and procedures to prevent and address bullying in the workplace.

The Joint Commission has also published guidelines that provide actions organizations can take to effectively address disruptive and inappropriate behaviors in the workplace.[31]

1. "Educate all team members – both physicians and non-physician staff – on appropriate professional behavior defined by the organization's code of conduct. The code and education should emphasize respect. Include training in basic business etiquette (particularly phone skills) and people skills.
2. Hold all team members accountable for modeling desirable behaviors, and enforce the code consistently and equitably among all staff regardless of seniority or clinical discipline in a positive fashion through reinforcement as well as punishment.
3. Develop and implement policies and procedures/processes appropriate for the organization that address:
   - "Zero tolerance" for intimidating and/or disruptive behaviors, especially the most egregious instances of disruptive behavior such as assault and other criminal acts. Incorporate the zero tolerance policy into medical staff bylaws and employment agreements as well as administrative policies.
   - Medical staff policies regarding intimidating and/or disruptive behaviors of physicians within a health care organization should be complementary and supportive of the policies that are present in the organization for non-physician staff.
   - Reducing fear of intimidation or retribution and protecting those who report or cooperate in the investigation of intimidating, disruptive and other unprofessional behavior. Non-retaliation clauses should be included in all policy statements that address disruptive behaviors.
   - Responding to patients and/or their families who are involved in or witness intimidating and/or disruptive behaviors. The response should include hearing and empathizing with their concerns, thanking them for sharing those concerns, and apologizing.
   - How and when to begin disciplinary actions (such as suspension, termination, loss of clinical privileges, reports to professional licensure bodies).

4. Develop an organizational process for addressing intimidating and disruptive behaviors that solicits and integrates substantial input from an inter-professional team including representation of medical and nursing staff, administrators and other employees.
5. Provide skills-based training and coaching for all leaders and managers in relationship-building and collaborative practice, including skills for giving feedback on unprofessional behavior, and conflict resolution. Cultural assessment tools can also be used to measure whether or not attitudes change over time.
6. Develop and implement a system for assessing staff perceptions of the seriousness and extent of instances of unprofessional behaviors and the risk of harm to patients.
7. Develop and implement a reporting/surveillance system (possibly anonymous) for detecting unprofessional behavior. Include ombuds services and patient advocates, both of which provide important feedback from patients and families who may experience intimidating or disruptive behavior from health professionals. Monitor system effectiveness through regular surveys, focus groups, peer and team member evaluations, or other methods. Have multiple and specific strategies to learn whether intimidating or disruptive behaviors exist or recur, such as through direct inquiries at routine intervals with staff, supervisors, and peers.
8. Support surveillance with tiered, non-confrontational interventional strategies, starting with informal "cup of coffee" conversations directly addressing the problem and moving toward detailed action plans and progressive discipline, if patterns persist. These interventions should initially be non-adversarial in nature, with the focus on building trust, placing accountability on and rehabilitating the offending individual, and protecting patient safety. Make use of mediators and conflict coaches when professional dispute resolution skills are needed.
9. Conduct all interventions within the context of an organizational commitment to the health and well-being of all staff, with adequate resources to support individuals whose behavior is caused or influenced by physical or mental health pathologies.
10. Encourage inter-professional dialogues across a variety of forums as a proactive way of addressing ongoing conflicts, overcoming them, and moving forward through improved collaboration and communication.
11. Document all attempts to address intimidating and disruptive behaviors."

Effective workplace policies

Addressing bullying in the practice of medicine requires acknowledgement of the problem and acceptance of responsibility by the industry, the local organization, and the individual professionals. Incidents of workplace violence, including bullying, may be underreported[36] but building the right culture within an organization can help overcome this. The director of the Vanderbilt Center for Patient & Professional Advocacy identifies two key steps for organizations to address bullying in the workplace:[37]

1. Make the administration aware that unprofessional behavior is a threat. If the team doesn't recognize that there is a problem, they won't have a plan to do something about it, nor recognize the threats to quality care.
2. Educate the entire staff—from physicians down to custodians-about why unprofessional—or hostile—behavior is a problem. If the staff recognizes that the leaders are concerned about bullying, they're more likely to come forward when they feel that bullying has occurred, or better yet, tell their co-worker that their behavior is inappropriate.

Health care organizations of all types and sizes should have some policy in place to prevent and address workplace violence, including bullying. A review of the OSHA and Joint Commission guidelines, in addition to existing codes of conduct and policies found online or provided directly

by organizations, reveals common elements for organizations to consider in developing policies. An effective workplace policy should:

- Describe the management's commitment to providing a safe and healthy workplace. Show the staff that their leaders are concerned about bullying and unprofessional behavior and that they take it seriously.
- Clearly define workplace violence, harassment, and bullying, specifically including intimidation, threats and other forms of aggressive behavior.
- Specify to whom the policy applies (i.e., medical staff, administration, patients, contractors, etc.).
- Define both expected and prohibited behaviors.
- Outline steps for employees to take when they feel they are a victim of workplace bullying.
- Provide contact information and a clear process for a confidential means of documenting and reporting incidents.
- Prohibit retaliation and ensure privacy and confidentiality.
- Document training requirements.

In addition to formal policies, organizations should strategize to create a culture in which bullying does not occur. Fostering respect and appreciation among colleagues across disciplines and ranks can contribute to an atmosphere in which employees feel safe, secure, and confident in their roles and professions. Tactics to help create this type of organizational culture include:

- Surveying employees anonymously and confidentially to assess their perceptions of the workplace culture and prevalence of bullying behavior, including their ideas about the impact of this behavior on themselves and patients.
- Showing employees their feedback is taken seriously by using the survey results to inform the development of programs and resources for employees, such as Employee Assistance Programs, that allow them a place to confidentially address experiences of bullying.
- Encouraging open discussions in which employees can talk freely about problems and/or encounters with behavior that may constitute bullying.
- Assessing situations and intervening as soon as reports are received (as is appropriate per policies) and enforcing consequences for perpetrators of bullying.
- Establishing procedures and conducting interventions within the context of the organizational commitment to the health and well-being of all staff.

CONCLUSION

Bullying in the workplace is a complex type of unprofessional conduct. Bullying in medicine happens as a result of a combination of individual, organizational, and systemic issues. The first line of defense against this destructive behavior are physicians, residents, and medical students. There is no justification for bullying, disrespect, harassment, intimidation, threats, or violence of any kind to occur among professionals whose primary purpose is to heal. Physicians choose medicine as their life's work for many reasons, one of the most important being their desire to help and care for people. Naturally, physicians want and deserve to be treated with respect and recognized as professionals, not "providers." Avoiding and working to prevent unprofessional behavior like bullying are worthwhile steps toward earning that respect and assuring medicine keeps its purpose. Correcting the issue can't be viewed as a physician-only problem, however. To effectively reduce bullying in the workplace, organizations should establish policies and procedures and implement programs and training to address the problem at all possible levels.

RECOMMENDATIONS

The Board of Trustees recommends that the following be adopted in lieu of Resolution 402-A-19 and that the remainder of this report be filed:

1. That our American Medical Association (AMA) reaffirm the following policies:
   a. H-215.978, "Workplace Violence Prevention"
   b. H-295.955, "Teacher-Learner Relationship In Medical Education"
   c. H-515.966, "Violence and Abuse." (Reaffirm HOD Policy)

2. That our AMA define "workplace bullying" as repeated, emotionally or physically abusive, disrespectful, disruptive, inappropriate, insulting, intimidating, and/or threatening behavior targeted at a specific individual or a group of individuals that manifests from a real or perceived power imbalance and is often, but not always, intended to control, embarrass, undermine, threaten, or otherwise harm the target. (New HOD Policy)

3. That our AMA adopt the following guidelines for the establishment of workplace policies to prevent and address bullying in the practice of medicine: (New HOD Policy)

   Health care organizations, including academic medical centers, should establish policies to prevent and address bullying in their workplaces. An effective workplace policy should:

   - Describe the management's commitment to providing a safe and healthy workplace. Show the staff that their leaders are concerned about bullying and unprofessional behavior and that they take it seriously.
   - Clearly define workplace violence, harassment, and bullying, specifically including intimidation, threats and other forms of aggressive behavior.
   - Specify to whom the policy applies (i.e., medical staff, students, administration, patients, contractors, etc.).
   - Define both expected and prohibited behaviors.
   - Outline steps for individuals to take when they feel they are a victim of workplace bullying.
   - Provide contact information for a confidential means for documenting and reporting incidents.
   - Prohibit retaliation and ensure privacy and confidentiality.
   - Document training requirements and establish clear expectations about the training objectives.

   In addition to formal policies, organizations should strategize to create a culture in which bullying does not occur. Fostering respect and appreciation among colleagues across disciplines and ranks can contribute to an atmosphere in which employees feel safe, secure and confident in their roles and professions. Tactics to help create this type of organizational culture include:

   - Surveying staff, and medical students in academic settings, anonymously and confidentially to assess their perceptions of the workplace culture and prevalence of bullying behavior, including their ideas about the impact of this behavior on themselves and patients. Use the results to inform the development of programs and resources, showing the respondents that their feedback is taken seriously.
   - Encouraging open discussions in which staff can talk freely about problems and/or encounters with behavior that may constitute bullying.

- Establishing programs for staff and students, such as Employee Assistance Programs, that provide a place to confidentially address personal experiences of bullying.
- Establishing procedures and conducting interventions within the context of the organizational commitment to the health and well-being of all staff.

Fiscal Note: Minimal – Less than $500

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REPORT OF THE BOARD OF TRUSTEES

B of T Report 10, November 2020

Subject: Compassionate Release for Incarcerated Patients (Resolution 430-A-19)

Presented by: Russ Kridel, MD, Chair

Referred to: Reference Committee D

Resolution 430-A-19, introduced by the Medical Student Section and referred by the House of Delegates asked that:

> Our American Medical Association support policies that facilitate compassionate release on the basis of serious medical conditions and advanced age; collaborate with appropriate stakeholders to draft model legislation that establishes clear, evidence-based eligibility criteria for timely compassionate release; and promote transparent reporting of compassionate release statistics, including numbers and demographics of applicants, approvals, denials, and revocations, and justifications for decisions.

BACKGROUND

Compassionate release, also known as medical release, is a program or policies that allow eligible, seriously ill prisoners early release or parole before sentence completion.[1] Compassionate release was authorized on the federal level under the Sentencing Reform Act of 1984 and subsequently adopted by 49 states and the District of Columbia.[2] Medical eligibility guidelines vary by jurisdiction, but most states require a terminal or severely debilitating medical condition, a condition that cannot be appropriately cared for within the prison, and a prisoner who poses no threat to society.[1]

Compassionate release is a matter of ethics as the continued incarceration of patients with serious or debilitating illness can constitute a violation of human dignity if appropriate palliative care is unavailable.[3] In addition to ethical reasons, compassionate release has been called for to address the aging prison population, overcrowded facilities, increasing deaths in custody, and soaring medical costs of the criminal justice system.[1,4]

In 2016, a total of 6.6 million persons were involved in the US criminal justice system, including 1.5 million in state and federal prisons.[5] From 1993 to 2013, the population in state prisoners age 55-and-older more than tripled, increasing from 3 percent to 10 percent.[6] Between 2009 and 2013, the population of US federal prisoners aged 49 or younger decreased by 1 percent, whereas the number of prisoners aged 50 or older increased by 25 percent.[7]

Racial and ethnic minority groups are disproportionately represented in the justice-involved population. In 2017, blacks represented 12 percent of the US adult population but 33 percent of the sentenced prison population. Whites accounted for 64 percent of adults but 30 percent of prisoners. And while Hispanics represented 16 percent of the adult population, they accounted for 23 percent of inmates. From a health perspective, it is not uncommon for justice-involved individuals to

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experience multiple chronic conditions, mental health disorders, and physical disabilities at relatively young ages.[9] They are also more likely to have experienced stress and trauma, have a substance use disorder, experienced homelessness, and have limited access to health care.[9]

EXISTING AMA POLICY

It is the AMA's position that correctional and detention facilities should provide medical, psychiatric, and substance misuse care that meets prevailing community standards, including appropriate referrals for ongoing care upon release from the correctional facility in order to prevent recidivism (Policy D-430.997, "Support for Health Care Services to Incarcerated Persons"). The AMA supports of the National Commission on Correctional Health Care (NCCHC) standards that improve the quality of health care services, including mental health services, delivered to the nation's correctional facilities, and encourages all correctional systems to support NCCHC accreditation (D-430.997, "Support for Health Care Services to Incarcerated Persons").

The AMA encourages state Medicaid agencies to work with their local departments of corrections, prisons, and jails to assist incarcerated individuals who may not have been enrolled in Medicaid at the time of their incarceration to apply and receive an eligibility determination for Medicaid. The AMA encourages states to suspend rather than terminate Medicaid eligibility upon intake into the criminal justice system and throughout the incarceration process, and to reinstate coverage when the individual transitions back into the community. The AMA urges Congress, the Centers for Medicare & Medicaid Services, and state Medicaid agencies to provide Medicaid coverage for health care, care coordination activities and linkages to care delivered to patients up to 30 days before the anticipated release to help establish coverage effective upon release, assist with transition to care in the community, and help reduce recidivism (Policy H-430.986, "Health Care While Incarcerated").

Furthermore, the AMA has urged the Society of Correctional Physicians and the NCCHC to work to develop policies and guidelines on how to transition to long-term care facilities for individuals recently released from incarceration, with consideration to length of incarceration, violent tendencies, and medical and psychiatric history (Policy H-280.948, "Long-Term Care Residents With Criminal Backgrounds "). The AMA does not have policy specific to compassionate release.

DISCUSSION

Compassionate release policies were authorized in recognition of the fact that appropriate care for patients with severe or debilitating illnesses is difficult, and sometimes impossible, to achieve in the correctional setting.[3,10,11] In 2013, the U.S. Department of Justice, Office of the Inspector General found that the Federal Bureau of Prisons (BOP's) compassionate release program was "poorly managed and implemented inconsistently," resulting in eligible inmates likely not being considered for release and terminally ill inmates dying before their requests were decided.[12] During a one year span in the BOP, only 85 (3.24 percent) out of 2,621 requests for compassionate release were granted.[12] State prison systems are likely to have similar rates of release, though only 13 states are required to track and report compassionate release statistics and few of them are required to make the information publicly available.[2]

Barriers to Implementing Compassionate Release Policies

The limited use of compassionate release is due to barriers at the patient, professional, policy, and administrative levels. At the patient level, individuals who are incarcerated may not be aware that they are eligible for compassionate release or incorrectly believe that they are ineligible. In a

survey of medically complex patients across three geographically disparate prisons and jails, 43 percent of respondents lacked the knowledge necessary to apply for compassionate release, and 75 percent indicated they would apply if eligible.[11,13]

At the policy level, both the medical eligibility criteria, based on medical evidence, and the administrative approval process, based on legal and correctional evidence, can limit the compassionate release process.[1] The federal criteria for a reduction in sentence for medical circumstances require either a terminal medical condition (a life expectancy of 18 months or less) or a debilitated medical condition (See Table 1). While some states have adopted the federal medical eligibility criteria, others have adopted their own criteria, resulting in variability in requirements across jurisdictions.

In determining medical eligibility, clinicians may have concerns about the legal consequences of releasing someone who lives beyond the expected timeframe since there are terminal illnesses with unpredictable trajectories.[4] Furthermore, the correctional evidence review process is often complex and time-consuming, requiring multiple layers of review.[2] A final decision may require approvals by the warden, a parole or review board, and even the state's governor.[10] These barriers can be compounded by administrative barriers such as objections by a victim advocate or prosecutor, concerns about public safety, and availability of post release community care plans to ensure placement in community hospice or return to the family home for care as well as arranging insurance coverage (i.e., applying for Medicaid coverage).[3, 10]

CONCLUSION

The use of compassionate release laws has been advocated for as a mechanism to address the growing number of older prisoners, overcrowding, increasing numbers of in-prison deaths, and the soaring medical costs of the criminal justice system, but also as a matter of medical ethics as the continued incarceration of patients with serious or debilitating illness can constitute a violation of human dignity if appropriate palliative care is unavailable. While most jurisdictions have adopted laws authorizing compassionate release, this authority is being underutilized due to barriers at the patient, professional, policy and administrative levels. In order to increase the use of compassionate release policies, there needs to be better communication and education on these policies, not only to individuals who are incarcerated, but also to their families, correctional health care professionals, and parole board members.[11]

The medical profession plays a significant role in the compassionate release process in that physicians are required to determine medical eligibility for potential candidates. The eligibility criteria should be clear to clinicians and they should be comfortable determining if someone meets the criteria without fear of liability. The Board of Trustees recommends that the AMA collaborate with appropriate stakeholders to develop clear, evidence-based eligibility criteria for timely compassionate release. This guidance can be shared with legislators and other relevant stakeholders once it is developed.

Finally, to ensure that compassionate release laws are being appropriately managed and implemented consistently, the AMA should support the transparent reporting of compassionate release statistics, including numbers and demographics of applicants, approvals, denials, and revocations, and justifications for decisions.

RECOMMENDATION

The Board of Trustees recommends that the following policy be adopted in lieu of Resolution 430-A-19 and the remainder of this report be filed.

> Our American Medical Association supports policies that facilitate compassionate release on the basis of serious medical conditions and advanced age; will collaborate with appropriate stakeholders to develop clear, evidence-based eligibility criteria for timely compassionate release; and promote transparent reporting of compassionate release statistics, including numbers and demographics of applicants, approvals, denials, and revocations, and justifications for decisions.

Fiscal Note: Modest - between $1,000 - $5,000

Table 1 - Federal Criteria for a Reduction in Sentence

Medical Circumstances	
Terminal Medical Condition	Inmates diagnosed with a terminal, incurable disease and whose life expectancy is 18 months or less, and/or has a disease or condition with an end-of-life trajectory under 18 USC § 3582(d)(1)
Debilitated Medical Condition	Inmates who have an incurable, progressive illness or who have suffered a debilitating injury from which they will never recover. If the inmate is: completely disabled, meaning the inmate cannot carry on any self-care and is totally confined to a bed or chair or capable of only limited self-acre and is confined to a bed or chair more than 50 percent of waking hours. Review should also include any cognitive deficits of the inmate. A cognitive deficit is not required in case of severe physical impairment, but may be a factor when considering the inmate's ability or inability to reoffend.

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AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 401
(November 2020)

Introduced by: Women Physicians Section

Subject: Fatigue Mitigation Respite for Faculty and Residents

Referred to: Reference Committee D

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1 Whereas, AMA Policy H-15.958, "Fatigue, Sleep Disorders, and Motor Vehicle Crashes," notes
2 the risks associated with sleep deprivation and actions physicians can take to help protect
3 patients; and
4
5 Whereas, About 20-30 percent of shift workers experience prominent insomnia symptoms and
6 excessive daytime sleepiness consistent with circadian rhythm sleep disorder, also known as
7 shift work disorder;[5] and
8
9 Whereas, Drowsy driving causes almost 1,000 estimated fatal motor vehicle crashes in the
10 United States (2.5 percent of all fatal crashes), 37,000 injury crashes, and 45,000 property
11 damage-only crashes;[2] and
12
13 Whereas, Physicians have a higher likelihood of dying from accidents than from other causes
14 relative to the general populations;[4] and
15
16 Whereas, Physicians' risk of crashing while driving after working extended shifts (≥24 hours)
17 was 2.3 times greater and the risk for a "near miss" crash was 5.9 times greater, compared to a
18 non-extended shift. The estimated risk of a crash rose by 9.1 percent for every additional
19 extended work shift hour;[3] and
20
21 Whereas, Forty-one percent (41%) of physicians report falling asleep at the wheel after a night
22 shift;[6] and
23
24 Whereas, A simulation study demonstrated that being awake for 18 hours, which is common for
25 physicians working a swing shift (i.e., from 6 p.m. to 2 a.m.), produced an impairment equal to a
26 blood alcohol concentration (BAC) of 0.05 and rose to equal 0.10 after 24 hours without
27 sleep;[7] and
28
29 Whereas, Driving simulator studies show driving home from the night shift is associated with two
30 to eight times the incidents of off track veering, decreased time to first accident, increased eye
31 closure duration, and increased subjective sleepiness. Night-shift work increases driver
32 drowsiness, degrading driving performance and increasing the risk of near-crash drive
33 events;[8] and
34
35 Whereas, Actual driving studies post-night shift versus post-sleep night showed eleven near-
36 crashes occurred in 6 of 16 post night-shift drives (37.5 percent), and 7 of 16 post night-shift
37 drives (43.8 percent) were terminated early for safety reasons, compared with zero near-
38 crashes or early drive terminations during 16 post-sleep drives;[9] and

1 Whereas, Institutional support for self-care and fatigue mitigation can help protect physician
2 well-being and model appropriate behaviors for physicians in training; therefore be it
3
4 RESOLVED, That our American Medical Association advocate for legislation and policies that
5 support fatigue mitigation programs, which include, but are not limited to, a quiet place to rest or
6 funding for alternative transport and return to work for vehicle recovery at a later time for all
7 medical staff who feel unsafe driving due to fatigue after working overnight or extended shifts.
8 (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000

Received: 09/30/20

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RELEVANT AMA POLICY

Resident/Fellow Clinical and Educational Work Hours H-310.907
Our AMA adopts the following Principles of Resident/Fellow Clinical and Educational Work Hours, Patient Safety, and Quality of Physician Training:
1. Our AMA supports the 2017 Accreditation Council for Graduate Medical Education (ACGME) standards for clinical and educational work hours (previously referred to as “duty hours”).
2. Our AMA will continue to monitor the enforcement and impact of clinical and educational work hour standards, in the context of the larger issues of patient safety and the optimal learning environment for residents.
3. Our AMA encourages publication and supports dissemination of studies in peer-reviewed publications and educational sessions about all aspects of clinical and educational work hours, to include such topics as extended work shifts, handoffs, in-house call and at-home call, level of supervision by attending physicians, workload and growing service demands, moonlighting, protected sleep periods, sleep deprivation and fatigue, patient safety, medical error, continuity of care, resident well-being and burnout, development of professionalism, resident learning outcomes, and preparation for independent practice.
4. Our AMA endorses the study of innovative models of clinical and educational work hour requirements and, pending the outcomes of ongoing and future research, should consider the evolution of specialty- and rotation-specific requirements that are evidence-based and will optimize patient safety and competency-based learning opportunities.
5. Our AMA encourages the ACGME to:
a) Decrease the barriers to reporting of both clinical and educational work hour violations and resident intimidation.
b) Ensure that readily accessible, timely and accurate information about clinical and educational work hours is not constrained by the cycle of ACGME survey visits.
c) Use, where possible, recommendations from respective specialty societies and evidence-based approaches to any future revision or introduction of clinical and educational work hour rules.
d) Broadly disseminate aggregate data from the annual ACGME survey on the educational environment of resident physicians, encompassing all aspects of clinical and educational work hours.

6. Our AMA recognizes the ACGME for its work in ensuring an appropriate balance between resident education and patient safety, and encourages the ACGME to continue to:
a) Offer incentives to programs/institutions to ensure compliance with clinical and educational work hour standards.
b) Ensure that site visits include meetings with peer-selected or randomly selected residents and that residents who are not interviewed during site visits have the opportunity to provide information directly to the site visitor.
c) Collect data on at-home call from both program directors and resident/fellow physicians; release these aggregate data annually; and develop standards to ensure that appropriate education and supervision are maintained, whether the setting is in-house or at-home.
d) Ensure that resident/fellow physicians receive education on sleep deprivation and fatigue.
7. Our AMA supports the following statements related to clinical and educational work hours:
a) Total clinical and educational work hours must not exceed 80 hours per week, averaged over a four-week period (Note: “Total clinical and educational work hours” includes providing direct patient care or supervised patient care that contributes to meeting educational goals; participating in formal educational activities; providing administrative and patient care services of limited or no educational value; and time needed to transfer the care of patients).
b) Scheduled on-call assignments should not exceed 24 hours. Residents may remain on-duty for an additional 4 hours to complete the transfer of care, patient follow-up, and education; however, residents may not be assigned new patients, cross-coverage of other providers’ patients, or continuity clinic during that time.
c) Time spent in the hospital by residents on at-home call must count towards the 80-hour maximum weekly hour limit, and on-call frequency must not exceed every third night averaged over four weeks. The frequency of at-home call is not subject to the every-third-night limitation, but must satisfy the requirement for one-day-in-seven free of duty, when averaged over four weeks.
d) At-home call must not be so frequent or taxing as to preclude rest or reasonable personal time for each resident.
e) Residents are permitted to return to the hospital while on at-home call to care for new or established patients. Each episode of this type of care, while it must be included in the 80-hour weekly maximum, will not initiate a new “off-duty period.”
f) Given the different education and patient care needs of the various specialties and changes in resident responsibility as training progresses, clinical and educational work hour requirements should allow for flexibility for different disciplines and different training levels to ensure appropriate resident education and patient safety; for example, allowing exceptions for certain disciplines, as appropriate, or allowing a limited increase to the total number of clinical and educational work hours when need is demonstrated.
g) Resident physicians should be ensured a sufficient duty-free interval prior to returning to duty.
h) Clinical and educational work hour limits must not adversely impact resident physician participation in organized educational activities. Formal educational activities must be scheduled and available within total clinical and educational work hour limits for all resident physicians.
i) Scheduled time providing patient care services of limited or no educational value should be minimized.
j) Accurate, honest, and complete reporting of clinical and educational work hours is an essential element of medical professionalism and ethics.
k) The medical profession maintains the right and responsibility for self-regulation (one of the key tenets of professionalism) through the ACGME and its purview over graduate medical education, and categorically rejects involvement by the Centers for Medicare & Medicaid Services, The Joint Commission, Occupational Safety and Health Administration, and any other federal or state government bodies in the monitoring and enforcement of clinical and educational work hour regulations, and opposes any regulatory or legislative proposals to limit the work hours of practicing physicians.
l) Increased financial assistance for residents/fellows, such as subsidized child care, loan deferment, debt forgiveness, and tax credits, may help mitigate the need for moonlighting. At the same time, resident/fellow physicians in good standing with their programs should be afforded the opportunity for internal and external moonlighting that complies with ACGME policy.
m) Program directors should establish guidelines for scheduled work outside of the residency program, such as moonlighting, and must approve and monitor that work such that it does not interfere with the ability of the resident to achieve the goals and objectives of the educational program.
n) The costs of clinical and educational work hour limits should be borne by all health care payers. Individual resident compensation and benefits must not be compromised or decreased as a result of changes in the graduate medical education system.

o) The general public should be made aware of the many contributions of resident/fellow physicians to high-quality patient care and the importance of trainees' realizing their limits (under proper supervision) so that they will be able to competently and independently practice under real-world medical situations.
8. Our AMA is in full support of the collaborative partnership between allopathic and osteopathic professional and accrediting bodies in developing a unified system of residency/fellowship accreditation for all residents and fellows, with the overall goal of ensuring patient safety.
9. Our AMA will actively participate in ongoing efforts to monitor the impact of clinical and educational work hour limitations to ensure that patient safety and physician well-being are not jeopardized by excessive demands on post-residency physicians, including program directors and attending physicians.
Citation: CME Rep. 5, A-14; Modified: CME Rep. 06, I-18

Fatigue, Sleep Disorders, and Motor Vehicle Crashes H-15.958
Our AMA: (1) recognizes sleepiness behind the wheel as a major public health issue and continues to encourage a national public education campaign by appropriate federal agencies and relevant advocacy groups.
(2) recommends that the National Institutes of Health and other appropriate organizations support research projects to provide more accurate data on the prevalence of sleep-related disorders in the general population and in motor vehicle drivers, and provide information on the consequences and natural history of such conditions.
(3) recommends that the U.S. Department of Transportation (DOT) and other responsible agencies continue studies on the occurrence of highway crashes and other adverse occurrences in transportation that involve reduced operator alertness and sleep.
(4) encourages continued collaboration between the DOT and the transportation industry to support research projects for the devising and effectiveness- testing of appropriate countermeasures against driver fatigue, including technologies for motor vehicles and the highway environment.
(5) urges responsible federal agencies to improve enforcement of existing regulations for truck driver work periods and consecutive working hours and increase awareness of the hazards of driving while fatigued. If changes to these regulations are proposed on a medical basis, they should be justified by the findings of rigorous studies and the judgments of persons who are knowledgeable in ergonomics, occupational medicine, and industrial psychology.
(6) recommends that physicians: (a) become knowledgeable about the diagnosis and management of sleep-related disorders; (b) investigate patient symptoms of drowsiness, wakefulness, and fatigue by inquiring about sleep and work habits and other predisposing factors when compiling patient histories; (c) inform patients about the personal and societal hazards of driving or working while fatigued and advise patients about measures they can take to prevent fatigue-related and other unintended injuries; (d) advise patients about possible medication-related effects that may impair their ability to safely operate a moto vehicle or other machinery; (e) inquire whether sleepiness and fatigue could be contributing factors in motor vehicle-related and other unintended injuries; and (f) become familiar with the laws and regulations concerning drivers and highway safety in the state(s) where they practice.
(7) encourages all state medical associations to promote the incorporation of an educational component on the dangers of driving while sleepy in all drivers education classes (for all age groups) in each state.
(8) recommends that states adopt regulations for the licensing of commercial and private drivers with sleep-related and other medical disorders according to the extent to which persons afflicted with such disorders experience crashes and injuries.
(9) reiterates its support for physicians' use of E-codes in completing emergency department and hospital records, and urges collaboration among appropriate government agencies and medical and public health organizations to improve state and national injury surveillance systems and more accurately determine the relationship of fatigue and sleep disorders to motor vehicle crashes and other unintended injuries.
Citation: CSA Rep. 1, A-96; Appended: Res. 418, I-99; Reaffirmed: CSAPH Rep. 1, A-09; Modified: CSAPH Rep. 01, A-19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 402
(November 2020)

Introduced by: New York

Subject: Air Quality and the Protection of Citizen Health

Referred to: Reference Committee D

Whereas, The upper Hudson River, located in three counties of New York State has been the site of multiple pollution issues (Ciba-Geigy – Chromium and Cyanide in the Feeder Canal, GE – PCB in the Hudson River)[2,3;]; and

Whereas, The Wheelabrator Waste to Energy Plant and the Leigh Cement Facility are emitting over 300 pounds of heavy metals into the air each year for the last 25 years[4]; and

Whereas, Emission compliance is tested only every 30 months[5] and there is a history of violations to EPA guidelines[6]; and

Whereas, These metallic elements do not disappear from the environment, are considered systemic toxicants that are known to induce multiple organ damage, even at lower levels of exposure, and they are also classified as human carcinogens (known or probable) according to the U.S. Environmental Protection Agency, and the International Agency for Research on Cancer[7]; and

Whereas, Study of the potential ecological risks has revealed that the degree of ecological harm caused by heavy metal dust is very strong in both urban and suburban areas[8]; therefore be it

RESOLVED, That our American Medical Association review the Environmental Protection Agency's guidelines for monitoring the air quality which is emitted from smokestacks, taking into consideration the risks to citizens living downwind of smokestacks (Directive to Take Action); and be it further

RESOLVED, That our AMA develop a report based on a review of the EPA's guidelines for monitoring air quality emitted from smokestacks ensuring that recommendations to protect the public's health are included in the report. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000

Received: 10/09/20

References:
1 Governor's Cancer Research Initiative – Warren County Cancer Incidence Report
2 https://www.epa.gov/hwcorrectiveactionsites/hazardous-waste-cleanup-ciba-geigy-hercules-plant-queensbury-glen-falls-new
3 https://www.epa.gov/enforcement/case-summary-ge-agrees-further-investigate-upper-hudson-river-floodplain-comprehensive
4 https://www.epa.gov/air-emissions-inventories/2014-national-emissions-inventory-nei-data
5 https://poststar.com/news/local/lehigh-cement-gets-state-ok-to-burn-paper-and-plastic/article_a6b97aeb-3a4e-58c4-a789-6188b82e13ae.html
6 https://www.adirondackalmanack.com/2019/12/epa-settles-with-glens-falls-lehigh-cement-co.html
7 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4144270/ Heavy Metals Toxicity and the Environment Paul B Tchounwouet al
8 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5664660/ Int J Environ Res Public Health. 2017 Oct; 14(10): 1159.
9 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4681084/pdf/40557_2015_Article_85.pdf

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 403
(November 2020)

Introduced by: New York

Subject: Support for Impairment Research

Referred to: Reference Committee D

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1 Whereas, There has been a proliferation of new and designer recreational drugs, most of which
2 are difficult to detect; and
3
4 Whereas, One of the leading causes of motor vehicle operator (driver) impairment is fatigue
5 without substance use or abuse; and
6
7 Whereas, There are no biochemical or physiological assays for fatigue, akin to breathalyzer
8 readings for ethanol, leading to undercounting and under appreciation of its relevance; and
9
10 Whereas, Evidence is lacking for reliable and reproducible methods of impairment assessment
11 unrelated to the few easily detectable intoxicants; and
12
13 Whereas, The United States Department of Defense (DOD), the Defense Advanced Research
14 Projects Agency (DARPA), and the Institute of Medicine (IOM) have conducted extensive
15 research on neurocognitive testing to assess alertness and impairment; therefore be it
16
17 RESOLVED, That our American Medical Association study the impairment of drivers and other
18 operators of mechanized vehicles by substances, fatigue, medical or mental health conditions
19 (Directive to Take Action); and be it further
20
21 RESOLVED, That this report include whether there are office or hospital-based methods to
22 efficiently and effectively assess impairment of drivers with recommendations for further
23 research that may be needed. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000

Received: 10/09/20

References:
1. Human Performance Under Sustained Operations
2. Identifying Cognitive State from Eye Metrics
3. NASA's Evidence Reports on Human Health Risks
4. Neurocognitive Monitors – Toward the Prevention of Cognitive Performance Decrements
5. Operational Neuroscience – Neurophysiological Measures in Applied Environments
6. Task Performance and Eye Activity – Predicting Behavior Relating to Cognitive Workload
7. World Anti-Doping Agency – Athlete Biological Passport Guidelines

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 404
(November 2020)

Introduced by: American Association of Public Health Physicians

Subject: Early Vaccination for Correctional Workers and Incarcerated Persons

Referred to: Reference Committee D

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1 Whereas, There are over 2 million persons incarcerated in the United States[1]; and
2
3 Whereas, There are approximately 750,000 persons working in correctional facilities, including
4 many physicians and other health care professionals; and
5
6 Whereas, The incidence of SARS-CoV-2 in inmates is 3-5 times that of the general
7 population[2,3]; and
8
9 Whereas, The COVID-19 death rate in inmates is 1.3 times that of the general population, even
10 before adjusting for age[3]; and
11
12 Whereas, Correctional workers and inmates are located in a congregate setting, which is
13 usually overcrowded by non-correctional standards, and where it is impossible to implement
14 fully the CDC recommended COVID-19 precautions[4]; and
15
16 Whereas, More than 95% of inmates are released at some time[4]; and
17
18 Whereas, Correctional workers go home daily; and
19
20 Whereas, Correctional workers and released persons can transmit to the community any
21 airborne infection that circulates in a correctional facility, including SARS-COV infection[5];
22 therefore be it
23
24 RESOLVED, That our American Medical Association advocate that conditions of incarceration
25 in correctional facilities be improved to allow for the generally accepted CDC COVID-19 safety
26 precautions to take place (Directive to Take Action); and be it further
27
28 RESOLVED, That our AMA support that inmates and correctional workers should be considered
29 in a high-risk classification, along those other persons vulnerable for contacting and spreading
30 COVID-19 infection (Directive to Take Action); and be it further
31
32 RESOLVED, That our AMA support the National Academies of Sciences, Engineering, and
33 Medicine (NASEM) recommendation that correctional workers and incarcerated persons be
34 considered in high risk groups and provided with a safe, effective, FDA-approved COVID-19
35 vaccine in Phase 1b (for those with comorbid and underlying conditions, including age and
36 frailty) or Phase 2 (for all other correctional workers and incarcerated persons) of any
37 vaccination campaign. (Directive to Take Action)

Fiscal Note: Minimal - less than $1,000

Received: 10/14/20

References:
[1] Bureau of Justice Statistics, Correctional Populations in the United States, 2017-2018. https://www.bjs.gov/index.cfm?ty=pbdetail&iid=7026, accessed October 14, 2020.
[2] Jimenez MC et al. Epidemiology of COVID-19 Among Incarcerated Individuals and Staff in Massachusetts Jails and Prisons. *JAMA Netw Open.* 2020;3(8):e2018851. https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2769617, accessed October 14, 2020.
doi:10.1001/jamanetworkopen.2020.18851
[3] Saloner B et al. COVID-19 Cases and Deaths in Federal and State Prisons. *JAMA* 2020 Aug 11; 324(6):602-603. https://jamanetwork.com/journals/jama/fullarticle/2768249, accessed October 14, 2020.
[4] Rubin R. The Challenge of Preventing COVID-19 Spread in Correctional Facilities. *JAMA.* 2020 May 12;323(18):1760-1761. https://jamanetwork.com/journals/jama/fullarticle/2764379, accessed October 14, 2020.
[4] Bureau of Justice Statistics (Hughes T and Wilson DJ), Re-Entry Trends in the United States. https://www.bjs.gov/content/reentry/reentry.cfm, accessed October 14, 2020.
[5] Montoya-Barthelemy AG et al. COVID-19 and the Correctional Environment: The American Prison as a Focal Point for Public Health. *Am J Prev Med* 2020 Jun; 58(6):888-891. https://www.ajpmonline.org/article/S0749-3797(20)30144-6/fulltext, accessed October 14, 2020.

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 405
(November 2020)

Introduced by: District of Columbia

Subject: Attacking Disparities in COVID-19 Underlying Health Conditions

Referred to: Reference Committee D

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1 Whereas, COVID-19 mortality is much higher in individuals with obesity, diabetes, and
2 hypertension, compared with those who do not have these conditions; and
3
4 Whereas, Racial disparities in the prevalence of these conditions contribute to disparities in
5 COVID-19 mortality; and
6
7 Whereas, These health conditions can be rapidly improved by medical and nutritional
8 interventions; and
9
10 Whereas, The Dietary Approaches to Stop Hypertension (DASH) study showed that a simple
11 dietary intervention reduced blood pressure within two weeks; and
12
13 Whereas, In some cases, these conditions can be prevented by healthful diets, particularly
14 plant-based diets; and
15
16 Whereas, While media attention has focused on reducing coronavirus transmission through
17 personal hygiene, masks, and social distancing, there has been insufficient attention to the
18 urgent need to address the underlying medical conditions, particularly obesity, diabetes, and
19 hypertension, that make COVID-19 especially deadly; therefore be it
20
21 RESOLVED, That Our American Medical Association urge federal, state, and municipal leaders
22 to prominently include in their COVID-19 public health advisories information on the role of
23 underlying medical conditions in COVID-19 and in the role of nutrition, particularly plant-based
24 diets, as well as physical activity, in addressing these conditions. (Directive to Take Action)

Fiscal Note: Minimal - less than $1,000

Received: 10/14/20

RELEVANT AMA POLICY

Racial and Ethnic Disparities in Health Care H-350.974
1. Our AMA recognizes racial and ethnic health disparities as a major public health problem in the United States and as a barrier to effective medical diagnosis and treatment. The AMA maintains a position of zero tolerance toward racially or culturally based disparities in care; encourages individuals to report physicians to local medical societies where racial or ethnic discrimination is suspected; and will continue to support physician cultural awareness initiatives and related consumer education activities. The elimination of racial and ethnic disparities in health care an issue of highest priority for the American Medical Association.
2. The AMA emphasizes three approaches that it believes should be given high priority:

A. Greater access - the need for ensuring that black Americans without adequate health care insurance are given the means for access to necessary health care. In particular, it is urgent that Congress address the need for Medicaid reform.
B. Greater awareness - racial disparities may be occurring despite the lack of any intent or purposeful efforts to treat patients differently on the basis of race. The AMA encourages physicians to examine their own practices to ensure that inappropriate considerations do not affect their clinical judgment. In addition, the profession should help increase the awareness of its members of racial disparities in medical treatment decisions by engaging in open and broad discussions about the issue. Such discussions should take place in medical school curriculum, in medical journals, at professional conferences, and as part of professional peer review activities.
C. Practice parameters - the racial disparities in access to treatment indicate that inappropriate considerations may enter the decisionmaking process. The efforts of the specialty societies, with the coordination and assistance of our AMA, to develop practice parameters, should include criteria that would preclude or diminish racial disparities
3. Our AMA encourages the development of evidence-based performance measures that adequately identify socioeconomic and racial/ethnic disparities in quality. Furthermore, our AMA supports the use of evidence-based guidelines to promote the consistency and equity of care for all persons.
4.Our AMA: (a) actively supports the development and implementation of training regarding implicit bias, diversity and inclusion in all medical schools and residency programs; (b) will identify and publicize effective strategies for educating residents in all specialties about disparities in their fields related to race, ethnicity, and all populations at increased risk, with particular regard to access to care and health outcomes, as well as effective strategies for educating residents about managing the implicit biases of patients and their caregivers; and (c) supports research to identify the most effective strategies for educating physicians on how to eliminate disparities in health outcomes in all at-risk populations.
Citation: CLRPD Rep. 3, I-98; Appended and Reaffirmed: CSA Rep.1, I-02; Reaffirmed: BOT Rep. 4, A-03; Reaffirmed in lieu of Res. 106, A-12; Appended: Res. 952, I-17; Reaffirmed: CMS Rep. 10, A-19

Combating Obesity and Health Disparities H-150.944
Our AMA supports efforts to: (1) reduce health disparities by basing food assistance programs on the health needs of their constituents; (2) provide vegetables, fruits, legumes, grains, vegetarian foods, and healthful dairy and nondairy beverages in school lunches and food assistance programs; and (3) ensure that federal subsidies encourage the consumption of foods and beverages low in fat, added sugars, and cholesterol.
Citation: Res. 413, A-07; Reaffirmation A-12; Reaffirmation A-13; Modified: CSAPH Rep. 03, A-17

Obesity as a Major Health Concern H-440.902
The AMA: (1) recognizes obesity in children and adults as a major public health problem; (2) will study the medical, psychological and socioeconomic issues associated with obesity, including reimbursement for evaluation and management of patients with obesity; (3) will work with other professional medical organizations, and other public and private organizations to develop evidence-based recommendations regarding education, prevention, and treatment of obesity; (4) recognizes that racial and ethnic disparities exist in the prevalence of obesity and diet-related diseases such as coronary heart disease, cancer, stroke, and diabetes and recommends that physicians use culturally responsive care to improve the treatment and management of obesity and diet-related diseases in minority populations; and (5) supports the use of cultural and socioeconomic considerations in all nutritional and dietary research and guidelines in order to treat patients affected by obesity.

Citation: Res. 423, A-98; Reaffirmed and Appended: BOT Rep. 6, A-04; Reaffirmation A-10; Reaffirmed in lieu of Res. 434, A-12; Reaffirmation A-13; Modified: Res. 402, A-17

Culturally Responsive Dietary and Nutritional Guidelines D-440.978
1. Our AMA and its Minority Affairs Section will: (a) encourage the United States Department of Agriculture (USDA) to include culturally effective guidelines that include listing an array of ethnic staples and use of multicultural symbols to depict serving size in their Dietary Guidelines for Americans and Food Guide; (b) seek ways to assist physicians with applying the USDA Dietary Guidelines for Americans and MyPlate food guide in their practices as appropriate; (c) recognize that lactose intolerance is a common and normal condition among many Americans, especially African Americans, Asian Americans, and Native Americans, with a lower prevalence in whites, often manifesting in childhood; and (d) monitor existing research and identify opportunities where organized medicine can impact issues related to obesity, nutritional and dietary guidelines, racial and ethnic health disparities as well as assist physicians with delivering culturally effective care.
2.Our AMA will: (a) propose legislation that modifies the National School Lunch Act, 42 U.S.C. 1758, so as to eliminate requirements that children produce documentation of a disability or a special medical or dietary need in order to receive an alternative to cows milk; and (b) recommend that the U.S. Department of Agriculture and U.S. Department of Health and Human Services clearly indicate in the Dietary Guidelines for Americans and other federal nutrition guidelines that meat and dairy products are optional, based on an individuals dietary needs.
Citation: BOT Rep. 6, A-04; Modified: CSAPH Rep. 1, A-14; Modified: Res. 203, A-18

RELEVANT LITERATURE
Barrera FJ, Shekhar S, Wurth R, et al. Prevalence of diabetes and hypertension and their associated risks for poor outcomes in Covid-19 patients. J Endocr Soc. 2020 Jul 21;4(9):bvaa102. doi: 10.1210/jendso/bvaa102. eCollection 2020 Sep 1.

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 406
(November 2020)

Introduced by: Alma B. Littles, MD, Delegate

Subject: Face Masking in Hospitals During Flu Season

Referred to: Reference Committee D

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1 Whereas, Studies of COVID-19 disease epidemiology during the SARS-CoV-2 pandemic clearly
2 demonstrate that facial masks covering the mouth and nose decrease transmission of this
3 disease; and
4
5 Whereas, Influenza viruses and the SARS-CoV-2 virus are of approximately the same size,
6 yielding a logical conclusion that facial masks worn to blunt SARS-CoV-2 transmission should
7 also decrease influenza transmission to a similar degree; and
8
9 Whereas, The populations of Australia (representative for Oceania), Chile (representative for
10 South America) and South Africa (representative for Africa) have experienced extremely low
11 rates of influenza during their recently concluded "flu" seasons of 2020[1], a time overlapping the
12 SARS-CoV-2 pandemic and thus a time during which facial mask-wearing was being practiced
13 by most of these nations' populations; and
14
15 Whereas, Similar trends of extremely low summer seasonal influenza rates have been observed
16 in the United States during 2020[1]; and
17
18 Whereas, The precipitous decline of influenza activity worldwide has been attributed to
19 widespread facial mask-wearing that has emerged to counter the SARS-CoV-2 pandemic[1]; and
20
21 Whereas, Influenza, like COVID-19, is a disease that most persons survive but also a disease
22 that has caused thousands of premature deaths, ranging from about 12,000 to about 61,000
23 annually during the "influenza seasons" (approximately October 1 through March 31) of the past
24 10 years[2,3]; and
25
26 Whereas, During flu season, the death toll due to pneumonia, which in most cases is caused by
27 a bacterial agent, is roughly three to five times larger than that due to influenza viruses[4]; and
28
29 Whereas, The death tolls of influenza and pneumonia fall disproportionately upon persons with
30 multiple chronic illnesses or who are elderly (aged 65 or greater[5]), a demographic group that
31 constitutes the majority of hospitalized patients; and
32
33 Whereas, It can therefore be anticipated that mandatory wearing of facial masks that cover the
34 nose and mouth by patients, all hospital-based health care workers, and all hospital visitors
35 during flu season should help greatly decrease transmission not only of influenza but also of
36 pneumonia within hospitals, as has been observed in general regarding transmission of SARS-
37 CoV-2; and

Whereas, Visitors to hospitalized patients, as well as physicians and hospital employees providing care to hospitalized patients during flu season may or may not have been immunized themselves against influenza and/or pneumonia; and

Whereas, Even immunized visitors, physicians or hospital employees may not have developed immunity to influenza, despite being immunized, because every year's influenza immunization effectiveness has fallen far short of 100% (being ~45% in 2019-20[6]; ~47% in 2018-19[7]; and ~36% in 2017-18[8]); and

Whereas, Unmasked physicians, nurses, other health care workers, other hospital employees and hospital visitors, as well as patients when in areas outside of their assigned bed or room, represent potential vectors for the transmission of influenza and pneumonia to other persons present within hospitals; and

Whereas, Hospital organizations should work to minimize any hospital-acquired disease transmission to their hospitalized patients, physicians, employees, and visitors; and

Whereas, Hospital organizations may fear a negative public relations consequence if they choose to require facial masks of all physicians, hospital employees, patients, and hospital visitors during flu season, partly because the wearing of facial masks has become a politicized matter,[9] despite voluminous scientific data on the topic that affirm the wisdom of such a requirement; and

Whereas, It is logical to therefore assert that a requirement for all hospital employees, physicians, and visitors to wear a facial mask may require imposition by a third-party accrediting organization in order to become enacted; and

Whereas, The Joint Commission is a third-party organization, which accredits the majority of US hospitals[10] and which has the power to strongly influence hospital and hospital system policies and procedures via its quasi-regulatory powers; and

Whereas, Other third-party organizations with similar powers also exist to accredit much smaller numbers of hospitals in the United States; therefore be it

RESOLVED, That our American Medical Association encourage The Joint Commission and other hospital accreditation organizations recognized by major insurers to stipulate that all hospitals require hospital employees, physicians, patients, and visitors to wear a facial mask that completely covers the mouth and nose while within hospital walls (unless they are consuming food while "socially distanced," or unless they are patients in their own rooms while "socially distanced") (Directive to Take Action); and be it further

RESOLVED, That our AMA encourage publication of commentaries supportive of such regulations and standards in scientific journals and other publications (Directive to Take Action); and be it further

RESOLVED, That our AMA study the comparative disease-reduction effectiveness of various types of masks (N-95 masks versus "surgical" masks versus simple cloth facial coverings), toward potentially refining or making more specific any future mandates for facial coverings for persons while in-hospital as a visitor, patient or health care worker. (Directive to Take Action)

Fiscal Note: Moderate - between $5,000 - $10,000

Received: 10/14/20

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1. https://www.cdc.gov/mmwr/volumes/69/wr/mm6937a6.htm?s_cid=mm6937a6_w Accessed September 19, 2020
2. https://www.cdc.gov/flu/about/burden/past-seasons.html Accessed July 17, 2020
3. https://www.cdc.gov/flu/about/season/flu-season.htm Accessed September 21, 2020
4. https://www.cdc.gov/coronavirus/2019-ncov/covid-data/pdf/covidview.pdf Accessed September 19, 2020
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6. https://www.cdc.gov/mmwr/volumes/69/wr/mm6907a1.htm Accessed August 13, 2020
7. https://www.cdc.gov/mmwr/volumes/68/wr/mm6806a2.htm Accessed August 13, 2020
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9. https://www.nbcnews.com/health/health-news/wearing-mask-has-become-politicized-science-says-it-shouldn-t-n1232604 Accessed August 13, 2020
10. Jha, AK. Accreditation, quality and making hospital care better. JAMA. 2018;320:2410-11

RELEVANT AMA POLICY

H-45.977, "Flu Protection Guidelines for Air Travel"

Our AMA supports the efforts of the Centers for Disease Control and Prevention to develop and disseminate guidelines on influenza and other contagious pathogens for all airline personnel and passengers.
(Sub. Res. 426, A-09; Reaffirmed: CSAPH Rep. 01, A-19)

H-440.831, "Protecting Patients and the Public Through Physician, Health Care Worker, and Caregiver Immunization"

1. AMA policy is that, in the context of a highly transmissible disease that poses significant medical risk for vulnerable patients or colleagues or threatens the availability of the health care workforce, particularly a disease that has the potential to become epidemic or pandemic, including influenza, and for which there is an available, safe, and effective vaccine, physicians, health care workers (HCWs), and family caregivers who have direct patient care responsibilities or potential direct exposure have an obligation to accept immunization unless there is a recognized medical reason to not be immunized. In scenarios in which there is a documented medical contraindication to immunization of a physician or HCW, appropriate protective measures should be taken.
2. Our AMA (a) encourages hospitals, health care systems, and health care providers to provide immunizations to HCWs against influenza and other highly transmissible diseases, at no cost to the employee, both for their own protection and to reduce the risk of infectious disease transmission to others; and (b) encourages health care institutions to develop mechanisms to maximize the rate of influenza immunization for HCWs, including the option of making immunization a condition of employment.
(Res. 8, A-15; Modified: CSAPH Rep. 1, I-15)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 407
(November 2020)

Introduced by: American College of Preventive Medicine, American College of Occupational and Environmental Medicine, Aerospace Medical Association, American Association of Public Health Physicians, American Society of Addiction Medicine, Academy of Physicians in Clinical Research, Iowa

Subject: Full Commitment by our AMA to the Betterment and Strengthening of Public Health Systems

Referred to: Reference Committee D

Whereas, The mission of our AMA is to promote the art and science of medicine and the betterment of public health; and

Whereas, The current AMA strategic focus areas include accelerating medical education, improving health outcomes, and enhancing professional satisfaction and practice sustainability; and

Whereas, All physicians have a responsibility to the health, safety and well-being of all citizens and their patients; and

Whereas, The COVID-19 pandemic has exposed many deficits in the infrastructure and funding of the US public health systems; and

Whereas, The current public health infrastructure was not prepared for the severity of this pandemic; and

Whereas, The public health infrastructure should provide all health care workers every protection to practice in a safe, healthy and effective manner; therefore be it

RESOLVED, That our American Medical Association champion the betterment of public health by enhancing advocacy and support for programs and initiatives that strengthen public health systems, to address pandemic threats, health inequities and social determinants of health outcomes. (Directive to Take Action)

Fiscal Note: Moderate - between $5,000 - $10,000

Received: 10/14/20

Reference Committee E

CSAPH Report(s)

01 Drug Shortages: 2020 Update
02 Neuropathic Pain as a Disease Update
03 Dietary Supplements: Update on Regulation, Industry, and Product Trends
04 Public Health Impacts of Cannabis Legalization

Resolution(s)

501 CBD Oil Use and the Marketing of CBD Oil
502 Drug Manufacturing Safety
503 Federal Initiative to Treat Cannabis Dependence
504 Supplemental Resources for Inflight Medical Kit
505 Regulation and Control of Self-Service Labs
506 Education for Patients on Opiate Replacement Therapy
507 Pharmacy Benefit Managers and Drug Shortages
508 Home Infusion of Hazardous Drugs
509* Hydroxychloroquine and Combination Therapies – Off-Label Use
510* Access to Opioid Agonist Treatment for Incarcerated Persons

**** contained in the Handbook Addendum***

REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 1, November 2020

Subject: Drug Shortages: 2020 Update

Presented by: Kira A. Geraci-Ciardullo, MD, MPH, Chair

Referred to: Reference Committee E

INTRODUCTION

American Medical Association (AMA) Policy H-100.956, "National Drug Shortages," directs the Council on Science and Public Health (CSAPH) to continue to evaluate the drug shortage issue and report back at least annually to the House of Delegates (HOD) on progress made in addressing drug shortages in the United States. This report provides an update on continuing trends in national drug shortages and ongoing efforts to further evaluate and address this critical public health issue.

METHODS

English-language reports were selected from a PubMed and Google Scholar search from September 2017 to August 2020, using the text term "drug shortages." Additional articles were identified by manual review of the references cited in these publications. Further information was obtained from the Internet sites of the US Food and Drug Administration (FDA), National Academies of Sciences, Engineering, and Medicine (NASEM), U.S. Department of Health and Human Services (HHS), American Society of Health-System Pharmacists (ASHP), Duke Margolis Center for Health Policy, and by direct contact with key FDA, ASHP, and University of Utah Drug Information Service (UUDIS) staff who monitor drug shortages and related issues daily.

BACKGROUND

The CSAPH has issued ten reports on drug shortages.[1-10] The findings and conclusions of the first five reports are summarized in CSAPH Report 2-I-15, "National Drug Shortages: Update."[4] The remainder of this report will update information on drug shortages since the 2019 report was developed, specifically commenting on the drug shortage situation during the COVID-19 pandemic as well as issues associated with the drug supply chain that lead to drug shortages.

CURRENT TRENDS IN DRUG SHORTAGES

Drug shortages remain an ongoing public health concern in the United States and the AMA continues to monitor the situation and take action when appropriate. The rate of new shortages is increasing and common shortages are severely impacting patient care and pharmacy operations. Hospitals were already experiencing shortages of key injectable drugs prior to COVID-19 and unprecedented demand due to large numbers of critically ill patients with COVID-19 is worsening shortages.

The two primary data sources for information on drug shortages in the United States continue to be the Drug Shortage Program at the FDA and the Drug Shortage Resource Center maintained by

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ASHP in cooperation with the UUDIS.[11,12] According to the most recent data compiled by ASHP and UUDIS, in 2019 there were 166 new shortages. Each quarter since the third quarter of 2017 until second quarter 2019 saw an increase in drug shortages. A spike in shortages occurred again in the first quarter of 2020, in conjunction with the emergence of the COVID-19 pandemic. In 2018 55 percent of shortages were injectable; this decreased to 39 percent in 2019. The top five classes of drugs implicated in active drug shortages include CNS medications (51); antimicrobials (37); cardiovascular medications (29); chemotherapy agents; and ophthalmics (19). The reasons for drug shortages vary and unknown/unreported reasons account for 82 percent of drug shortages, up from 51 percent in 2018 (See Appendix for ASHP/UUDIS data).[13] In the past year, significantly more suppliers did not provide a reason for shortages and FDA's Drug Shortage Task Force Report notes that more than 60 percent of shortages are due to manufacturer quality issues.[14]

The seventh annual report on drug shortages from the FDA to Congress published in April 2020 summarizes the major actions the FDA took in calendar year 2019 related to drug shortages.[15] Notably, using a range of available tools, the FDA worked with manufacturers to successfully prevent 154 shortages during 2019.

The FDA continues to utilize a mobile app to provide up-to-date access to information about drugs in shortage as well as notifications about new and resolved drug shortages and gives physicians the ability to report a drug shortage. The FDA Drug Shortages webpage includes a current shortages list, mobile app, and additional information (Box 1).[12] The ASHP Shortage Resource Center provides a list of shortages, guidance on managing critical shortages, as well as shortage metrics (Box 1).[11]

DRUG SHORTAGES AND COVID-19

As noted, hospitals were already experiencing shortages of injectable drugs prior to the COVID-19 pandemic. Unprecedented demand due to large numbers of critically ill patients with COVID-19 is worsening shortages, especially analgesics, sedatives, and paralytics because of the need to put many patients on ventilators.

Advocacy efforts are successfully creating changes that may improve the current situation. In response to shortages of medications for some chronic diseases, AMA, ASHP, and the American Pharmacists Association (APhA) made a Joint Statement on Ordering, Prescribing or Dispensing COVID-19 Medications.[16] The AMA also signed onto a letter to the U.S. Drug Enforcement Administration (DEA) regarding shortages of injectable Schedule II Controlled Substances that are increasingly needed for ventilation of patients.[17] After receiving the letter, the DEA immediately responded and increased annual production quotas and established regular communication with the AMA and the other letter signatories to identify controlled substances that are in shortage and monitor the rapidly changing situation.[18] DEA also issued two exceptions to regulations for DEA-registered hospital/clinics to facilitate continuous patient care during quickly changing scenarios.[19] FDA is working diligently on their COVID-19 drug shortage response and the Agency has clarified existing compounding guidance to provide flexibility for drugs in shortage.[20] Drug shortages vary by region and situations change rapidly, reporting any shortages experienced to FDA is recommended.

Dexamethasone

Shortages of dexamethasone, which is a generic drug and produced by many manufacturers, are ongoing. The FDA drug shortage website reports that a dexamethasone shortage was first posted February 2019. This was, however, just one supplier and that shortage is now resolved. Additional

suppliers have indicated shortages starting in May 2020, with the reason provided as "demand increase for the drug." All shortages listed note that "intermittent availability expected" with varying timeframes for resolution. The list is constantly changing with additional manufacturers, formulations, vial sizes, and doses.[12] In mid-July, dexamethasone sodium phosphate was added to the lists of drugs for temporary compounding by outsourcing facilities and pharmacy compounders during the COVID-19 public health emergency.[21]

Remdesivir

The FDA first issued an Emergency Use Authorization (EUA) for the new drug, remdesivir (Veklury), in May 2020 for the treatment of hospitalized adult and pediatric patients with severe COVID-19. The EUA was expanded in August 2020 to include treatment of all hospitalized adult and pediatric patients with suspected or laboratory-confirmed COVID-19, irrespective of their severity of disease.[22]

In May Gilead Sciences, Inc. donated 2 separate supplies of remdesivir to the U.S. Government. On June 28, 2020, a Memorandum of Agreement was signed between HHS and Gilead for HHS to receive 100% of the July production supply of the drug and 90% of the August and September production supplies.[23,24] To distribute the limited doses of available remdesivir in a fair and equitable manner, the HHS Office of the Assistant Secretary for Preparedness and Response (HHS/ASPR) is overseeing the allocation of the commercially available drug with a defined process (Figure 1).[25] ASPR has also been holding frequent calls to update stakeholders on the allocation process.

DRUG SUPPLY CHAIN AND DRUG SHORTAGES

The COVID-19 pandemic has exposed vulnerabilities in the global medicine supply chain leading to uncertainty, an increasing number of drug shortages, and potential quality issues. Inspections of foreign and domestic drug manufacturing facilities have been on hold, deficiencies in the drug supply chain have been amplified, and clinical trials have been disrupted.[26]

In a recent letter to the FDA related to Reauthorization of the Prescription Drug User Fee Act (PDUFA), the AMA noted that "[d]rug shortages remain an ongoing public health concern in the United States and strengthening the supply chain to ensure an uninterrupted supply of essential medicines that are safe, meet standards for quality, and are beneficial to health should be a public health priority."[27]

The AMA further stated that "[t]o maintain a strong and safe supply chain, regulators must know where medicines and their ingredients are manufactured and how they pass through the supply chain. The recently passed Coronavirus Aid, Relief, and Economic Security (CARES) Act took some steps to address supply chain issues, but more can be done, including expanding global reporting requirements for indicators of drug shortages, requiring drug manufacturers and ingredient suppliers to monitor and report on their capacity and ingredient quality, and providing incentives to manufacturers for manufacturing innovation and developing shortage mitigation plans."[27]

Your Council on Science and Public Health remains very concerned about medication quality issues and currently has this topic under study for report back to the HOD in 2021.

CURRENT DRUG SHORTAGE ACTIVITIES

American Medical Association

AMA staff continues to remain engaged in drug shortage activities. Notably, AMA co-convened a summit with ASHP, the American Hospital Association (AHA), and the United States Pharmacopeia (USP) on the topic of Safe, Effective, and Accessible High-Quality Medicines as a Matter of National Security on July 27-31, 2020.[28] The summit covered a broad range of topics related to supply chain resilience and opportunities to strengthen the U.S. and global regulatory systems were discussed. A comprehensive report detailing the summit and resulting recommendations is currently in development.

In April 2020, AMA staff provided a webinar for CME credit on the topic of drug shortages. The webinar was sponsored by the Organized Medical Staff Section (OMSS) and was open to interested individuals. The webinar is currently posted on the AMA Ed Hub™.[29]

AMA staff has also contributed to the document, *Coping with and Mitigating the Effects of Shortages of Emergency Medical Products: Strategies for Healthcare and Public Health*, which is an update to a 2012 publication from the Association of State and Territorial Health Officials (ASTHO). In 2012, ASTHO was funded by ASPR to convene a group of stakeholders from national Emergency Medical Services (EMS), emergency/trauma care associations, and select federal agencies to identify approaches for healthcare and EMS to cope with and lessen the impacts of drug shortages on patient care. Expert recommendations were compiled into a report, *Coping with and Mitigating the Effects of Shortages of Emergency Medications*.[30] In 2017 ASTHO was again funded by ASPR to convene experts to identify additional coping and mitigation strategies, with a focus on healthcare and public health. The report, which highlights the challenges, strategies, and recommendations identified by stakeholders, is being finalized for publication.

U.S. Food and Drug Administration

<u>Inter-agency Drug Shortages Task Force</u>. Last year, the FDA convened an inter-agency Drug Shortages Task Force to study the problem of drug shortages, determine the root causes of drug shortages, and make recommendations for enduring solutions.[31] This effort was designed to help address the number of drug shortages that continue to occur. The Task Force has released a report, *Drug Shortages: Root Causes and Potential Solutions*, that attempts to identify root causes and offer recommendations for government and industry based on insights gleaned from stakeholders in the private and public sectors. These recommendations are intended to help prevent and mitigate future drug shortages.[14,32]

The Task Force found that the number of ongoing drug shortages has been rising, and that their impact is likely underappreciated. Drugs in shortage were more likely to be relatively low-price and financially unattractive drugs and were more likely to be sterile injectables. Shortages often occurred as a result of disruption in supply due to a variety of factors. Importantly, prices rarely rose after shortages began, and, during shortages, production typically did not increase enough to restore supply to pre-shortage levels. Many manufacturers reported discontinuing the production of drugs before a shortage for commercial reasons (e.g., loss of profitability). These results suggest a broken marketplace, where scarcity of drugs in shortage or at risk of shortage does not result in the price increases predicted by basic economic principles.[14,32]

The Task Force offered three key recommendations to address the root causes of shortages (see Figure 2 for a summary). The first recommendation is to take steps to increase understanding of the

impacts of drug shortages and companies' contracting practices that may contribute to them. The report encourages more systematic and transparent study of current contracting practices to support development of model contracts designed to promote reliable access to safe, effective, and affordable drugs. The second recommendation is to develop a system to measure and rate a facility's quality management maturity. The rating would evaluate the robustness of a manufacturing facility's quality system and its ability to deliver high-quality products reliably and without disruption. This effort would introduce transparency into the market, and provide companies committed to quality management maturity with a competitive advantage, potentially enabling them to obtain sustainable prices as well as grow market share. The third recommendation is to consider new contracting approaches that help ensure a reliable supply of drugs. This may include providing financial incentives to make certain that manufacturers, especially of older generic drugs, earn sustainable returns on their products.[14,32]

The report also highlights the need for international action. Global implementation of guidelines related to pharmaceutical product supply chains, quality systems, and management of product lifecycles, as well as expansion and standardization of global reporting requirements for indicators of drug shortages could assist in drug shortage mitigation efforts of manufacturers for the international market. In addition, the report described legislative proposals in the President's FY2020 Budget and planned FDA initiatives to prevent and mitigate shortages that look at improved data sharing, risk management, and lengthened expiration dates for drugs.[14,32]

Manufacturing Modernization. As noted in the previous drug shortage report, CSAPH Report 2-A-19, the FDA is continuing their initiative to encourage manufacturers to adopt advanced manufacturing technologies, such as continuous manufacturing, that increase production reliability and capacity and can assist in medical product shortage mitigation.[33,34]

SUMMARY

The rate of new medical product shortages is increasing and shortages of essential medications are severely impacting patient care and pharmacy operations. The ongoing supply challenges of mostly generic medications, typically injectable products, that are off-patent persist. However, numerous organizations, the FDA, and our AMA remain involved in conversations with myriad stakeholders with a continued commitment to addressing this critical issue.

The recent report from the FDA Inter-agency Drug Shortages Task Force Report highlighting the root causes and potential solutions of drug shortages underscored topics that have been discussed for several years by the AMA and your Council. Many of the Task Force report topics are already adequately addressed in AMA drug shortage policy, including improvement quality systems; expedited facility inspections; necessary resiliency and redundancy in manufacturing capability; evaluation of root causes of drug shortages; transparent analysis of economic drivers and reasonable and sustainable payment rates for prescription drugs; greater transparency of the manufacturing process; and including drug manufacturing sites as part of the nation's critical infrastructure plan. However, your Council feels that some amendments to the policy related to manufacturing innovations, global supply chain harmonization and transparency, manufacturer incentives, and general updating are warranted at this time.

RECOMMENDATIONS

The Council on Science and Public Health recommends that the following be adopted and the remainder of the report be filed:

That Policy H-100.956, "National Drug Shortages" be amended by addition and deletion to read as follows:

1. Our AMA considers drug shortages to be an urgent public health crisis, and recent shortages have had a dramatic and negative impact on the delivery and safety of appropriate health care to patients.

2. Our AMA supports recommendations that have been developed by multiple stakeholders to improve manufacturing quality systems, identify efficiencies in regulatory review that can mitigate drug shortages, and explore measures designed to drive greater investment in production capacity for products that are in short supply, and will work in a collaborative fashion with these and other stakeholders to implement these recommendations in an urgent fashion.

3. Our AMA supports authorizing the Secretary of the U.S. Department of Health and Human Services (DHHS) to expedite facility inspections and the review of manufacturing changes, drug applications and supplements that would help mitigate or prevent a drug shortage.

4. Our AMA will advocate that the US Food and Drug Administration (FDA) and/or Congress require drug manufacturers to establish a plan for continuity of supply of vital and life-sustaining medications and vaccines to avoid production shortages whenever possible. This plan should include establishing the necessary resiliency and redundancy in manufacturing capability to minimize disruptions of supplies in foreseeable circumstances including the possibility of a disaster affecting a plant.

5. The Council on Science and Public Health shall continue to evaluate the drug shortage issue, including the impact of group purchasing organizations on drug shortages, and report back ~~at least annually~~ to the House of Delegates when warranted on progress made in addressing drug shortages.

6. Our AMA urges continued analysis of ~~the development of a comprehensive independent report on~~ the root causes of drug shortages that includes consideration of~~. Such an analysis should consider~~ federal actions, ~~the number of~~ evaluation of manufacturer,~~s~~ Group Purchasing Organization (GPO), and distributor practices, ~~as well as~~ contracting practices by market participants on competition, access to drugs, ~~and~~ pricing, and ~~. In particular, further transparent~~ ~~In particular, a further~~ analysis of economic drivers~~ is warranted~~. ~~is warranted~~. ~~The federal Centers for Medicare & Medicaid Services (CMS) should review and evaluate its 2003 Medicare reimbursement formula of average sales price plus 6% for unintended consequences including serving as a root cause of drug shortages.~~

7. Our AMA urges regulatory relief designed to improve the availability of prescription drugs by ensuring that such products are not removed from the market due to compliance issues unless such removal is clearly required for significant and obvious safety reasons.

8. Our AMA supports the view that wholesalers should routinely institute an allocation system that attempts to fairly distribute drugs in short supply based on remaining inventory and considering the customer's purchase history.

9. Our AMA will collaborate with medical specialty society partners and other stakeholders in identifying and supporting legislative remedies to allow for more reasonable and sustainable payment rates for prescription drugs.

10. Our AMA urges that during the evaluation of potential mergers and acquisitions involving pharmaceutical manufacturers, the Federal Trade Commission consult with the FDA to determine whether such an activity has the potential to worsen drug shortages.

11. Our AMA urges the FDA to require manufacturers to provide greater transparency regarding the pharmaceutical product supply chain, including production locations of drugs, and provide more detailed information regarding the causes and anticipated duration of drug shortages.

12. Our AMA supports the collection and standardization of pharmaceutical supply chain data in order to determine the data indicators to identify potential supply chain issues, such as drug shortages.

13. Our AMA encourages global implementation of guidelines related to pharmaceutical product supply chains, quality systems, and management of product lifecycles, as well as expansion of global reporting requirements for indicators of drug shortages.

14. Our AMA urges drug manufacturers to accelerate the adoption of advanced manufacturing technologies such as continuous pharmaceutical manufacturing.

15. Our AMA supports the concept of creating a rating system to provide information about the quality management maturity, resiliency and redundancy, and shortage mitigation plans, of pharmaceutical manufacturing facilities to increase visibility and transparency and provide incentive to manufacturers. Additionally, our AMA encourages GPOs and purchasers to contractually require manufacturers to disclose their quality rating, when available, on product labeling.

16. Our AMA encourages electronic health records (EHR) vendors to make changes to their systems to ease the burden of making drug product changes.

17. Our AMA urges the FDA to evaluate and provide current information regarding the quality of outsourcer compounding facilities.

18. Our AMA urges DHHS and the U.S. Department of Homeland Security (DHS) to examine and consider drug shortages as a national security initiative and include vital drug production sites in the critical infrastructure plan. (Modify Current HOD Policy)

Fiscal Note: Less than $1000

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Box 1. Resources available to assist in mitigation of drug shortages.

1. ASHP Resource Center
2. ASHP list of current shortages
3. ASHP and University of Utah guidance on small-volume parenteral solutions shortages
4. ASHP and University of Utah guidance on injectable opioid shortages
5. FDA Drug Shortages Page (includes current shortages list, mobile app, and additional information)

Figure 1. ASPR Allocation and Distribution Strategy for Remdesivir

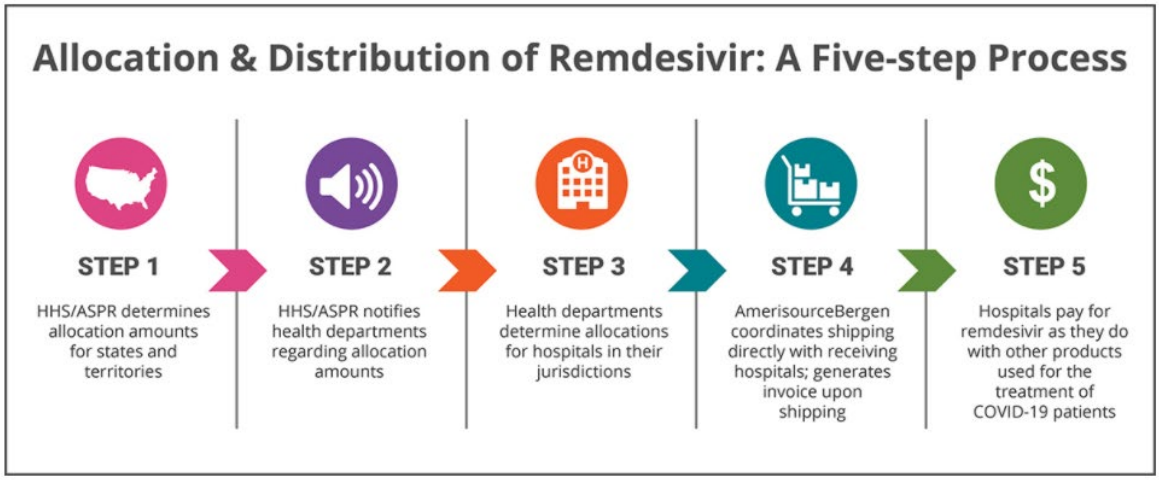
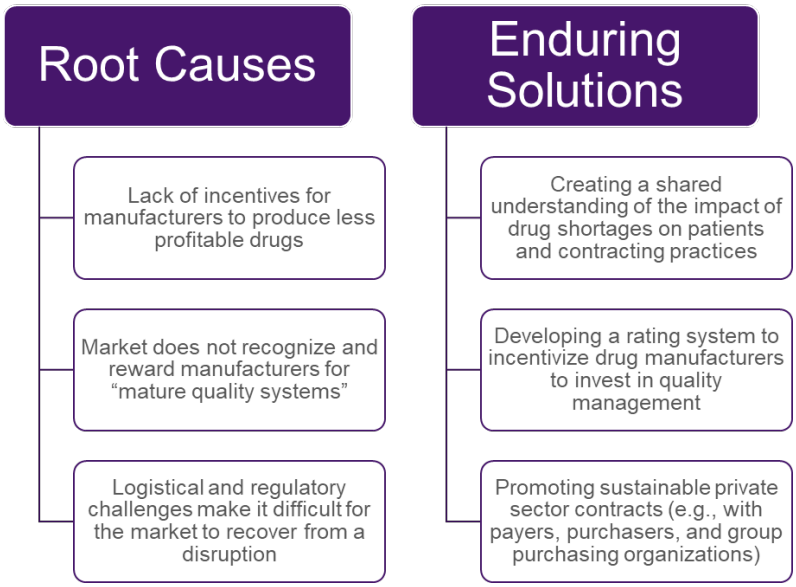


Figure 2. Root Causes and Potential Solutions from the FDA Inter-agency Drug Shortages Task Force Report



APPENDIX

ASHP/University of Utah Drug Information Service Drug Shortage Data

Figure 1.

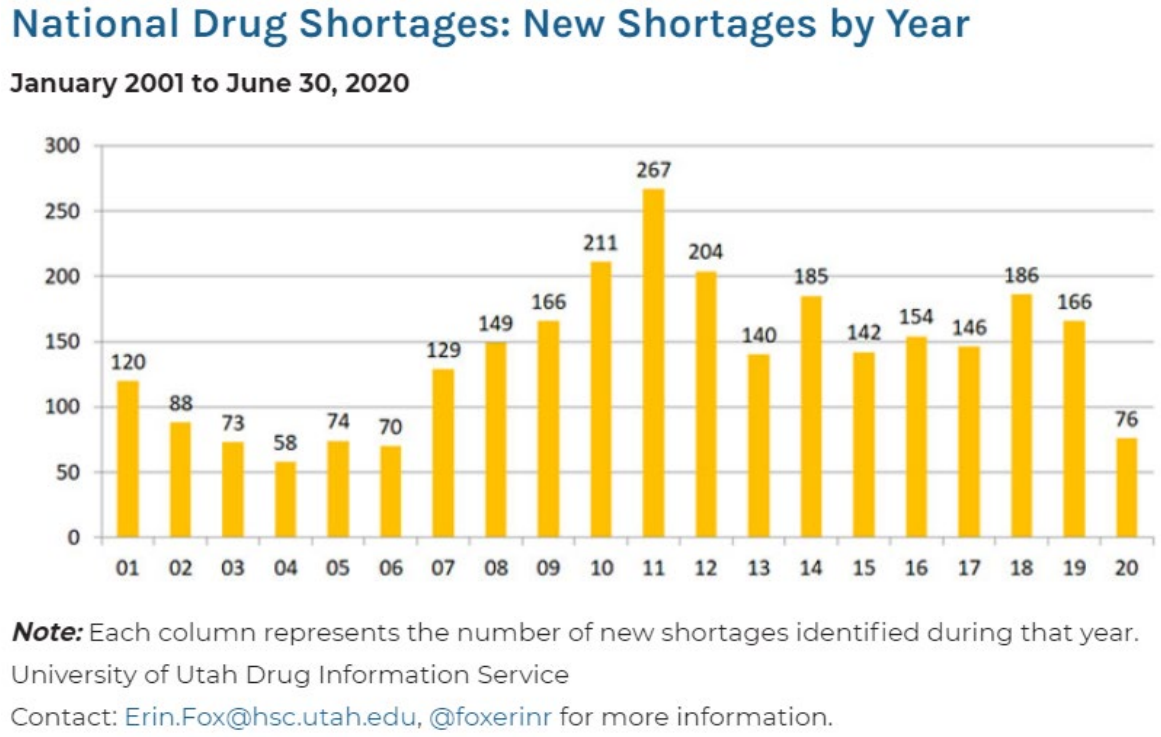


Figure 2.

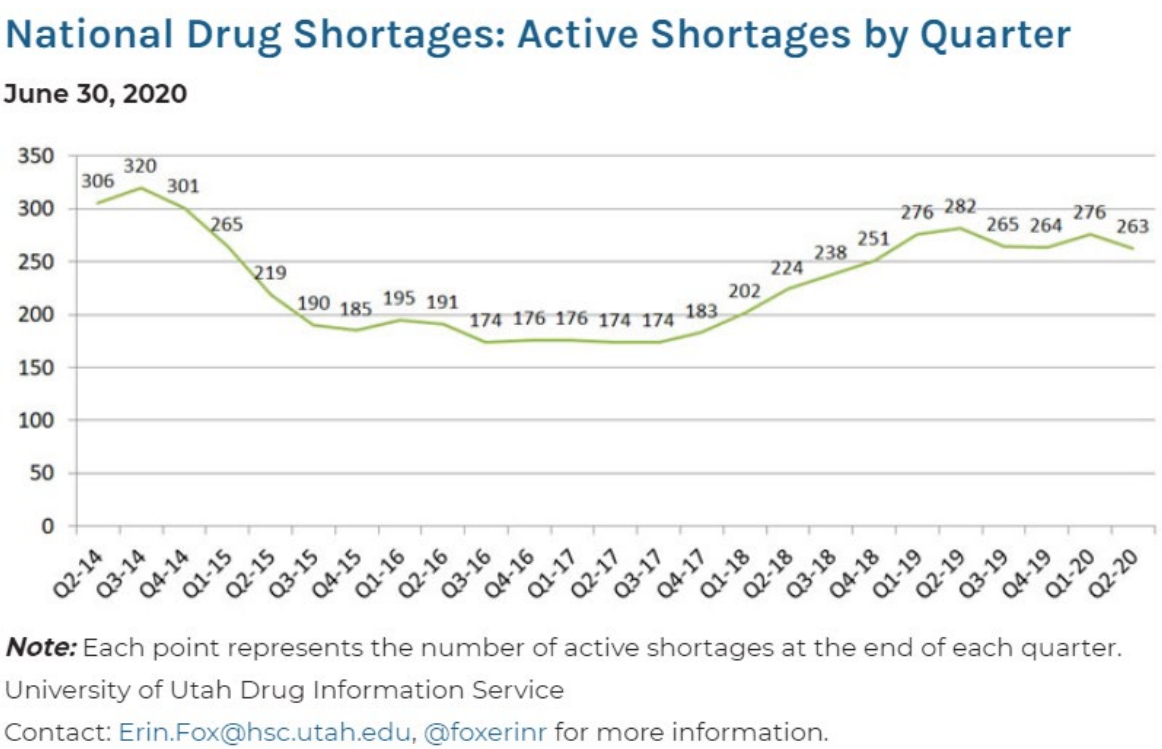


Figure 3.

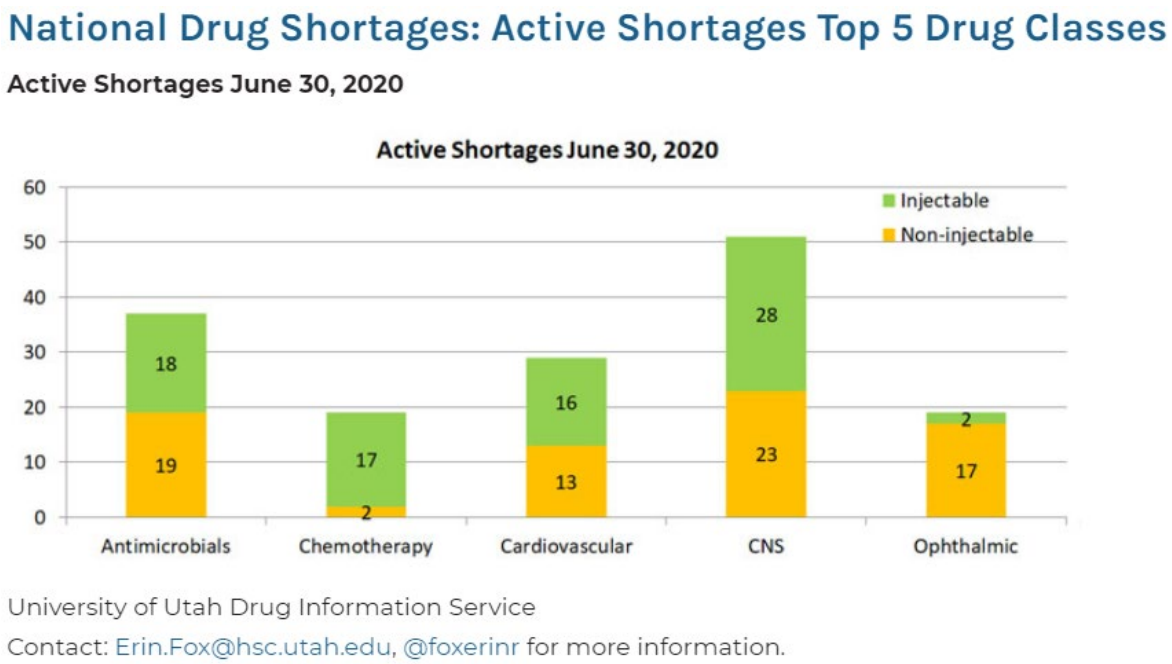
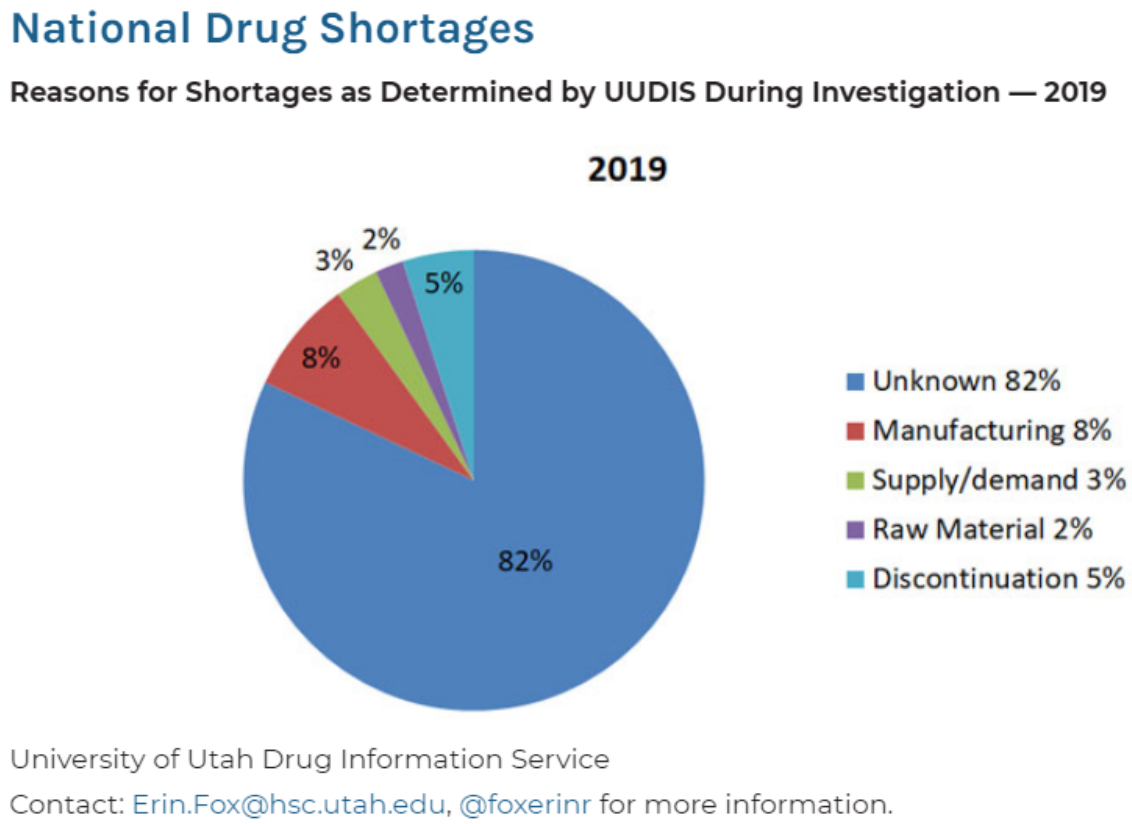


Figure 4.



REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 2, November 2020

Subject: Neuropathic Pain as a Disease Update

Presented by: Kira A. Geraci-Ciardullo, MD, MPH, Chair

Referred to: Reference Committee E

INTRODUCTION

The AMA Council on Science and Public Health (CSPAH) presented Report 3-I-17, Neuropathic Pain as a Disease, to the AMA House of Delegates.[1] The adopted recommendation of the report states "that the Federation Task Force on Pain Care evaluate the relative merits of declaring neuropathic pain as a distinct disease state, and provide a recommendation to the Council on Science and Public Health."

The AMA Pain Care Task Force (PCTF) deliberated this important issue at their November 25, 2019 meeting, came to a consensus opinion on the declaration of neuropathic pain as a disease, and communicated this opinion back to CSAPH. This report serves as CSAPH communicating the PCTF decision back to the AMA House of Delegates.

BACKGROUND

As noted in CSAPH Report 3-I-17, the "[u]nderstanding of the human pain experience has evolved over time. Although a detailed understanding of the neuroanatomy underlying the perception of noxious stimuli (nociception), exists, neuroimaging studies have identified several brain regions that are activated during the pain experience, dubbed the "pain matrix;" many of the same regions are also activated during various emotional and behavioral responses. Chronic pain is now recognized as an integrative sum of nociceptive input and factors related to cognition, mood, and context, as well as individual biologic, psychologic and social factors and various co-morbidities."[1]

CSAPH Report 3-I-17 defined nociceptive pain as follows: "Nociceptive pain is caused by tissue injury generating pain through the primary somatosensory nervous system via a process involving activation of peripheral nociceptors, transduction, transmission, modulation and perception of noxious stimuli. Nociceptive pain can be acute, subacute or chronic, may be complicated by inflammation, and may be visceral or referred in origin."[1] Information about pain is transmitted from the site of nociception through, for example, the spinothalamic tracts of the spinal cord to the midbrain and then onward, directly or indirectly, to the cerebral cortex, thus allowing the organism to adapt in a constructive way to the stimulus.

The definition of neuropathic pain used in CSAPH Report 3-I-17 is the 2012 definition of the International Association for the Study of Pain (IASP), which states that neuropathic pain is "pain initiated or caused by a lesion or disease of the somatosensory system."[2] The report stated that the basis for this definition is that "neuropathic pain is not a single disease, but a syndrome caused by a range of different diseases and lesions, which manifests as an array of symptoms and signs."[1] Classic examples of neuropathic pain are diabetic neuropathy and alcohol-related peripheral

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neuropathy, where metabolic or toxic effects damage neurons, resulting in painful sensations. According to a study discussed in the 2017 report, "many different types of neural lesions and systemic diseases trigger neuropathic pain symptoms (e.g., diabetes, post-herpetic neuralgia, radiculopathies, stroke, spinal cord injury, chemotherapy, certain surgeries, alcohol misuse, vitamin deficiencies, heavy metal toxicity, and many other causes and triggers)."[3]

CSAPH Report 3-I-17 report delved into the complexities of chronic pain, reviewing that, "[w]ith neural injury or repetitive nociceptive stimuli, remodeling of the nervous system and alteration in gene expression occurs. Such changes reflect neuroplasticity that impacts pain in the peripheral and central nervous system, leading to increased excitability within pain circuits and generating peripheral and central sensitization, which underlie the phenomena of hyperalgesia, allodynia, and the spread of pain to adjacent uninjured regions (secondary hyperalgesia). Based on neuroimaging research, cross sectional studies of structural and functional changes accompanying chronic pain, including neuropathic pain, support clear differences compared with both normal conditions and the presence of acute nociceptive pain, but it remains unclear what the cause and effect relationships might be, or whether such brain alterations should be viewed primarily as an adaptive response to continuing nociceptive input."[1]

CSAPH Report 3-I-17 points out that many diseases are accompanied by chronic pain, but it goes into some detail describing findings from neuroimaging studies that demonstrate differences in structure and functioning of the nervous system such that chronic pain differs from both normal states and states of acute nociceptive pain. It also describes that neuropathic pain "is characterized by adaptive cellular and functional changes which appear to persist after healing of the original injury."[1] CSAPH Report 3-I-17 drew also from a previous CSAPH report from 2010, "Maldynia: Pathophysiology and Nonpharmacologic Treatment," which later was published in a peer-reviewed journal.[4]

For the purposes of the current report, nociceptive pain, whether acute or chronic, is distinguished from neuropathic pain, whether acute or chronic. Nociceptive pain should be defined as it was in CSAPH Report 3-I-17. Neuropathic pain should be understood including the syndrome as the IASP defined it in 2012, but also encompassing the pain resulting from neuroadaptation associated with chronic pain. CSAPH Report 3-I-17 describes the cellular and functional changes in the nervous system in chronic pain, with "neuroplastic and neuroimmune responses which become drivers of chronic pain," including peripheral and central sensitization as well as "disinhibition resulting from an imbalance of excitatory and inhibitory influences at the spinal cord level" and "descending facilitation from the brain stem and higher centers."[1]

CORRESPONDANCE TO CSAPH FROM AMA PAIN CARE TASK FORCE

In a memo to CSAPH, the PCTF communicated its consensus opinion along with additional rationale and commentary to support their opinion. The AMA PCTF supports the designation of neuropathic pain as a distinct disease state.

The PCTF noted that members engaged in lengthy discussion of the consequences of this decision, which were not taken lightly. Although the IASP defines neuropathic pain as a clinical description (and not a diagnosis) which requires a demonstrable lesion or a disease that satisfies established neurological diagnostic criteria, the PCTF is supportive of designating neuropathic pain a distinct disease state. The PCTF, however, cautions that a neuropathic pain disease designation should only be used when appropriate, and not overused. Additionally, the cause of the neuropathic pain should be carefully elucidated, and all underlying causes and/or types of neuropathy should be considered.

The PCTF understands that treating patients with neuropathic pain is complicated, challenging, and takes substantial time. Enhancing the scientific evidence base and successful treatment options for patients is critical. The PCTF is hopeful that support for the designation of neuropathic pain as a distinct disease state will allow for and encourage more research into the condition, payer coverage of treatment options, and improved resources for patients suffering with neuropathic pain.

Importantly, the PCTF also feels that the designation of neuropathic pain as a distinct disease state will validate patient experiences and provide a basis for their determination to move ahead without knowing the exact pathology causing their pain. Furthermore, this designation may assist in the alleviation of stigma patients with neuropathic pain face. The PCTF encourages physicians to engage in meaningful conversation about the pathology of complex pain and set appropriate expectations collaboratively with their patients. Encouraging patients to focus on function and quality of life can help reduce maladaptive changes in their condition.

CONSIDERATIONS OF THE COUNCIL

CSAPH appreciates the collaboration with the PCTF and thanks them for their response to the Council's request for guidance. The Council believes it is preferable, with our AMA recommending that neuropathic pain be designated as a distinct disease, that it be defined to the extent that its distinctions from nociceptive pain are clear to physicians, patients, researchers, and others. Hence, included in this report is the appropriate background material, with that material incorporated in the recommendations presented below.

RECOMMENDATIONS

The Council on Science and Public Health recommends that the following and the remainder of the report be filed:

1. That a new policy, Neuropathic Pain, be adopted:
   Our AMA:
   a. Supports the designation of neuropathic pain as a disease state distinct from nociceptive pain, encompassing metabolic, toxic, mechanical, and other injuries to nerve cells, as well as neuroplastic and neuroimmune adaptations to nerve cells in response to chronic pain.
   b. Encourages research related to neuropathic pain, payer coverage of treatment options for neuropathic pain, and improved resources for patients suffering with neuropathic pain.
   c. Encourages physicians to engage in meaningful conversation with their patients about what is known about the pathology of neuropathic pain and to set appropriate expectations collaboratively with their patients.
   d. Cautions that a neuropathic pain disease designation should only be used when appropriate, not overused, and that the cause of the neuropathic pain be carefully elucidated.

2. That part (d) of Policy D-160.922, "Future of Pain Care," which called for the AMA Pain Care Task Force to evaluate the merits of declaring neuropathic pain as a distinct disease state and provide a recommendation to the Council on Science and Public Health, be rescinded.

Fiscal Note: Less than $500

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3. Colloca L, Ludman T, Bouhassira D, et al. Neuropathic pain. *Nat Rev Dis Primers.* 2017;3:17002.
4. Dickinson BD, Head CA, Gitlow S, Osbahr AJ, 3rd. Maldynia: pathophysiology and management of neuropathic and maladaptive pain--a report of the AMA Council on Science and Public Health. *Pain medicine (Malden, Mass).* 2010;11(11):1635-1653.

APPENDIX: Member Organizations of the AMA Pain Care Task Force

American Medical Association
American Academy of Family Physicians
American Academy of Hospice and Palliative Medicine
American Academy of Neurology
American Academy of Orthopedic Surgeons
American Academy of Pain Medicine
American Academy of Pediatrics
American Academy of Physical Medicine and Rehabilitation
American Association of Neurological Surgeons and
Congress of Neurological Surgeons
American College of Occupational and Environmental Medicine
American College of Physicians
American Osteopathic Association
American Psychiatric Association
American Society of Addiction Medicine
American Society of Anesthesiologists
American Society of Clinical Oncology
Medical Association of the State of Alabama
California Medical Association
Maine Medical Association
Massachusetts Medical Society

REPORT 3 OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH (November 2020)
Dietary Supplements: Update on Regulation, Industry, and Product Trends
(Reference Committee E)

EXECUTIVE SUMMARY

Objective. Patients and physicians expect the dietary supplements they purchase and recommend to be safe, quality products that are accurately labeled with their contents. Many dietary supplements, principally vitamins and minerals, are key components of modern evidence-based medicine for many conditions. However, illegal, fraudulent, adulterated and misbranded products can put patients at risk and adverse events (AEs) should be accurately collected. Additionally, confusion exists, for both patients and their caregivers, related to the regulation of dietary supplements and herbal products. The Council on Science and Public Health initiated this report to bring renewed attention to this important topic that affects many patients and to offer recommendations to strengthen AMA policy related to the dietary supplements.

Methods. English-language articles were selected from a search of the PubMed database through February 2020 using the search term "dietary supplement(s)." Additional articles were identified from a review of the references cited in retrieved publications. Searches of selected medical specialty society and international, national, and local government agency websites were conducted to identify clinical guidelines, position statements, and reports.

Results. While millions of patients use dietary supplements regularly, the current regulatory structure in place for dietary supplements does not offer adequate protection to the public. In the 26 years since the passage of the Dietary Supplement Health and Education Act (DSHEA), the dietary supplement industry has been reshaped by a complex global supply chain, the Internet, and newly discovered ingredients of unknown safety. An estimated 75,000 new supplement products have been introduced since 1994, and the U.S. Food and Drug Administration (FDA) has received adequate safety data for fewer than 250 new ingredients. The FDA also has no way to determine what ingredient are contained in the tens of thousands of products on the market. Furthermore, with violations identified in over half of inspected dietary supplement manufacturers, more effective enforcement tools are required to protect the health of patients. All patients would benefit from a regulatory framework that promotes product safety and provides appropriate tools and resources for the FDA to maintain appropriate oversight.

Conclusion. The advancement of a safe and transparent dietary supplement marketplace will require a trustworthy supply chain and will involve robust AE, drug interaction, and tainted product reporting. Unethical individuals and companies engage in the manufacture and distribution of intentionally adulterated, misbranded, and improperly labeled dietary supplement products and pose significant risks to patient health and safety. The reliance on an industry that self regulates is insufficient and ineffective at protecting the health of patients. As the dietary supplement industry continues to grow and patients continue to use dietary supplements, efforts to revise and modernize FDA oversight of the industry and the DSHEA itself are necessary. A mandatory product registry would be a simple, low-burden way for the FDA and patients to obtain a complete picture of the marketplace and better protect public health by providing greater transparency, enabling prioritization of limited agency resources, and enhancing efforts to respond to emerging safety concerns. Additionally, both physician and patient education are paramount to understand this industry and the risks associated with dietary supplement products.

REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 3, November 2020

Subject: Dietary Supplements: Update on Regulation, Industry, and Product Trends

Presented by: Kira A. Geraci-Ciardullo, MD, MPH, Chair

Referred to: Reference Committee E

INTRODUCTION

Patients and physicians expect the dietary supplements they purchase and recommend to be safe, quality products that are accurately labeled with their contents. Many dietary supplements, principally vitamins and minerals, are key components of modern evidence-based medicine for many conditions. However, illegal, fraudulent, adulterated and misbranded products can put patients at risk. Adverse events (AEs) can occur with use of dietary supplements, and when they do, they should be accurately collected, tabulated and analyzed. Additionally, confusion exists, for both physicians and patients, related to the regulation of dietary supplements and herbal products.

The Council on Science and Public Health initiated this report to bring renewed attention to this important topic that affects many patients and to offer recommendations to strengthen American Medical Association (AMA) policy related to the dietary supplements.

BACKGROUND

The dietary supplement industry has grown from approximately 4,000 products in 1994 to as many as 90,000 in 2017, according to some estimates.[1,2] Surveys indicate that over half of Americans consume dietary supplement products.[3,4] Additionally, with the recent surge in the cannabidiol (CBD) market, which absent a clear regulatory pathway already includes a substantial number of products sold as dietary supplements, the number of products sold is expected to continue to increase. The economic value of the industry is projected to reach nearly $60 billion in the United States, and nearly $200 billion worldwide, by 2025.[5,6]

As the industry grows and more individuals are using dietary supplement products, a renewed focus on the risks associated with these products and the regulatory processes involved in bringing them to market is warranted. This report will provide an overview of the current regulatory framework for dietary supplements and comment on research-related activities, the dietary supplement industry, and product trends.

METHODS

English-language articles were selected from a search of the PubMed database through February 2020 using the search term “dietary supplement(s)” alone and coupled with “drug interactions” and “regulation.” Additional articles were identified from a review of the references cited in retrieved publications. Searches of selected medical specialty society and international, national, and local government agency websites were conducted to identify clinical guidelines, position statements, and reports.

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DIETARY SUPPLEMENT REGULATION

Dietary Supplement Health and Education Act

The Federal Food, Drug, and Cosmetic Act (FD&C Act) defines a dietary supplement as a product, taken orally, containing a dietary ingredient intended to supplement the diet.[7] Dietary ingredients include vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandulars, and metabolites. Dietary supplements can also be extracts or concentrates of the listed items.[8] Dietary supplements come in many forms, including tablets, capsules, powders, energy bars, and liquids and are available for purchase over-the-counter in stores throughout the United States and via the Internet. Herbal supplements are considered a type of dietary supplement and are included in this definition.

Since, by statutory definition, dietary supplements are only intended to supplement the diet, they are not therapeutic medications and are not intended to treat, diagnose, mitigate, prevent, or cure diseases. The U.S. Food and Drug Administration (FDA) oversees not only "conventional" food products and medications but also dietary supplements. Dietary supplements are regulated by the FDA differently from foods and differently from drugs. Whether a product is classified as a dietary supplement, conventional food, or drug is based on its intended use, and most often, classification as a dietary supplement is determined by the information that a manufacturer provides. Medications go through a rigorous FDA approval process before entering the market; drugs are considered unsafe until evidence shows they are safe. Dietary supplements do not undergo this approval process and are considered safe until proven unsafe.

FDA regulates the processing, manufacturing, labeling, and packaging of dietary supplements through the Dietary Supplement Health and Education Act (DSHEA), enacted as an amendment to the FD&C Act in 1994.[9] Dietary supplement companies are responsible for having evidence that their products are safe, and that the label claims are truthful and not misleading. As long as the product does not contain a "new dietary ingredient (NDI)," the company does not have to provide safety evidence to the FDA before the product is marketed. The term NDI means a dietary ingredient that was not marketed in the United States in a dietary supplement before October 15, 1994; however, no authoritative list of ingredients marketed before October 15, 1994 exists.[10] Therefore, manufacturers and distributors, and not federal regulators, are responsible for determining if an ingredient is an NDI.

Under DSHEA, manufacturers and distributors of dietary supplements and dietary ingredients are prohibited from marketing products that are adulterated or misbranded. Manufacturers are responsible for labeling their products before marketing to ensure that they meet all the requirements of DSHEA and FDA regulations. The FDA is responsible for taking action against any adulterated or misbranded dietary supplement product only after it reaches the market and a violation is found. The FDA pursues enforcement actions on dietary supplement products for the following reasons:

- Safety: The presence of unsafe ingredients or composition is generally determined from postmarket surveillance, such as monitoring adverse event reports (AERs), to identify potential concerns.[11]
- Manufacturing violations: Manufacturers must follow current good manufacturing practice (cGMP) to ensure the identity, purity, strength, and composition of their products.
- Marketing and misbranding (shared authority with the Federal Trade Commission (FTC)): Once a dietary supplement is on the market, it is the responsibility of the FDA to monitor product labels and package insert information to make sure that the information is accurate

and that any claims made are truthful and not misleading. The FDA, however, has limited resources to effectively do this.

Some penalties and enforcement actions exist which the FDA is able to pursue in instances of safety and cGMP violations. These include administrative actions such as warning letters, civil penalties such as product recalls and injunctions, and criminal penalties including both misdemeanor offenses of up to 1 year in prison and $500,000 in fines, and felony offenses of up to 3 years in prison and $500,000 in fines. Enforcement of penalties for marketing and misbranding is a shared authority with FTC, and the FDA cannot impose penalties if the only violation is misbranding. Civil penalties under the FDA include injunctions and product recalls, and under FTC include administrative actions, injunctions, and fines for consumer relief and recovery of illegal profits.

Dietary Supplement Labeling

Dietary supplement marketing, labeling, and advertising are all covered by regulations enforced by both the FDA and the FTC. Unlike drugs, supplements are not intended to treat, diagnose, prevent, or cure diseases. The FTC acts as the primary regulator of dietary supplement advertising and the FDA possesses primary enforcement responsibility for dietary supplement claims made in "labeling."

The Nutrition Labeling and Education Act of 1990 gave the FDA the discretion to regulate health claims for foods and dietary supplements and DSHEA made manufacturers responsible for ensuring dietary supplements have appropriate labeling that reflects safety and efficacy. Three classes of claims can legally be used on the labels of dietary supplements:[12]

1. Health claims: Statements that relate the consumption of a dietary ingredient to a reduced risk of a disease or health-related condition. Health claims require authorization by the FDA, but once a claim has been approved, it may be used by all manufacturers according to the regulations established by the FDA (example: "Adequate calcium throughout life, as part of a well-balanced diet, may reduce the risk of osteoporosis.").
2. Nutrient content claims: Provide information on the level of a nutrient in a product in absolute terms or relative to another component and help ensure that descriptive terms, such as high or low, are used consistently for all types of dietary supplement products and are meaningful to consumers. Most nutrient content claim regulations apply only to those nutrients that have an established Daily Value (DV). Percentage claims for dietary supplements are used to describe the percentage level of a dietary ingredient in a dietary supplement and may refer to dietary ingredients for which there is no established DV. Nutrient content claims require FDA review before they can be used on a product (example: "40% omega-3 fatty acids, 10 mg per capsule").
3. Structure/function claims: Describe the effect a substance has on the structure or function of the body. These types of claims are not pre-approved by the FDA, but manufacturers must have substantiation that the claim is truthful and not misleading and must submit a notification with the text of the claim to FDA no later than 30 days after marketing the dietary supplement with the claim. If a dietary supplement label includes such a claim, it must state in a disclaimer (using wording that is specified in the DSHEA) that the FDA has not evaluated the claim. The disclaimer must also state that the dietary supplement product is not intended to "diagnose, treat, cure or prevent any disease," because only a drug can legally make such a claim. Structure/function claims may not explicitly or implicitly link the claimed effect of the nutrient or dietary ingredient to a disease or to a state of health leading to a disease (example: "Helps improve memory.").

Another class of claim, a disease claim, is a claim to diagnose, cure, mitigate, treat, or prevent disease; as noted, such claims are prohibited on dietary supplements and require FDA approval to be used on approved drug products (example: "Reduces the pain and stiffness associated with arthritis.").

Criteria for the rigor of evidence needed to support a claim have not been established; scientific evidence may be provided by just one article assessing a compound *in vitro* that has not achieved recognition or agreement.[13] Importantly, studies have shown consumers are generally unaware of, or ignore, DSHEA disclaimers; studies also note that these disclaimers fail to communicate that patients should use caution in interpreting the efficacy claims manufacturers make for their dietary supplement and they have little reliable impact on patients' beliefs about the risk and effectiveness of dietary supplements. Furthermore, there is evidence that consumers erroneously believe that the labels of dietary supplements will include warnings of adverse effects where appropriate.[13,14]

While DSHEA, via statutory authority granted to the FDA, applies exclusively to the labeling of dietary supplements, the FTC is primarily responsible for the regulation of dietary supplement advertisements. The FTC regulates "unfair methods of competition" in commerce and "unfair or deceptive" practices under Sections 5 and 12 of the Federal Trade Commission Act (FTCA). Two principles apply in FTC enforcement of advertisements: ads have to be (1) truthful and not misleading and (2) substantiated. Additionally, the FTC has the authority to compel manufacturers to submit their evidence in substantiation of the claims they make in advertisements. Cease and desist orders not only prohibit further deceptive practice but may require companies to pay a fine of $16,000 per ad per day in the instance of future violations. Cases have been rare; over the last decade, the FTC reports that is has filed 120 cases challenging health claims made for dietary supplements.[15]

Supplement Facts Panel

In May 2016, a final rule was published in the Federal Register detailing Revision of the Nutrition and Supplement Facts Labels.[16] The Supplement Facts label is the black and white box located on dietary supplement product containers that is intended to provide the chemical composition of a dietary supplement. Because of changes and evolution of the American diet and advancements in nutrition science, federal requirements for the label are being updated. Notable changes include updates to DV to reflect the current American diet; a change from reporting some vitamins in International Units (IU) to more commonly used measures of milligrams (mg) and micrograms (mcg); listing of folic acid as folate (measured in mcg of dietary folate equivalents); and listing of the amount of added sugar and percent DV. The deadline for large manufacturers to reflect the label changes was January 1, 2020. Smaller manufacturers have until January 1, 2021 to comply with these changes. A resource has been developed to educate consumers about the changes.[17]

The FDA requires manufacturers to list all of the ingredients in a dietary supplement on the Supplement Facts panel of the product, along with the amount of each by weight, except when the ingredients are part of a "proprietary blend."[18] A proprietary blend (or "complex," matrix," or "formulation") is a collection of ingredients often unique to a particular product and sometimes given a fanciful name. The specific amount of each individual ingredient in a proprietary blend does not have to be listed; however, the absence of a stated amount for each ingredient can have significant implications for patients and physicians, especially if the blend contains stimulant or stimulant-like ingredients or if the ingredient has a supplement-drug interaction with a patient's medication.

DSHEA Modernization and Product Registries

The FDA recently announced efforts to strengthen the regulation of dietary supplements by modernizing and reforming their oversight.[19] The Agency established a Dietary Supplement Working Group at the FDA to identify opportunities across the Agency to modernize the oversight of dietary supplements, develop a new rapid-response tool to alert the public of tainted or recalled products, foster the submission of NDI notifications so they can evaluate the safety of a new ingredient before it becomes available to consumers, update the compliance policy regarding NDIs, and engage in conversations to modernize DSHEA. A public meeting was held in May 2019, attended by a representative from the AMA, to discuss Responsible Innovation in Dietary Supplements; the stated purpose of the public meeting was to give interested parties an opportunity to present ideas for facilitating responsible innovation in the dietary supplement industry while preserving the FDA's ability to protect the public from unsafe, misbranded, or otherwise unlawful dietary supplements.[20] The FDA has not yet released any reports or guidance from the public meeting. Many stakeholders testified in support of appropriate enforcement tools and policies, which may include mandatory recall and related authorities over products that are marketed as dietary supplements but contain drugs or drug analogues; the utilization of risk-based inspections for dietary supplement manufacturing facilities; and strengthening of AER systems.

Of note, a recent survey conducted by the Pew Charitable Trusts found that most American adults believe the FDA should do more to ensure the safety of dietary supplements.[21,22] Experts in the field of dietary supplements and their regulatory structure support modernization and reform of DSHEA to include stronger safeguards resulting in access to quality products.[23]

Currently, the FDA has no mechanism to know what dietary supplement products are on the market. Because dietary supplement manufacturers are not required to submit product information, the FDA has limited knowledge about the products on the market, including their ingredients and the conditions under which they were manufactured. Several experts and organizations support the concept of an FDA product listing regime--if it can be effective at identifying and removing dangerous dietary supplement products from the marketplace.[24] Some features have been proposed for a mandatory product registry to safeguard the public and inform physicians, investigators, and regulators including linking each product to a unique identifier such as a stock keeping unit (SKU) barcode or QR code and the ability to flag all products produced by manufacturers who have received warning letters from the FDA.[23] Proponents of an FDA-managed, mandatory product registry also support giving the FDA additional authorities to decline to add labels to the registry if the label lists a prohibited ingredient as well as FDA-required investigations of products labeled as containing NDIs for which no evidence of safety exists or for products which have reports of undisclosed ingredients.

The Supplement OWL® (Online Wellness Library) dietary supplement product listing is an industry-wide initiative developed with the intent to create a more complete picture of the marketplace and is led by the Council for Responsible Nutrition, joined by the American Botanical Council, the American Herbal Products Association, the Consumer Healthcare Products Association, the Natural Products Association, and the United Natural Products Alliance. However, the Supplement OWL is voluntary for manufacturers and is only a list of products; it lacks all of the safety provisions recommended by experts and listed above to ensure a safer marketplace of dietary supplements.[25]

DIETARY SUPPLEMENT RESEARCH

DSHEA granted the authority to establish regulations regarding dietary supplement manufacturing, regulate health claims and labeling of dietary supplements, and create governmental bodies to encourage research on supplements, such as centers and offices at the National Institutes of Health (NIH). Additionally, the FDA created a Botanical Safety Consortium, a public-private partnership that will gather leading scientific minds from industry, academia, and government to promote scientific advances in evaluating the safety of botanical ingredients and mixtures in dietary supplements.

National Institutes of Health

The NIH supports research and provides educational materials on dietary supplements.[26] The NIH Office of Dietary Supplements (ODS) provides scientific information about dietary supplements with the stated mission to strengthen knowledge and understanding of dietary supplements.[27] ODS hosts a website containing information about dietary supplement ingredients and co-funds research grants with several other NIH centers, including the National Center for Complementary and Integrative Health (NCCIH). ODS also supports the Dietary Supplement Label Database (DSLD) which includes label derived information from dietary supplement products marketed in the U.S.[28] DSLD was developed to serve the research community and as a resource for health care providers and the public. It also contains archived labels from products that have been removed from the market. Research suggests that even these NIH resources do not provide accurate information about the contents of dietary supplements for researchers or clinicians.[29]

DIETARY SUPPLEMENT INDUSTRY

Product Supply Chain and Quality

Beyond oversight by FDA and related agencies, the dietary supplement industry, can, and should, play an active and influential role in addressing dietary supplement quality and the problems associated with bad actors within the industry. The FDA inspected 656 dietary supplement production facilities in fiscal year 2017 and found violations in over half of them. The most common violations include failing to establish the identity, purity, strength, or composition of the final product.[30] Many companies do follow cGMP, adequately self-regulate, and make every effort to produce quality products, yet it is well documented in literature that unethical individuals and companies continue to engage in the manufacture and distribution of low quality, intentionally adulterated, or misbranded products labeled as dietary supplements that pose significant threats to patient health and safety.[31-34]

The supply chain behind the manufacture and distribution of dietary supplements can involve multiple ingredient suppliers, brokers, and contract manufacturers, both inside and outside of the United States. Because the supply chain is long and involves many links, problems with dietary supplement products can arise at various points and it can be difficult to track the lineage of ingredients and the identities of parties involved in the production of a single product.

Within the industry supply chain, ingredient providers, brokers, product manufacturers, distributors and product marketers all have the responsibility to self-regulate through qualifying and validating their suppliers, ensuring a secure supply chain, testing ingredients and finished products, identifying and removing high-risk products from product assortments, and implementing other mechanisms to assure that ingredients and final products do not contain undisclosed illegal ingredients with the potential to harm patients. Makers of fraudulent products ignore legal

obligations and FDA lacks the resources for more frequent inspections, substantive surveillance, and enforcement of the law.[35]

A regulatory framework that helps promote safe, quality dietary supplement products is necessary. Experts have suggested efforts are needed from both the FDA and industry to increase manufacturer awareness of cGMP regulations and quality standards, including quality control specifications for the identity, purity, strength, and composition of finished dietary supplements as well as their ingredients. Wider use of the public standards developed by the United States Pharmacopeial Convention (USP) or other public compendial standards, along with following cGMP, has been recommended for dietary supplements.[36] USP has also developed a General Chapter, <2251> Adulteration of Dietary Supplements with Drugs and Drug Analogs to assist manufacturers.[37]

Product Testing

With the large increase in dietary supplement manufacturers and the subsequent rise in dietary supplement safety concerns, several companies have started independent product certification services to provide an additional level of security and risk minimization for consumers who rely on dietary supplement products. Many companies test products to verify they contain the labeled dose(s) of the active ingredient(s) and not to contain microbes, heavy metals, other toxins, and/or substances that are banned by athletic organizations.[38] Testing labs include ConsumerLab.com,[39] USPharmacopeia,[40] NSF International,[41] and UL.[42]

Additional resources exist for patients and physicians who are seeking more information about products, product ingredients, or products with reported violations (Box 1). USP provides a list of products they have independently verified for quality,[40] NSF has a listing of products that are NSF Certified for Sport®,[41] and the U.S. Antidoping Agency (USADA) hosts a resource for dietary supplement safety education and awareness, Supplement 411.[43] Additionally, other, more comprehensive resources exist, but may require a paid subscription. An example is the Natural Medicines Research Collaboration Natural Medicines database, which claims to contain over 1200 monographs on natural ingredients, including vitamins, herbs, minerals, non-herbal supplements, naturally sourced chemical compounds, and foods; Natural Medicines provides monographs that include information on a variety of topics including interactions for both health care professionals and patients.[44]

DIETARY SUPPLEMENT PRODUCT TRENDS

General Trends

Not all dietary supplements lack evidence of efficacy. Many products considered dietary supplements are an important part of patient health care, including products to treat vitamin and mineral deficiencies and supplementation during pregnancy. However, many products that have medical benefits are commonly overused among the general population in an attempt to improve or maintain health and use in these ways provides little benefit. Studies have noted that dietary supplement use was not associated with mortality benefits in a nationally representative sample of U.S. adults, that supplement use itself does not have direct health benefits, and in some cases excess intake might increase harmful effects, including cancer and mortality.[38,45] Only approximately a quarter of patients who are using dietary supplements are doing so based on the recommendation of their physician.[46] Additionally, a study commissioned by the FTC found that the majority of patients in the United States are overly optimistic about the results they can achieve[13]

Investigators have also commented on significant misperceptions of understanding related to the safety and efficacy of dietary supplements and FDA authorities. Investigators found that patients incorrectly believe that dietary supplements are approved by the government; that dietary supplements have been tested for safety and effectiveness; that the content of all dietary supplements are analyzed; and that manufacturers are required to disclose known adverse effects.[14] Each of these beliefs is a misconception.

Experts on the subject of dietary supplements note that patients may not be aware of the lack of efficacy of products and respond to advertisements, recommendations from friends and family, and longstanding habits of use. Consistently, mainstream media produces articles related to popular dietary supplements. At the beginning of each new year, it is common to see many lists about dietary supplement trends for the year ahead, whether based on evidence of efficacy or not. Lists of dietary supplement trends for 2020 include bone marrow, berberine, nootropic products, collagen peptides, and cannabidiol (CBD).[47,48] Brain enhancement (nootropic) dietary supplement products are an emerging and increasing problem, as many contain unapproved pharmaceutical products.[49] The Council on Science and Public Health recently commented on this emerging issue in CSAPH report 9-A-16, Increasing Awareness of Nootropic Use.[50]

Commonly Adulterated Products

Adulteration of dietary supplements is usually either economic adulteration, when a less expensive ingredient is used in place of a more expensive ingredient listed on the label, or pharmaceutical adulteration, when an active pharmaceutical is included in a product and not listed on the label.[34] Adding to the complexity and safety risks associated with adulteration, pharmaceutical adulteration includes the use of not only FDA-approved drugs, or drugs formerly approved by the FDA and withdrawn, but also drugs used in other countries (and never FDA-approved), and experimental drugs minimally or never tested in humans.[51,52]

Dietary supplements are associated with an estimated 23,000 emergency department visits each year, and many of these visits are due to products that are adulterated with pharmaceutical drugs. The most commonly adulterated dietary supplements are those marketed as weight loss, sexual enhancement, or sports supplements.[33,34,53-57] Many times, active pharmaceuticals are identified in dietary supplements even after FDA warnings to the manufacturer.[52,58] The drug ingredients in these dietary supplements have the potential to cause AEs related to accidental misuse, overuse, interaction with other medications, or with other pharmaceuticals within the supplement, and related to underlying health conditions in the user.[59]

Additionally, extensive efforts have been made to silence physician-researchers investigating adulterated dietary supplements.[60,61] Despite research being vetted through peer review and published in reputable journals, dietary supplement manufacturers have attempted to intimidate researchers with strategic lawsuits against public participation (SLAPP), which attempt to suggest research was biased, unethical, or vindictive, instead of publishing rebuttals to challenge the research. Although anti-SLAPP laws exist and are intended to prevent people from using courts, and even the threat of a lawsuit, to intimidate people who are exercising their First Amendment rights, some courts have allowed these lawsuits go to trial to not undermine a supplement company's constitutional right to a jury trial.

Cannabidiol

CBD is a major cannabinoid in marijuana and does not appear to have any psychoactive effects similar to those caused by Δ^9-tetrahydrocannabinol (THC). Most cannabinoid compounds are

derived from the plant genus cannabis. Various breeds or strains of cannabis for medicinal use have a significant variety in the ratios of CBD-to-THC and are known to contain other non-psychotropic cannabinoids. "Marijuana" is listed as a Schedule 1 controlled substance under the Controlled Substances Act (CSA); CBD and other components of cannabis are also Schedule 1 compounds by definition because they are considered "derivatives" or "components" of marijuana.

Hemp, however, is excluded from this rule since the Agricultural Improvement Act (the 2018 Farm Bill) removed hemp-derived products from Schedule I status under the CSA.[62] The Farm Bill defined hemp as a strain of the cannabis plant containing no more than 0.3% THC. The 2018 Farm Bill does not legalize CBD generally and CBD remains a Schedule 1 substance under the CSA. The 2018 Farm Bill does create exceptions to this Schedule 1 status in certain situations: any cannabinoid that is derived from hemp will be legal, if and only if that hemp is produced in a manner consistent with the Farm Bill, associated federal regulations, association state regulations, and is produced by a licensed grower. All other cannabinoids, produced in any other setting, remain a Schedule I substance under the CSA and are illegal. The one exception is pharmaceutical-grade CBD products that have been approved by the FDA, of which there is one. Epidiolex from GW Pharmaceuticals, a purified 98% oil-based CBD extract of known and constant composition, is FDA approved to treat rare forms of epilepsy, and is Schedule V.

The legal landscape of CBD remains complex. As states have legalized cannabis use for medical purposes and for any purpose, a variety of non-FDA approved or regulated products have become more mainstream. Among these products are CBD oils or other products rich in CBD. CBD products are used by the public for a variety of purported indications, including seizure reduction, as an anti-inflammatory, and for alleviating anxiety. Often, CBD products are (incorrectly) called CBD-only products; many states define "CBD-only" as containing less than 0.3% THC (the same as hemp). For many products, it is difficult to determine if the product is hemp-derived (Schedule 1 exempt) or not, and variability in CBD and THC content is common. Recently, an analysis of twenty popular CBD products and found that only three contained what was listed on the labels.[63]

The FDA has taken the position that CBD cannot be legally sold in either supplements or foods and has repeatedly said it needs more data to better understand the risks and benefits of CBD.[64,65] The FDA has estimated it could take between three and five years to complete a rulemaking process that would allow CBD to be added to food and dietary supplements. If it is eventually permitted, FDA will need to establish science-based standards for dosing, composition, nomenclature, product claims, and numerous other manufacturing and marketing issues to further the goals of protecting the public and providing more clarity to industry and the public.[66,67] To further progress the knowledge related to CBD, the FDA has re-opened a public docket indefinitely for the submission of scientific data related to CBD.[67]

The FDA has focused its limited enforcement resources on removing CBD products that make claims of curing or treating disease, leaving many CBD products on the market as both foods and dietary supplements available for sale. Some experts believe this is an opportunity for the FDA to reform and improve oversight of dietary supplements and ingredients to create clear, reasonable pathways for low-dose CBD and other new substances to be safely introduced into supplements and food.[65]

Widespread agreement exists that additional research is needed regarding CBD, both for efficacy and long-term safety. Currently, CBD and hemp oils remain a widely available but unproven therapeutic option for many patients. CBD became the top selling "dietary supplement" in the United States in 2018 according to a recent report from the American Botanical Council.[63] Experts note that physicians should remain open to the possible future role CBD products may play in the

management of a variety of difficult to treat diseases,[68] yet use caution and consider of the risks present in patients' use of CBD products and the possibility of product contamination.[69]

ADVERSE EVENT REPORTING, INTERACTIONS, AND PRODUCT REPORTING

Post-market surveillance is a key part of identifying safety problems associated with both pharmaceutical products and dietary supplement products. The FD&C Act defines a dietary supplement AE as "any health-related event associated with the use of a dietary supplement that is adverse" (e.g., headache, abdominal pain, allergic reaction, rash, and dizziness or lightheadedness). A serious adverse event (SAE) is defined as an AE that "results in death, a life-threatening experience, inpatient hospitalization, a persistent or significant disability or incapacity, or a congenital anomaly or birth defect; or requires, based on a reasonable medical judgement, a medical or surgical intervention to prevent an outcome described above."[7]

While few of the many high-quality studies evaluating dietary supplements and ingredients looking for positive health benefits from their use have found such results, several studies have produced evidence of harm.[46] It has been reported that less than 40 percent of patients reveal use of dietary supplements to their health care professionals and no metrics could be located related to how many health care professionals directly ask patients about dietary supplement use. The US Government Accountability Office estimates that a small fraction of the estimated 50,000 adverse reactions each year from dietary supplements are reported to the FDA. The lack of reporting, along with the poor quality of the information received in the few reports make it nearly impossible for the FDA to find and remove dangerous supplements.[70,71]

Literature documents that concomitant use of dietary supplements and prescribed medications is common, problematic, and can result in life-threatening ADEs, hospitalizations, and fatalities.[72] Adding to the risk for patients, dietary supplements often contain multiple active ingredients and are often inaccurately labeled. Myriad products and ingredients have been implicated in interactions and ADEs, yet investigators note underreporting, lack of case reports, and incomplete reports.[23,72-76] In several instances, local public health departments, the Centers for Disease Control and Prevention (CDC), or the Department of Defense have been more successful at linking cases of illness to dietary supplement products than physician reporting and the FDA.[75]

Suspected supplement-related AEs should be reported to the FDA.[38] All reporting by physicians is voluntary and also strongly recommended; the FDA gives extra credence to physician reports and the voluntary system of passive surveillance is the only opportunity the FDA has to detect harmful dietary supplements. The Safety Reporting Portal (SRP)[77] streamlines the process of reporting product safety issues to the FDA and the NIH, formerly done through FDA's Adverse Event Reporting System (FAERS)[78] and MedWatch[79] Online Voluntary Reporting Form. The SRP can be used by manufacturers, health care professionals, researchers, public health officials, and patients.[80] Contaminated dietary supplement products can be also be reported via an FDA portal.[81] Box 2 provides a list of resources for reporting dietary supplement safety issues.

Some dietary supplements are known to cause clinically important interactions with drugs and should be avoided by most patients receiving any pharmacologic therapy. Many other dietary supplement products, however, are predicted to cause interactions based limited in vitro studies.[72,82] Additionally, some dietary supplements have the potential to interfere with laboratory results.[83] Risk-based and open conversation with patients is crucial in minimizing and appropriately identifying interactions.

PATIENT-PHYSICIAN INTERACTION

Physicians or their office staff should include discussion of dietary supplements when reviewing medications with all patients. Reporting suspected AEs related to dietary supplements is critical, and dietary supplements should also be considered as source of unexplained AEs. Risk-based patient counseling of patients should include discussion about the variable quality of dietary supplements, the presence of unreputable products in the marketplace, and information on which products are commonly adulterated; additionally, physicians can ask patients to bring dietary supplement products with them to appointments for review and discussion.[52] Physicians should also make an effort to evaluate any potential drug-supplement interactions based on the products patients are using or considering. Box 1 contains a list of resources for information about dietary supplement products.

When counseling patients about dietary supplements, it should be noted that supplementation is not a substitute for a healthful and balanced diet and, in most cases, provides little benefit. Targeted supplementation may be warranted for high-risk populations for whom nutritional requirements may not be met through diet alone, including people at certain life stages and those with specific risk factors.[38]

CURRENT AMA POLICY AND ACTIVITIES

AMA currently has policy related to dietary supplements. Policy H-150.954, “Dietary Supplements and Herbal Remedies,” notes AMA’s support of the FDA MedWatch program, encourages the reporting of adverse events associated with dietary supplements, and urges manufacturers to investigate and include on the label any adverse effects, contraindications, and possible drug interactions. Policy D-150.991, “Herbal Products and Drug Interactions,” supports FDA efforts to create a publicly accessible database of adverse event and drug interaction information on dietary supplements. Policy H-150.954 also urges for modifications to strengthen DSHEA, supports FDA and FTC enforcement efforts, and supports appropriate dietary supplement labeling. This policy also notes the AMA’s support of educating patients and physicians about the risks associated with dietary supplements. Policy H-150.946, “Advertising for Herbal Supplements,” states that the naming, packaging, and advertising of dietary supplement products be such that they cannot be confused with pharmaceutical products. Policy H-115.988, “Qualitative Labeling of All Drugs,” supports efforts to require both active and inactive ingredients of over-the-counter and prescription drugs and dietary supplements to be listed on the manufacturer's label or package insert. Policy D-120.982, “Illegal Online Prescribing Operations,” supports efforts that help the Drug Enforcement Administration and the FDA to better regulate and control the illegal online sales and distributions of drugs, dietary supplements, and herbal remedies.

Additionally, the AMA is a member of the Dietary Supplement Quality Collaborative (DSQC), a group committed to the advancement of policies and initiatives designed to improve and maintain the quality and safety of products marketed as dietary supplements.[84] The DSQC supports policies and resources to advance innovation; help ensure safe, quality supplements; remove illegal and tainted products from the marketplace; and promote consumer education. To this end, through DSQC, AMA has contributed to the writing of a white paper seeking to educate stakeholders about the dangers of tainted dietary supplements and recommend solutions to aid in minimizing the risks associated with them.[35] The AMA has also been a signatory to letters requesting support for the FDA’s Office of Dietary Supplement Programs.

SUMMARY

Millions of patients use dietary supplements yet today, the regulatory structure in place for dietary supplements does not adequately protect the public. In the 26 years since the passage of DSHEA, the dietary supplement industry has been reshaped by a complex global supply chain, the Internet, and newly discovered ingredients of unknown safety. An estimated 75,000 new supplement products have been introduced since 1994, and the FDA has received adequate safety data for fewer than 250 new ingredients. The FDA also has no way to determine what ingredients are present in the tens of thousands of products on the market.[23,24]

Furthermore, with violations in over half of inspected dietary supplement manufacturers,[30] more effective enforcement tools are required to protect the health of patients. All patients will benefit from a regulatory framework that promotes product safety and provides appropriate tools and resources for the FDA to maintain appropriate oversight.[34]

CONCLUSION

The advancement of a safe and transparent dietary supplement marketplace will require a trustworthy supply chain and will involve robust AE, drug interaction, and tainted product reporting. The reliance on an industry that self-regulates is insufficient and ineffective at protecting the health of patients. Unethical individuals and companies engage in the manufacture and distribution of intentionally adulterated, misbranded, and improperly labeled dietary supplement products and pose significant risks to patient health and safety. As the dietary supplement industry continues to grow and patients continue to use dietary supplement, efforts to revise and modernize the DSHEA and FDA oversight of the industry and are necessary. The FDA has no mechanism to know what dietary supplement products, containing what ingredients, are on the market. Some have suggested that a mandatory product registry would be a simple, low-burden way for the FDA and patients to obtain a complete picture of the marketplace and better protect public health by providing greater transparency, enabling prioritization of limited agency resources, and enhancing efforts to respond to emerging safety concerns. Additionally, both physician and patient education are paramount to understand this industry and the risks associated with dietary supplement products.

RECOMMENDATIONS

The Council on Science and Public Health recommends that the following be adopted and the remainder of the report be filed:

1. That Policy H-150.954, "Dietary Supplements and Herbal Remedies" be amended by addition and deletion to read as follows:

    (1) <u>Our AMA supports efforts to enhance U.S. Food and Drug Administration (FDA) resources, particularly to the Office of Dietary Supplement Programs, to appropriately oversee the growing dietary supplement sector and adequately increase inspections of dietary supplement manufacturing facilities</u>.

    (2) <u>Our AMA supports the FDA having appropriate enforcement tools and policies related to dietary supplements, which may include mandatory recall and related authorities over products that are marketed as dietary supplements but contain drugs or drug analogues, the utilization of risk-based inspections for dietary</u>

supplement manufacturing facilities, and the strengthening of adverse event reporting systems.

(3) Our AMA supports continued research related to the efficacy, safety, and long-term effects of dietary supplement products.

(4) Our AMA will work with the FDA to educate physicians and the public about FDA's ~~MedWatch program~~ Safety Reporting Portal (SRP) and to strongly encourage physicians and the public to report potential adverse events associated with dietary supplements and herbal remedies to help support FDA's efforts to create a database of adverse event information on these forms of alternative/complementary therapies.

(5) Our AMA strongly urges physicians to inquire about patients' use of dietary supplements and engage in risk-based conversations with them about dietary supplement product use.

(6) Our AMA continues to strongly urge Congress to modify and modernize the Dietary Supplement Health and Education Act to require that:

(a) dietary supplements and herbal remedies including the products already in the marketplace undergo FDA approval for evidence of safety and efficacy;

(b) dietary supplements meet standards established by the United States Pharmacopeia for identity, strength, quality, purity, packaging, and labeling;

(c) FDA establish a mandatory product listing regime that includes a unique identifier for each product (such as a QR code), the ability to identify and track all products produced by manufacturers who have received warning letters from the FDA, and FDA authorities to decline to add labels to the database if the label lists a prohibited ingredient or new dietary ingredient for which no evidence of safety exists or for products which have reports of undisclosed ingredients; and

(d) regulations related to new dietary ingredients (NDI) are clarified to foster the timely submission of NDI notifications and compliance regarding NDIs by manufacturers; and

(7) Our AMA supports FDA postmarketing requirements for manufacturers to report adverse events, including drug interactions; and legislation that declares metabolites and precursors of anabolic steroids to be drug substances that may not be used in a dietary supplement.

(8) Our AMA will work with the Federal Trade Commission (FTC) to support enforcement efforts based on the FTC Act and current FTC policy on expert endorsements and supports adequate funding and resources for FTC enforcement of violations of the the FTC Act.

(9) Our AMA strongly urges that criteria for the rigor of scientific evidence needed to support a structure/function claim on a dietary supplement be established by the FDA and minimally include requirements for robust human studies supporting the claim.

(10) Our AMA strongly urges dietary supplement manufacturers and distributors to clearly label all products with truthful and not misleading information and for ~~supports that~~ the product labeling ~~of dietary supplements and herbal remedies~~ to:

~~(a) that bear structure/function claims contain the following disclaimer as a minimum requirement: "This product has not been evaluated by the Food and Drug Administration and is not intended to diagnose, mitigate, treat, cure, or prevent disease." This product may have significant adverse side effects and/or interactions with medications and other dietary supplements; therefore it is important that you inform your doctor that you are using this product;~~

(a) not include structure/function claims that are not supported by evidence from robust human studies;

(b) ~~should~~ not contain prohibited disease claims~~.~~;

(c) eliminate "proprietary blends" and list and accurately quantify all ingredients contained in the product;

(d) require advisory statements regarding potential supplement-drug and supplement-laboratory interactions and risks associated with overuse and special populations; and

(e) include accurate and useful disclosure of ingredient measurement.

(11) Our AMA supports and encourages the FDA's regulation and enforcement of labeling violations and FTC's regulation and enforcement of advertisement violations of prohibited disease claims made on dietary supplements and herbal remedies.

(12) Our AMA urges that in order to protect the public, manufacturers be required to investigate and obtain data under conditions of normal use on adverse effects, contraindications, and possible drug interactions, and that such information be included on the label.

(13) Our AMA will continue its efforts to educate patients and physicians about the ~~possible ramifications~~ risks associated with the use of dietary supplements and herbal remedies~~.~~ and supports efforts to increase patient, healthcare practitioner, and retailer awareness of resources to help patients select quality supplements, including educational efforts to build label literacy.

2. That Policy H-120.926, "Expedited Prescription Cannabidiol Drug Rescheduling," be amended by addition and deletion to read as follows:

Regulation of Cannabidiol Products
Our AMA will: (1) encourage state controlled substance authorities, boards of pharmacy, and legislative bodies to take the necessary steps including regulation and legislation to reschedule U.S. Food and Drug Administration (FDA)-approved cannabidiol products, or make any other necessary regulatory or legislative change, as expeditiously as possible so that they will be available to patients immediately after approval by the FDA and rescheduling by the U.S. Drug Enforcement Administration; ~~and~~ (2) advocate that an FDA-approved cannabidiol medication should be governed only by the federal and state regulatory provisions that apply to other prescription-only products, such as dispensing through pharmacies, rather than by these various state laws applicable to unapproved cannabis products~~.~~; and (3) support comprehensive FDA regulation of cannabidiol products and practices necessary to ensure product quality, including identity, purity, and potency.

3. That policy D-150.991, "Herbal Products and Drug Interactions," that notes our AMA's support of FDA efforts to create a publicly accessible database of adverse event and drug interaction information on dietary supplements, be reaffirmed.

Fiscal Note: Less than $1000

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Box 1. Resources for dietary supplement product information.

1. USP verified products [40]
2. NSF Certified for Sport® products [41]
3. USADA Supplement 411 [43]
4. Natural Medicines Research Collaboration Natural Medicines database (paid subscription)[44]

Box 2. Resources for reporting dietary supplement safety issues.

1. The Safety Reporting Portal (SRP) [77]
2. Reporting Unlawful Sales of Medical Products on the Internet [81]
3. How to Report a Problem with Dietary Supplements [80]
4. FDA's Adverse Event Reporting System (FAERS) [78]
5. MedWatch Online Voluntary Reporting Form [79]

REPORT 4 OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH (November 2020)
(Resolutions 408-A-19, 411-A-19 and Alternate Resolution 913-I-19)
Public Health Impacts of Cannabis Legalization
(Reference Committee E)

EXECUTIVE SUMMARY

Objective. To review developments in cannabinoid pharmacology, update relevant sections of Council Report 5-I-17, "Clinical Implications and Policy Considerations of Cannabis Use," and evaluate the public health impacts in states that have legalized cannabis for adult use to determine whether modifications to AMA are warranted.

Methods. English language reports were selected from searches of the PubMed, Google Scholar, and Cochrane Library databases from August 2017 to August 2020 using the (text or MeSh) search terms "marijuana or cannabis or cannabinoid or cannabidiol" in combination with "legalization or laws," and "health," "mental or public health," "addiction or cannabis use disorder," "health effects," "use," "benefits or harms," "youth or adolescents," "edibles," "driving," "taxes," "social equity or justice" and "treatment." Additional articles were identified through related article searches and by manual review of the reference lists of retrieved articles. Websites managed by federal and state agencies, and applicable regulatory and advocacy organizations also were consulted for relevant information.

Results. Thirty-three states have legalized medicinal use of cannabis. Eleven of these states have legalized cannabis for adult use. All 17 states that have not legalized medical use of cannabis allow the use of cannabidiol (CBD) in some way, as does the federal government for CBD products derived from hemp containing ≤0.3% Δ-9-tetrahydrocannabinol (THC). The health effects of cannabis and cannabinoids described in Council Report 5-I-17 remain valid; additionally, attention has been drawn to increased cardiovascular risks with cannabis use.

The overall prevalence of cannabis use in the U.S has increased steadily since 2011, mostly among young adults aged 18-25 years and adults 26 years of age and older. Adolescent use has declined during the same time period; findings from state-based surveys in states with legalized adult use contradict to a certain degree patterns reported by national surveys in individual states, but in the fastest growing demographic (18-25 years-old), prevalence of use is highest in states with legalized adult use. Legalization of cannabis for adult use also is associated with increased traffic fatalities, exposures reported to poison control centers (including infants and children), emergency department visits, and cannabis-related hospitalizations. Changes in methods and patterns/intensity of cannabis use in pregnant women are most concerning. Legalization has led to a large decrease in cannabis-related arrests for adults, less so for juveniles, and with limited effects on disparities in that population. States that have legalized cannabis for adult use have garnered increasing revenues on a quarterly/annual basis, with variable portions earmarked for public health measures or designed to address social equity concerns.

Conclusion. Developments in states' retail cannabis market have advanced more rapidly than public health frameworks to minimize harms. Amendments to current AMA policy are recommended to address these developments.

REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 4, November 2020

Subject: Public Health Impacts of Cannabis Legalization
(Resolutions 408-A-19, 411-A-19 and Alternate Resolution 913-I-19)

Presented by: Kira A. Geraci-Ciardullo, MD, MPH, Chair

Referred to: Reference Committee E

INTRODUCTION

This Council report responds to three referred resolutions on cannabis.

Resolution 408-A-19, "Banning Edible Cannabis Products," introduced by the Illinois Delegation and referred to the Board of Trustees, asked:

> That our American Medical Association adopt policy supporting a total ban on recreational edible cannabis products;

Resolution 411-A-19, "AMA to Analyze Benefits/Harms of Legalization of Marijuana," introduced by the New York Delegation and referred to the Board of Trustees, asked:

> That our American Medical Association review pertinent data from those states that have legalized marijuana; and,

Alternate Resolution 913-I-19, "Public Health Impacts and Unintended Consequences of Legalization and Decriminalization of Cannabis for Medicinal and Recreational Use," was adopted, but an additional proposed resolve, referred to the Board of Trustees, asked:

> That our AMA amend Policy H-95.924, "Cannabis Legalization for Recreational Use," by addition and deletion to read as follows:
>
> H-95.924, "~~Cannabis~~ Legalization of Cannabis Use for Medical or Any Other Purposes ~~for Recreational Use~~" Our AMA: (1) ~~believes~~ warns that cannabis is a dangerous drug and as such is a serious public health concern; (2) advocates that cannabis and cannabinoid use are a serious public health concern; (~~2~~ 3) warns against the legalized use and sale of cannabis and cannabinoids due to their potential negative impact on human health ~~believes that the sale of cannabis for recreational use should not be legalized~~; (~~3~~ 4) ~~discourages~~ warns against cannabis and cannabinoid use, ~~especially by persons vulnerable to the drug's effects and in high-risk populations such as youth,~~ by children, adolescents, pregnant women, and women who are breastfeeding; (4 5) ~~believes~~ strongly advocates that states that have already legalized cannabis for medical purposes or any other purposes ~~(for medical or recreational use or both)~~ should be required to take steps to regulate ~~the product~~ cannabis and cannabinoids effectively in order to protect public health and safety and that laws and regulations related to legalized cannabis use should consistently be evaluated to determine their effectiveness; (~~5~~ 6) strongly encourages local, state, and federal public health agencies to improve surveillance efforts to ensure data is

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available on the short- and long-term health effects of cannabis and cannabinoid use; and (~~6~~ 7) supports decriminalization and public health based strategies, rather than incarceration, in the handling of individuals possessing cannabis or cannabinoids for personal use.

This report updates relevant sections of Council Report 5-I-17, "Clinical Implications and Policy Considerations of Cannabis Use," summarizes current state legislation legalizing adult cannabis and cannabinoid use, and reviews other pertinent information and developments in these jurisdictions to evaluate the public health impacts of legalization.[1] The term cannabis will be used throughout when referring to the *Cannabis sativa* plant rather than the slang term marijuana/marihuana, unless the latter is officially included in a title, policy, or otherwise official language.

METHODS

English language reports were selected from searches of the PubMed, Google Scholar, and Cochrane Library databases from August 2017 to August 2020 using the (text or MeSh) search terms "marijuana or cannabis or cannabinoid or cannabidiol" in combination with "legalization or laws," and "health," "mental or public health," "addiction or cannabis use disorder," "health effects," "use," "benefits or harms," "youth or adolescents," "edibles," "driving," "taxes," "social equity or justice" and "treatment." Additional articles were identified through related article searches and by manual review of the reference lists of retrieved articles. Websites managed by federal and state agencies, and applicable regulatory and advocacy organizations also were consulted for relevant information.

CURRENT AMA AND FEDERATION POLICY

The Council has issued six previous reports on cannabis covering: (1) aspects of research and investigational and therapeutic use (including in-hospital); (2) the juxtaposition of cannabis within the evolution of U.S. national drug control policy; and, (3) the broader clinical implications and policy considerations associated with the proliferation of state-based medicinal and legalized adult use programs.[1-6]

AMA policy categorizes cannabis as a dangerous drug and public health concern (Policy H-95.924). Accordingly, our AMA supports increased educational programs on the use and misuse of alcohol, marijuana, and controlled substances, including specific measures aimed at K-12 curricula (H-170.992).

With respect to criminal penalties, our AMA believes that public health-based strategies, rather than incarceration, should be utilized in the handling of individuals possessing cannabis for personal use (H-95.924). A plea of cannabis intoxication should not be a defense in any criminal proceedings (H-95.997).

With respect to research, our AMA calls for further adequate and well-controlled studies of marijuana and related cannabinoids in patients who have serious conditions for which preclinical, anecdotal, or controlled evidence suggests possible efficacy (H-95.952). To facilitate the conduct of clinical research and development of cannabinoid-based medicines, the status of marijuana as a federal schedule I controlled substance should be reviewed and relevant federal agencies should implement measures designed to streamline the clinical research process (H-95.952). The consequences of long-term cannabis use in youth, pregnant women and those who are breastfeeding are special concerns. Our AMA discourages cannabis use, especially in these populations (and in those who are otherwise vulnerable to the drug's effects), and supports specific

point of sale warnings and product labeling about the potential dangers of use during pregnancy and breastfeeding (H-95.924).

In order to promote public health and safety, research on the impact of cannabis legalization and decriminalization also is encouraged and information derived from such activities should be disseminated. Local, state, and federal public health agencies can assist by improving surveillance efforts to capture relevant data on both short-and long-term health effects of cannabis. Our AMA supports the development of resources on the human health effects of cannabis and on methods for counseling and educating patients on cannabis and cannabinoid use (H-95.924).

AMA policy otherwise separates cannabis legalization for medicinal (D-95.969) or recreational use (H-95.924). AMA policy opposes state-based legalization of cannabis for medical use (whether via legislative, ballot, or referendum processes) and supports the traditional federal drug approval process for assessing the safety and efficacy of cannabis-based products for medical use. U.S. Food and Drug Administration (FDA) approved cannabinoid products include:

- Dronabinol (Marinol®) is an oral formulation (capsules) containing synthetic delta-9-tetrahydrocannabinol (THC) approved for the treatment of HIV-wasting and chemotherapy-induced nausea and vomiting when conventional treatments are inadequate; a liquified formulation (Syndros®) also is available.

- Nabilone (Cesamet®), a synthetic THC analogue that activates the endogenous cannabinoid type 1 (CB_1) receptor, is an oral formulation approved for the treatment of the nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments.

- Cannabidiol (CBD) oral solution (Epidiolex®) is approved for the treatment of seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, and tuberous sclerosis complex in patients one year of age and older. (Note: AMA Policy H-120.926, "Expedited Prescription Cannabidiol Drug Rescheduling," supports legislative and regulatory measures designed to expedite the availability of FDA-approved cannabidiol products and to reassert that patient access should be managed like other prescription-only products.)

- Nabiximols (Sativex®) is a 1:1 ratio of THC and CBD, extracted from specially bred cannabis plants and formulated as an oromucosal spray for the treatment of spasticity in patients with multiple sclerosis. This product is approved in 20 countries, including Canada, but remains investigational in the U.S.

Cannabis products that have not been approved by the FDA (but are marketed for human ingestion in many states) should carry the following warning label: "Marijuana has a high potential for abuse. This product has not been approved by the FDA for preventing or treating any disease process" (D-95.969). Hospitals and health systems also should not recommend the use of such products within their facilities and should educate medical staffs on cannabis use, its effects, and symptoms (withdrawal syndrome) that may appear in patients who abruptly discontinue use. AMA policy also recognizes that physicians may need to engage in a dialogue with their patients about cannabis/cannabinoid use, that such discussions are protected, and that physicians whose behavior conforms to state cannabis laws should not be subject to federal prosecution.

Our AMA also opposes legalizing the sale of cannabis for adult use and supports stronger public health messaging on the health effects of cannabis and cannabinoid inhalation and ingestion (H-95.924). States that have already legalized cannabis (for medical or legalized adult use or both)

should ensure that processes are in place to regulate the product to effectively protect public health and safety with an ongoing evaluation of their effectiveness. A "substantial portion" of tax revenues derived from state-based programs should be used for public health purposes including prevention and treatment of substance use disorders, the aforementioned cannabis-related educational programs, research on the health effects of cannabis use, and public health surveillance efforts.

The AMA also has policy on addressing synthetic cannabinoids and recognizing new psychoactive substances as a public health threat. The Council addressed these substances in detail in its 2017 report, Emerging Drugs of Abuse are a Public Health Threat. Synthetic cannabinoids are outside the scope of this report. Issues relevant to the regulation of CBD are covered in detail in the Council on Science and Health Report on dietary supplements (CSAPH Report 2) being considered at this meeting. As a result, issues related to CBD and are outside of the scope of this report.

Many medical societies in the Federation have taken positions that are consistent with AMA policy. The California Medical Association (CMA) is one exception. It is on record as urging the legalization and regulation of cannabis to allow for greater clinical research, oversight, accountability, and quality control.[7] CMA believes that the most effective way to protect the public's health is to tightly control, track, and regulate cannabis and to comprehensively research and educate the public on its health impacts, not through ineffective prohibition.[7] CMA policy also opposes policies of health plans, health systems, and hospitals with pain management programs that automatically eliminate patients who use therapeutic cannabis.

CANNABIS AND CANNABINOID PRIMER

In order to better understand certain issues surrounding cannabis, substances derived from the plant, their pharmacology, and implications for adult legalization, a brief review is provided.

Cannabis Plant

Cannabis sativa contains a complex array of chemical compounds, including more than 100 phytocannabinoids that are exclusively produced in cannabis, and more than 200 terpenoids (comprising "essential oils") which are responsible for the aroma of cannabis. Phytocannabinoids and terpenoids are synthesized in secretory cells inside glandular trichomes that are most highly concentrated in unfertilized female flowers.[8,9] THC is the most concentrated phytocannabinoid and the main psychoactive substance; delta-8-THC is similar in potency to THC, but is normally present in only trace amounts.[10] CBD, which possesses its own pharmacologic profile and lacks THC's intoxicating effects, and cannabinol are the other major phytocannabinoids; CBD is the most common phytocannabinoid in hemp (fiber) plants.

Other phytocannabinoids of pharmacologic interest include cannabichromene, cannabigerol, tetrahydrocannabaverin, and cannabidivarin.[11] These substances have their own pharmacologic profiles, effects of which are largely unstudied in humans.[11] Precursor acid forms of the neutral phytocannbinoids, that break down in the presence of heat, exist in the plant and may be available in concentrated forms in dispensaries in some states; other "secondary" phytocannabinoids isolates have become available as well.

Selective Mendelian breeding has created cannabis varieties (termed chemovars or chemotypes) with altered concentrations and ratios of phytocannabinoids and terpenes. General categories based on cannabinoid content have been described as THC-predominant (typical of legalized adult use marketplaces), "balanced" THC and CBD varietals, and CBD-predominant; some strains have been

created that are enriched in specific terpenes.[12] The average THC content of illicit cannabis samples confiscated in the U.S. increased from ~4% to 12% between 1995 and 2014.[13] The majority of advertised cannabis flower products with both state medicinal and legalized adult use programs now exceed 15% THC, and some exceed 20% in states with legalized adult use. Genetic engineering, either via genetic modification of plants or using recombinant DNA in microorganisms (yeast, bacteria, algae) also is being used to increase yields of THC or CBD, or of the lesser studied phytocannabinoids.[14] These developments have implications for both the traditional pharmaceutical industry and the legalized adult use marketplace, and for evaluating both the risks and harms of cannabis and cannabinoid use in the published literature over time.

Endocannabinoid System

Phytocannabinoids exert their effects, in part, via the endogenous cannabinoid (endocannabinoid) system. This system comprises two specific neuromodulators that are arachidonic acid derivatives [anandamide (AEA) and 2-arachidonoylglycerol (2-AG)], enzymes for their biosynthesis and inactivation, and two transmembrane, G-protein coupled cannabinoid receptors (CB_1, CB_2).[15,16] CB_1 receptors are enriched and widely distributed in the brain, and to a lesser extent in peripheral tissues, in a region specific manner.[17-20] See Figure 1 for a summary of the functions that have been associated with CB_1 receptors. Expressed mainly peripherally on circulating immune system cells, the spleen, macrophage derived cells, and the liver, CB_2 receptors are normally present in low concentrations in the brain (brainstem and hippocampus), but following injury or inflammation are upregulated in reactive microglia and astrocytes where they inhibit neuroinflammation.[15,18,20]

2-AG is an agonist at CB_1 and CB_2 receptors; AEA is a partial agonist at CB_1 receptors and largely inactive at CB_2 receptors. These substances act in a retrograde manner, being released from postsynaptic sites, migrating to presynaptic CB_1 receptors and inhibiting neurotransmitter release, dampening activity within discrete excitatory and inhibitory pathways.[19]

THC is a partial agonist at CB_1 and CB_2 receptors.[18,21] CBD is a partial agonist of the CB_2 receptor, although it also binds to and acts as an antagonist at other non-cannabinoid G-protein receptors. CBD also inhibits the uptake of AEA and its metabolism and activates TRPV receptors and $5HT_{1A}$ receptors. CBD has low affinity for CB_1 receptors, but in low concentrations is capable of functioning as an effective antagonist (or perhaps as a noncompetitive negative allosteric modulator) of THC and other 2-AG agonists.[22,23] Peripherally, activation of CB_2 receptors exerts anti-inflammatory and immunomodulatory effects, mobilizes hematopoietic stem cells, decreases gastrointestinal motility, and reduces visceral pain.

Disposition of THC and Cannabadiol Based on Route of Administration

Based on information obtained in pharmacokinetic studies of approved drug products, oral THC capsules (Marinol®) demonstrate low (6% to 20%) and variable bioavailability among test subjects. Gastric acidity causes some isomerization of THC to the delta-8-derivative and the drug is subject to a significant first pass effect. Peak plasma concentrations of THC are achieved within 1 to 6 hours, but may remain elevated for several hours.[24-27] Initially, THC is oxidized in the liver to 11-hydroxy-THC, a potent psychoactive metabolite, which undergoes further oxidation to the primary inactive (acidic) metabolite (THC-COOH). Although THC is cleared rapidly by the liver it has a very large volume of distribution (≈10 L/kg).[24] Thus, the terminal half-life of THC is on the order of 20 to 36 hours.[24,27] With chronic use, the limiting step for the terminal phase of elimination is redistribution from peripheral tissue storage sites.

Following inhalation, THC and CBD are rapidly absorbed into the blood stream and redistributed. Considerable amounts of the dose contained in one cigarette are lost in sidestream smoke and destroyed by pyrolysis.[24,28] Peak blood levels of THC and CBD are achieved at the end of smoking and then decline rapidly over the next 30 minutes.[24] The pharmacokinetics of vaporized and smoked cannabinoids are comparable; however, infrequent users report more pronounced effects with vaping than smoking.[29,30] Smoked or vaped cannabis is associated with much larger peak plasma THC concentrations, but a shorter duration of effect than orally administered THC. The time course of plasma concentrations after smoking or vaping marijuana is similar to that obtained after intravenous administration.[26]

Considerably smaller amounts of 11-OH-THC are formed when THC is inhaled, compared with the oral route.[24,31] After oral administration of THC, THC-containing edibles, or cannabis-based extracts, the concentrations of THC and 11-OH-THC are much lower than those found upon smoked administration, exhibit marked variability among various preparations, and are slower to reach a peak level; however, they are capable of causing comparable subjective effects and substantial impairment of cognitive/psychomotor functioning.[31-34]

RELEVANT FEDERAL LAW AND POLICY

Under the U.S. Controlled Substances Act (CSA) of 1970, marihuana remains classified as a Schedule I controlled substance, and the DEA and FDA have reinforced that interpretation, meaning it has no currently accepted medical use in treatment in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse.[35,36] The term "marihuana" means all parts of the plant *Cannabis sativa*, whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin.[37] As noted in the introduction, FDA has approved three cannabinoid-based prescription medicines

Council Report 5-I-17 discussed legal challenges, federal agency findings, and federal policy recommendations that were intended to manage the conflict between federal and state laws and emerging issues on medical or legalized adult use of cannabis. That discussion remains valid with a few notable exceptions and developments.

Early in the Trump administration, then-Attorney General Jeff Sessions rescinded existing Department of Justice guidance (the Cole Memorandum) that was intended to make clear that state-legalized cannabis was not an enforcement priority. In response, the House of Representatives approved spending bill amendments in both 2019 and 2020 to block the Department of Justice from using its funding to interfere with the implementation of state, territorial and tribal cannabis programs.

Also, in 2018, the Agricultural Improvement Act (the 2018 Farm Bill) was passed.[38] This law removed hemp from the definition of marihuana in Schedule I of the Controlled Substances Act, thereby legalizing the production of hemp under federal law. The bill defined hemp as any cannabis plant, including derivatives or extracts, that contains less than 0.3 percent of THC.[38]

STATE LAWS ON CANNABIS

At the state level, trends in law continue to move from legal prohibition, to decriminalization, to the legalization of medical use of cannabis, to cannabis legalized for adult use (commonly referred to as recreational use).[39-42] To varying degrees these trends have been shaped by arguments that cannabis is less harmful than alcohol and tobacco and may demonstrate certain health benefits; that

arrests and criminal convictions for cannabis possession are disproportionately harmful (including their effect on minoritized populations), and that legalization has the potential to eliminate the illicit market, enable regulation of use (including product potency and purity), reduce prison overcrowding, redistribute law enforcement activities, and raise government revenue.[43]

California (CA) was the first jurisdiction in the United States (U.S.) to legalize the use of cannabis for medical purposes in 1997. Today, 33 states, the District of Columbia (D.C.), Guam, and Puerto Rico have legalized the use of cannabis for medical purposes through either a legislative process or ballot measure.[39-42] As described in Council Report 5-I-17, these laws vary greatly by jurisdiction from how patients access the product (home cultivated or dispensary), to qualifying conditions, product safety and testing requirements, packaging and labeling requirements, the retail marketplace, and consumption method. In jurisdictions that have legalized cannabis for medicinal use, physicians can "certify" or "recommend" a qualifying patient for the medicinal use of cannabis, but physicians cannot prescribe cannabis for medical purposes because, as a Schedule I Controlled Substance, it is illegal under federal law. Eleven of these states (and four others without medical use of cannabis laws) have decriminalized and removed jail time for possession of small amounts of cannabis.[42]

In 2012, Colorado (CO) and Washington (WA) were the first U.S. jurisdictions to legalize the adult use of cannabis.[44,445] At this point, a total of 11 states and D.C. have legalized cannabis for adult use, ten through the ballot measure process, and two (Illinois [IL[and Vermont [VT]) via legislation.[39,41] As noted in the 2017 Council report, most of these jurisdictions have created for-profit, commercial cannabis production and distribution markets where the product is sold and taxed; Washington, DC (DC) and VT are exceptions. DC has adopted a "grow and give" model whereby residents are permitted to possess, use, grow, and give away cannabis, but they cannot sell it.[46] VT's adult use law, passed in 2018, also allows residents to possess recreational cannabis (1 oz) or grow up to six plants (only two mature at a time) but retail sales are currently not allowed.[47] Possession limits for adult use in other states range from 1 to 2.5 oz of usable cannabis flower, with most allowing variable numbers of plants, and limits on the amount of hash, solid or liquid infused products, or concentrates that can be possessed.[39] See Figure 2 for a timeline of legalization and actual implementation.

RETAIL MARKETPLACE: LEGALIZED CANNABIS FOR ADULT USE

As the marketplace for legalization of cannabis for adult use has grown dramatically, an expansive retail environment has developed with "novel cannabis products, formulations and methods of administration."[48] Different formulations (extracts, concentrates) of cannabis have emerged that can be smoked, vaporized, or used to create (infused) edibles (e.g., gummy bears, lozenges, candies, lollipops, brownies/cookies/other foods, and beverages), tinctures and oils for consumption , as well as topicals.[49,50] Extracts are a type of concentrate formed by using solvents to wash the cannabinoid-rich trichomes off the plant and remove phytocannabinoids and terpenes. Hydrocarbons (e.g., butane, propane), ethanol, or supercritical fluid extraction using CO_2 are the most common approaches.[50] Depending on the method, the resulting concentrate comes in various forms (e.g., waxes, shatter, resin), that can be further processed into various textures (e.g., budder, crumble, honeycomb). Concentrates made without the use of solvents are produced using mechanical or physical means to remove and gather trichomes (e.g., hash, kief, rosin). Some dispensaries also feature products enriched in other phytocannabinoids, most commonly CBD, cannabinol, cannabigerol, or tetrahydrocannabinolic acid (THCA) and products that are enriched in certain terpenes.[48] See Table 1 for a graphic display and description.

THE HEALTH EFFECTS OF CANNABIS AND CANNABINOIDS

The National Academies of Sciences, Engineering, and Medicine (National Academies, NASEM) published a comprehensive report in January 2017 commissioned by federal, state, philanthropic, and nongovernmental organizations, entitled "The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and the Recommendations for Research."[51] The report's recommendations outline priorities for a research agenda and highlight the potential for improvements in data collection efforts and enhanced surveillance capacity.[6]

The report contained 98 conclusions based on the accumulated evidence related to cannabis or cannabinoid use and health.[56] It examined a broad range of possible health effects of cannabis and cannabinoids. Health effects examined included those related to cancer; cardiometabolic risk; respiratory disease; immunity; injury and death; prenatal, perinatal, and neonatal exposure; psychosocial and mental health; problem cannabis use; and cannabis use and the misuse of other substances. The findings were organized into 5 evidence categories: conclusive, substantial, moderate, limited, and no/insufficient evidence.

Health Uses: The report found conclusive or substantial evidence that cannabis or cannabinoids are effective: (1) as antiemetics in the treatment of chemotherapy-induced nausea and vomiting (oral cannabinoids); and (2) for improving patient-reported multiple sclerosis spasticity symptoms (oral cannabinoids); and (3) for the treatment of chronic pain in adults (cannabis).

The report found moderate evidence that use of cannabis or cannabinoids: (1) are effective in improving short-term sleep outcomes in individuals with sleep disturbance associated with obstructive sleep apnea syndrome, fibromyalgia, chronic pain, and multiple sclerosis (cannabinoids, primarily nabiximols); (2) are associated with improved cognitive performance among individuals with psychotic disorders (history of use).

The report also found substantial evidence of a statistical association between cannabis smoking and: (1) more frequent chronic bronchitis episodes (long-term cannabis smoking); (2) increased risk of motor vehicle crashes; (3) lower birth weight of offspring (maternal cannabis smoking); (4) the development of schizophrenia or other psychoses, with the highest risk among the most frequent users; and substantial evidence that initiating use at an earlier age and smoking cigarettes (males) as risk factors for progression to problematic cannabis use.

The report found moderate evidence of a statistical association between cannabis use and: (1) increased risk of overdose injuries, including respiratory distress, among pediatric populations in U.S. states where cannabis is legal; (2) impairment in the cognitive domains of learning, memory, and attention; (3) a number of mental health domains including increased symptoms of mania and hypomania in individuals diagnosed with bipolar disorders (regular cannabis use); small increased risk for the development of depressive disorders; increased incidence of suicidal ideation and suicide attempts with a higher incidence among heavier users; increased incidence of suicide completion; and increased incidence of social anxiety disorder (regular cannabis use).

In general, the findings and conclusions of this report remain valid. Two additional comprehensive systematic reviews have been published since the NASEM report. A review on cannabis-related harms was in substantial agreement with the NASEM report.[52] This study also called attention to increased cardiovascular risks associated with cannabis use, prenatal exposure and cognitive dysfunction/behavioral disturbances in offspring, and hyperemesis syndrome. Case studies have linked cannabis use to acute myocardial infarction, cardiac arrythmias, cardiomyopathies, stroke, and arteritis, mostly in younger men with few cardiovascular risk factors.[53] A scientific statement

issued by the American Heart Association in August 2020 warned that cannabis use may be linked to an increased risk of heart attacks, atrial fibrillation and heart failure.[54] A recent retrospective analysis of nationwide inpatient data found that cannabis use was an independent predictor for acute myocardial infarction-related hospitalization in adolescents and young adults.[55] The other review used evidence mapping and appraisal to evaluate published studies on the therapeutic benefits of cannabis and cannabinoids. This study also was in substantial alignment with the NASEM report.[56]

PUBLIC HEALTH IMPACTS OF STATE LEGALIZATION OF CANNABIS

Despite the fact that 11 states and D.C. have now legalized the adult use of cannabis, evaluation of the impacts of legalization on health and safety remain somewhat limited. Retail sales have not commenced in ME, and are not allowed in VT and D.C. Insufficient time has elapsed since retail sales commenced in some states (e.g., IL, Michigan [MI], Massachusetts [MA]) to get meaningful results and/or a state program for formal analysis of post-legalization effects has not been created. Importantly some states established a framework for future analysis by evaluating and compiling various baseline measures (pre-legalization) to be used for comparison (e.g., OR, MI, MA).

Otherwise, CO [through its Department of Public Health and Environment (CDPHE) and appointed Retail Marijuana Public Health Advisory Committee (RMPHAC)] and WA [in partnership with the Washington State Institute for Public Policy (WSIPP)], and two other states (OR and AK), lead the way on having examined state-specific health and safety outcomes and patterns of cannabis use since legalization. State-based data and surveys, as well as national surveys such as the Substance Abuse and Mental Health Services Administration's (SAMHSA) National Survey on Drug Use and Health (NSDUH) and the Center for Disease Control and Prevention's (CDC) Behavioral Risk Factor Surveillance System (BRFSS), Monitoring for the Future (MTF) and Pregnancy Risk Assessment Monitoring System (PRAMS) have been relied on. Where available larger, state representative surveys that have been implemented longitudinally may be more relevant on certain measures.[57]

General issues being examined include the impact of legalization for the adult use of cannabis on:

- patterns of use by children and adolescents, college and university students, other adults, and pregnant women. In youth, monitoring changes in the perceived risk and social acceptability of cannabis and cannabis advertising also has been emphasized;
- incidents of impaired driving and traffic fatalities;
- cannabis-related hospital or emergency department visits and other cannabis-related (toxic) exposures;
- changes in the incidence, costs and treatment for mental health disorders, including treatment admissions for cannabis use disorder;
- effects on the market for alcohol and other drugs;
- criminal behaviors (including civil penalties, arrests, prosecution and incarceration); and, government revenues and costs of implementing legalization.

Considerable attention also has been devoted to the association between medicinal and/or legalized adult use and opioid-related measures and outcomes.

CO has the most extensive state-based data. Their findings are emphasized for some topics, buttressed with comparable data, where available, from other states that have legalized cannabis for adult use.

General Age-Related Patterns Use

In the U.S., the most commonly used illicit drug (based on federal status) in the past year among those aged 12 or older was cannabis, totaling approximately 43.5 million people or 15.9% of the population; nearly 44% of this group are of past month users.[58] The overall prevalence of cannabis use in the U.S. has increased steadily since 2011 (38% increase), accounted for mostly by increased use among young adults aged 18-25, and adults 26 years of age and older. Annual cannabis use is at historic highs (42.5%) since 2013 among 19-22 year-olds (both college and non-college peers).[59] In 2016, 43% past-month cannabis users who were 18 years and older reported daily or near-daily cannabis use (20 or more days per month), a 30% increase since 2002. This pattern of use declined about 23% in adolescents over the same time period. According to the 2019 MTF survey, there has been an uptake in daily use among younger students (grades 8 and 10) since 2017.[60] Based on the BRFSS, daily use of cannabis in adults in CO has increased from 6% in 2014 to 9% in 2018, but the methods of use in CO adults have remained fairly constant.[61]

Adolescent use has declined nationally since 2011, remaining fairly steady from 2015 to 2018.[58] Combined NSDUH data for 2017-18 suggest that 6.5% or 1.6 million adolescents (12-17 years old) were current (past month) users of cannabis. The prevalence of past month use in this survey was higher than the national average in CO (9.36%) as well as all other states with legalized adult use; six of these states (WA, VT, OR, MA, Nevada, ME) and DC showed increased adolescent use according to NSDSUH, contrary to the national trend.[58,62]

A nationally representative survey of U.S. adults aged 18 years or older using KnowledgePanel concluded that prevalence of past-year use of any form of cannabis is more common among in states with legalized adult use (20.3%) compared with use in medically legal states (15.4%), and nonlegal states (11.9%).[63] Perceptions of risk from using cannabis also have continued to decrease. An analysis based on the National College Health Assessment survey also concluded that cannabis use has accelerated to a greater degree among students who attend colleges in states with legalization of cannabis for adult use.[64]

When examining high school students specifically, state surveys have found higher rates of use and different trends than national surveys. CDPHE in conjunction with the Departments of Human Services and Education conducts the statewide Health Kids Survey. In 2019, the overall current or past 30-day marijuana use prevalence among CO high school students was 20.6% (slightly lower than national estimates based on the Youth Risk Behavioral Survey) but not increasing.[65] Similarly, according to the Healthy Youth Survey, past month cannabis use across grades 10 and 12 in WA state has deceased since the legalization of the adult use of cannabis, but the prevalence (~18%) is higher than estimates from national surveys.[66] The OR Health Authority Survey found similar trends (reduced use since legalization) among students in grade 11.[67]

Although adolescents who use cannabis still prefer smoking, recent changes in the usual methods of marijuana consumption have been documented with the prevalence of dabbing and vaporizing of concentrates increasing in CO, a pattern reflected across other parts of the country.[68] Data from the online international cannabis policy study conducted in 2018 among 16-19 year-olds found that the prevalence of past 30-day vaping of cannabis was 13.8%. Nearly one-third of these users in the U.S. reported vaping cannabis oil and consuming THC solid concentrates such as wax and shatter.[69]

These reported increases in the vaping of THC oil as a method of consumption are concerning given the CDC's investigation on the national outbreak of lung injury associated with the use of vaping products.[70] Among the cases or deaths reported to CDC (in which substance use was

available), 82% reported using THC-containing products, 33% exclusively. Sixteen percent reported acquiring products only from commercial sources (recreational and/or medical dispensaries, vape or smoke shops, stores, and pop-up shops); most others were obtained from family/friends, dealers, online, or other sources.

Increases that have been reported in daily (or near daily) use and changes in consumption patterns with the use of more concentrated products also presents cause for concern. Respondents who report using cannabis daily consume almost twice as much per day compared with those reporting less frequent use.[71] In adolescents with no history of heavy cannabis use, the use of cannabis concentrates is associated with progression to persistent use, more so than the use of other cannabis products.[72] As noted in CSAPH Report 5-I-17, adolescents are of particular interest in cannabis-policy discussions because the negative health effects of the drug are heightened when use begins in adolescence. In addition to health effects, including the increased risk of cannabis use disorder, evidence also suggests that cannabis use in adolescence and early adulthood is associated with poor social outcomes, including unemployment, lower income, and lower levels of life and relationship satisfaction.[73-75]

Use among Pregnant Women

Cannabis is the most commonly used (illicit) drug during pregnancy, and THC crosses the placenta and is found in breast milk.[76] Endocannabinoids play an important role in fetal neurodevelopment and in postnatal synaptic plasticity. Preclinical and emerging human evidence suggests that prenatal exposure to cannabis may "lead to subtle, persistent changes in targeted aspects of higher-level cognition"[77] and neurobehavioral outcomes in children. However, real world evidence is limited to three longitudinal cohorts, with different designs and outcomes, all of which were initiated at a time of much lower (average) THC exposure from cannabis.[78-80] Additionally, epigenetic effects of THC have been described.[81]

The American College of Obstetricians and Gynecologists updated its committee opinion in 2017 reaffirming that prenatal exposure is associated with low birth weight and discouraging physicians from suggesting the use of marijuana during preconception, pregnancy, and lactation.[76,82-84] Effects on low birth weight are independent of maternal age, race, ethnicity, level of education and tobacco use during pregnancy.[82] Infants exposed to cannabis in utero also may be more likely to end up in the NICU or experience preterm birth.[83,85]

Overall, based on NSDUH, cannabis use during pregnancy has doubled over the last 15 years with 7.0% of pregnant women between the ages of 18 and 44 years reporting past-month cannabis use in 2017 compared with 3.4% in 2002; daily or near daily use more than tripled (0.9 to 3.4%).[86] The majority of use was described as "non-medical" and is most prevalent during the first trimester. Pregnant women may use cannabis to help with nausea or to improve mood, are more likely to perceive it as natural and safe, and are unsure or unaware if cannabis is addictive or if risks are associated with prenatal cannabis use.[87]

Compared with 2014, PRAMS data for CO showed that among new mothers in 2018, 16.5 percent used cannabis prior to pregnancy (47% increase), 8.2 percent used cannabis during pregnancy (44% increase), and 7.9 percent of breastfeeding mothers used cannabis after delivery (160% increase), all substantially higher than national averages.[88] Umbilical cord sampling for cannabis metabolites detected prenatal use at an even higher rate than self-reported values.[89] Cannabis use during pregnancy in CO was statistically higher among women with an unintended pregnancy (12.5%) than among women who intended to become pregnant (4.5%). When cannabis use during pregnancy was compared among different demographics, both education and age showed statistical

differences, whereas race and ethnicity did not.[88] Across three states (AK, CO, WA) that had legalized adult use by 2016, women were more likely to use cannabis during preconception, during the prenatal period, and postpartum, compared with states without legalized adult use.[90] Clinicians can "play a key role in preventing harms associated with cannabis use in pregnancy by educating patients about the potential risks of frequent use, advising all patients who are pregnant to quit cannabis use, and providing patients with safe and effective medically approved ways to improve mood and treat nausea and vomiting in pregnancy."[91]

Impaired Driving

A serious consequence of legalizing cannabis for adult use is an increase in traffic crashes and fatalities. Although it is well established that acute THC intoxication impairs driving, CSAPH Report 5-I-17 explained some of the complexities involved with correlating blood concentrations of THC with driving impairment and outcomes, and in establishing legal standards. Unlike alcohol, there is poor correlation between blood or other fluid concentrations of THC or its metabolites and when the cannabis product might have been consumed, and behavioral effects or field sobriety or functional tests for cannabis/THC have not been validated. In CO, about 1 in 5 adults with past month use report driving within 2-3 hours after consumption, a value that has not increased with legalization of cannabis for adult use.[92] In WA among those 18-25 years of age reporting past year cannabis use, more than 40% reported driving with 3 hours of use at last once, with 1 in 7 reporting such driving on at least 6 occasions.[93]

In CO and WA, the THC blood limit for an inference of driving impairment is 5 ng/ml in those 21 and older; any detectable amount is considered a violation in individuals less than 21 years of age. Between 2013 and 2018, there has been an increase in traffic deaths in CO in which drivers tested positive for cannabis and an increase in the percentage of all traffic deaths that were presumed to be cannabis related.[94]

Based on an analysis of traffic fatality rates through 2018 obtained from the most recent report of the National Highway Traffic Safety Administration's Fatality Analysis Reporting System, legalization was associated with an increase in traffic fatalities compared with the 5 years preceding legalization among the first 4 states to legalize adult cannabis use (CO, WA, OR, and AK).[95] These states are the only ones that have legalized adult use for which there are at least 2 full years of traffic fatality data available following the opening of retail stores. On a national scale, this rate would translate to an excess 6800 deaths. The calculated rate in this study was comparable to the rate reported after commercialization of retail sales in a previous study of traffic fatalities in CO and WA.[96] Another recent study that examined data through 2017 and extended the comparison period to 2005 found that traffic fatalities increased (at a lower rate than above) in CO but not WA.[97] A trend for increased fatalities also may exist in neighboring jurisdictions.[98]

Cannabis-Related Exposures

Cannabis-related exposures generally refer to the number of human exposures related to either accidental/unintentional or excessive/intentional consumption or inhalation of cannabis and cannabis edibles. Some of these may end up as calls or reports to Poison Control Centers, emergency department visits (which also may report to Poison Control), or hospitalizations.

<u>Poison Control</u>. The number of calls to Rocky Mountain Poison and Drug Safety (serving CO) with a cannabis mention increased five-fold from 2006 to 2017, stabilizing between 2014 and 2017, when 222 reports occurred, and then increasing somewhat again.[99] Between January 2017 and June 2020, 973 exposures were reported by healthcare facilities and residences, mostly edibles (44.9%),

followed by the cannabis plant (29.1%) and concentrates (10.7%). Reporting rates for these substances have remained mostly unchanged since the middle of 2018. Patients ≤5 years old accounted for one-third of these reports, and those 6 to 12 years of age accounted for 9%.[92] In CO, there has been a significant increase since 2014, from 6.9% to 11.2%, in the percentage of homes with children 1-14 years old that reported having cannabis or cannabis products in or around the home.[100] It is estimated that approximately 23,000 homes (or 22.4%) in CO with children 1-14 years old had cannabis in the home with potentially unsafe storage, a rate that has increased 60% since 2014.[100]

Since retail sales opened in WA in 2014, calls to the WA State Poison Control Center involving cannabis in 2018 have more than doubled from 245 to 497; reports in children ≤5 years of age tripled from 34 to 94 (18.9% of total), and those in children 6-12 years of age more than doubled to 31 (6.2% of total).[101] Thirty-two percent of cannabis exposure calls involved edibles. Because of these trends, particularly among young children, a new logo was required in 2017 on all cannabis edible packaging (Figure 3). After increasing from 2013-2016, calls reported to OR poison control decreased in 2017 and then started increasing again in 2018; approximately 20% of cannabis exposures in 2017 were in children aged 5 years and under.[102]

Finally, a recent analysis of all 50 states from 2010-2017 found that an increase in cannabis exposures reported to the U.S. National Poison Data System occurred after commercialization (retail sales) in states with legalized adult use.[103] The overall magnitude of the increase was 67-77% relative to the pre-legalization average, depending on the composition of comparison states. The relative increases were higher in minors, males, and among those who were classified as suffering medical consequences.

<u>Cannabis-Related Emergency Department Visits and Hospital Admissions</u>

In addition to emergency department visits and sometimes hospitalizations for unexpected pediatric exposures to cannabis, emergency department visits and hospitalizations can be prompted by acute intoxication leading to drowsiness/lethargy/confusion, dizziness/vertigo/ataxia, psychotic symptoms, agitation or anxiety, and extreme tachycardia or other cardiovascular events.[102] Chronic use, especially of high potency derivatives, can lead to hyperemesis syndrome, which may require treatment for intractable vomiting, dehydration, and electrolyte abnormalities.[104] In individuals with a *history* of recreational use, the most common reasons for hospitalization were alcohol and drug rehabilitation or detoxification and psychological/psychiatric evaluation.[105]

In an informative analysis, the CO Department of Public Health analyzed rates of cannabis exposures, diagnoses, and billing codes from 2000 to 2016 per 100,000 hospitalizations.[92] From a baseline rate of 575/100K, hospitalization rates increased steadily to 894/100K when medical cannabis was legalized but not commercialized (2001-2009), experiencing another significant jump to 1,440/100K during the commercialization of medical cannabis (2010-2013), and further increasing again to 2,696 possible cannabis-related hospitalizations per 100,000 during the initial commercial phase of legalized adult use (2014-Sept 2015). An updated analysis indicates that the yearly number of cannabis-related hospitalizations doubled after the initial year of legalized adult use (2013) compared to with 2017.[106] Similar trends were noted in a study of cannabis-related hospitalizations from 2002-2016, a time period covering major changes in WA state policies and marketplace for medical cannabis, legalization for adult use, and then the initial period of retail sales.[107]

Cannabis Use Disorder and Related Treatment Admissions

A proportion of people who initiate cannabis use eventually meet the criteria for cannabis use disorder (CUD), although the estimated prevalence varies widely depending on the diagnostic criteria and sampling methods that were used. Nevertheless, CUD influences key brain responses and functions relevant to substance use and it manifests as other substance use disorders based on the reinforcing properties of THC, regardless of method of use or formulation.[108]

Epidemiological data indicate that "the majority of those who use cannabis do not have problems related to their use, but a substantial subset of people (using cannabis/THC) do report experiencing symptoms and consequences consistent with a CUD."[109] Data from the National Epidemiologic Survey on Alcohol and Related Conditions (NESARC) study indicate that the past year prevalence of DSM-IV cannabis abuse and dependence doubled from 1.5% in 2001-02 to 2.9% in 2012-13.[110] A similar analysis of NSDUH data (DSM-IV criteria) concluded that past year prevalence was relatively unchanged over the same time period (1.6-1.5%).[111] The disparate findings likely reflect differences in sampling methods (live interview versus online survey) and changes in societal norms over time which may influence respondents.[112] Again, depending on the method, between 11% (NSDUH, 2016) and 30% (NESARC, 2013) past-year cannabis users met DSM-IV criteria for cannabis abuse or dependence.[110,112] A recent meta-analysis using DSM-IV or ICD-9 criteria estimated that individuals who use cannabis have a 1 in 5 risk of developing cannabis abuse or dependence and risks increase if cannabis is initiated early and used frequently.[113] Other data suggest that in individual populations, the prevalence of cannabis abuse or dependence roughly doubles for those who initiate use before 17 years of age, and is much higher for adolescents who use weekly or more often.[114] Among youth and emerging adults in the U.S., prevalence of cannabis use and dependence appears to increase with time since initiation of use. This increase appears to be steeper for youth than emerging adults. The adjusted 12-month prevalence among youth with lifetime cannabis use ranged from 10.9 in the first year after starting cannabis use, increasing in each year to 20.6% in the fourth year and beyond. Values for young adults (aged 18-25) were lower at all times and increased at a lower rate eventually reaching about 10% four years after initiaition.[115]

A few previous studies examining the effects of state medical cannabis laws on CUD found mixed results.[116,117] A study in CO, WA, OR, and AK based on NSDUH surveys from 2008 to 2016 found a small increase in past year cannabis abuse and dependence among respondents aged 12 to 17 years, and more significant increases in frequent use and abuse or dependence among adults 26 years or older.[118] One look back study of the 2012-2014 NESARC study using DSM-5 criteria for CUD estimated that the prevalence of 12-month and lifetime CUD were 2.5% and 6.3%, respectively.[119]

In summary, most of the published longitudinal trends on cannabis use disorder are based on DSM-IV criteria for cannabis abuse and dependence, which were combined into one set of diagnostic criteria for DSM-V. The DSM-V criteria for CUD perform similarly to other substance use disorders. Although little is known about how legalization of cannabis for adult use will impact CUD, the availability of high potency products, easy access (cost and proximity), methods of use that are more appealing than smoking, decreased perceptions of risk, and changes in social norms and marketing, all point to a need for vigilance in this area.

Treatment Admissions

Treatment-seeking for CUD comprises a substantial proportion of all substance use treatment admissions. In 2017, cannabis remains by far the most common substance in adolescents seeking treatment; more than 70% percent of publicly funded treatment admissions in individuals aged 12 to 17 years were for primary cannabis use.[120]

Total publicly funded substance use disorder treatment admissions in the U.S. declined about 0.7% from 2007-2017 (see the Treatment Episode Data Set [TEDS-A]).[120] The proportion of cannabis admissions aged 12 years or older increased from 16% in 2007 to 19% in 2010, before declining to 13% percent in 2017. The average age at admission was 27 years among admissions for primary use of cannabis. Non-Hispanic Whites represented 42 percent of admissions, 31 percent were non-Hispanic Blacks, and 20 percent were of Hispanic origin. Consistent with the national picture, cannabis-related treatment admissions in WA declined in the three years following legalization of adult use 2012-2015.[121] In AK, among the approximately 6,800 total people who received public-paid substance dependence treatment in 2018, about 8% (550) received primary treatment for cannabis use disorder, similar to the proportion from 2016-17.[122] In CO, the overall treatment admission rate for those reporting cannabis as the primary drug has decreased every year from 2012-2017, except for a brief uptake in 2014-15 in those 21 years and older.[94]

Opioid Use

Increases in unintentional overdoses and deaths due to illicit fentanyl, heroin and prescription opioids remain the biggest drivers of the unintentional overdose death epidemic.[123] Nearly 70% of the 67,367 deaths in 2018 involved an opioid.

Several ecological or epidemiological studies and convenience survey samples have reported population-level associations between the existence of state medicinal cannabis laws and reductions in opioid-related morbidity/mortality, reduced opioid prescribing in Medicaid and Medicare enrollees, as well as subsets of privately insured individuals, self-reported reductions in opioid use (and risks) among medical users (i.e., substitution of cannabis), and intersections between cannabis use and opioids among drivers, including fatalities.[124-132] Effects of medical cannabis laws on reducing opioid prescriptions and dampening increases in opioid-related deaths have been linked, in part of the presence and density of dispensary distribution within states.[126,132]

A review of 25 such studies concluded:[133]

- States that with medical cannabis laws have reported a slower rate of increase in opioid overdose deaths which has persisted over time. Findings are strengthened when controlling for operation of state prescription drug monitoring programs and demographics which also influence patterns of use. The relative contribution of treatment for opioid use disorder in such states is not understood.
- Some epidemiologic and ecological studies provide evidence that cannabis availability may reduce opioid use and/or harms. Some of these studies are "limited by selection bias, cross sectional designs and reliance on self-reported assessments of the opioid sparing effects of cannabis."

While cannabis availability may reduce opioid consumption, based on urine drug testing in patients on chronic opioid therapy, legalization of the adult use of cannabis led to a small increase in positive cannabinoid test results, but compliance with opioid therapy was unaffected.[134] Additionally, in a cross-sectional study of toxicological testing data of drivers from the 2011–2016 Fatality Analysis Reporting System (FARS) and the 2013–2014 National Roadside Survey of

Alcohol and Drug Use by Drivers (NRS), drivers who tested positive for marijuana were significantly more likely to test positive for prescription opioids.[135]

CO's legalization of the adult use of cannabis resulted in a significant slowing of the upward trend in opioid-related deaths in 2015 after retail sales were initiated.[136] This turned out to be a short-term effect as deaths accelerated again in 2016 and 2017. A more recent study of states with medical cannabis laws and with legalized adult use confirmed previous findings of lower prescription rates in Medicare Part D enrollees, with incremental additional deceases in opioid prescribing in states with legalized adult use.[137] In another study of Medicaid recipients from 2010-2017 among states and D.C., where adult use had been legalized, prescriptions for Schedule III, but not Schedule II opioids were significantly reduced.[138]

Overall, "it remains unclear whether the presumed benefit of legalizing marijuana in reducing opioid-related harms outweighs the policy's externalities, such as its impact on mental health and traffic safety."[132]

Social and Criminal Justice

AMA policy supports decriminalization of cannabis (i.e., reduction in the penalty associated with possession of a small amount of cannabis from a criminal offense subject to arrest to a civil infraction), a view also held by the American Academy of Pediatrics.[139] Legalization of adult use allows cannabis and cannabinoid products or their legal sale and the removal of all penalties for possession of small amount of cannabis.

Criminal arrest. One large multistate comparison found that between 2000 and 2016, decriminalization substantially reduced adult and youth arrest rates for cannabis possession (less so for youth), but adult legalization had little or no impact on youth arrest rates.[140] A related outcome that is highly relevant is "whether cannabis legalization can be used to promote social equity and help communities of color that have been and still are disproportionately affected by prohibition."[141]

Arrests for cannabis violations have decreased dramatically in states with legalized adult use, falling 90-99% in AK, WA, OR and D.C.[142] In WA, a study that included data only through the initial period of legal adult sales, found that cannabis arrest rates among both African American and White adults decreased significantly and stayed at a dramatically lower rate after the marijuana retail market opened. Cannabis accounted for nearly half (47%) of all criminal drug use cases processed in calendar year 2012 in WA, a number which dropped dramatically to about 12% of all drug cases handled by the police by 2016.[143]

However, relative disparities in cannabis arrest rates for Blacks increased for those of legal age, and remained unchanged for younger adults.[144] Another study in OR found that adult cannabis legalization was associated with an increase in juvenile cannabis allegations, although relative disparities decreased for Black compared with White youth.[145] AK also reported a modest increase in the number of youth who have been referred to juvenile justice systems for cannabis offenses since 2016.[146] Juvenile offenders engage in both cannabis use and polysubstance use at higher rates than the general adolescent population.[147]

Crime Rates. Cannabis laws more broadly, and the legalization of recreational marijuana more specifically, had minimal effects on violent or major crime in CO or WA or on property crime rates through 2015, except for a decline of burglary rates in WA.[148] This contrasts with reports from the CO Bureau of Investigation of modest upticks in property crimes and a more significant increase in

violent crimes beginning in 2016-2018.[94] Legalization for adult use was associated with increased resolution of serious crimes in WA even though crime rates were steady as policy devoted more resources to their clearance.[143]

Expungement of Prior Cannabis Related Arrests and Convictions. Even with legalization of cannabis for adult use, for those who have a cannabis-related criminal record for a minor offence, the damage persists. Eight states have created a pathway for expungement although it is usually limited to possession, and may have other limiting conditions (e.g., waiting period, no other criminal convictions, petition hurdles).[142] IL included automatic expungement for convictions of possessing 1 oz or less in its bill; individuals can initiate the process and cases are being identified by law enforcement searches; more than 11,000 have been pardoned.

Social Equity in the Legal Cannabis Business. Some states have established social equity programs to encourage and enable participation (based on a set of criteria) in the cannabis industry by people from communities that have previously been disproportionately harmed by cannabis prohibition and enforcement. MA provides free, statewide, technical assistance, and a training program that provides education, skill-based training, and tools for success in the cannabis industry to applicants; about 4% of cannabis applications in MA were from self-identified minorities.[149] IL offers technical assistance and support in creating a business plan and applying for a license, and also established lower thresholds for license approval, lower fees and access to low interest loans.[150] IL also has its "Restore, Renew, Reinvest" program for communities that have been adversely affected by past prohibition efforts. MI offers substantial discounts on applicant, license and permit fees while expanding eligibility to persons with prior cannabis infractions.[151] Certain other states (e.g., OR) also have eliminated prior cannabis convictions as a disqualification. CA established a "Community Reinvestment Fund" to support communities disproportionately affected by past federal and state drug policies.

Governmental Costs and Revenue

The legalization and commercialization of cannabis results in revenue for states through taxes and fees, but it also comes with costs, both in regulating and enforcement actions and in protecting public health and safety. Of the 9 states with active retail sales, six employ cultivation levies on growers, while all but AK charge an excise tax specifically on cannabis sales. Seven states also charge a general sales tax and/or allow a local option. Once these laws are fully implemented, legalized adult-use cannabis programs have generated significant annual sales that continue to trend upward annually, yielding surpluses from taxes and fees after accounting for the costs to administer the program. States have implemented adult-use regulatory programs for as little as $1.8 million (AK) up to $60 million for CA (medical and adult use together). For a summary of state administrative agencies, possession limits for legalized adult use, tax rates, recent tax revenues, and administrative costs see Table 2. In some states (e.g., MA) dispensaries for legalized adult use were closed for a period of time during early phases of the COVID-19 pandemic. While the creation of legalized adult use programs leads to reductions in the number of authorized medical users, the number of medical marijuana patients increased by thousands in MA during COVID closures.

How states distribute their cannabis tax revenues also is of interest. Virtually all states allocate a portion of funds for various cannabis/substance use treatment and education efforts.[152]

DISCUSSION

The last 20 years have seen a evolution in state laws increasing access to cannabis and cannabis products to the point where two-thirds of the country now have medical cannabis laws, 11 states

among this group and D.C have legalized the adult use of cannabis, and the other one-third have passed laws allowing the use of CBD in some way; Federal regulations also are now permissive for the use and marketing of certain CBD products.

In trying to evaluate public health impacts in states that have legalized cannabis for adult use, it is important to understand that state retail markets are in different developmental phases to becoming fully established, a process measured in terms of years. All of these states had preexisting, established medical cannabis programs, some more robust than others, especially the states (CO, WA, OR, and to a lesser extent AK) that have provided the most evidence to date. Many studies of the public health impacts of medical cannabis laws exist (and over a longer time period), so it is relevant to question what the appropriate comparison "group" is, especially for states with more recent movement into legalized adult use. In most studies this has been the pre- and post-legalization periods. Some states have set up a process to accomplish this, aided by development of detailed baseline analyses. It is tempting, but premature, to infer that what has happened in the earlier adopter states will be generalizable to other states that have subsequently begun retail sales. One thing that is common is the expansive array of cannabis varietals and novel cannabinoid products and formulations that have been developed, some at very high concentrations, accompanied by an array of administration routes and methods, some posing more health risks to users than others.

As reviewed in this and other reports on this topic, use of cannabis and cannabinoids are associated with some therapeutic benefits, as well as a range of harms and risks of social consequences. In particular, research into the possible therapeutic uses of cannabidiol is in an expansive phase. Harms and risks of social consequences are much more prevalent in the subset of users with generally recognized risk factors including initiation of use at younger ages, high intensity (i.e., frequency and potency) and mode of use.[153] A major difficulty in understanding impacts, risks and benefits of these substances under the umbrella of legalization is the substantial change in potency of products that has occurred over the years, and the range of products now available.

Nationally, cannabis use has increased in the U.S. among 18-25 year-olds, and adults 26+ but decreased in adolescents. Legalization has not significantly impacted recent patterns of adolescent use, but in the fastest growing demographic (18-25 year-olds), the eight states with highest prevalence of past month use are among those that have legalized adult use (ranging from 30.44% in WA to 37.67% in VT).[57] Although not specific to states with legalized adult use, it will be important to monitor recent changes in products used, methods of consumption, and intensity of use, as these are predictors of several harmful outcomes.

Cannabis use in pregnant women has doubled, and women in states with legalized adult use (by 2016) were more likely to use cannabis during preconception, pregnancy, and postpartum. It also seems clear that individuals who use cannabis, particularly younger adults, are driving under the influence of cannabis or cannabis products at a fairly high rate, that such use is associated with traffic accidents and fatalities, and these occur in higher rates in states with legalized adult use.

A robust finding has been the association of legalized adult use with an increase in reported poison control exposures and cannabis-related hospitalizations. Depending on the state, ingestion is the most common route for these exposures, with 20-33% of these reports involving children under the age of 5. In WA, the median age of children (range 0-9 years) was 2 years (2010-2016).[154] In one study involving a children's hospital in CO, the median age also was 2 years with about half of the exposure due to edibles, usually obtained by the child either due to lack of child-resistant packaging (at the time), poor child supervision or inadequate storage.[155] All states should educate the public in this area and require packaging that is child proof, conveys a meaningful and easily

understood unit of consumption, and that clearly differentiates the cannabis edible from food. Incremental increases in cannabis-related hospitalizations have been associated with both medical cannabis laws and legalization of adult use.

Publicly reported trends in cannabis use disorder and treatment admissions have lagged behind changes in consumption patterns. One would expect increased intensity of use and administration of higher concentrations to eventually become evident. Substantial research into the intersections of cannabis laws and various measures of opioid use and harm has largely been limited to medical cannabis laws; the impact of legalization for adult use, over a sufficient time period is only now being examined. Any protective effects of cannabis availability in this area is probably more than offset by impacts on mental health, cannabis use disorder, driving accidents, and other consequences of cannabis use requiring healthcare and community resources.

Legalization of cannabis for adult use has led to a large decrease in cannabis-related arrests for adults, but racial disparities still exist, especially in youth, where possession and use are still illegal. Overall effects on crime rates appear to be neither protective nor provocative. Some states have set up processes for expungement of prior cannabis-related convictions, mostly with limited success because of cumbersome processes that may interfere with successful minority participation. Some states have also set up specific programs to advance participation in the cannabis industry by people from communities that have been disproportionately harmed by previous prohibition and enforcement, and some have created funding streams for community development and provision of services.

Ultimately, the full public health impacts of cannabis legalization will involve the intersection of a number of competing interests including; (1) the regulated marketplace, (i.e., product properties, availability/supply, access/price, preventing youth access, combining current medical and "recreational" markets); (2) impacts on still operating illicit markets; (3) similar to alcohol and tobacco, impacts of advertising, labeling, price and taxes on purchase; (4) effectiveness of public health surveillance and monitoring; and, (5) the extent to which education and community outreach can foster changes in risky behaviors that are subject to individual control.

With respect to behaviors that are subject to individual control, in addition to general abstinence, and avoidance of use in specific populations (e.g., pregnancy, preexisting mental health disorder), the following set of evidence-based measures for lower risk cannabis use have been previously identified:[156]

- avoid early age initiation of cannabis use (i.e., definitively before the age of 16 years);
- choose low-potency tetrahydrocannabinol (THC) or balanced THC-to-cannabidiol (CBD)–ratio cannabis products;
- avoid combusted cannabis inhalation and give preference to nonsmoking use methods (e.g., oral solutions/oils, tincture, edibles);
- avoid deep or other risky inhalation practices;
- avoid high-frequency (e.g., daily or near-daily) cannabis use;
- abstain from cannabis-impaired driving, and,
- avoid combining risk behaviors (e.g., early initiation and high-frequency use).

RECOMMENDATIONS

The Council on Science and Public Health recommends that the following statement be adopted in lieu of Resolution 408-A-19, Resolution 411-A-19, and the additional proposed resolve from Alternate Resolution 913-I-19 and the remainder of the report be filed:

> That Policy H-95.924, "Cannabis Legalization for Recreational Use," be amended by addition and deletion to read as follows:
> Cannabis Legalization for ~~Recreational~~ Adult Use (commonly referred to as recreational use)
>
> Our AMA: (1) believes that cannabis is a dangerous drug and as such is a serious public health concern; (2) believes that the sale of cannabis for ~~recreational~~ adult use should not be legalized; (3) discourages cannabis use, especially by persons vulnerable to the drug's effects and in high-risk populations such as youth, pregnant women, and women who are breastfeeding; (4) believes states that have already legalized cannabis (for medical or ~~recreational~~ adult use or both) should be required to take steps to regulate the product effectively in order to protect public health and safety including but not limited to: regulating retail sales, marketing, and promotion intended to encourage use; limiting the potency of cannabis extracts and concentrates; requiring packaging to convey meaningful and easily understood units of consumption, and requiring that for commercially available edibles, packaging must be child-resistant and come with messaging about the hazards about unintentional ingestion in children and youth. (5) ~~that~~ laws and regulations related to legalized cannabis use should consistently be evaluated to determine their effectiveness; (~~5~~6) encourages local, state, and federal public health agencies to improve surveillance efforts to ensure data is available on the short- and long-term health effects of cannabis, especially emergency department visits and hospitalizations, impaired driving, and prevalence of psychiatric and addictive disorders, including cannabis use disorder; (~~6~~7) supports public health based strategies, rather than incarceration, in the handling of individuals possessing cannabis for personal use; (~~7~~,8) encourages research on the impact of legalization and decriminalization of cannabis in an effort to promote public health and public safety; (~~8~~,9) encourages dissemination of information on the public health impact of legalization and decriminalization of cannabis; (~~9~~,10) will advocate for stronger public health messaging on the health effects of cannabis and cannabinoid inhalation and ingestion, with an emphasis on reducing initiation and frequency of cannabis use among adolescents, especially high potency products; use among women who are pregnant or contemplating pregnancy; and avoiding cannabis-impaired driving; (11) supports social equity programs to address the impacts of cannabis prohibition and enforcement policies that have disproportionately impacted marginalized and minoritized communities, and (~~10~~12) will coordinate with other health organizations to develop resources on the impact of cannabis on human health and on methods for counseling and educating patients on the use cannabis and cannabinoids.
>
> Fiscal note: Less than $500

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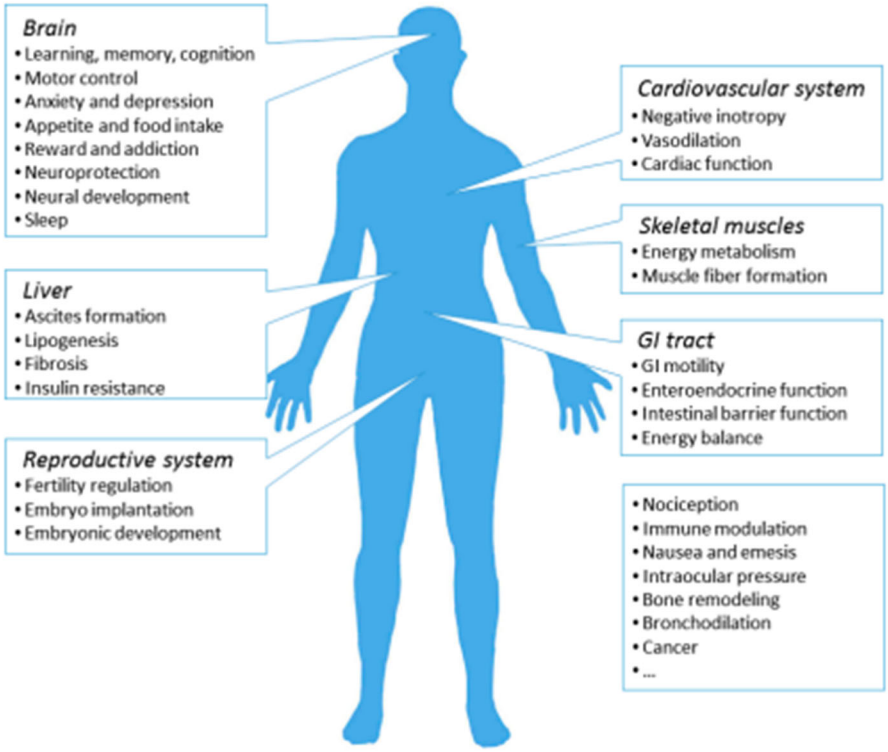

Figure 1. Major localization and associated functions of the CB1 receptor, the majority of which are expressed in the brain from: Zou S, Kumar U. Cannabinoid Receptors and the Endocannabinoid System: Signaling and Function in the Central Nervous System. *Int J Mol Sci.* 2018 Mar 13;19(3):833. doi: 10.3390/ijms19030833. Open Access.

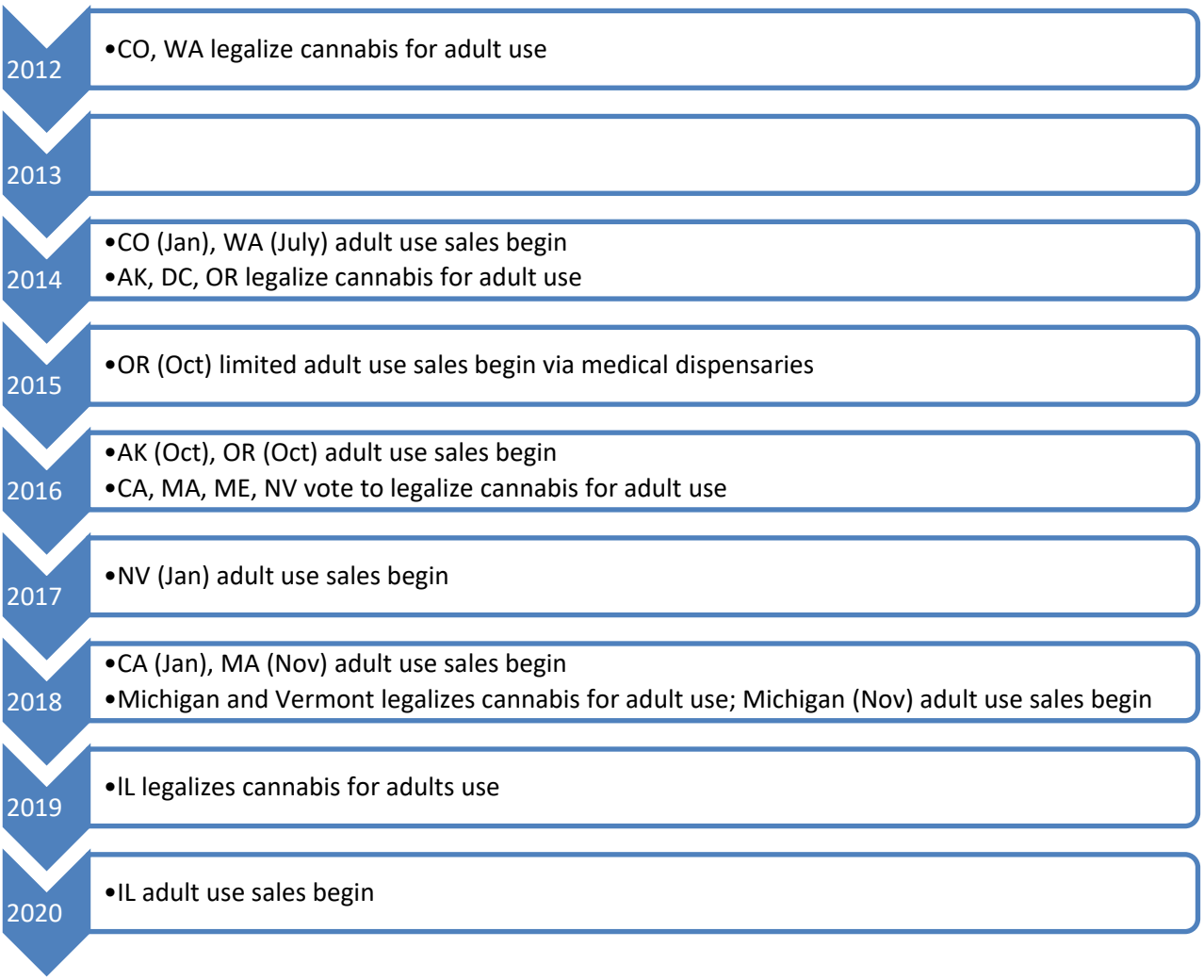

Figure 2. Timeline of legalization and implementation of cannabis for adult use. Constructed figure.

Figure 3. Washington State logo for cannabis edibles. Washington State Liquor and Cannabis Board

Table 1. Summary of cannabis extracts

Product	Description	Method of Use	Average Levels of THC and CBD[2]
Hash			
	Hash or hashish is the oldest and best-known type of cannabis extract. It is a light to dark brown substance composed of compressed or purified trichomes, which are the stalked resin glands that contain most of the cannabinoids present in the cannabis plant. Hash that has been pressed is usually solid, whereas water-purified hash develops a paste-like consistency and is often called "bubble melt hash" or "bubble hash."	- **Smoked** (either alone or mixed in with dried cannabis or tobacco) - **Vaped** - **Dabbed**	THC: 40–80% CBD: less than 5%
Kief			
	Kief refers to the collection of trichomes that accumulate when sifted from dried cannabis, often using a three-chamber grinder.	- **Smoked** (either alone or mixed in with dried cannabis or tobacco)	THC: 40–50% CBD: less than 5%
Wax (crumble, budder)			
	Wax is a solvent-based (e.g., butane[3]) extract that is named after its appearance and consistency. Wax varies in level of THC depending on quality, but can contain well over 50% THC. **Crumble** is the drier and more crumbly form of wax, whereas **budder** contains a higher moisture content.	- **Vaped** - **Dabbed**	THC: 26–70% CBD: --
Shatter			
	Shatter is amber and glass-like in appearance and consistency. It is generally high in THC and low in CBD. Compression following the extraction process turns shatter into a substance called "cookie crumble" or "honeycomb."	- **Vaped** - **Dabbed**	THC: ~ 70% CBD: --
Live Resin			
	Live resin is made the same way as wax, but with fresh cannabis plant material that has been immediately frozen after harvest. This is the reason for the term "live." This process gives live resin a "more intense and complex" smell and taste, so it is more expensive than typical wax and budder products. The moisture in this extract gives it a slightly different appearance from wax and budder.	- **Vaped** - **Dabbed**	THC: 40–50% CBD: --
Rosin			
	Rosin refers to cannabis extracts that were made using "rosin tech," which is essentially the application of heat and compression to the resinous sap from cannabis plant matter, most often flower (or bud), kief or hash. This extraction method results in a sappy and translucent cannabis extract that is similar in appearance and composition to **shatter.** It is believed that rosin can reach comparable THC concentrations to that in solvent-based extracts, but this has yet to be scientifically tested.	- **Vaped** - **Dabbed**	THC: ~ 70% CBD: --

Product	Description	Method of Use	Average Levels of THC and CBD[1]
Tinctures and Oil Sprays			
	Tinctures and oil sprays are products consisting of a cannabis extract, a carrier liquid, such as coconut-derived MCT (medium-chain triglycerides) oil, and sometimes terpenes. These products vary widely in their THC and CBD levels and reasons for use. Tinctures come in plastic or glass bottles with droppers and are administered under the tongue (sublingually). Oil sprays are similarly intended to be sprayed under the tongue.	- **Sublingual** - **Ingested**	**High THC:** THC: 20–30 mg/ml CBD: 0–1 mg/ml **High CBD:** THC: 0.7–2 mg/ml CBD: 15–55 mg/ml **Balanced:** THC: 1–12.5 mg/ml CBD: 1–12.5 mg/ml
Softgels and Capsules			
	Softgels and capsules are comprised of similar ingredients to that of tinctures and oil sprays: a cannabis extract, a carrier liquid (e.g., MCT) and, sometimes, terpenes. These products vary widely in their THC and CBD levels.	- **Ingested**	**High THC:** THC: 2.5–10 mg/capsule CBD: 0–1 mg/capsule Capsules on the illicit market appear to contain up to 100 mg of THC. **High CBD:** THC: 0–1 mg/capsule CBD: 9–25 mg/capsule **Balanced:** THC: 2–3 mg/capsule CBD: 2–3 mg/capsule
Vape Cartridges and Disposable Pens			
	Vape cartridges and pens contain high concentrated cannabis extracts and varying terpene (flavour) profiles. High THC vape products are the most commonly sold. However, it appears that high CBD and "balanced" vape products are becoming increasingly available.	- **Vaped**	**High THC:** THC: 70–95% CBD: 0–10% **High CBD:** THC: 0–5% CBD: 60–70% **Balanced:** THC: 40–60% CBD: 20–40%

Source: Gabrys R. Canadian Centre on Substance Use and Addiction. Clearing the Smoke on Cannabis Edible Cannabis Products, Cannabis Extracts and Cannabis Topicals. https://www.ccsa.ca/sites/default/files/2020-05/CCSA-Edible-Cannabis-Extracts-and-Topicals-Report-2020-en.pdf.

Table 2: Tax rates, recent tax revenues, and administrative cost (adult use)

State	Licensing & Tracking	Possession Limits	Taxes	Tax Revenue	Administrative Costs
Colorado	Colorado Dept. of Revenue	1 oz usable, 6 plants (no more than 3 mature), 8 g hash/concentrates; 800 mg edible	Cultivator excise tax of 15% sales to retail stores Retail tax of 15% Local option retail tax up to 8%	>1 billion in tax revenue from initiation to June 2019; $203 million for Jan-Jun 2020	$16 million
Washington	Washington State Liquor and Cannabis Board	1 oz usable, 16 oz solid cannabis-infused, 72 oz liquid infused, 7 g concentrates	37% tax on retail sales 6.5% retail sales tax (plus local tax)	$395 million in 2019; $248 million thru Jun 2020	$42 million
Oregon	Oregon Liquor Control Commission	1 oz usable in public, 8 oz homegrown, 4 plants, 16 oz solid, 72 oz liquid-infused, 1 oz hash/extract at home	17% retail sales tax Local option sales tax up to 3%	$133 million for FY 2020	$10 million
Alaska	Marijuana Control Board	1 oz usable, 6 plants (no more than 3 mature)	Cultivator excise tax of $50/oz flowers; $15/oz stems and leaves; $25/oz for immature flowers/buds; $1 per clone	$24.5 million FY 2020	$2 million
Nevada	Nevada Dept. of Taxation	1 oz usable, 6 plants, 3.5 g hash/concentrates	Cultivator wholesale excise tax 15% Retail tax 10% Sales tax 6.85% (plus local)	Jul 2019-May 2020, $95 million in tax revenue	$3.5 million
California	CalCannabis Cultivations Licensing (CA Dept. of Food & Agriculture	1 oz usable, 6 plants, 8 g hash/concentrates	Cultivator tax of $9.65/ounce for flowers; $2.87 ounce for leaves Fresh plant material $1.35/ounce Excise tax (15% of Retail Sales) Retail sales tax (7.25% plus local)	California passed $1 billion in cannabis tax revenue two years after launching legal market.	$61 million
Massachusetts	Massachusetts Cannabis Control Commission	1 oz usable (up to 10 oz secured), 6 plants, 5 g concentrates	10.75% Excise tax on retail sales 6.25% Retail sales tax Local option excise tax of up to 3%	$122 million in tax revenue collected in the FY 2019-2020	?
Michigan	Michigan Dept. of Licensing and Regulatory Affairs	2.5 oz usable, 12 plants, 15 g concentrates	10% Retail excise tax 6% State sales tax	Since Dec 2019, $35 million in excise/sales tax	?

Illinois	Illinois Dept. of Financial & Professional Regulation	1 oz usable, 5 g hash/concentrates	Cultivator excise tax (7%) on sales to dispensaries Retail Excise Taxes: 10% with THC level of <35%, 25% for THC>35%; 20% on cannabis-infused products; Local option tax up to 3%	$52.8 million Jan-Jun 2020 with further increase in July	?
Maine	Office of Marijuana Policys	2.5 oz usable, up to 15 plants (no more than 3 mature), 6 g hash/concentrates	Cultivator excise tax of $335 per pound/ $94 per pound trim/$1.50 per seedling/$0.35 per seed Retail sales tax of 10%	Sales on Hold	

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 501
(November 2020)

Introduced by: Illinois

Subject: CBD Oil Use and the Marketing of CBD Oil

Referred to: Reference Committee E

Whereas, Cannabidiol (CBD) oil is advertised in health clubs and convenience stores and online; and

Whereas, CBD oil is often marketed in ways that falsely imply medical doctor approval, verification or endorsement; and

Whereas, There is only one Food and Drug Administration (FDA)-approved drug in which CBD is the active ingredient for the indication of two rare types of epilepsy syndromes; and

Whereas, It is known that the side effects of CBD include elevated liver enzymes, diarrhea, somnolence and decreased appetite; and

Whereas, CBD oil is promoted for the treatment of a vast range of mental and physical ailments including: seizures, schizophrenia, depression, anxiety, Tourette syndrome, ADHD, pain reduction and sleep disorders; and

Whereas, CBD is one of more than 100 identified compounds in the cannabis plant, commonly known as marijuana and CBD is put into products including ingestible oils, bath salts and drinks; and

Whereas, CBD oil is not an FDA-approved product and is considered a dietary supplement and the composition and purity of the product generally extracted from hemp is not overseen by any U.S. regulatory body and adulteration, contamination with pesticides, herbicides and heavy metals and variable percentage of CBD product can and does occur; therefore be it

RESOLVED, That our American Medical Association support banning the advertising of cannabidiol (CBD) as a component of marijuana in places that children frequent (New HOD Policy); and be it further

RESOLVED, That our AMA support legislation to prohibit companies from selling CBD products if they make any unproven health and therapeutic claims, and to require companies to include a Food and Drug Administration-approved warning on CBD product labels. (New HOD Policy)

Fiscal Note: Minimal - less than $1,000

Received: 07/17/20

RELEVANT AMA POLICY

H-120.926 - Expedited Prescription Cannabidiol Drug Rescheduling
Our AMA will: (1) encourage state controlled substance authorities, boards of pharmacy, and legislative bodies to take the necessary steps including regulation and legislation to reschedule U.S. Food and Drug Administration (FDA)-approved cannabidiol products, or make any other necessary regulatory or legislative change, as expeditiously as possible so that they will be available to patients immediately after approval by the FDA and rescheduling by the U.S. Drug Enforcement Administration; and (2) advocate that an FDA-approved cannabidiol medication should be governed only by the federal and state regulatory provisions that apply to other prescription-only products, such as dispensing through pharmacies, rather than by these various state laws applicable to unapproved cannabis products. Res. 502, A-18

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 502
(November 2020)

Introduced by: Illinois

Subject: Drug Manufacturing Safety

Referred to: Reference Committee E

Whereas, It has recently been revealed in the media as well as written notifications from pharmacies informing the American public that certain medications produced outside but consumed inside the United States have contained carcinogenic substances; and

Whereas, Such tainted medications are widely consumed within the US and include, but are not limited to, Valsartan and Losartan; and

Whereas, Multiple medications are produced overseas and marketed broadly within the US; and

Whereas, Significant budgetary hurdles exist in empowering the U.S. Food and Drug Administration to inspect all foreign drug manufacturers on a frequent and rigorous basis; therefore be it

RESOLVED, That our American Medical Association support efforts to ensure that the U.S. Food and Drug Administration (FDA) resumes safety testing for all drug manufacturing facilities on a frequent and rigorous basis, as done in the past (Directive to Take Action); and be it further

RESOLVED, That our AMA call for the FDA to reaffirm the safety of the manufacture of drugs and the adequacy of volume in the pipeline. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000

Received: 07/17/20

The topic of this resolution is currently under study by the Council on Science and Public Health.

RELEVANT AMA POLICY

D-100.983 - Prescription Drug Importation and Patient Safety
Our AMA will: (1) support the legalized importation of prescription drug products by wholesalers and pharmacies only if: (a) all drug products are Food and Drug Administration (FDA)-approved and meet all other FDA regulatory requirements, pursuant to United States laws and regulations; (b) the drug distribution chain is "closed," and all drug products are subject to reliable, "electronic" track and trace technology; and (c) the Congress grants necessary additional authority and resources to the FDA to ensure the authenticity and integrity of prescription drugs that are imported; (2) oppose personal importation of prescription drugs via the Internet until patient safety can be assured; (3) review the recommendations of the forthcoming report of the Department of Health and Human Services (HHS) Task Force on Drug Importation and, as appropriate, revise its position on whether or how patient safety can be assured under legalized drug importation; (4) educate its members regarding the risks and benefits associated with drug importation and reimportation efforts;
(5) support the in-person purchase and importation of Health Canada-approved prescription drugs obtained directly from a licensed Canadian pharmacy when product integrity can be assured, provided such drugs are for personal use and of a limited quantity; (6) advocate for an increase in funding for the US Food and Drug Administration to administer and enforce a program that allows the in-person purchase and importation of prescription drugs from Canada, if the integrity of prescription drug products imported for personal use can be assured; and (7) support the personal importation of prescription drugs only if: (a) patient safety can be assured; (b) product quality, authenticity and integrity can be assured; (c) prescription drug products are subject to reliable, “electronic” track and trace technology; and (d) prescription drug products are obtained directly from a licensed foreign pharmacy, located in a country that has statutory and/or regulatory standards for the approval and sale of prescription drugs that are comparable to the standards in the United States. BOT Rep. 3, I-04 Reaffirmation A-09 Reaffirmed in lieu of: Res. 817, I-16 Appended: CMS Rep. 01, I-18 Appended: Res. 115, A-19

D-100.978 - FDA Drug Safety Policies
Our AMA will monitor and respond, as appropriate, to the implementation of the drug safety provisions of the Food and Drug Administration Amendments Act of 2007 (FDAAA; P.L. 110-85) so that the Food and Drug Administration can more effectively ensure the safety of drug products for our patients. Sub. Res. 505, A-08

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 503
(November 2020)

Introduced by: Illinois

Subject: Federal Initiative to Treat Cannabis Dependence

Referred to: Reference Committee E

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1 Whereas, There is no effective medication for treating dependence on cannabis; and
2
3 Whereas, Many states are making cannabis available for recreational purposes; and
4
5 Whereas, It is well known the use of cannabis can lead to addiction; and
6
7 Whereas, Physicians have no Food and Drug Administration-approved, safe and effective
8 medication to assist in treating cannabis addiction; therefore be it
9
10 RESOLVED, That our American Medical Association urge the National Institutes of Health to
11 award appropriate incentive grants to universities, pharmaceutical companies and other capable
12 entities to develop treatment options for cannabis dependence; and that the cost of these grants
13 be financed by taxes on those who profit from selling cannabis. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000

Received: 07/17/20

Reference:

Lintzeris, N and associates, Nabiximois for the treatment of cannabis dependence: A randomized clinical trial, JAMA Intern Med, 2019; 179(9):1242-1253

RELEVANT AMA POLICY

H-95.924 - Cannabis Legalization for Recreational Use
Our AMA: (1) believes that cannabis is a dangerous drug and as such is a serious public health concern; (2) believes that the sale of cannabis for recreational use should not be legalized; (3) discourages cannabis use, especially by persons vulnerable to the drug's effects and in high-risk populations such as youth, pregnant women, and women who are breastfeeding; (4) believes states that have already legalized cannabis (for medical or recreational use or both) should be required to take steps to regulate the product effectively in order to protect public health and safety and that laws and regulations related to legalized cannabis use should consistently be evaluated to determine their effectiveness; (5) encourages local, state, and federal public health agencies to improve surveillance efforts to ensure data is available on the short- and long-term health effects of cannabis; (6) supports public health based strategies, rather than incarceration, in the handling of individuals possessing cannabis for personal use; (7) encourages research on the impact of legalization and decriminalization of cannabis in an effort to promote public health and public safety; (8) encourages dissemination of information on the public health impact of legalization and decriminalization of cannabis; (9) will advocate for stronger public health messaging on the health effects of cannabis and cannabinoid inhalation and ingestion; and (10) will coordinate with other health organizations to develop resources on the impact of cannabis on human health and on methods for counseling and educating patients on the use cannabis and cannabinoids. CSAPH Rep. 05, I-17 Appended: Res. 913, I-19

D-95.969 - Cannabis Legalization for Medicinal Use
Our AMA: (1) believes that scientifically valid and well-controlled clinical trials conducted under federal investigational new drug applications are necessary to assess the safety and effectiveness of all new drugs, including potential cannabis products for medical use; (2) believes that cannabis for medicinal use should not be legalized through the state legislative, ballot initiative, or referendum process; (3) will develop model legislation requiring the following warning on all cannabis products not approved by the U.S. Food and Drug Administration: "Marijuana has a high potential for abuse. This product has not been approved by the Food and Drug Administration for preventing or treating any disease process."; (4) supports legislation ensuring or providing immunity against federal prosecution for physicians who certify that a patient has an approved medical condition or recommend cannabis in accordance with their state's laws; (5) believes that effective patient care requires the free and unfettered exchange of information on treatment alternatives and that discussion of these alternatives between physicians and patients should not subject either party to criminal sanctions; (6) will, when necessary and prudent, seek clarification from the United States Justice Department (DOJ) about possible federal prosecution of physicians who participate in a state operated marijuana program for medical use and based on that clarification, ask the DOJ to provide federal guidance to physicians; and (7) encourages hospitals and health systems to: (a) not recommend patient use of non-FDA approved cannabis or cannabis derived products within healthcare facilities until such time as federal laws or regulations permit its use; and (b) educate medical staffs on cannabis use, effects and cannabis withdrawal syndrome. CSAPH Rep. 05, I-17 Appended: Res. 211, A-18 Appended: CSAPH Rep. 3, I-19

H-95.952 - Cannabis and Cannabinoid Research
1. Our AMA calls for further adequate and well-controlled studies of marijuana and related cannabinoids in patients who have serious conditions for which preclinical, anecdotal, or controlled evidence suggests possible efficacy and the application of such results to the understanding and treatment of disease.
2. Our AMA urges that marijuana's status as a federal schedule I controlled substance be reviewed with the goal of facilitating the conduct of clinical research and development of cannabinoid-based medicines, and alternate delivery methods. This should not be viewed as an endorsement of state-based medical cannabis programs, the legalization of marijuana, or that scientific evidence on the therapeutic use of cannabis meets the current standards for a prescription drug product.
3. Our AMA urges the National Institutes of Health (NIH), the Drug Enforcement Administration (DEA), and the Food and Drug Administration (FDA) to develop a special schedule and implement administrative procedures to facilitate grant applications and the conduct of well-designed clinical research involving cannabis and its potential medical utility. This effort should include: a) disseminating specific information for researchers on the development of safeguards for cannabis clinical research protocols and the development of a model informed consent form for institutional review board evaluation; b) sufficient funding to support such clinical research and access for qualified investigators to adequate supplies of cannabis for clinical research purposes; c) confirming that cannabis of various and consistent strengths and/or placebo will be supplied by the National Institute on Drug Abuse to investigators registered with the DEA who are conducting bona fide clinical research studies that receive FDA approval, regardless of whether or not the NIH is the primary source of grant support.
4. Our AMA supports research to determine the consequences of long-term cannabis use, especially among youth, adolescents, pregnant women, and women who are breastfeeding.
5. Our AMA urges legislatures to delay initiating the legalization of cannabis for recreational use until further research is completed on the public health, medical, economic, and social consequences of its use.
6. Our AMA will advocate for urgent regulatory and legislative changes necessary to fund and perform research related to cannabis and cannabinoids.
7. Our AMA will create a Cannabis Task Force to evaluate and disseminate relevant scientific evidence to health care providers and the public. CSA Rep. 10, I-97 Modified: CSA Rep. 6, A-01 Modified: CSAPH Rep. 3, I-09 Modified in lieu of Res. 902, I-10 Reaffirmed in lieu of Res. 523, A-11 Reaffirmed in lieu of Res. 202, I-12 Reaffirmed: CSAPH Rep. 2, I-13 Modified: CSAPH Rep. 05, I-17 Reaffirmed in lieu of: Res. 434, A-19 Appended: Res. 913, I-19

H-95.923 - Taxes on Cannabis Products
Our AMA encourages states and territories to allocate a substantial portion of their cannabis tax revenue for public health purposes, including: substance abuse prevention and treatment programs, cannabis-related educational campaigns, scientifically rigorous research on the health effects of cannabis, and public health surveillance efforts. CSAPH Rep. 05, I-17

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 504
(November 2020)

Introduced by: Illinois

Subject: Supplemental Resources for Inflight Medical Kit

Referred to: Reference Committee E

Whereas, According to the Bureau of Transportation Statistics, 770 million passengers boarded domestic flights in the United States in the year 2018 and 802 million passengers boarded domestic flights in the US in the year 2019; and

Whereas, Inflight medical emergencies (IMEs) are estimated to occur in approximately 1 in 604 flights, or 24 to 130 IMEs per 1 million passengers; and

Whereas, IMEs are common and occur in constrained areas with limited medical resources; and

Whereas, Inflight medical events are increasingly frequent because a growing number of individuals with pre-existing medical conditions travel by air; and

Whereas, The most common inflight emergency involves syncope or near syncope, which requires measurement of blood pressure and pulse for optimal assessment; and

Whereas, Travelers with diabetes may have altered dietary habits and medication dosing, so are at risk for hyper- or hypoglycemia; and

Whereas, Health care personnel are asked to assist affected passengers and have variable level of training and expertise in evaluating vital signs; and

Whereas, Efforts by health care volunteers are protected by Good Samaritan laws, there is an obligation and opportunity to optimize treatment in these situations; and

Whereas, The minimum requirements for the emergency medical kit do not include automated blood pressure cuff, pulse oximeter or glucose monitors; and

Whereas, The noise level of the airplane makes it difficult to auscultate for blood pressure, with cruising noise levels at around 85 dB but up to 105 dB during takeoff and landing; and

Whereas, Resources include automated external defibrillators, advanced life support injectables including epinephrine, atropine, lidocaine, analgesics, and first aid materials, but do not include pulse oximeters, automated blood pressure cuffs or glucose monitors; and

Whereas, Treatment and support decisions can be optimized with accurate vital signs, oxygen levels and blood sugar levels; and

Whereas, Blood glucose testing equipment is not required in the U.S.; and

Whereas, A pulse oximeter is a lightweight and inexpensive device that can determine heart rate as well as oxygen saturation; and

Whereas, An automated blood pressure cuff is a lightweight, inexpensive device that uses a pressure sensor and not sound to detect intraarterial systolic blood pressure; and

Whereas, A glucose monitor is a lightweight and relatively inexpensive device that can provide an accurate point of care blood sugar level; and

Whereas, A pulse oximeter, an automated blood pressure cuff and a glucose monitor are not among the standard supplies on a domestic U.S. flight; and

Whereas, The costs of these devices is minimal in comparison to the cost of diverting a flight for emergency medical attention due to inadequate evaluation on board; and

Whereas, In the absence of medical personnel during an inflight emergency, a pulse oximeter, automated blood pressure cuff and glucose monitor can be used to determine accurate data that can be shared with on ground medical support team; therefore be it

RESOLVED, That our American Medical Association advocate for U.S. passenger airlines to carry standard pulse oximeters, automated blood pressure cuffs and blood glucose monitoring devices in their emergency medical kits. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000

Received: 07/17/20

References:

American Speech-Language-Hearing Association (ASHA). Feb 25, 2014 Durden, Rick Pulse Oximeters: Too Cheap to Ignore. The Aviation Consumer, October 29, 2019
https://www.bts.gov/

Martin-Gill, C, Doyle, TJ Yealy, DM, In Flight Emergencies: A Review. JAMA 2018 Dec 25;320(24):2580-2590. doi: 10.1001/jama.2018.19842.

RELEVANT AMA POLICY

H-45.981- Improvement in US Airlines Aircraft Emergency Kits

1. Our AMA urges federal action to require all US air carriers to report data on in-flight medical emergencies, specific uses of in-flight medical kits and emergency lifesaving devices, and unscheduled diversions due to in-flight medical emergencies; this action should further require the Federal Aviation Administration to work with the airline industry and appropriate medical specialty societies to periodically review data on the incidence and outcomes of in-flight medical emergencies and issue recommendations regarding the contents of in-flight medical kits and the use of emergency lifesaving devices aboard commercial aircraft.
2. Our AMA will: (a) support the addition of naloxone to the airline medical kit; (b) encourage airlines to voluntarily include naloxone in their airline medical kits; and (c) encourage the addition of naloxone to the emergency medical kits of all US airlines (14CFR Appendix A to Part 121 - First Aid Kits and Emergency Medical Kits). Res. 507, A-97 Amended: CSA Rep. 3, I-99 Reaffirmed: CSAPH Rep. 1, A-09 Reaffirmed in lieu of: Res. 502, A-16 Appended: Res. 524, A-18

H-45.979 - Air Travel Safety
Our AMA: (1) encourages the ongoing efforts of the Federal Aviation Administration, the airline industry, the Aerospace Medical Association, the American College of Emergency Physicians, and other appropriate organizations to study and implement regulations and practices to meet the health needs of airline passengers and crews, with particular focus on the medical care and treatment of passengers during in-flight emergencies; (2) encourages physicians to inform themselves and their patients on the potential medical risks of air travel and how these risks can be prevented; and become knowledgeable of medical resources, supplies, and options that are available if asked to render assistance during an in-flight medical emergency; and (3) will support efforts to educate the flying physician public about in-flight medical emergencies (IFMEs) to help them participate more fully and effectively when an IFME occurs, and such educational course will be made available online as a webinar. CSA Rep. 5, I-98 Appended: CSA Rep. 3, I-99 Reaffirmed: CSAPH Rep. 1, A-09 Appended: Res. 718, A-14 Reaffirmation I-14 Reaffirmed in lieu of Res. 503, A-15 Reaffirmed in lieu of: Res. 502, A-16 Reaffirmed in lieu of: Res. 516, A-17 Reaffirmed: BOT Rep. 22, A-18 Reaffirmed: BOT Rep. 30, A-18

H-45.978 - In-flight Medical Emergencies
Our AMA urges: (1) urges that decisions to expand the contents of in-flight emergency medical kits and place emergency lifesaving devices onboard commercial passenger aircraft be based on empirical data and medical consensus; in-flight medical supplies and equipment should be tailored to the size and mission of the aircraft, with careful consideration of flight crew training requirements; and (2) the Federal Aviation Administration to work with appropriate medical specialty societies and the airline industry to develop and implement comprehensive in-flight emergency medical systems that ensure:
(a) rapid 24-hour access to qualified emergency medical personnel on the ground;
(b) at a minimum, voice communication with qualified ground-based emergency personnel;
(c) written protocols, guidelines, algorithms, and procedures for responding to in-flight medical emergencies;
(d) efficient mechanisms for data collection, reporting, and surveillance, including development of a standardized incident report form;
(e) adequate medical supplies and equipment aboard aircraft;
(f) routine flight crew safety training;
(g) periodic assessment of system quality and effectiveness; and
(h) direct supervision by physicians with appropriate training in emergency and aerospace medicine. CSA Rep. 3, I-99 Reaffirmed: CSAPH Rep. 1, A-09 Reaffirmation I-14 Reaffirmed in lieu of: Res. 502, A-16 Reaffirmed in lieu of: Res. 516, A-17

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 505
(November 2020)

Introduced by: Illinois

Subject: Regulation and Control of Self-Service Labs

Referred to: Reference Committee E

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1 Whereas, In recent years the number of laboratories selling self-ordered tests to patients has
2 increased significantly; and
3
4 Whereas, Laboratories advertise and promote their business on the Internet, and include
5 companies like HealthOneLabs, Accesa Labs, Private MD Labs, Walk-In--Lab, HNL Lab Tests
6 Direct, and several others; and
7
8 Whereas, Most laboratories selling self-ordered tests to patients state that their tests are run
9 with high-quality controls and procedures, and that correct and validated results are emailed to
10 the consumer directly; and
11
12 Whereas, Laboratories that sell self-ordered tests directly to patients clearly state that no
13 medical referral is needed, and that their results are validated and reviewed by an "independent
14 network of physicians," of unspecified qualifications or licensures; and
15
16 Whereas, Many patients self-order tests out of fear or ignorance, and end up with results that
17 they are unable to interpret or apply to their individual needs; and
18
19 Whereas, Many patients go to their physician with pages of results which they may not have
20 needed in the first place and try to obtain a diagnostic interpretation and/or a therapeutic
21 intervention based on said results, which places the physician at medical and legal jeopardy;
22 therefore be it
23
24 RESOLVED, That our American Medical Association study issues with patient-directed self-
25 service testing, including the accreditation and licensing of laboratories that sell self-ordered
26 tests and physician liability related to non-physician-ordered tests. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000

Received: 07/17/20

RELEVANT AMA POLICY

H-480.941 - Direct-to-Consumer Laboratory Testing
Our AMA will: (1) advocate for vigilant oversight of direct-to-consumer (DTC) laboratory testing by relevant state and federal agencies; and (2) encourage physicians to educate their patients about the risks and benefits of DTC laboratory tests, as well as the risks associated with interpreting DTC test results without input from a physician or other qualified health care professional. Res. 526, A-18

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 506
(November 2020)

Introduced by: Oklahoma

Subject: Education for Patients on Opiate Replacement Therapy

Referred to: Reference Committee E

Whereas, We are in a time of potentially increased respiratory illness, given the threat of COVID-19 and flu season in the United States; and

Whereas, We are simultaneously in a time of increased use of opiate replacement therapy for the treatment of opiate use disorder and chronic pain; and

Whereas, Anecdotally, a death scenario occurs when patients in their 60s and 70s who are on relatively high dose maintenance opioid replacement therapy, take their usual dose after onset of a respiratory illness; and

Whereas, AMA Policy D-95.987, “Prevention of Opioid Overdose” is to educate physicians and at-risk patients, but it fails to specifically address the needs of older patients who are at risk of death from opiate maintenance therapy when the onset of respiratory illness occurs; therefore be it

RESOLVED, That our American Medical Association amend Policy D-95.987, “Prevention of Opioid Overdose,” by addition to read as follows:
1. Our AMA: (A) recognizes the great burden that opioid addiction and prescription drug abuse places on patients and society alike and reaffirms its support for the compassionate treatment of such patients; (B) urges that community-based programs offering naloxone and other opioid overdose prevention services continue to be implemented in order to further develop best practices in this area; and (C) encourages the education of health care workers and opioid users about the use of naloxone in preventing opioid overdose fatalities; and (D) will continue to monitor the progress of such initiatives and respond as appropriate.
2. Our AMA will: (A) advocate for the appropriate education of at-risk patients and their caregivers in the signs and symptoms of opioid overdose; and (B) encourage the continued study and implementation of appropriate treatments and risk mitigation methods for patients at risk for opioid overdose.
3. Our AMA will support the development and implementation of appropriate education programs for persons in recovery from opioid addiction and their friends/families that address how a return to opioid use after a period of abstinence can, due to reduced opioid tolerance, result in overdose and death.
<u>4. Our AMA will implement an education program for patients on opiate replacement therapy and their family/caregivers to increase understanding of their increased risk of death with concurrent opiate maintenance therapy and the onset of a serious respiratory illness such as SARS-CoV-2.</u> (Modify Current HOD Policy)

Reference:
https://ajp.psychiatryonline.org/doi/10.1176/appi.ajp.2020.20030348

Fiscal Note: Estimate cost of $72,000 to implement resolution.

Received: 08/17/2020

RELEVANT AMA POLICY

Prevention of Opioid Overdose D-95.987
1. Our AMA: (A) recognizes the great burden that opioid addiction and prescription drug abuse places on patients and society alike and reaffirms its support for the compassionate treatment of such patients; (B) urges that community-based programs offering naloxone and other opioid overdose prevention services continue to be implemented in order to further develop best practices in this area; and (C) encourages the education of health care workers and opioid users about the use of naloxone in preventing opioid overdose fatalities; and (D) will continue to monitor the progress of such initiatives and respond as appropriate.
2. Our AMA will: (A) advocate for the appropriate education of at-risk patients and their caregivers in the signs and symptoms of opioid overdose; and (B) encourage the continued study and implementation of appropriate treatments and risk mitigation methods for patients at risk for opioid overdose.
3. Our AMA will support the development and implementation of appropriate education programs for persons in recovery from opioid addiction and their friends/families that address how a return to opioid use after a period of abstinence can, due to reduced opioid tolerance, result in overdose and death.
Citation: Res. 526, A-06; Modified in lieu of Res. 503, A-12; Appended: Res. 909, I-12; Reaffirmed: BOT Rep. 22, A-16; Modified: Res. 511, A-18; Reaffirmed: Res. 235, I-18

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 507
(November 2020)

Introduced by: New York

Subject: Pharmacy Benefit Managers and Drug Shortages

Referred to: Reference Committee E

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1 Whereas, Pharmacy Benefit Managers (PBMs) are poorly regulated entities which act as
2 middlemen between health plans, pharmacies and drug manufacturers; and
3
4 Whereas, They have been associated with adverse business practices including opaque
5 operations 'spread pricing', and skyrocketing drug costs; and
6
7 Whereas, PBM's play an important part in the pharmaceutical supply chain--sometimes
8 bankrupting pharmacies and making (and breaking) markets for pharmaceutical agents; and
9
10 Whereas, Drug manufacturers are legally obligated to report existing or pending drug shortages
11 to the Food and Drug Administration, that requirement extends only to drug supply disruptions,
12 not detailed information on their supply chain, in which PBMs play a key role; and
13
14 Whereas, Common retail prescription medications are frequently and chronically 'backordered'
15 at a retail pharmacy, but often readily available at the hospital; therefore be it
16
17 RESOLVED, That our American Medical Association conduct a study which will investigate the
18 role pharmacy benefit managers play in drug shortages. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000

Received: 10/08/20

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 508
(November 2020)

Introduced by: Association for Clinical Oncology, American College of Rheumatology

Subject: Home Infusion of Hazardous Drugs

Referred to: Reference Committee E

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1 Whereas, AMA Policy H-55.986, "Home Chemotherapy and Antibiotic Infusions," was approved
2 by our AMA in 1989 and has been reaffirmed during the 2000, 2010, and 2020 Annual Meetings
3 without amendment; and
4
5 Whereas, Advances in infusion biologic drugs, chemotherapies, anti-neoplastics, and
6 immunotherapies have significantly broadened access, variety, and utilization of infused drugs
7 as front-line treatments for a number of diseases including cancers since the drafting of policy
8 H-55.986; and
9
10 Whereas, The American Society of Clinical Oncology (ASCO) has a proven history of
11 maintaining continuously updated standards on chemotherapy administration safety and
12 standards for the safe workplace handling of hazardous oncology drugs.[1,2] These standards call
13 for rigorous safeguards to ensure proper practitioner certification, patient education, treatment
14 monitoring, accurate drug preparation/handling/administration, and related health care setting
15 policies to protect both patients and staff when providing infusion therapy services; and
16
17 Whereas, The American College of Rheumatology (ACR) has a proven history of maintaining
18 continuously updated guidance on both the complexity of biologic agents, patient access to
19 biologic agents, and patient safety and site of service for infusible biologics.[3,4,5] This guidance
20 emphasizes the highly complex nature of biologic agents particularly with respect to
21 administration and monitoring, and stipulates the need for administration in a monitored
22 healthcare setting with supervision by a provider appropriately trained in biologic administration;
23 and
24
25 Whereas, While home infusions may be appropriate for patients in certain disease settings for
26 certain infusion treatments as a result of informed, shared decision making between the
27 physician and patient, they are not generally appropriate for the provision of biologic agents,
28 hazardous drugs or anticancer therapy services in the absence of circumstances where the
29 benefits of doing so outweigh the potential risks; and
30
31 Whereas, The Centers for Medicare & Medicaid Services (CMS) finalized a rule in 2019 for a
32 home infusion therapy services benefit, to be implemented beginning in 2021. Additionally, CMS
33 released numerous regulatory flexibilities to assist health care settings coping with the COVID-
34 19 Public Health Emergency (PHE) including new provisions that opened the path for potential
35 increases in use of home infusion for biologic agents and anticancer therapy; and

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[1] https://www.asco.org/practice-policy/quality-standards/standards/chemotherapy-safety-standards
[2] https://www.asco.org/practice-policy/quality-standards/standards/standards-safe-handling-hazardous-drugs
[3] https://www.rheumatology.org/Portals/0/Files/Complexity%20of%20Biologics.pdf
[4] https://www.rheumatology.org/Portals/0/Files/Patient%20Access%20to%20Biologics%20aka%20Model%20Biologics.pdf
[5] https://www.rheumatology.org/Portals/0/Files/Biologics-Patient-Safety-and-site-of-Service.pdf

Whereas, The decision to administer biologic agents, hazardous drugs and anticancer therapies in a home setting should be made in exceptional circumstances by the treating physician in consultation with the patient, and after consideration of precautions necessary to protect medical staff, patients and caregivers from adverse events associated with drug infusion and disposal. While tradeoffs during a PHE could potentially indicate that access implications outweigh potential risks, these risks are not generally outweighed by the potential benefits of delivering biologic agents, hazardous drugs or anticancer therapy services in a home setting when the PHE is no longer in place; and

Whereas, Our AMA strives to maintain policies that meet with the most up to date standards of care across all medical specialties; therefore be it

RESOLVED, That our American Medical Association update its existing home infusion policy, H-55.986, “Home Chemotherapy and Antibiotic Infusions,” by addition and deletion to read as follows:

> “Our AMA (1) endorses the use of home injections and/or infusions of FDA approved drugs and group C drugs (including ~~chemotherapy and/or~~ antibiotic therapy) for appropriate patients under physicians' supervision <u>if requested as a result of informed, shared decision making between the physician and patient</u>; ~~and~~ (<u>2) discourages the use of home infusions for biologic agents, immune modulating therapy, and anti-cancer therapy unless emergency circumstances are present where the benefits of doing so outweigh the potential risks</u>; (<u>3</u>) encourages CMS and/or other insurers to provide adequate reimbursement for such treatment; ~~and~~ (<u>4</u>) supports educating legislators and administrators about the risks and benefits ~~of such~~ <u>home infused antibiotics and supportive care</u> treatments in terms of cost saving, increased quality of life and decreased morbidity, and about the need to ~~provide~~ <u>emphasize patient and provider safety when considering emergency at home</u> access to ~~such~~ ~~treatments~~ biologic, immune modulating, and <u>anti-cancer therapy; and (5) advocates for</u> ~~by~~ appropriate reimbursement policies <u>when home infusion services are utilized</u>. (Modify Current HOD Policy); and be it further

RESOLVED, That our AMA oppose extension of the temporary flexibility related to home infusion for Part B drugs, specifically biologics and anti-cancer drugs, that was approved as part of the response to the public health emergency (New HOD Policy); and be it further

RESOLVED, That our AMA oppose any requirement by insurers for home administration of drugs, if in the treating physician’s clinical judgment it is not appropriate, or the precautions necessary to protect medical staff, patients and caregivers from adverse events associated with drug infusion and disposal are not in place; this includes withholding of payment for other settings. (New HOD Policy)

Fiscal Note: Minimal - less than $1,000

Received: 10/14/20

RELEVANT AMA POLICY

Home Chemotherapy and Antibiotic Infusions H-55.986
Our AMA (1) endorses the use of home injections and/or infusions of FDA approved drugs and group C drugs (including chemotherapy and/or antibiotic therapy) for appropriate patients under physicians' supervision, and encourages CMS and/or other insurers to provide adequate reimbursement for such treatment; and (2) supports educating legislators and administrators about the benefits of such treatments in terms of cost saving, increased quality of life and decreased morbidity, and about the need to provide access to such treatments by appropriate reimbursement policies.
Citation: Res. 186, I-89; Reaffirmed: Sunset Report and Reaffirmation A-00; Reaffirmed: CSAPH Rep. 1, A-10; Reaffirmed: CSAPH Rep. 01, A-20

Home Infusion Therapies D-210.997
Our AMA will: (1) work with the Centers for Medicare and Medicaid Services to develop a coordinated system among the various Medicare plans to ensure an expedited, seamless process for provision of home infusion therapies to reduce the need of the patient to remain in the hospital unnecessarily; and (2) work with home infusion stakeholders to seek a legislative remedy to Medicare's lack of coverage for the services, supplies and equipment necessary to provide infusions in the home setting.
Citation: Res. 718, A-08; Reaffirmed: CMS Rep. 01, A-18

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 509
(November 2020)

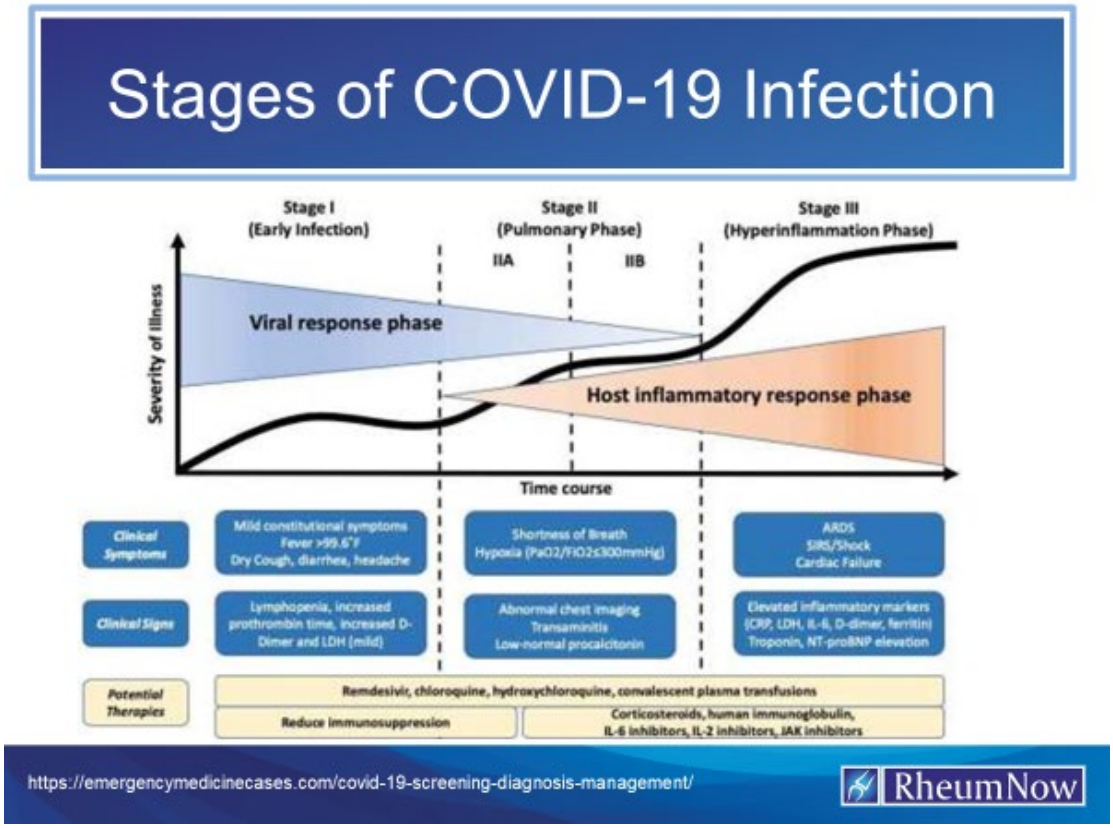
Introduced by: Georgia

Subject: Hydroxychloroquine and Combination Therapies – Off-Label Use

Referred to: Reference Committee E

Whereas, SARS-CoV-2 is the novel coronavirus that causes COVID-19; and

Whereas, Three distinct stages of COVID-19 infection have been observed in some people who test positive for the disease and have variable degrees of symptoms as noted (1); and



Whereas, During the early infection phase (Stage 1), the virus multiplies inside the body and is likely to cause mild symptoms that may be confused with a common cold or flu; and

Whereas, The second phase is the pulmonary phase (Stage 2), when the Immune System becomes strongly affected by infection and leads to primarily respiratory symptoms such as persistent cough, shortness of breath and low oxygen levels. Problems with blood clotting--especially with the formation of blood clots--may be predominant in Stage 2; and

Whereas, The third hyperinflammatory phase (Stage 3), occurs when a hyperactivated immune system may cause injury to the heart, kidneys, and other organs. A "cytokine storm"--where the body attacks its own tissues--may occur in this phase; and

Whereas, There is no current Federal Drug Administration (FDA) indication for the treatment of Early Coronavirus infection, but early emergency use authorization (EUA) originally approved the use of hydroxychloroquine and then rescinded it (2); and

Whereas, The FDA limited use of convalescence plasma but now has rescinded that limitation (3); and

Whereas, Hydroxychloroquine and Chloroquine are FDA approved medications for over 50 years, and these medications are safely prescribed long-term for other indications (2); and

Whereas, AMA President, Patrice A. Harris, MD, issued the following statement: “The AMA is calling for a stop to any inappropriate prescribing and ordering of medications, including chloroquine or hydroxychloroquine, and appealing to physicians and all health care professionals to follow the highest standards of professionalism and ethics” (4); and

Whereas, The AMA, American Pharmacists Association, and American Society of Health System Pharmacists issued a joint statement on March 25, 2020 on inappropriate ordering, prescribing, or dispensing of medications to treat COVID-19 (4); and

Whereas, Some states, pharmacy boards and institutions have forbidden the use of these medications for COVID-19 infection (4, 5); and

Whereas, A proposed regimen to treat COVID-19 for Stage 1, includes 10 days of hydroxychloroquine, Azithromycin, zinc, and on occasion Vitamin D (6); and

Whereas, This regimen is not being advocated for Stage 2 and Stage 3 COVID therapy; and

Whereas, The original studies published in *The Lancet* and T*he New England Journal of Medicine* (NEJM) initially citing harm due to hydroxychloroquine and chloroquine use were retracted by said journals due to dubious research methodology and incorrect conclusions (7, 8, 9); and

Whereas, AMA policy H-120.988, “Patient Access to Treatments Prescribed by Their Physicians,” supports a physician’s autonomy to prescribe medications the physician believes to be in the patient’s best interest, where the benefits outweigh risk and the patient consents; and

Whereas, Physicians have used off label medications for years and this use is supported by existing policy; and

Whereas, Data regarding harm have been limited due to poorly designed studies or studies usually in Stage 2 or later, or stopped without harm but no effect in phase 2 and hypothesis (7, 8, 9, 10, 11, 12); and

Whereas, There are many studies that indicate that the use of Hydroxychloroquine, Azithromycin is effective and front-line physicians are using the therapy where permissible (13, 14, 15); and

Whereas, The COVID-19 pandemic is a serious medical issue, people are dying, and physicians must be able to perform as sagacious prescribers; therefore be it

RESOLVED, That our American Medical Association rescind its statement calling for physicians to stop prescribing hydroxychloroquine and chloroquine until sufficient evidence becomes available to conclusively illustrate that the harm associated with use outweighs benefit early in the disease course. Implying that such treatment is inappropriate contradicts AMA Policy H-120.988, "Patient Access to Treatments Prescribed by Their Physicians," that addresses off label prescriptions as appropriate in the judgement of the prescribing physician (Directive to Take Action); and be it further

RESOLVED, That our AMA rescind its joint statement with the American Pharmacists Association and American Society of Health System Pharmacists, and update it with a joint statement notifying patients that further studies are ongoing to clarify any potential benefit of hydroxychloroquine and combination therapies for the treatment of COVID-19 (Directive to Take Action); and be it further

RESOLVED, That our AMA reassure the patients whose physicians are prescribing hydroxychloroquine and combination therapies for their early-stage COVID-19 diagnosis by issuing an updated statement clarifying our support for a physician's ability to prescribe an FDA-approved medication for off label use, if it is in her/his best clinical judgement, with specific reference to the use of hydroxychloroquine and combination therapies for the treatment of the earliest stage of COVID-19 (Directive to Take Action); and be it further

RESOLVED, That our AMA take the actions necessary to require local pharmacies to fill valid prescriptions that are issued by physicians and consistent with AMA principles articulated in AMA Policy H-120.988, "Patient Access to Treatments Prescribed by Their Physicians," including working with the American Pharmacists Association and American Society of Health System Pharmacists. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000

Received: 10/23/20

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The American Medical Association, American Pharmacists Association, and American Society of Health System Pharmacists issued a j oint statement on March 25, 2020 on inappropriate ordering, prescribing or dispensing of medications to treat COVID-19. https://www.ama-assn.org/system/files/2020-04/board-of-pharmacy-covid-19-prescribing.pdf
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RELEVANT AMA POLICY

Patient Access to Treatments Prescribed by Their Physicians H-120.988

1. Our AMA confirms its strong support for the autonomous clinical decision-making authority of a physician and that a physician may lawfully use an FDA approved drug product or medical device for an off-label indication when such use is based upon sound scientific evidence or sound medical opinion; and affirms the position that, when the prescription of a drug or use of a device represents safe and effective therapy, third party payers, including Medicare, should consider the intervention as clinically appropriate medical care, irrespective of labeling, should fulfill their obligation to their beneficiaries by covering such therapy, and be required to cover appropriate 'off-label' uses of drugs on their formulary.
2. Our AMA strongly supports the important need for physicians to have access to accurate and unbiased information about off-label uses of drugs and devices, while ensuring that manufacturer-sponsored promotions remain under FDA regulation.
3. Our AMA supports the dissemination of generally available information about off-label uses by manufacturers to physicians. Such information should be independently derived, peer reviewed, scientifically sound, and truthful and not misleading. The information should be provided in its entirety, not be edited or altered by the manufacturer, and be clearly distinguished and not appended to manufacturer-sponsored materials. Such information may comprise journal articles, books, book chapters, or clinical practice guidelines. Books or book chapters should not focus on any particular drug. Dissemination of information by manufacturers to physicians about off-label uses should be accompanied by the approved product labeling and disclosures regarding the lack of FDA approval for such uses, and disclosure of the source of any financial support or author financial conflicts.
4. Physicians have the responsibility to interpret and put into context information received from any source, including pharmaceutical manufacturers, before making clinical decisions (e.g., prescribing a drug for an off-label use).
5. Our AMA strongly supports the addition to FDA-approved labeling those uses of drugs for which safety and efficacy have been demonstrated.
6. Our AMA supports the continued authorization, implementation, and coordination of the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act.
Citation: (Res. 30, A-88; Reaffirmed: BOT Rep. 53, A-94; Reaffirmed and Modified by CSA Rep. 3, A-97; Reaffirmed and Modified by Res. 528, A-99; Reaffirmed: CMS Rep. 8, A-02; Reaffirmed: CMS Rep. 6, A-03; Modified: Res. 517, A-04; Reaffirmation I-07; Reaffirmed: Res. 819, I-07; Reaffirmation A-09; Reaffirmation I-10; Modified: BOT Rep. 5, I-14; Reaffirmed: Res. 505, A-15)

Long-Term Care Prescribing of Atypical Antipsychotic Medications H-25.989

Our AMA: (1) will collaborate with appropriate national medical specialty societies to create educational tools and programs to promote the broad and appropriate implementation of non-pharmacological techniques to manage behavioral and psychological symptoms of dementia in nursing home residents and the cautious use of medications; (2) supports efforts to provide additional research on other medications and non-drug alternatives to address behavioral problems and other issues with patients with dementia; and (3) opposes the proposed requirement that physicians who prescribe medications with "black box warnings on an off-label basis certify in writing that the drug meets the minimum criteria for coverage and reimbursement by virtue of being listed in at least one of the authorized drug compendia used by Medicare."
Citation: (Res. 819, I-11)

Food and Drug Administration H-100.980
(1) AMA policy states that a strong and adequately funded FDA is essential to ensuring that safe and effective medical products are made available to the American public as efficiently as possible. (2) Our AMA: (a) continue to monitor and respond appropriately to legislation that affects the FDA and to regulations proposed by the FDA; (b) continue to work with the FDA on controversial issues concerning food, drugs, biologics, radioactive tracers and pharmaceuticals, and devices to try to resolve concerns of physicians and to support FDA initiatives of potential benefit to patients and physicians; and (c) continue to affirm its support of an adequate budget for the FDA so as to favor the agency's ability to function efficiently and effectively. (3) Our AMA will continue to monitor and evaluate proposed changes in the FDA and will respond as appropriate.
Citation: Sub. Res. 548, A-92; BOT Rep. 32, A-95; BOT Rep. 18, A-96; Reaffirmed: BOT Rep. 7, I-01; Reaffirmation I-07; Reaffirmed: Sub. Res. 504, A-10; Reaffirmation A-15; Reaffirmed: CMS Rep. 06, I-16; Reaffirmed: CMS Rep. 07, A-18;

FDA H-100.992
1. Our AMA reaffirms its support for the principles that: (a) an FDA decision to approve a new drug, to withdraw a drug's approval, or to change the indications for use of a drug must be based on sound scientific and medical evidence derived from controlled trials, real-world data (RWD) fit for regulatory purpose, and/or postmarket incident reports as provided by statute; (b) this evidence should be evaluated by the FDA, in consultation with its Advisory Committees and expert extramural advisory bodies; and (c) any risk/benefit analysis or relative safety or efficacy judgments should not be grounds for limiting access to or indications for use of a drug unless the weight of the evidence from clinical trials, RWD fit for regulatory purpose, and postmarket reports shows that the drug is unsafe and/or ineffective for its labeled indications.
2. The AMA believes that social and economic concerns and disputes per se should not be permitted to play a significant part in the FDA's decision-making process in the course of FDA devising either general or product specific drug regulation.
3. It is the position of our AMA that the Food and Drug Administration should not permit political considerations or conflicts of interest to overrule scientific evidence in making policy decisions; and our AMA urges the current administration and all future administrations to consider our best and brightest scientists for positions on advisory committees and councils regardless of their political affiliation and voting history.
Citation: Res. 119, A-80; Reaffirmed: CLRPD Rep. B, I-90; Reaffirmed: Sunset Report, I-00; Reaffirmation A-06; Appended: Sub. Res. 509, A-06; Reaffirmation I-07; Reaffirmation I-09; Reaffirmation I-10; Modified: CSAPH Rep. 02, I-18; Modified: CSAPH Rep. 02, I-19;

FDA Intrusion into the Practice of Medicine H-270.977
The AMA strongly opposes the FDA's intrusion into the practice of medicine by making decisions for individual care and mandated informed consent documents written without the input of specialists in the related field of medicine.
Citation: (Res. 544, A-92; Reaffirmed: BOT Rep. 28, A-03; Reaffirmed: CMS Rep. 4, A-13)

Code of Medical Ethics 7.3.10 Expanded Access to Investigational Therapies
Physicians who care for patients with serious, life-threatening illness for whom standard therapies have failed, are unlikely to be effective, or do not exist should determine whether questions about access to investigational therapy through the U.S. Food and Drug Administrations expanded access program are likely to arise in their clinical practice. If so, physicians should familiarize themselves with the program to be better able to engage in shared decision making with patients.
When a patient requests expanded access to an investigational therapy, physicians should:
(a) Assess the patients individual clinical situation to determine whether an investigational therapy would be appropriate, including:
(i) whether there is a satisfactory alternative therapy available to diagnose, monitor, or treat the patients disease or condition;
(ii) the nature of potential risks of the investigational therapy and whether those risks are not unreasonable in the context of the patients disease or condition;

(iii) whether the potential benefit to the patient justifies the risks of the investigational therapy;
(iv) whether the patient meets inclusion criteria for an existing clinical trial of the investigational therapy.
(b) As part of the informed consent process, advise the patient (or parent/guardian if the patient is a minor) that the investigational therapy has not yet been demonstrated to be effective in treating the patients condition and may pose as yet unknown risks. Physicians should explain the importance of clinical trials, encourage patients who meet inclusion criteria to participate in an existing trial rather than seek access to investigational therapy through the FDA expanded access program, and direct patients who wish to participate in research to appropriate resources.
(c) Decline to support an application for expanded access to an investigational therapy when:
(i) the physician judges the treatment with the investigational therapy not to be in the patients best interest, and explain why; or
(ii) the physician does not have appropriate resources and ability to safely supervise the patients care under expanded access.
In such cases, physicians should refer the patient to another physician with whom to discuss possible application for expanded access.
(d) Discuss the implications of expanded access for the patient and family and help them form realistic expectations about what it will mean to be treated with the investigational therapy outside a clinical trial. Physicians should alert patients:
(i) to the possibility of financial or other responsibilities associated with receiving an investigational therapy through expanded access;
(ii) to the lack of infrastructure to systematically monitor and evaluate the effects of the investigational therapy outside a clinical trial;
(iii) that they need information about how to contact the manufacturer for guidance if they seek emergency care from a health care professional who is not affiliated with a clinical trial of the investigational therapy;
(iv) that the physician has a responsibility to collect and share clinical information about the patients course of treatment with the investigational therapy, as well as to report any adverse events that may occur over the course of treatment;
(v) to the conditions under which the physician would recommend stopping treatment with the investigational therapy.
AMA Principles of Medical Ethics: V,VI
The Opinions in this chapter are offered as ethics guidance for physicians and are not intended to establish standards of clinical practice or rules of law.

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 510
(November 2020)

Introduced by: Michigan

Subject: Access to Opioid Agonist Treatment for Incarcerated Persons

Referred to: Reference Committee E

Whereas, An estimated 65 percent of the United States prison population has an active substance use disorder (SUD), and between 24 to 36 percent of persons with opioid use disorder (OUD) pass through U.S. prisons and jails each year; however, only five percent of people with OUD in jail and prison settings receive appropriate medication treatment; and

Whereas, The Centers for Disease Control and Prevention and World Health Organization guidelines recommend any opioid agonist treatment (OAT) during incarceration and upon release from prison; however, only approximately half of all U.S. prisons/jails provide treatment options to incarcerated individuals; and

Whereas, Most correctional institutions mandate withdrawal of any OAT upon entry into the criminal justice system, often preventing individuals from engaging in OAT outside of prison in fear of the abrupt cessation of their treatments; and

Whereas, Within one year of leaving prison, up to 10 percent of those who were formerly incarcerated die, and 15 percent of deaths of former inmates are due to opioid-related overdoses; and

Whereas, A 2013 study in Washington State determined that overdose was the leading cause of death of persons who were formerly incarcerated; and

Whereas, OAT, which includes the full agonist methadone and the partial agonist buprenorphine, is an evidence-based, effective treatment for OUD that lessens the harmful health and societal effects of such substance use disorders; and

Whereas, OAT has been studied within correctional facilities in numerous settings in the U.S. and worldwide and has been shown to decrease re-incarceration rates by 20 percent and reduce the hazard of death by 75 percent following release; and

Whereas, One study found that those in a prison who started OAT were less likely to report using heroin and sharing syringes during their incarceration than those on the waiting list for OAT; and

Whereas, Those who start OAT during incarceration have higher rates of successful re-entry into the community, reduced heroin use, and declining recidivism compared to those who do not; and

Whereas, The American Psychiatric Association (APA) policy states that "Jails and prisons should make available quality treatment for substance use disorders to all inmates who qualify for such treatment" and that whenever possible patients who are treated with medication (buprenorphine or methadone) for their OUD should be continued; and

Whereas, The 2017 Presidential Commission on "Combating Drug Addiction and the Opioid Crisis" recommended increased usage of OAT in corrections settings due to preliminary data suggesting OAT treatment reduces risk of overdose and improves outcomes for those with OUD; and

Whereas, The American Society of Addiction Medicine recommends pharmacotherapy (either methadone or buprenorphine) and psychosocial treatment for those with OUD in the criminal justice system and the initiation of pharmacotherapy a minimum of 30 days before release from prison; and

Whereas, Our AMA has endorsed the use of medication for OUD in prisons, encouraged public funding for such programs, and supported the establishment of post-incarceration programs to continue OUD; therefore be it

RESOLVED, That our American Medical Association amend policy H-430.987, "Opiate Replacement Therapy Programs in Correctional Facilities," by addition to read as follows:

H-430.987 Opiate Replacement Therapy Programs in Correctional Facilities

1. Our AMA endorses: (a) the medical treatment model of employing opiate replacement therapy (ORT) as an effective therapy in treating opiate-addicted persons who are incarcerated; and (b) ORT for opiate-addicted persons who are incarcerated, in collaboration with the National Commission on Correctional Health Care and the American Society of Addiction Medicine.
2. Our AMA advocates for legislation, standards, policies and funding that encourage correctional facilities to increase access to evidence-based treatment of opioid use disorder, including initiation and continuation of opioid replacement therapy in conjunction with counseling, in correctional facilities within the United States and that this apply to all incarcerated individuals including pregnant women.
3. Our AMA supports legislation, standards, policies, and funding that encourage correctional facilities within the United States to work in ongoing collaboration with addiction treatment physician-led teams, case managers, social workers, and pharmacies in the communities where patients, including pregnant women, are released to offer post-incarceration treatment plans for opioid use disorder, including education, medication for addiction treatment and counseling, and medication for preventing overdose deaths and help ensure post-incarceration medical coverage and accessibility to medication assisted therapy.
4. <u>Our AMA encourages all correctional facilities to use a validated screening tool to identify withdrawal and determine potential need for treatment for opioid use disorder for all incarcerated persons upon entry.</u> (Modify Current HOD Policy)

Fiscal Note: Minimal - less than $1,000

Received: 10/27/20

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RELEVANT AMA POLICY

Opiate Replacement Therapy Programs in Correctional Facilities H-430.987

1. Our AMA endorses: (a) the medical treatment model of employing opiate replacement therapy (ORT) as an effective therapy in treating opiate-addicted persons who are incarcerated; and (b) ORT for opiate-addicted persons who are incarcerated, in collaboration with the National Commission on Correctional Health Care and the American Society of Addiction Medicine.
2. Our AMA advocates for legislation, standards, policies and funding that encourage correctional facilities to increase access to evidence-based treatment of opioid use disorder, including initiation and continuation of opioid replacement therapy in conjunction with counseling, in correctional facilities within the United States and that this apply to all incarcerated individuals including pregnant women.
3. Our AMA supports legislation, standards, policies, and funding that encourage correctional facilities within the United States to work in ongoing collaboration with addiction treatment physician-led teams, case managers, social workers, and pharmacies in the communities where patients, including pregnant women, are released to offer post-incarceration treatment plans for opioid use disorder, including education, medication for addiction treatment and counseling, and medication for preventing overdose deaths and help ensure post-incarceration medical coverage and accessibility to medication assisted therapy.

Citation: Res. 443, A-05; Reaffirmed: CSAPH Rep. 1, A-15; Appended: Res. 223, I-17

Reference Committee F

CLRPD Report(s)

01 International Medical Graduates Section Five-Year Review
02 Organized Medical Staff Section Five-Year Review
03 Establishment of the Private Practice Physicians Section

HOD Comm on Compensation of the Officers

01 Report of the House of Delegates Committee on the Compensation of the Officers

Resolution(s)

601 Support for the Establishment of Medical-Legal Partnerships
602 Towards Diversity and Inclusion: A Global Nondiscrimination Policy Statement and Benchmark for our AMA
603 Report on the Preservation of Independent Medical Practice
604 Timely Promotion and Assistance in Advance Care Planning and Advance Directives
605 Development of Resources on End of Life Care

REPORT OF THE COUNCIL ON LONG RANGE PLANNING AND DEVELOPMENT

CLRPD Report 1, November 2020

Subject: International Medical Graduates Section Five-Year Review

Presented by: Shannon Pryor, MD, Chair

Referred to: Reference Committee F

The Council analyzed information from a letter of application submitted in June 2019 from the International Medical Graduates Section (IMGS) for renewal of delineated section status and representation in the AMA House of Delegates (HOD). The letter focuses on activities beginning in June 2014.

AMA Bylaw 7.0.9 states, "A delineated section must reconfirm its qualifications for continued delineated section status and associated representation in the House of Delegates by demonstrating at least every 5 years that it continues to meet the criteria adopted by the House of Delegates." AMA Bylaw 6.6.1.5 states that one function of the Council on Long Range Planning and Development (CLRPD) is "to evaluate and make recommendations to the House of Delegates, through the Board of Trustees, with respect to the formation and/or change in status of any section. The Council will apply criteria adopted by the House of Delegates."

APPLICATION OF CRITERIA

Criterion 1: Issue of Concern – Focus will relate to concerns that are distinctive to the subset within the broader, general issues that face medicine. A demonstrated need exists to deal with these matters, as they are not currently being addressed through an existing AMA group.

The IMGS is the only group within the AMA that represents and promotes the interests of physicians who have graduated from medical schools outside the United States or Canada. The IMGS serves its constituents by bringing critical IMG professional issues to the forefront of organized medicine and by providing targeted educational and policy resources.

The mission statement of the IMGS includes the following objectives:

- Represent the views of IMGs in the AMA HOD
- Increase the impact of IMG viewpoints in organized medicine
- Promote IMG participation and visibility at all levels of organized medicine
- Establish two-way communications between grassroots IMGs and organized medicine

During the last five years the following priority issues have been the focus of the IMGS:

- Licensure Parity – 34 states have separate and unequal graduate medical education (GME) requirements for U.S. medical graduates and IMGs and there are significant variations in the GME requirements between states. The IMGS continuously collaborates with staff of the AMA Advocacy Unit to work toward uniformity of licensure requirements for IMGs and graduates of U.S. and Canadian medical schools, including eliminating any disparity in

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the years of GME required for licensure and a uniform standard for the allowed number of administrations of licensure examinations. The IMGS worked with the Advocacy Resource Center to develop a model resolution for states to achieve licensure equality between U.S. medical graduates and IMGs. Several states have adopted this policy.

- Immigration – The IMGS works with the AMA Washington D.C. office to stay abreast of the immigration issues that affect the J-1 Visa Waiver and Conrad 30 Waiver programs for IMGs practicing in underserved areas. Congressional bills that allow for expansion of the Conrad 30 program beyond the assigned 30 slots are monitored on a regular basis. Reauthorizations of the Conrad 30 bill have resulted in more than 16,000 physicians practicing in underserved areas. Additionally, the IMGS has authored or contributed to a total of 17 resolutions and reports that have been adopted by the AMA HOD regarding the Conrad 30 and J-1 Visa Waiver programs.

- Graduate Medical Education Expansion – Thousands of qualified IMGs (many who are U.S. citizens or permanent residents) have been unable to enter the physician workforce due to the number of GME positions being capped by Congress in 1994. Simultaneously, the physician workforce shortage continues to grow. The section's legislative priority has been to call for an increase in the number of GME positions to help alleviate the physician workforce shortage and increase access to care for patients.

- Discrimination – Discriminatory issues have been addressed by the IMGS through resolutions submitted to the HOD, educational sessions, open forums, webinars, employment contract guidelines and the filing of amicus briefs. Some professional issues addressed include the Bachelor of Medicine and Bachelor of Surgery (MBBS) degree equivalent; licensure disparity; disparities in the residency selection process; and visa issues related to delays, denials, caps and green card backlogs. The IMGS has worked with AMA staff to communicate with the U.S. Citizenship Immigration Services and U.S. congresspeople regarding these issues.

CLRPD assessment: The IMGS provides the only formal structure for physicians who graduated from medical schools outside the United States and Canada to participate directly in the deliberations of the HOD and the activities of the AMA. The section's areas of focus are of specific concern to IMGs, and the IMGS works to ensure that the unique viewpoints of IMGs are represented in organized medicine.

Criterion 2: Consistency – Objectives and activities of the group are consistent with those of the AMA. Activities make good use of available resources and are not duplicative.

The IMGS has worked to connect its activities to the AMA's strategic goals. Some efforts have included the launch of a digital community that has hosted approximately 15 online discussions on issues connected to the AMA's strategic direction, such as improving health outcomes, solutions to a healthier nation and health equity. More than 700 members signed up for the digital community in the first six months of its existence, and discussions have led to more than 25,000 pageviews and comments by physician members.

The IMGS also collaborated with the Improving Health Outcomes group on awareness campaigns that provide outreach and information to underserved areas on blood pressure and diabetes. In 2019, the IMGS collaborated with the Medical Student and Resident and Fellow Sections to participate in the AMA Research Symposium/Expo for the eighth consecutive year. During the

event, Educational Commission for Foreign Medical Graduates (ECFMG)-certified physicians who are awaiting residency showcase research for adjudication by expert physician panels.

The IMGS strives to equip physician leaders with the knowledge, skills, resources and opportunities to influence organized medicine. The Busharat Ahmad, MD Leadership Development Program has been available at each Annual and Interim Meeting since 2008 and aims to provide participants with skills to become more effective leaders. Several sessions qualified physicians for *AMA PRA Category 1 Credit™*.

In addition, members of the IMGS serve as AMA ambassadors to champion the value of AMA membership and publicize AMA work. IMGs also participate in the Members Move Medicine campaign, helping to demonstrate the value of the AMA and IMGS and carry the AMA message forward.

CLRPD Assessment: The IMGS has worked to align its goals and activities with the strategic direction of the AMA. The section collaborates regularly with other AMA groups and units to develop and participate in programs that support the AMA's strategic goals while avoiding duplication of effort and resources.

Criterion 3: Appropriateness – The structure of the group will be consistent with its objectives and activities.

Nearly 6,000 IMGS members participate in some aspect of the business of the IMGS by attending meetings; participating in webinars, digital communities, committees, elections and/or online reference committees; responding to surveys; and/or participating at ethnic society meetings and exhibits.

The IMGS provides opportunities for its members to participate in the policymaking process biannually during annual and interim meetings of the HOD. An online member forum allows section members an opportunity to comment on and ratify reports and resolutions in advance of each meeting. The section has established deadlines for member input, which allows time for review by the Resolution and Policy Committee and IMGS members. Resolution guidelines and a checklist are provided to members via newsletters and the section's web page. All resolutions are vetted by section delegates, the Resolution and Policy Committee and the governing council (GC).

Elections for the IMGS GC are held annually and provide another mechanism for IMG members to become involved in section governance. Nominations are reviewed and scored by the IMGS nominating committee, which is comprised of section members. This process results in a roster of candidates for elections. The IMGS GC directs the section's agenda, endorses section members for leadership positions within the AMA and other organizations, carries out the policies and actions adopted by the IMGS, and works with AMA leaders to ensure alignment with the AMA strategic plan.

CLRPD Assessment: The IMGS provides a variety of opportunities for its members to participate in the activities of the section and the AMA policymaking process. The GC is elected by and from the section's membership. The IMGS structure is consistent with the objectives of this section.

Criterion 4: Representation Threshold – Members of the formal group would be based on identifiable segments of the physician population and AMA membership. The formal group would be a clearly identifiable segment of AMA membership and the general physician population. A

substantial number of members would be represented by this formal group. At minimum, this group would be able to represent 1,000 AMA members.

Members of the IMGS are graduates of medical schools outside the United States or Canada. IMGs who join the AMA automatically become members of the IMGS. Involvement in the IMGS GC, committees, meetings and events require that a physician be a current AMA member.

The IMGS membership increased from approximately 37,000 to 43,554 members from 2014 to 2019. IMGS members represent 17.4% of AMA membership and account for 24.9% of all physicians in the United States, according to CLRPD Report 1-A-19, "Demographic Characteristics of the House of Delegates and AMA Leadership." Per that same report, the potential membership of the IMGS, i.e., all IMGs in the United States, is 306,782.

CLRPD Assessment: The IMGS is comprised of members from an identifiable segment of AMA membership and the general physician population. This group represents more than 1,000 AMA members.

Criterion 5: Stability – The group has a demonstrated history of continuity. This segment can demonstrate an ongoing and viable group of physicians will be represented by this section and both the segment and the AMA will benefit from an increased voice within the policymaking body.

The IMG Advisory Committee became a section in 1997. The IMGS has averaged approximately 77 attendees at each section meeting since 2015. IMGS meetings and events are promoted via section newsletters, AMA Morning Rounds, 75 ethnic society partners and 25 IMG state chair groups. An ECFMG membership category was created to include early career physicians seeking assistance and support from the IMGS. This membership category includes approximately 5,000 ECFMG-certified physicians awaiting residency. From 2015 to 2018, IMG Symposium meetings averaged approximately 65 attendees and yielded 12 new AMA members.

Since its inception, the IMGS has authored over 115 resolutions addressing a broad range of IMG issues. Since 2014, the section has introduced 17 resolutions to our AMA HOD. New policies adopted by the HOD resulted in letters from the AMA being written to legislators on the topics of expansion of GME positions through alternative funding and the green card backlog for immigrant physicians on H-1B Visas; the development of educational programs during annual and interim meetings on competency and aging physicians; the creation of resources to help IMGs participate in organized medicine; and IMGS collaboration with the Council on Medical Education to communicate with management of the National Residency Matching Program on the issue of bias in the Electronic Residency Application Service.

Additionally, the IMGS has collaborated or will collaborate with other AMA units on HOD reports on topics including competency and aging physicians, physician burnout and wellness, legalization of the Deferred Action for Legal Childhood Arrival (DALCA), and the grandfathering of qualified applicants practicing in U.S. institutions with restricted medical licensure.

CLRPD Assessment: The IMGS has a history of more than 20 years with the AMA and continues to seek out opportunities to grow membership and engagement. The AMA HOD benefits from the distinct voice of the section; activities of the IMGS have led to the creation of policy and AMA activities addressing issues of relevance to IMGs.

Criterion 6: Accessibility – Provides opportunity for members of the constituency who are otherwise underrepresented to introduce issues of concern and to be able to participate in the policymaking process within the AMA HOD.

The IMGS addresses issues that affect IMGs and creates opportunities for its members to engage in the policymaking process. According to CLRPD Report 1-A-19, IMGS make up 17.4% of AMA members and 22.9% of all physicians and medical students yet comprise only 6.7% of delegates and 9.2% of alternate delegates, demonstrating a significant level of underrepresentation in the AMA's policymaking body.

Section members have the opportunity to submit resolutions, as well as participate on committees and an online member forum. All resolutions are vetted by section delegates, the Resolution and Policy Committee and the GC. The section's Resolution and Policy Committee meets via teleconference biannually to discuss policymaking ideas that have been submitted, and authors of resolutions are invited to participate in each teleconference. IMGS members may also voice their opinions on policy initiatives during business meetings, reference committee hearings and IMGS caucuses. The online forum allows for both commenting on and ratification of resolutions, and has generated significant activity, averaging over 1,000 comments and approvals per year from 2015-2018 (a new process and subsequent delayed promotion hampered participation in 2019). The section makes resolution guidelines and a checklist available to members via newsletters and their web page. The IMGS also provides an opportunity for other sections and councils to provide input on resolutions being considered for annual and interim meetings, which are shared with the IMGS GC.

CLRPD Assessment: The IMGS provides opportunities for members of its constituency who are otherwise underrepresented to introduce issues of concern and participate in the HOD policymaking process.

CONCLUSION

The CLRPD has determined that the IMGS meets all criteria; therefore, it is appropriate to renew the delineated section status of the section, allowing the continued focused representation of IMGS members in the HOD.

RECOMMENDATION

The Council on Long Range Planning and Development recommends that our American Medical Association renew delineated section status for the International Medical Graduates Section through 2025 with the next review no later than the 2025 Annual Meeting and that the remainder of this report be filed. (Directive to Take Action)

Fiscal Note: Less than $500

REPORT OF THE COUNCIL ON LONG RANGE PLANNING AND DEVELOPMENT

CLRPD Report 2, November 2020

Subject: Organized Medical Staff Section Five-Year Review

Presented by: Shannon Pryor, MD, Chair

Referred to: Reference Committee F

The Council on Long Range Planning and Development (CLRPD) analyzed information from a letter of application submitted in June 2019 from the Organized Medical Staff Section (OMSS) for renewal of delineated section status and representation in the AMA House of Delegates (HOD). The letter focused on activities beginning in June 2014.

AMA Bylaw 7.0.9 states, "A delineated section must reconfirm its qualifications for continued delineated section status and associated representation in the House of Delegates by demonstrating at least every 5 years that it continues to meet the criteria adopted by the House of Delegates." AMA Bylaw 6.6.1.5 states that one function of the Council on Long Range Planning and Development (CLRPD) is "to evaluate and make recommendations to the House of Delegates, through the Board of Trustees, with respect to the formation and/or change in status of any section. The Council will apply criteria adopted by the House of Delegates."

APPLICATION OF CRITERIA

Criterion 1: Issue of Concern - Focus will relate to concerns that are distinctive to the subset within the broader, general issues that face medicine. A demonstrated need exists to deal with these matters, as they are not currently being addressed through an existing AMA group.

The OMSS addresses matters concerning hospital and health system medical staffs and, more generally, issues facing physicians, whether employed or in private practice, practicing within the hospital setting. Major concerns/issues addressed by the OMSS include, but are not limited to:

- Medical staff self-governance and the physician-hospital relationship;
- Medical staff functions such as credentialing, privileging, peer review, etc.;
- Physician protections such as due process rights, etc.;
- Quality improvement in the hospital setting;
- Hospital accreditation standards [Medicare's Conditions of Participation (CoPs) and deeming authorities] and other hospital-related regulatory and legislative matters;
- Hospital management models, such as co-management service line agreements and other joint management arrangements;
- Development of physician leaders in the hospital setting;
- Physician employment and contracting in the hospital setting; and
- Relationships between independent and employed members of the medical staff.

The OMSS empowers physicians affiliated with medical staffs to improve patient outcomes and physician experience, and to otherwise effect positive change in their practice environments. OMSS membership is open to AMA members selected by their hospital or health system medical

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staffs to represent the interests and concerns of their medical staff peers at biannual OMSS meetings and to serve as liaisons between the OMSS and local medical staffs. As an advocate, the OMSS continues to play a critical role in helping medical staffs and their physicians remove roadblocks that impede patient care.

CLRPD Assessment: The OMSS is the sole component group that focuses on issues concerning hospital and health system medical staffs, and more generally, issues facing physicians practicing within the hospital setting. The section provides a direct and ongoing relationship between the AMA and this cohort of physicians.

Criterion 2: Consistency - Objectives and activities of the group are consistent with those of the AMA. Activities make good use of available resources and are not duplicative.

In 2017, the OMSS updated its publication, "AMA Physicians Guide to Medical Staff Organization Bylaws"—a reference manual for drafting or amending medical staff bylaws and improved understanding of emerging issues in health care that impact the medical staff. Additionally, the OMSS has produced the following resources:

- In 2017, the section delivered the presentation, "Managing Disruptive Behavior" to a group of more than 200 medical staff professionals at a conference of the National Association of Medical Staff Services, and worked with AMA Credentialing Services to develop a white paper on the topic for distribution at medical staff professional meetings and other relevant trade shows. In 2018, the OMSS created an online education module, "Addressing Disruptive Physician Behavior," which more than 400 registrants have completed to date.

- Since 2014, Medicare's CoPs have permitted unification of multiple medical staffs across a multi-hospital system. In 2017, the section observed that medical staffs were not officially unifying, but rather were unifying some functions while leaving others separate. The OMSS coined the term "systematization" to describe this phenomenon and has educated medical staff leaders on this topic.

- The OMSS conducted a comprehensive review of AMA policy on medical staff topics that led to the adoption of new policy, H-225.942, "Physician and Medical Staff Member Bill of Rights," which outlines the responsibilities and rights of both the medical staff organization and its individual members, and explicitly stated for the first time in AMA policy why medical staffs should be self-governing.

- A physician's surrender of privileges during an investigation has always been reportable to the National Practitioner Data Base (NPDB), even when the investigation ultimately clears the physician of any wrongdoing. However, 2016 revisions to The NPDB Guidebook prompted hospitals and other reporting entities to adopt a broader definition of "investigation," which interprets any leave of absence as a "surrender of privileges." OMSS addressed this alarming change by developing protective model medical staff bylaws language and a whitepaper to educate physicians on processes they should follow when taking a leave of absence or surrendering privileges.

Medical staff leaders, other physician members of the medical staff, hospital/health system administrators, health care law attorneys, medical staff professionals, state/specialty medical society leadership and staff, and other stakeholders look to the OMSS for guidance on the section's major concerns and other issues. Examples of OMSS collaborative efforts include the following:

- OMSS works closely with the National Association of Medical Staffing Services (NAMSS) on credentialing and privileging issues to ensure physician and resident interests are protected and the processes become as streamlined as possible.

- The section is working closely with the American Board of Medical Specialties (ABMS) as it begins implementation of a study of recommendations to revamp the Maintenance of Certification (now called Continuing Board Certification) process.

- Other Federation organizations, such as the American College of Surgeons regularly seek the section's advice on issues impacting upon OMSS members and their colleagues.

OMSS work continues to be in alignment with the AMA's three strategic arcs, for example:

- Input from OMSS medical staff representatives assist in guiding the AMA's work in the management of chronic diseases.

- The medical staffs and individual medical staff members are on the front line of care delivery to identify scientific and clinical expertise that future physicians must learn. Equally important, it is many of these physicians who will continue to mentor newly minted physicians.

- As educator and advocate to health system/hospital/medical group medical staffs and their physicians, the OMSS is focused on issues concerning physicians and health care systems. OMSS medical staff representatives report back to AMA on the activities that create roadblocks to the delivery of patient care and that detract from the joy of medical practice.

CLRPD Assessment: The OMSS serves its constituents by bringing unique professional issues to the forefront of organized medicine and by providing targeted educational and policymaking resources. Additionally, the section has selected areas of focus that align closely with the AMA's strategic direction and other AMA efforts/products and has sought opportunities for collaboration on cross-cutting issues and programs with other organizations.

Criterion 3: Appropriateness - The structure of the group will be consistent with its objectives and activities.

Prior to 2016, membership in the OMSS was reserved for physicians who had been officially selected to represent their medical staffs at OMSS business meetings. While supportive of this representative model, OMSS was concerned that it might be impairing the section's ability to engage physicians by limiting interaction with the AMA to a maximum of just one physician per medical staff. In 2016, OMSS decoupled "membership" in the section from voting rights at OMSS business meetings, expanding eligibility from physicians officially representing their medical staffs to all physicians who belong to a medical staff. However, voting and other rights (e.g., introducing business, making motions, serving in elected positions) remain limited to certified OMSS representatives.

In 2018, OMSS launched a comprehensive recertification process in which OMSS representatives were required to reconfirm their continuing status as the representative of the medical staff on file. This process resulted in the de-certification of a substantial number of representatives, most of whom had retired or who simply failed to respond to multiple email and phone inquiries from section leadership and staff. While the recertification effort reduced the number of OMSS

representatives to 137, the section has been diligent to rebuild its membership, growing the number of certified representatives by 17% (24 representatives) since 2018.

Section members are offered a wide range of opportunities to participate in OMSS activities. Although the Annual and Interim Meetings of the HOD are the most obvious of these opportunities, the section actively promotes the notion that one need not attend meetings to contribute to the work of OMSS and provides a variety of opportunities for between-meeting engagement, for example:

- OMSS committees: education (expanded in 2015 to include non-governing council members, policy (established in 2018), membership and engagement (established in 2018);
- Online member forum enables all representatives to contribute to the policymaking activities of the section, regardless of whether they can attend meetings;
- Quarterly conference calls update representatives on the work of the section;
- Surveys gauge representatives' interest in potential topics for future education programs;
- Surveys provide a voice to representatives in the section's strategic planning activities;
- Peer-to-peer outreach program for members who wish to contribute to recruitment efforts;
- Calls to action on vital legislative and regulatory issues (e.g., Joint Commission field reviews); and
- Weekly emails (sent to more than 800 subscribers) with relevant medical staff news.

In 2016 and 2017, the OMSS Governing Council (GC) conducted a comprehensive review of the section's work and developed a strategic framework to better focus the section's future efforts on patient outcomes and physician experience through education, advocacy, best practices and collaboration to ensure maximum impact.

CLRPD Assessment: The structure of the OMSS allows members to participate in the deliberations and pursue the objectives of the section, including opportunities for between-meeting engagement. The OMSS has decoupled membership in the section from voting rights at OMSS business meetings, which expanded membership eligibility to all physicians who belong to a medical staff. The OMSS GC developed a strategic framework to enhance the section's focus and impact of future efforts.

Criterion 4: Representation Threshold - Members of the formal group would be based on identifiable segments of the physician population and AMA membership. A substantial number of members would be represented by this formal group. At minimum, this group would be able to represent 1,000 AMA members. It is important to note this threshold will not be used to determine representation, as each new section will be allocated only one delegate and one alternate delegate in the AMA HOD.

As of the 2019 Annual Meeting of the HOD, 161 OMSS representatives had been certified as official representatives of medical staffs. Assuming an average medical staff size of 150 physicians, 15% of practicing physicians are AMA members; therefore, OMSS conservatively estimates that approximately 3,600 AMA member physicians currently are directly represented in the OMSS through their staffs' OMSS representatives.

However, OMSS assumes (conservatively) that 60% of all practicing physicians (i.e., not including medical students, residents, or retired physicians) are members of at least one medical staff. Using data from CLRPD Report 1-A-19, "Demographic Characteristics of the House of Delegates and AMA Leadership," the section can deduce that the total potential representation in the OMSS is

approximately 63,000 (60% of 104,591 AMA practicing physician members who are appointed to at least one medical staff).

CLRPD Assessment: The OMSS conservatively estimates that 3,600 AMA member physicians are directly represented through their staffs' OMSS representatives, which exceeds the minimum threshold of 1,000 AMA members. Further, the total potential representation in the OMSS encompasses a significant number of AMA members.

Criterion 5: Stability - The group has a demonstrated history of continuity. This segment can demonstrate an ongoing and viable group of physicians, who will be represented by this section. Both the segment and the AMA will benefit from an increased voice within the policymaking body.

Established in 1983, the OMSS submits an average of five to seven resolutions for consideration of the HOD at each meeting, over 90% of which are eventually adopted in some form. OMSS resolutions on pressing issues of medical staffs originate in one of two ways: 1) individual OMSS representatives who, through the experiences of the medical staffs they represent; or 2) OMSS representatives acting on behalf of their state-level OMSS groups whose medical societies are not well positioned to identify a problem or address an issue for the AMA policymaking process.

In addition to OMSS annual and interim meetings, the section hosts three "Medical Staff Update" webinars each year, which have averaged 46 attendees each since 2014. In total, 76% of currently certified OMSS representatives have attended at least one live event in the last three years. The impact of each OMSS meeting is felt far beyond the individuals in attendance, as OMSS representatives are expected to report back to the medical staffs they represent on the actions of the meeting and the ongoing activities of the section. The section facilitates this task by making available, soon after each meeting, a detailed meeting summary and PowerPoint presentation that representatives use to provide updates to their medical staffs. A 2018 census of OMSS representatives found that nearly 90% of respondents frequently or sometimes report on OMSS actions and activities during their medical staff meetings. Many representatives also report back to their state and specialty medical societies.

The OMSS traditionally has communicated with its members and other individuals interested in medical staff topics through a monthly email newsletter with approximately 800 subscribers. In 2017, OMSS launched a Facebook group, which currently has 210 members, to provide a platform for members to discuss relevant topics and stay connected on a personal level. Additionally, the section is actively exploring opportunities and platforms to engage members year-round in the policymaking process.

While the OMSS continues to explore other engagement options, the section has shifted its outreach focus to two key groups: 1) peers of existing OMSS members (i.e., peer-to-peer outreach program); and 2) individuals who have engaged with the AMA through a medical staff-related resource. This focus, and communication with these groups, yielded 20 new OMSS representatives in 2018.

CLRPD Assessment: The OMSS has a long history with the AMA and since its inception has taken numerous steps to align its structure with the policymaking activities of the AMA. The section has introduced or significantly contributed to many resolutions and reports that resulted in new policies; therefore, the HOD has benefited from the distinct voice of the OMSS.

Criterion 6: Accessibility - Provides opportunity for members of the constituency, who are otherwise under-represented, to introduce issues of concern and to be able to participate in the policymaking process within the HOD.

Although supporting data are not available, it is reasonable to surmise that most members of the HOD are members of at least one medical staff. Many OMSS representatives (over 30%) serve as AMA delegates for their state or specialty medical societies. Thus, it appears that medical staff members and their concerns are well-represented in the HOD; however, it can be difficult to usher medical staff-related resolutions through the policymaking processes of state and specialty medical societies. This is true for multiple reasons, but perhaps primarily because many of these organizations lack the time, resources and expertise necessary to develop solutions to complex and nuanced medical staff problems.

The OMSS is the recognized center of expertise within the AMA for medical staff and hospital issues; therefore, the OMSS serves as an entry point to the HOD for most resolutions addressing these matters, even though such issues directly affect a large percentage of AMA delegates. In this sense, the OMSS provides an opportunity for "underrepresented" members to introduce issues of concern and to participate in the Association's policymaking process.

The section is a conduit for members to provide input on topics under consideration within the HOD. OMSS reviews resolutions and reports under consideration at each meeting and, in a democratic process led by the Governing Council, determines which items the section should take positions on and what those positions should be. The OMSS provides its members with opportunities to testify on behalf of the section at reference committee hearings and participate in briefing/strategy sessions before HOD reference committee hearings and during post-reference committee debriefings, both of which are open to all OMSS representatives and other AMA members interested in medical staff matters.

CLRPD Assessment: Medical staff physicians' concerns are significant and are frequently topics of discussion in reference committees and HOD sessions. The OMSS reviews, assesses and provides testimony on a wide variety of reports and resolutions related to issues facing physicians, whether employed or in private practice, who practice within the hospital setting. Consequently, having the perspective and expertise of the OMSS is important to the AMA when creating policy.

CONCLUSION

The CLRPD has determined that the OMSS meets all required criteria; therefore, it is appropriate to renew the delineated section status of the OMSS.

RECOMMENDATION

The Council on Long Range Planning and Development recommends that our American Medical Association renew delineated section status for the Organized Medical Staff Section through 2025 with the next review no later than the 2025 Annual Meeting and that the remainder of this report be filed. (Directive to Take Action)

Fiscal Note: Less than $500

REPORT OF THE COUNCIL ON LONG RANGE PLANNING AND DEVELOPMENT

CLRPD Report 3, November 2020

Subject: Establishment of the Private Practice Physicians Section

Presented by: Shannon Pryor, MD, Chair

Referred to: Reference Committee F

In April 2019, the Council on Long Range Planning and Development (CLRPD) received a Letter of Application from the Private Practice Physicians Congress (PPPC) requesting a change in status from a caucus to a section, the Private Practice Physicians Section (PPPS). AMA Bylaws on Sections (§7.00) define the mission of AMA sections and identify each section as fixed or delineated. This report presents CLRPD's evaluation of the proposal for the PPPS using the criteria identified by Policy G-615.001, "Establishment and Functions of Sections" in consideration of requests for establishing new sections or changing the status of member component groups.

APPLICATION OF CRITERIA

Following an initial review and discussion of the PPPC proposal for section status, the CLRPD posed additional questions to the leadership of the group for clarification of some of the information presented in its Letter of Application. This report presents each criterion followed by excerpts of the letter and PPPC leadership's response to CLRPD's request for additional information. The Council's assessment of how this information aligns with each criterion is included.

1. Issue of Concern - Focus will relate to concerns that are distinctive to the subset within the broader, general issues that face medicine. A demonstrated need exists to deal with these matters, as they are not currently being addressed through an existing AMA group.

According to an AMA 2018 benchmark survey,[1] 2016 was the first year in which less than half of practicing physicians had an ownership stake in their practice and 2018 marked the first year in which there were fewer physician owners than employees. The findings underscore a trend of shifting ownership across physician practices. Over the last several years, the number of self-employed physicians has been on the decline. In 2018, nearly half (47.4%) of all patient care physicians were employed physicians--up 6% from 2012. In 2018, 45.9% of all patient care physicians were self-employed--down 7 points since 2012. Seven percent of physicians were independent contractors. In 2018, over half of physicians (54%) worked in physician-owned practices as an employee, owner or contractor—down from 60% in 2012. The share of physicians in solo practice dropped from 18.4% in 2012 to 14.8% in 2018. Of physicians who worked in physician-owned practices, 40% were small businesses with 10 or fewer physicians. Over the same period, the share of physicians working directly for a hospital or a practice at least partly owned by a hospital increased from 5.6% to 8%, with the share of physicians in hospital-owned practices increasing to 26.7%. While the AMA does not track specific data on private practice physicians per se, data from CLRPD Report 1-A-19[2] indicate that 7.7% of AMA members are solo practitioners and 1.4% of AMA members represent two-physician practices.

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Established in 2008 as a caucus, the PPPC provides a dedicated forum to create awareness of private practice physician issues and strengthen the AMA's ability to represent this physician constituency. In many traditional private practice settings, physicians spend years, even decades, developing rapport with their patients and gaining an intimate knowledge of their medical history. Physicians make decisions based on their understanding of their patients' lifestyles and the effects those lifestyles have on patient health.

Over the past 12 years, through the forum and during meetings of the Congress, AMA members have identified and discussed private practice-related issues including: meeting patient expectations, remaining independent amidst rising costs of government reporting and changing reimbursement models, managing quality measures to maximize ability to meet payer requirements for reporting, managing inefficient EHR data entry without proper training and support, avoiding burnout and eliminating site of service payment differentials.

CLRPD Assessment: The proposed PPPS would be dedicated to advocacy on private practice physician policy issues, provide leadership development and educational opportunities for medical students and young physicians, and monitor trends and issues that affect private practice physicians.

2. Consistency - Objectives and activities of the group are consistent with those of the AMA. Activities make good use of available resources and are not duplicative.

As a caucus, the PPPC has very limited input into the business of the HOD, namely proposing and ushering through original resolutions regarding areas of concern to private practice physicians. Except for a room at each HOD meeting, the Congress has performed all of its activities without the advantages of AMA resources. In 2014, the PPPC received grants from the Physicians Foundation to assist its funding of educational programs and activities. Since 2008, PPPC has used a free Google Group Listserv for communications with its members.

Members of the AMA Integrated Physician Practices Section (IPPS) have delivered presentations during PPPC meetings; however, the perspectives of the two groups differ in that IPPS focuses on integration of care, which often takes place in large multispecialty systems; conversely, the PPPC focuses on the preservation of independent, private practices. Additionally, PPPC has engaged with the Medical Student Section, the Resident and Fellow Section, and the Young Physicians Section and found there is an interest among members of these sections to learn more about the lifestyle and interests of private practice physicians.

The goals of the PPPS include, but are not limited to, the following:

- Providing a forum for networking, mentoring, advocacy, educational activities and leadership development for private practice physicians, young physicians, residents and medical students.
- Contributing to AMA efforts to increase membership, participation, and leadership of private practice physicians in the AMA.
- Monitoring trends, identifying and addressing emerging professional issues affecting private practice physicians.
- Enhancing outreach, communications and working relationships between the AMA and organizational entities that are relevant to the activities of the section.
- Expanding AMA advocacy on private practice policy issues such as health system reform that enables private practices to remain economically and professionally viable.

CLRPD Assessment: The PPPS would generate projects relevant to private practice physicians and physicians in training who have an interest in private practice. Improving outreach and creating new opportunities for participation among private practice physicians may incentivize non-members of this demographic to become AMA members. Within the AMA, there are no component groups solely devoted to advocacy and education related to issues that are specific to the private practice of medicine.

3. Appropriateness - The structure of the group will be consistent with its objectives and activities.

The PPPS would provide a voice for physicians who are active members of the AMA in physician-owned private practices and a forum for physicians who are interested in or committed to the concept of physician owned and controlled practices to network. The section's Credentials Committee will review all applications for membership and determine whether an applicant's practice meets the criteria for membership. The PPPS would seek to be inclusive of AMA members; therefore, if an individual did not initially meet membership criteria, they could make a request for reconsideration by the governing council (GC).

As a section, the GC will submit nominations for elected positions of the GC, delegate and alternate delegate and allow for nominations and elections from the membership. Terms of service will be two years as proposed in the draft IOP. The GC and the delegates will meet prior to the AMA HOD meetings and at other times through the year.

The officers of the PPPS shall be the seven elected, voting members of the GC: chair, vice chair, secretary, delegate, alternate delegate, a member at-large from a practice of 1 to 8 physicians, and a member at-large from a practice of 9 to 50 physicians. Additionally, immediately upon completion of his or her term as chair, the immediate past chair shall serve, ex officio, as a voting member of the GC. All section members shall be eligible for election or appointment to the GC. If a GC member ceases to meet the eligibility requirements before the expiration of the term for which he or she was elected, the term of such member shall terminate, and the position declared vacant. The GC shall direct the programs and activities of the PPPS that are subject to approval by the BOT or HOD.

CLRPD Assessment: The structure of the proposed PPPS is conducive to sharing key concerns and identifying meaningful opportunities for private practice physicians, which supports the objectives of this group. In accordance with the AMA Bylaws, sections are required to have an elected GC from the voting members of the section and establish a business meeting that would be open to its members. The PPPC presently has an established online forum, which could create an avenue for a voting body to elect GC members. While the PPPC conducts a caucus at HOD meetings, as the Private Practice Physicians Section, the caucus will be restructured to mirror the assemblies used by the current delineated sections.

4. Representation Threshold - Members of the formal group would be based on identifiable segments of the physician population and AMA membership. A substantial number of members would be represented by this formal group. At minimum, this group would be able to represent 1,000 AMA members. It is important to note this threshold will not be used to determine representation, as each new section will be allocated only one delegate and one alternate delegate in the AMA HOD.

According to CLRPD Report 1-A-19, "Demographic Characteristics of the House of Delegates and AMA Leadership," the combined number of physician members in solo (19,263) and small

physician practices (3,560) is approximately 12% of AMA physician members. According to the 2018 AMA benchmark survey, 47.1% of practicing physicians have an ownership stake in their practice--approximately 400,000 physicians. If AMA market share is considered to be 12% to 15%, then 48,000 to 60,000 physicians in private practice are AMA members and would be represented in the PPPS. While these numbers are estimates, the total is well above the 1,000 AMA member threshold.

CLRPD Assessment: Private practice physicians remain a substantial market segment for our AMA and this section would represent over 1,000 AMA members.

5. Stability - The group has a demonstrated history of continuity. This segment can demonstrate an ongoing and viable group of physicians, who will be represented by this section. Both the segment and the AMA will benefit from an increased voice within the policymaking body.

The PPPC became more organized as its membership grew. Since 2013, the group's membership increased from around 50 to over 200 AMA members. Attendance at PPPC meetings ranges from 80 to 150 members--with 20 to 30 new members at each meeting. The PPPC listserv of approximately 200 participants connects the group's membership between and during meetings. Members are very well informed on the socioeconomic facets of medicine and PPPC leadership has remained stable.

The Congress convenes subcommittees focused on education, social media and member engagement and would institute a training program for members to assume leadership roles within the section. Section status would allow the group to develop and engage members in educational programs on private practice and leadership. Previously, the PPPC organized these types of programs for medical students and young physicians, which were well attended. Section status with the support of staff, who perform multiple tasks that enhance the work of sections, e.g., engaging in research, managing communications, promoting membership growth, preparing for meetings, and facilitating the development of educational activities on topics of interest to section members would provide a formalized structure with systematic and administrative processes to ensure stability of the section.

CLRPD Assessment: Since its inception, the Congress has taken steps to align its structure with the activities of the AMA. PPPC leadership has built a solid foundation for the group, which, at this stage, would benefit from a delegate's voice to address private practice issues in the HOD. As the number of private practice physicians in the country continues to decline, the AMA's policymaking process could be strengthened by ensuring that the perspectives of these physicians are represented.

6. Accessibility - Provides opportunity for members of the constituency, who are otherwise under-represented, to introduce issues of concern and to be able to participate in the policymaking process within the HOD.

AMA Masterfile data reflect the number of physicians by practice size as opposed to the number of physicians who have an ownership stake in a practice; however, it may be assumed that solo and two-physician practices are physician owned. CLRPD Report 1-A-19, "Demographic Characteristics of the House of Delegates and AMA Leadership," indicates solo practice physicians represent 15.0% and 9.7% of AMA delegates and alternate delegates respectively. Physicians in two-physician practices represent 2.2% of AMA delegates and 2.2% of alternate delegates. Even with a considerable number of physicians in the HOD, many members of these groups have an

obligation to represent the priorities of their state or specialty delegations rather than issues specifically related to private practice.

Currently, the PPPC has few opportunities to provide input into the business of the HOD, namely proposing and ushering through original resolutions regarding specific areas of concern for private practice physicians. During HOD meetings, members of the Congress have developed private practice-related resolutions; however, often issues of specific concern to private practice physicians are not brought forward for discussion in the House. While many private practice physicians are active in the HOD through various delegations, the majority are from small medical practices and the AMA has neither an established community/cohort, nor institutional support to address unique issues and concerns of these physicians through the policymaking process of the HOD.

The PPPC has become recognized as a nexus for private practice physicians within the AMA. The Association would benefit from providing the PPPS with an opportunity for "underrepresented" members seeking to preserve the independent practice of medicine to introduce specific issues of concern and participate in the AMA policymaking process. As a section, the PPPS would develop a formalized policymaking process and the section would introduce resolutions, which could change the dynamic.

CLRPD Assessment: Accessibility relates to a group having an opportunity to engage in the policymaking process of the HOD with respect to their specific issues of concern. A group comprised of a large number of individuals is not necessarily guaranteed access to this process. Even with the number of private practice physicians in the HOD, many members of this group have an obligation to represent the priorities of their respective state or specialty delegations. Given the limited opportunity to present issues of concern specific to this group, the CLRPD believes it would be appropriate to afford private practice physicians with an opportunity for a focused voice on their issues of concern, which are listed on pages 2-3.

DISCUSSION

Following an initial review and discussion of the PPPC proposal for section status, the CLRPD posed additional questions to leaders of the caucus for clarification of some of the information presented in its Letter of Application for Section Status. Further, Council members engaged in numerous, extended deliberations regarding the PPPC's request and met with its leadership for discussion.

Private practice physicians often have a distinct set of experiences related to medical practice and patient care. Like other AMA member component groups, the PPPC convenes prior to HOD meetings, engages in coalition building, and provides opportunities for education and involvement. Initially, the Council was concerned that the same three physicians have been leading the Congress since its inception; however, the PPPC has thoughtfully developed a succession plan for leadership of the PPPS.

Accessibility is considered as part of the rationale for establishing sections within the Association. Policy G-615.002, "AMA Member Component Groups" states, "Delineated sections allow a voice in the house of medicine for large groups of physicians, who are connected through a unique perspective, but may be underrepresented. These sections will often be based on demographics or mode of practice." The CLRPD recognizes the continued decline in the number of independent, private practice physicians and that physician practice ownership is now below 50% among all physicians. Granting the PPPC section status will provide the new section with a voice through a delegate who participates in HOD meetings. The CLRPD concurs that the PPPC meets all criteria;

therefore, the Council recommends that the status for this member component group be changed to delineated section.

RECOMMENDATIONS

The Council on Long Range Planning and Development recommends that the following recommendations be adopted and the remainder of the report be filed:

1. That our American Medical Association transition the Private Practice Physicians Congress to the Private Practice Physicians Section as a delineated section. (Directive to Take Action)

2. That our AMA develop bylaw language to recognize the Private Practice Physicians Section. (Directive to Take Action)

Fiscal Note: $325,345/year (staff salary and benefits, governing council travel and meetings, annual and interim meeting costs, other staff travel and administrative expenses). All new sections in the recent past (Women Physicians Section, Senior Physicians Section, Integrated Physician Practice Section) had staff assigned and other AMA-allocated resources as Advisory Committees to the Board of Trustees prior to attaining section status.

REFERENCES

[1] AMA. *Updated data on physician practice arrangements; Physician ownership drops below 50 %.* https://www.ama-assn.org/about/research/physician-practice-benchmark-survey

[2] CLRPD. *Demographic Characteristics of the House of Delegates and AMA Leadership.* *https://www.ama-assn.org/system/files/2019-08/a19-clrpd-report-1.pdf*

REPORT OF THE HOUSE OF DELEGATES COMMITTEE
ON THE COMPENSATION OF THE OFFICERS

Compensation Committee Report, November 2020

Subject: REPORT OF THE HOUSE OF DELEGATES COMMITTEE ON THE COMPENSATION OF THE OFFICERS

Presented by: Diana E. Fite, MD, Chair

Referred to: Reference Committee F

This report by the committee at the November 2020 Special Meeting of the House of Delegates presents one recommendation. It also documents the compensation paid to Officers for the period July 1, 2019 thru June 30, 2020 and includes the 2019 calendar year IRS reported taxable value of benefits, perquisites, services, and in-kind payments for all Officers.

BACKGROUND

At the 1998 Interim Meeting, the House of Delegates (HOD) established a House Committee on Trustee Compensation, currently named the Committee on Compensation of the Officers, (the "Committee"). The Officers are defined in the American Medical Association's (AMA) Constitution and Bylaws. (Note: under changes to the Constitution previously approved by the HOD, Article V refers simply to "Officer," which includes all 21 members of the Board among whom are the President, President-Elect, Immediate Past President, Secretary, Speaker of the HOD and Vice Speaker of the HOD, collectively referred to in this report as Officers.) The composition, appointment, tenure, vacancy process and reporting requirements for the Committee are covered under the AMA Bylaws. Bylaws 2.13.4.5 provides:

> The Committee shall present an annual report to the House of Delegates recommending the level of total compensation for the Officers for the following year. The recommendations of the report may be adopted, not adopted, or referred back to the Committee, and may be amended for clarification only with the concurrence of the Committee.

At A-00, the Committee and the Board jointly adopted the American Compensation Association's definition of total compensation which was added to the Glossary of the AMA Constitution and Bylaws. Total compensation is defined as the complete reward/recognition package awarded to an individual for work performance, including: (a) all forms of money or cash compensation; (b) benefits; (c) perquisites; (d) services; and (e) in-kind payments.

Since the inception of this Committee, its reports document the process the Committee follows to ensure that current or recommended Officer compensation is based on sound, fair, cost-effective compensation practices as derived from research and use of independent external consultants, expert in Board compensation. Reports beginning in December 2002 documented the principles the Committee followed in creating its recommendations for Officer compensation.

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At A-08, the HOD approved changes that simplified compensation practices with increased transparency and consistency. At A-10, Reference Committee F requested that this Committee recommend that the HOD affirm a codification of the current compensation principle, which occurred at I-10. At that time, the HOD affirmed that this Committee has and will continue to base its recommendations for Officer compensation on the principle of the value of work performed, consistent with IRS guidelines and best practices recommended by the Committee's external independent consultant, who is expert in Board compensation.

At A-11, the HOD approved the alignment of Medical Student and Resident Officer compensation with that of all other Officers (excluding Presidents and Chair) because these positions perform comparable work.

Immediately following A-11, the Committee retained Mr. Don Delves, founder of the Delves Group, to update his 2007 research by providing the Committee with comprehensive advice and counsel on Officer compensation. The updated compensation structure was presented and approved by the HOD at I-11 with an effective date of July 1, 2012.

The Committee's I-13 report recommended and the HOD approved the Committee's recommendation to provide a travel allowance for each President to be used for upgrades because of the significant volume of travel representing our AMA.

At I-16, based on results of a comprehensive compensation review conducted by Ms. Becky Glantz Huddleston, an expert in Board Compensation with Willis Towers Watson, the HOD approved the Committee's recommendation of modest increases to the Governance Honorarium and Per Diems for Officer Compensation, excluding the Presidents and Chair, effective July 1, 2017. At A-17 the HOD approved modifying the Governance Honorarium and Per Diem definition so that Internal Representation, greater than eleven days, receives a per diem.

At A-18, based on comprehensive review of Board leadership compensation, the HOD approved the Committee's recommendation to increase the President, President-elect, Immediate Past-President, Chair, and Chair-elect honoraria by 4% effective July 1, 2018.

At A-18 and A-19, the House approved the Committee's recommendation to provide a Health Insurance Stipend to President(s) who are under Medicare eligible age when the President(s) and his/her covered dependents, not Medicare eligible, lose the President's employer provided health insurance during his/her term as President. Should the President(s) become Medicare eligible while in office, he/she received an adjusted Stipend to provide insurance coverage to his/her dependents not Medicare eligible.

The Committee's I-19 report recommended and the HOD approved the Committee's recommendation to increase the Governance Honorarium and Per Diem for Officers, excluding Presidents and Chair, by approximately 3% each effective July 1, 2020.

CASH COMPENSATION SUMMARY

The cash compensation of the Officers shown in the following table will not be the same as compensation reported annually on the AMA's IRS Form 990s because Form 990s are based on a calendar year. The total cash compensation in the summary is compensation for the days these officers spent away from home on AMA business approved by the Board Chair. The total cash compensation in the summary includes work as defined by the Governance Honorarium and Per Diem for Representation including conference calls with assigned groups outside of the AMA or

assigned Internal Representation days above 11 when the total of all teleconference meetings during a calendar day equal 2 or more hours approved by the Board Chair. Detailed definitions are in the Appendix.

The summary covers July 1, 2019 to June 30, 2020

AMA Officers	Position	Total Compensation	Total Days
David H Aizuss, MD	Officer	$ -	0.5
Grayson W Armstrong, MD, MPH	Resident Officer	$ 65,000	40
Susan R Bailey, MD	President-Elect	$ 288,860	92
Willarda V Edwards, MD, MBA	Officer	$ 72,800	41
Lisa Bohman Egbert, MD	Vice Speaker, House of Delegates	$ 68,900	46.5
Jesse M Ehrenfeld, MD, MPH	Chair & Young Physician Officer	$ 280,280	86.5
Scott Ferguson, MD	Officer	$ 68,900	38
Sandra Adamson Fryhofer, MD	Officer	$ 78,000	43
Gerald E Harmon, MD	Officer	$ 85,800	58.5
Patrice A Harris, MD, MA	President	$ 290,160	187
William E Kobler, MD	Officer	$ 83,200	53
Russ Kridel, MD	Chair-Elect	$ 207,480	44.5
Ilse R Levin, DO, MPH & TM	Officer	$ -	0.5
Thomas J Madejski, MD	Officer	$ -	0.5
Barbara L McAneny, MD	Immediate Past President	$ 284,960	92.5
William A McDade, MD, PhD	Officer	$ 71,500	38.5
Mario E Motta, MD	Officer	$ 72,150	39
Bobby Mukkamala, MD	Secretary	$ 74,100	50
Blake Elizabeth Murphy	Medical Student Officer	$ -	2
Harris Pastides, PhD, MPH	Public Board Member Officer	$ -	0.5
Jack Resneck, Jr, MD	Immediate Past Chair	$ 108,550	72
Bruce A Scott, MD	Speaker, House of Delegates	$ 83,850	51.5
Sarah Mae Smith	Medical Student Officer	$ 91,650	58.5
Michael Suk, MD, JD, MPH, MBA	Officer	$ 72,150	35
Willie Underwood, III, MD, MSc, MPH	Officer	$ 71,500	39.5
Kevin W Williams, MSA	Public Board Member Officer	$ 65,000	25

President, President-Elect, Immediate Past President, and Chair
In 2019 – 2020, each of these positions received an annual Governance Honorarium which was paid in monthly increments. These four positions spent a total of 458 days on approved Assignment and Travel, or 114.5 days each on average.

Chair-Elect
This position received a Governance Honorarium of approximately 75% of the Governance Honorarium provided to the Chair.

All other Officers
All other Officers received cash compensation, which included a Governance Honorarium of $65,000 paid in monthly installments. The remaining cash compensation is for Assignment and Travel Days that are approved by the Board Chair to externally represent the AMA and for Internal Representation days above 11. These days were compensated at a per diem rate of $1,300.

Assignment and Travel Days
The total Assignment and Travel Days for all Officers (excluding the President, President-Elect, Immediate Past President and Chair) were 777.5.

EXPENSES

Total expenses paid for period, July 1, 2019 – June 30, 2020, $744,035 compared to $882,074 for the previous period, representing a 15.7% decrease. This includes $3,320 in upgrades for Presidents' travel per the approved Presidential Upgrade Allowance of $2,500 per position per term.

BENEFITS, PERQUISITES, SERVICES, AND IN-KIND PAYMENTS

Officers are able to request benefits, perquisites, services, and in-kind payments, as defined in the "AMA Board of Trustees Standing Rules on Travel Expenses." These non-taxable business expense items are provided to assist the Officers in performing their duties.

- AMA Standard laptop computer or iPad
- iPhone
- American Express card (for AMA business use)
- Combination fax/printer/scanner
- An annual membership to the airline club of choice offered each year during the Board member's tenure
- Personalized AMA stationary, business cards, and biographical data for official use

Additionally, all Officers are eligible for $305,000 term life insurance and are covered under the AMA's $500,000 travel accident policy and $10,000 individual policy for medical costs arising out of any accident while traveling on official business for the AMA. Life insurance premiums paid by the AMA are reported as taxable income. Also, travel assistance is available to all Officers when traveling more than 100 miles from home or internationally.

Secretarial support, other than that provided by the AMA's Board office, is available up to defined annual limits as follows: President, during the Presidential year, $15,000, $5,000 each for the President-Elect, Chair, Chair-Elect, and Immediate Past President per year. Secretarial expenses incurred by other Officers in conjunction with their official duties are paid up to $750 per year per Officer. This is reported as taxable income.

Travel expenses incurred by family members are not reimbursable, except for the family of the incoming President at the Annual Meeting of the HOD.

Calendar year taxable life insurance and taxable secretarial fees reported to the IRS totaled $42,984 and $23,875 respectively for 2019. An additional $17,250 was paid to third parties for secretarial services during 2019.

FINDINGS

The Cash Compensation Summary, with the exception of 2019 calendar year taxable compensation, reflects the impact of the Coronavirus on the Officers in representing our AMA. Effective March 17, 2020 all travel ceased, and all in-person meetings were canceled or moved to a virtual format. Our AMA leadership quickly pivoted to continue representing the AMA, both

internally and externally, in a completely virtual environment. This pivot, while appearing seamless, required significant flexibility and behind-the-scenes planning of our Officers. As you know, both our Annual and Interim Meetings were suspended, and all Board meetings since March 17 have been virtual. This environment also necessitated changes in reporting for the term ended June 30, 2020 as evidenced by suspending the tracking of telephonic representation meetings since all meetings were and continue to be conducted virtually.

Based on the data reported it would appear that the President, President-Elect, Immediate Past-President and Chair-Elect had a lighter workload, which would be an incorrect conclusion. These individuals, while relieved of their travel burdens, worked tirelessly representing the AMA in podcasts, on Facebook, Zoom, Microsoft Teams and other media to advocate on behalf of physicians and patients. In addition, the Speaker and Vice Speaker have expended an extraordinary amount of effort to plan both the June and November Special Meetings.

This Committee commends and thanks our Officers for their representation of the AMA.

RECOMMENDATIONS

The Committee on Compensation of the Officers recommends that there be no changes to the Officers' compensation for the period beginning July 1, 2021 through June 30, 2022 and the remainder of the report filed. (Directive to Take Action)

Fiscal Note: None.

APPENDIX

POSITION	**GOVERNANCE HONORARIUM**
President	$290,160
Immediate Past President	$284,960
President-Elect	$284,960
Chair	$280,280
Chair-Elect	$207,480
Officers	$67,000

Definition of Governance Honorarium Effective July 1, 2017:

The purpose of this payment is to compensate Officers for all Chair-assigned internal AMA work and related travel. This payment is intended to cover all currently scheduled Board meetings, special Board or Board Committee meetings, task forces, subcommittees, Board orientation, development and media training, Board calls, sections, councils, or other internal representation meetings or calls, and any associated review or preparatory work, and all travel days related to all meetings as noted up to eleven (11) Internal Representation days.

Definition of Per Diem for Representation effective July 1, 2017:

The purpose of this payment is to compensate for Board Chair-assigned representation day(s) and related travel. Representation is either external to the AMA, or for participation in a group or organization with which the AMA has a key role in creating/partnering/facilitating, achievement of the respective organization goals such as the AMA Foundation, PCPI, etc. or for Internal Representation days above eleven (11). The Board Chair may also approve a per diem for special circumstances that cannot be anticipated such as weather-related travel delays. Per Diem for Chair-assigned representation and related travel is $1,400 per day.

Definition of Telephone Per Diem for External Representation effective July 1, 2017:

Officers, excluding the Board Chair and the President(s) who are assigned as the AMA representative to outside groups as one of their specific Board assignments or assigned Internal Representation days above eleven (11), receive a per diem for teleconference meetings when the total of all teleconference meetings of 30 minutes or longer during a calendar day equal 2 or more hours. Payment for those meetings would require approval of the Chair of the Board. The amount of the Telephonic Per Diem will be ½ of the full Per Diem which is $700.

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 601
(November 2020)

Introduced by: Women Physicians Section

Subject: Support for the Establishment of Medical-Legal Partnerships

Referred to: Reference Committee F

Whereas, Social determinants of health such as employment, housing, transportation, and literacy are known to effect patients' overall health status and health outcomes;[1] and

Whereas, Physicians and trainees are inadequately trained to effectively and respectfully screen patients for social determinants of health;[2] and

Whereas, Simply screening patients for social determinants of health without providing resources or treatment options is ineffective;[2] and

Whereas, Addressing social determinants of health cannot be done by the medical community in isolation, but will need changes in law and policy as well;[3] and

Whereas, The medical system is full of complicated policies and administrative barriers that can be difficult to overcome without knowledge in poverty law and administrative law;[4] and

Whereas, Medical-legal partnerships formally include lawyers on a care team to address legal issues that may lead to poor health outcomes and contribute to population health inequities;[5,6] and

Whereas, Medical-legal partnerships seek to address patients' needs regarding social determinants of health through providing healthcare, and social and legal support at the same location;[7] and

Whereas, The most common needs medical-legal partnerships address are: income, housing and utilities, education and employment, legal status, and personal and family stability;[7] and

Whereas, Providing legal assistance at the same location as healthcare facilitates patients' use of these services to remediate their lack of basic human needs such as food and shelter;[7] and

Whereas, Medical-legal partnerships exist across 48 states with 442 partnerships across 333 healthcare entities;[5] and

Whereas, Medical-legal partnerships provide education for medical professionals to better identify unmet needs in their patients and to begin addressing those needs;[8] and

Whereas; Medical-legal partnerships have been proven to improve health outcomes for patients including reducing hospital admissions for chronic health conditions, reducing stress and improving mental health, and increasing the use of preventive health services;[9] and

Whereas, Medical-legal partnerships have also been proven to increase patient compliance with treatment, including patients regularly taking prescribed medications;[10] and

Whereas, Medical-legal partnerships have demonstrated a cost-savings to health care organizations through assisting patients in gaining health insurance coverage and in end-of-life planning;[11] therefore be it

RESOLVED, That our American Medical Association encourage the widespread establishment of medical-legal partnerships to address unmet patient needs relating to social determinants of health. (Directive to Take Action)

Fiscal Note: Minimal - less than $1,000

Received: 09/30/20

References:
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3. "Commission on Social Determinants of Health, 2005-2008." *Social Determinants of Health*, World Health Organization, 25 Sept. 2017, www.who.int/social_determinants/thecommission/en/.
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10. Fleishman, Stewart B., et al. "The Attorney As the Newest Member of the Cancer Treatment Team." *Journal of Clinical Oncology*, vol. 24, no. 13, Jan. 2006, pp. 2123–2126., doi:10.1200/jco.2006.04.2788.
11. "Impact." *The Impact*, National Center for Medical-Legal Partnerships, medical-legalpartnership.org/impact/.

RELEVANT AMA POLICY

Legal Protection and Social Services for Commercially Sexually Exploited Youth D-60.969

Our AMA will work with state medical societies and specialty societies to: (1) where appropriate, advocate for legal protection and alternatives to incarceration for commercially sexually exploited youth as an alternative to prosecution for crimes related to their sexual or criminal exploitation; and (2) encourage the development of appropriate and comprehensive services as an alternative to criminal detention in order to overcome barriers to necessary services and care for commercially sexually exploited youth.
Citation: (Res. 4, I-14)

Providing Medical Services through School-Based Health Programs H-60.991

(1) The AMA supports further objective research into the potential benefits and problems associated with school-based health services by credible organizations in the public and private sectors. (2) Where school-based services exist, the AMA recommends that they meet the following minimum standards: (a) Health services in schools must be supervised by a physician, preferably one who is experienced in the care of children and adolescents. Additionally, a physician should be accessible to administer care on a regular basis. (b) On-site services should be provided by a professionally prepared school nurse or similarly qualified health

professional. Expertise in child and adolescent development, psychosocial and behavioral problems, and emergency care is desirable. Responsibilities of this professional would include coordinating the health care of students with the student, the parents, the school and the student's personal physician and assisting with the development and presentation of health education programs in the classroom. (c) There should be a written policy to govern provision of health services in the school. Such a policy should be developed by a school health council consisting of school and community-based physicians, nurses, school faculty and administrators, parents, and (as appropriate) students, community leaders and others. Health services and curricula should be carefully designed to reflect community standards and values, while emphasizing positive health practices in the school environment. (d) Before patient services begin, policies on confidentiality should be established with the advice of expert legal advisors and the school health council. (e) Policies for ongoing monitoring, quality assurance and evaluation should be established with the advice of expert legal advisors and the school health council. (f) Health care services should be available during school hours. During other hours, an appropriate referral system should be instituted. (g) School-based health programs should draw on outside resources for care, such as private practitioners, public health and mental health clinics, and mental health and neighborhood health programs. (h) Services should be coordinated to ensure comprehensive care. Parents should be encouraged to be intimately involved in the health supervision and education of their children.
Citation: (CSA Rep. D, A-88; Reaffirmed: Sunset Report, I-98; Reaffirmed: Res. 412, A-05; Reaffirmed in lieu of Res. 908, I-12)

Ensuring Access to Health Care, Mental Health Care, Legal and Social Services for Unaccompanied Minors and Other Recently Immigrated Children and Youth D-60.968
Our AMA will work with medical societies and all clinicians to (i) work together with other child-serving sectors to ensure that new immigrant children receive timely and age-appropriate services that support their health and well-being, and (ii) secure federal, state, and other funding sources to support those services.
Citation: (Res. 8, I-14)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 602
(November 2020)

Introduced by: Women Physicians Section

Subject: Towards Diversity and Inclusion: A Global Nondiscrimination Policy Statement and Benchmark for our AMA

Referred to: Reference Committee F

Whereas, Our AMA has as important goals, the promotion of healthcare diversity, the improvement of public health, and retention and expansion of membership; and

Whereas, Healthcare diversity, and the health of the public is improved when healthcare providers reflect the diversity of our patients; and

Whereas, AMA membership retention, expansion and participation are promoted when members and prospective members perceive themselves to be welcomed, fully enfranchised, protected, promoted and supported by their association, free from discrimination, and equally eligible for leadership; and

Whereas, Diversity in healthcare providers is promoted when equal opportunities exist in employment and leadership within healthcare organizations and in other practice settings; and

Whereas, Our AMA is obliged both as a large employer and as a place of public accommodation to practice nondiscrimination with respect to employment or access on account of or on the basis of race, color, sex, national origin, age, religion, disability, veteran status, sexual orientation or other protected characteristics; and

Whereas, Our AMA as a nonprofit physician membership association has additional morally based obligations to lead by example and not to discriminate as an organization on the basis of age, race, color, creed, gender, gender expression, national origin, locus of medical education or postgraduate training, cultural ethnicity, sexual orientation, disability, marital status, or military status, in any of its activities or operations**;** and

Whereas, The Code of Medical Ethics states that physicians “shall respect the rights of patients, colleagues, and other health professionals, and shall safeguard patient confidences and privacy within the constraints of the law”; and

Whereas, While numerous policies have been enacted over the years by our AMA that address selected aspects of discrimination by various groups against various groups, these policies are not uniform and relatively difficult to locate; there are policy gaps and inconsistencies relating to the lack of an organized approach to addressing the problem of discrimination, making it difficult to access the applicable policy or policies when a benchmark is needed against which to measure a proposed action being considered by the organization; and

Whereas, While our AMA has a nondiscrimination policy with respect to physician membership (AMA Bylaws 1-4)[1], it has at present no overarching nondiscrimination policy as a threshold and a benchmark tool against which to measure the taking of actions other than membership decisions, to determine whether entering into new policies, procedures, sponsorships, endorsements, promotion, legislative or other forms of advocacy, contracts, or proposed partnerships with other organizations; and

Whereas, Without a distinct threshold for consideration of, or benchmark tool against which to measure proposed organizational actions or partnerships as to potential or actual discriminatory effect, it is difficult to determine whether pursuit of such actions or partnerships should be avoided, modified or abandoned so as to avoid discrimination against members with protected characteristics, contrary to law and organizational moral principles, and to avert any resultant contravention of AMA ethical principles by those individual physician members involved in taking the proposed actions or participating in the proposed partnerships; and

Whereas, Not all third parties who conduct business with or for our AMA, such as independent contractors, consultants or vendors, necessarily recognize or independently endorse an obligation to comply with all applicable laws, rules and regulations; and if they do not comply, they will, under federal regulations, subject our AMA to potentially significant liability and adverse publicity; yet third parties are not at present apparently even subject to the published conflict of interest policy of the AMA; and

Whereas, Mandated signatories to the conflict of interest policy (e.g. AMA leaders, key staff and candidates) must agree to abide by AMA Policy H-140.837, “Policy on Conduct at AMA Meetings and Events.” The current conflict of interest policy refers to anti-harassment (AMA Policy H-140.837), however, it does not seem to address other forms of discrimination on the basis of protected characteristics; and

Whereas, Our AMA has not adopted a business conduct standards policy making explicit an obligation that every individual working on AMA business, be they member, employee or contractor, must adhere to the highest ethical standards, and demonstrate integrity, professionalism and respect for others and the law, in their dealings with and for the AMA; and

Whereas, Our AMA has not widely communicated a comprehensive strategy or program designed to eliminate bias and enhance diversity and inclusion throughout the association, the medical profession, and our healthcare system; therefore be it

RESOLVED, That our American Medical Association adopt an overarching nondiscrimination policy on the basis of sex, color, creed, race, religion, disability, ethnic origin, national origin, sexual orientation, gender identity, age, or for any other reason unrelated to character, competence, ethics, professional status or professional activities that applies to members, employees and patients (New HOD Policy); and be it further

RESOLVED, That our AMA demonstrate its commitment to complying with laws, rules or regulations against discrimination on the basis of protected characteristics (Directive to Take Action); and be it further

[1] Membership in the AMA or in any constituent association, national medical specialty society or professional interest medical association represented in the House of Delegates, shall not be denied or abridged because of sex, color, creed, race, religion, disability, ethnic origin, national origin, sexual orientation, gender identity, age, or for any other reason unrelated to character, competence, ethics, professional status or professional activities.

RESOLVED, That our AMA reaffirm Policy H-65.988, “Organizations Which Discriminate,” and Policy G-630.040, “Principles on Corporate Relationships,” in its overarching non-discrimination policy (Reaffirm HOD Policy); and be it further

RESOLVED, That our AMA reaffirm Policy G-600.067, “References to Terms and Language in Policies Adopted to Protect Populations from Discrimination and Harassment”; (New HOD Policy) and be it further

RESOLVED, That our AMA study the feasibility and need for a comprehensive business conduct standards policy to be fully integrated with the conflict of interest policy, and report back to the AMA House of Delegates within 18 months (Directive to Take Action); and be it further

RESOLVED, That our AMA provide an update on its comprehensive diversity and inclusion strategy to the AMA House of Delegates within 24 months. (Directive to Take Action)

Fiscal Note: Moderate - between $5,000 - $10,000

Received: 09/30/20

RELEVANT AMA POLICY

References to Terms and Language in Policies Adopted to Protect Populations from Discrimination and Harassment G-600.067
Our AMA will: (1) undertake a study to identify all discrimination and harassment references in AMA policies and the code of ethics, noting when the language is consistent and when it is not; (2) research language and terms used by other national organizations and the federal government in their policies on discrimination and harassment; (3) present the preliminary study results to the Minority Affairs Section, the Women’s Physician Section, and the Advisory Committee on LGBTQ Issues to reach consensus on optimal language to protect vulnerable populations including racial and ethnic minorities, sexual and gender minorities, and women, from discrimination and harassment; and (4) produce a report within 18 months with study results and recommendations.
Res. 009, A-19

Discrimination. B-1.4
Membership in the AMA or in any constituent association, national medical specialty society or professional interest medical association represented in the House of Delegates, shall not be denied or abridged because of sex, color, creed, race, religion, disability, ethnic origin, national origin, sexual orientation, gender identity, age, or for any other reason unrelated to character, competence, ethics, professional status or professional activities.

Support of Human Rights and Freedom H-65.965
Our AMA: (1) continues to support the dignity of the individual, human rights and the sanctity of human life, (2) reaffirms its long-standing policy that there is no basis for the denial to any human being of equal rights, privileges, and responsibilities commensurate with his or her individual capabilities and ethical character because of an individual's sex, sexual orientation, gender, gender identity, or transgender status, race, religion, disability, ethnic origin, national origin, or age; (3) opposes any discrimination based on an individual's sex, sexual orientation, gender identity, race, religion, disability, ethnic origin, national origin or age and any other such reprehensible policies; (4) recognizes that hate crimes pose a significant threat to the public health and social welfare of the citizens of the United States, urges expedient passage of appropriate hate crimes prevention legislation in accordance with our AMA's policy through letters to members of Congress; and registers support for hate crimes prevention legislation, via letter, to the President of the United States.
CCB/CLRPD Rep. 3, A-14; Reaffirmed in lieu of: Res. 001, I-16; Reaffirmation: A-17

Discriminatory Policies that Create Inequities in Health Care H-65.963
Our AMA will: (1) speak against policies that are discriminatory and create even greater health disparities in medicine; and (2) be a voice for our most vulnerable populations, including sexual, gender, racial and ethnic minorities, who will suffer the most under such policies, further widening the gaps that exist in health and wellness in our nation. Res. 001, A-18

Principles for Advancing Gender Equity in Medicine H-65.961
Our AMA:
1. declares it is opposed to any exploitation and discrimination in the workplace based on personal characteristics (i.e., gender);
2. affirms the concept of equal rights for all physicians and that the concept of equality of rights under the law shall not be denied or abridged by the U.S. Government or by any state on account of gender;
3. endorses the principle of equal opportunity of employment and practice in the medical field;
4. affirms its commitment to the full involvement of women in leadership roles throughout the federation, and encourages all components of the federation to vigorously continue their efforts to recruit women members into organized medicine;
5. acknowledges that mentorship and sponsorship are integral components of one's career advancement, and encourages physicians to engage in such activities;
6. declares that compensation should be equitable and based on demonstrated competencies/expertise and not based on personal characteristics;
7. recognizes the importance of part-time work options, job sharing, flexible scheduling, re-entry, and contract negotiations as options for physicians to support work-life balance;
8. affirms that transparency in pay scale and promotion criteria is necessary to promote gender equity, and as such academic medical centers, medical schools, hospitals, group practices and other physician employers should conduct periodic reviews of compensation and promotion rates by gender and evaluate protocols for advancement to determine whether the criteria are discriminatory; and
9. affirms that medical schools, institutions and professional associations should provide training on leadership development, contract and salary negotiations and career advancement strategies that include an analysis of the influence of gender in these skill areas.
Our AMA encourages: (1) state and specialty societies, academic medical centers, medical schools, hospitals, group practices and other physician employers to adopt the AMA Principles for Advancing Gender Equity in Medicine; and (2) academic medical centers, medical schools, hospitals, group practices and other physician employers to: (a) adopt policies that prohibit harassment, discrimination and retaliation; (b) provide anti-harassment training; and (c) prescribe disciplinary and/or corrective action should violation of such policies occur. BOT Rep. 27, A-19

9.5.5 Gender Discrimination in Medicine
Inequality of professional status in medicine among individuals based on gender can compromise patient care, undermine trust, and damage the working environment. Physician leaders in medical schools and medical institutions should advocate for increased leadership in medicine among individuals of underrepresented genders and equitable compensation for all physicians.
Collectively, physicians should actively advocate for and develop family-friendly policies that:
(a) Promote fairness in the workplace, including providing for:
(i) retraining or other programs that facilitate re-entry by physicians who take time away from their careers to have a family;
(ii) on-site child care services for dependent children;
(iii) job security for physicians who are temporarily not in practice due to pregnancy or family obligations.
(b) Promote fairness in academic medical settings by:
(i) ensuring that tenure decisions make allowance for family obligations by giving faculty members longer to achieve standards for promotion and tenure;
(ii) establish more reasonable guidelines regarding the quantity and timing of published material needed for promotion or tenure that emphasize quality over quantity and encourage the pursuit of careers based on individual talent rather than tenure standards that undervalue teaching ability and overvalue research;
(iii) fairly distribute teaching, clinical, research, administrative responsibilities, and access to tenure tracks;
(iv) structuring the mentoring process through a fair and visible system.
(c) Take steps to mitigate gender bias in research and publication.
AMA Principles of Medical Ethics: II,VII
The Opinions in this chapter are offered as ethics guidance for physicians and are not intended to establish standards of clinical practice or rules of law.
Issued: 2016

Organizations Which Discriminate H-65.988
The AMA (1) encourages holding educational or business meetings or social gatherings in facilities of organizations and clubs which do not refuse membership on the basis of gender, race or religion; and (2) encourages its constituent societies to follow a similar policy. Res. 62, A-87; Reaffirmed: CLRPD Rep. 3, I-97; Reaffirmed: CEJA Rep. 7, A-07; Reaffirmed: CEJA Rep. 04, A-17

Principles on Corporate Relationships G-630.040
The House of Delegates adopts the following revised principles on Corporate Relationships. The Board will review them annually and, if necessary, make recommendations for revisions to be presented to the House of Delegates.
(1) GUIDELINES FOR AMA CORPORATE RELATIONSHIPS. Principles to guide AMA's relationships with corporate America were adopted by our AMA House of Delegates at its December 1997 meeting and slightly modified at the June 1998 meeting. Subsequently, they have been edited to reflect the recommendations from the Task Force on Association/Corporate Relations, including among its members experts external to our AMA. Minor edits were also adopted in 2002. The following principles are based on the premise that in certain circumstances, our AMA should participate in corporate arrangements when guidelines are met, which can further our AMA's core strategic focus, retain AMA's independence, avoid conflicts of interest, and guard our professional values.
(2) OVERVIEW OF PRINCIPLES. The AMA's principles to guide corporate relationships have been organized into the following categories: General Principles that apply to most situations; Special Guidelines that deal with specific issues and concerns; Organizational Review that outlines the roles and responsibilities of the Board of Trustees, AMA Management and other staff units. These guidelines should be reviewed over time to assure their continued relevance to the policies and operations of our AMA and to our business environment. The principles should serve as a starting point for anyone reviewing or developing AMA's relationships with outside groups.
(3) GENERAL PRINCIPLES. Our AMA's vision and values statement and strategic focus should provide guidance for externally funded relationships. Relations that are not motivated by the association's mission threaten our AMA's ability to provide representation and leadership for the profession.
(a) Our AMA's vision and values and strategic focus ultimately must determine whether a proposed relationship is appropriate for our AMA. Our AMA should not have relationships with organizations or industries whose principles, policies or actions obviously conflict with our AMA's vision and values. For example, relationships with producers of products that harm the public health (e.g., tobacco) are not appropriate for our AMA. Our AMA will proactively choose its priorities for external relationships and collaborate in those that fulfill these priorities.
(b) The relationship must preserve or promote trust in our AMA and the medical profession. To be effective, medical professionalism requires the public's trust. Corporate relationships that could undermine the public's trust in our AMA or the profession are not acceptable. For example, no relationship should raise questions about the scientific content of our AMA's health information publications, AMA's advocacy on public health issues, or the truthfulness of its public statements.
(c) The relationship must maintain our AMA's objectivity with respect to health issues. Our AMA accepts funds or royalties from external organizations only if acceptance does not pose a conflict of interest and in no way impacts the objectivity of the association, its members, activities, programs, or employees. For example, exclusive relationships with manufacturers of health-related products marketed to the public could impair our AMA's objectivity in promoting the health of America. Our AMA's objectivity with respect to health issues should not be biased by external relationships.
(d) The activity must provide benefit to the public's health, patients' care, or physicians' practice. Public education campaigns and programs for AMA or Federation members are potentially of significant benefit. Corporate-supported programs that provide financial benefits to our AMA but no significant benefit to the public or direct professional benefits to AMA or Federation members are not acceptable. In the case of member benefits, external relations must not detract from AMA's professionalism.
(4) SPECIAL GUIDELINES. The following guidelines address a number of special situations where our AMA cannot utilize external funding. There are specific guidelines already in place regarding advertising in publications.
(a) Our AMA will provide health and medical information, but should not involve itself in the production, sale, or marketing to consumers of products that claim a health benefit. Marketing health-related products (e.g., pharmaceuticals, home health care products) undermines our AMA's objectivity and diminishes its role in representing healthcare values and educating the public about their health and healthcare.
(b) Activities should be funded from multiple sources whenever possible. Activities funded from a single external source are at greater risk for inappropriate influence from the supporter or the perception of it, which may be equally damaging. For example, funding for a patient education brochure should be done with multiple sponsors if possible. For the purposes of this guideline, funding from several companies, but each from a

different and non-competing industry category (e.g., one pharmaceutical manufacturer and one health insurance provider), does not constitute multiple-source funding. Our AMA recognizes that for some activities the benefits may be so great, the harms so minimal, and the prospects for developing multiple sources of funding so unlikely that single-source funding is a reasonable option. Even so, funding exclusivity must be limited to program only (e.g., asthma conference) and shall not extend to a therapeutic category (e.g., asthma). The Board should review single-sponsored activities prior to implementation to ensure that: (i) reasonable attempts have been made to locate additional sources of funds (for example, issuing an open request for proposals to companies in the category); and (ii) the expected benefits of the project merit the additional risk to our AMA of accepting single-source funding. In all cases of single-source funding, our AMA will guard against conflict of interest.
(c) The relationship must preserve AMA's control over any projects and products bearing our AMA name or logo. Our AMA retains editorial control over any information produced as part of a corporate/externally funded arrangement. When an AMA program receives external financial support, our AMA must remain in control of its name, logo, and AMA content, and must approve all marketing materials to ensure that the message is congruent with our AMA's vision and values. A statement regarding AMA editorial control as well as the name(s) of the program's supporter(s) must appear in all public materials describing the program and in all educational materials produced by the program. (This principle is intended to apply only to those situations where an outside entity requests our AMA to put its name on products produced by the outside entity, and not to those situations where our AMA only licenses its own products for use in conjunction with another entity's products.)
(d) Relationships must not permit or encourage influence by the corporate partner on our AMA. An AMA corporate relationship must not permit influence by the corporate partner on AMA policies, priorities, and actions. For example, agreements stipulating access by corporate partners to the House of Delegates or access to AMA leadership would be of concern. Additionally, relationships that appear to be acceptable when viewed alone may become unacceptable when viewed in light of other existing or proposed activities.
(e) Participation in a sponsorship program does not imply AMA's endorsement of an entity or its policies. Participation in sponsorship of an AMA program does not imply AMA approval of that corporation's general policies, nor does it imply that our AMA will exert any influence to advance the corporation's interests outside the substance of the arrangement itself. Our AMA's name and logo should not be used in a manner that would express or imply an AMA endorsement of the corporation, its policies and/or its products.
(f) To remove any appearance of undue influence on the affairs of our AMA, our AMA should not depend on funding from corporate relationships for core governance activities.
Funding core governance activities from corporate sponsors, i.e., the financial support for conduct of the House of Delegates, the Board of Trustees and Council meetings could make our AMA become dependent on external funding for its existence or could allow a supporter, or group of supporters, to have undue influence on the affairs of our AMA.
(g) Funds from corporate relationships must not be used to support political advocacy activities. A full and effective separation should exist, as it currently does, between political activities and corporate funding. Our AMA should not advocate for a particular issue because it has received funding from an interested corporation. Public concern would be heightened if it appeared that our AMA's advocacy agenda was influenced by corporate funding.
(5) ORGANIZATIONAL REVIEW. Every proposal for an AMA corporate relationship must be thoroughly screened prior to staff implementation. AMA activities that meet certain criteria requiring further review are forwarded to a committee of the Board of Trustees for a heightened level of scrutiny.
(a) As part of its annual report on the AMA's performance, activities, and status, the Board of Trustees will present a summary of the AMA's corporate arrangements to the House of Delegates at each Annual Meeting.
(b) Every new AMA Corporate relationship must be approved by the Board of Trustees, or through a procedure adopted by the Board. Specific procedures and policies regarding Board review are as follows: (i) The Board routinely should be informed of all AMA corporate relationships; (ii) Upon request of two dissenting members of the CRT, any dissenting votes within the CRT, and instances when the CRT and the Board committee differ in the disposition of a proposal, are brought to the attention of the full Board; (iii) All externally supported corporate activities directed to the public should receive Board review and approval; (iv) All activities that have support from only one corporation except patient materials linked to CME, within an industry should either be in compliance with ACCME guidelines or receive Board review; and (f) All relationships where our AMA takes on a risk of substantial financial penalties for cancellation should receive Board review prior to enactment.
(c) The Executive Vice President is responsible for the review and implementation of each specific arrangement according to the previously described principles. The Executive Vice President is responsible for obtaining the Board of Trustees authorization for externally funded arrangements that have an economic and/or policy impact on our AMA.
(d) The Corporate Review Team reviews corporate arrangements to ensure consistency with the principles and guidelines. (i) The Corporate Review Team is the internal, cross-organizational group that is charged with the

review of all activities that associate the AMA's name and logo with that of another entity and/or with external funding. (ii) The Review process is structured to specifically address issues pertaining to AMA's policy, ethics, business practices, corporate identity, reputation and due diligence. Written procedures formalize the committee's process for review of corporate arrangements. (iii) All activities placed on the Corporate Review Team agenda have had the senior manager's review and consent, and following CRT approval will continue to require the routine approvals of the Office of Finance and Office of the General Counsel. (iv) The Corporate Review Team reports its findings and recommendations directly to a committee of the Board.
(e) Our AMA's Office of Risk Management in consultation with the Office of the General Counsel will review and approve all marketing materials that are prepared by others for use in the U.S. and that bear our AMA's name and/or corporate identity. All marketing materials will be reviewed for appropriate use of AMA's logos and trademarks, perception of implied endorsement of the external entity's policies or products, unsubstantiated claims, misleading, exaggerated or false claims, and reference to appropriate documentation when claims are made. In the instance of international publishing of JAMA and the Archives, our AMA will require review and approval of representative marketing materials by the editor of each international edition in compliance with these principles and guidelines.
(6) ORGANIZATIONAL CULTURE AND ITS INFLUENCE ON EXTERNALLY FUNDED PROGRAMS.
(a) Organizational culture has a profound impact on whether and how AMA corporate relationships are pursued. AMA activities reflect on all physicians. Moreover, all physicians are represented to some extent by AMA actions. Thus, our AMA must act as the professional representative for all physicians, and not merely as an advocacy group or club for AMA members.
(b) As a professional organization, our AMA operates with a higher level of purpose representing the ideals of medicine. Nevertheless, non-profit associations today do require the generation of non-dues revenues. Our AMA should set goals that do not create an undue expectation to raise increasing amounts of money. Such financial pressures can provide an incentive to evade, minimize, or overlook guidelines for fundraising through external sources.
(c) Every staff member in the association must be accountable to explicit ethical standards that are derived from the vision, values, and focus areas of the Association. In turn, leaders of our AMA must recognize the critical role the organization plays as the sole nationally representative professional association for medicine in America. AMA leaders must make programmatic choices that reflect a commitment to professional values and the core organizational purpose. (BOT Rep. 20, A-99; Consolidated: CLRPD Rep. 3, I-01; Modified: CLRPD Rep. 1, A-03; Modified: CCB/CLRPD Rep. 3, A-12)

Retirement and Hiring Practices H-25.996
It is urged that physicians, individually and through their constituent, component, and specialty medical societies, continue to stress the need to reappraise policies calling for compulsory retirement and age discrimination in hiring from the standpoint of health among older people, and that they participate actively and lend medical weight in the efforts of other groups to create a new climate of opportunity for the older worker. Committee on Aging Report, I-62; Reaffirmed: CLRPD Rep. C, A-88; Reaffirmed: Sunset Report, I-98; Reaffirmed: CSAPH Rep. 2, A-08; Modified: CCB Rep. 01, A-18

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 603
(November 2020)

Introduced by: New York

Subject: Report on the Preservation of Independent Medical Practice

Referred to: Reference Committee F

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1 Whereas, The number of physicians in independent practice of medicine has been rapidly
2 dwindling; and
3
4 Whereas, AMA policy is to advocate for the preservation of independent medical practice; and
5
6 Whereas, Many physicians are not members of the AMA, possibly because they are not
7 satisfied with or are unaware of the activities of the AMA to help physicians stay in private
8 practice; therefore be it
9
10 RESOLVED, That our American Medical Association issue a report every two years
11 communicating their efforts to support independent medical practices. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000

Received: 10/12/20

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 604
(November 2020)

Introduced by: Senior Physicians Section

Subject: Timely Promotion and Assistance in Advance Care Planning and Advance Directives

Referred to: Reference Committee F

Whereas, Every human being will confront mortality, and medical care and decision making at the end of life are best managed with the help of Advance Directives[1,2]; and

Whereas, The COVID-19 pandemic has dramatically increased the number of people facing life threatening illness and even end-of-life, concomitantly with limited or no access to their loved ones at the bedside, which situation has exponentially increased stress on physicians and others caring for critically ill patients; and

Whereas, Advance Directives specify the extent of care a person wishes when they are unable to make medical decisions for themselves; and

Whereas, Advance Directives are legal in every state, at no, or very low cost, and easily fillable forms are readily available from a variety of sources e.g. MOLST /POLST, including local medical organizations, AARP, state governments, faith-based groups, hospitals, and online; and

Whereas, The use of Advance Directives has been shown to bring comfort, closure, peace-of-mind, and family support, and to reduce healthcare costs; and

Whereas, Studies show that only about 37% of Americans have completed Advance Directives and even physicians are known to be lax in modeling this beneficial health practice[3]; and

Whereas, The substantially lower rate of completion of advance directives among minority populations has been identified as a health disparity and equity issue; and

Whereas, The source preferred by patients for information about advance care planning is their own physician, and advance care planning discussions between a physician and a patient are now reimbursable, yet it has not become a routine part of medical care; and despite past AMA recommendations, advance directive forms are not yet fully integrated as part of the medical record; and

Whereas, Advance directives, when not routinely completed by patients or when not available to providers because they are not included in a medical record, are sometimes either not considered by, or not honored by providers; therefore be it

RESOLVED, That our American Medical Association: (1) begin an educational and media campaign including billing and reimbursement information for physicians, encouraging physicians to lead by example and complete their own advance directives, to help motivate the routine provision of advance care planning to patients, so as to encourage and equip patients to complete their own advance directives; (2) encourage practicing physicians to publicize the fact of having executed their own advance directives, via educational materials posted and/or available in offices and on websites, as a way of starting the conversation with patients and families; and (3) urge all primary care physicians to immediately begin to include advance care planning as a routine part of their adult patient care protocols, and that advance directives be included in patients' medical records as a matter of course (Directive to Take Action); and be it further

RESOLVED, That our AMA promote outreach (prioritized and made more urgent by the COVID-19 pandemic) on: (1) the importance of advance directives with all its stakeholder groups and with other organizations with which it has relationships; and (2) to the legal, medical, hospital, medical education, and faith-based communities, as well as to interested citizens, to promote completion of advance directives by all individuals who are of legal age and competent (Directive to Take Action); and be it further

RESOLVED, That our AMA formally support the designation of April 16 of every year as National Healthcare Decisions Day. (Directive to Take Action)

Fiscal Note: Estimated cost of implementation in excess of $250K with ongoing annual costs.

Received: 10/05/20

[1] Pollack, K.M; Morhaim, D.; and Williams, MA (2010, June). The Public's Perspectives on Advance Directives: Implications for State Legislative and Regulatory Policy. Health Policy. 96(1):57-63. doi: 10.1016/j.healthpol.2010.01.004. Epub 2010 Jan 27. Retrieved from: https://www.sciencedirect.com/science/article/abs/pii/S0168851010000096 .
[2] Morhaim, D.K.; Pollack, K (2013, June). End-of-Life Care Issues: A Personal, Economic, Public Policy, and Public Health Crisis. American Journal of Public Health (AJPH). 103(6): e8–e10. Retrieved from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3698717/ .
[3] Reuters Health (2017, July 11). Over one third of U.S. Adults have Advanced Medical Directives. Retrieved from: https://www.reuters.com/article/us-health-usa-advance-directives/over-one-third-of-u-s-adults-have-advanced-medical-directives-idUSKBN19W2NO .

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 605
(November 2020)

Introduced by: New York

Subject: Development of Resources on End of Life Care

Referred to: Reference Committee F

Whereas, The questions regarding life and death have been debated by scholars, philosophers, religious leaders and doctors for centuries and technology has blurred the distinction between a quality human life and biological life on a cellular or organ basis; and

Whereas, Economic, social and religious views influence modern definitions of human and biological life, making technology in modern medicine a double-edged sword, favoring the betterment of patients and their quality of life and care; and

Whereas, Physicians have been sworn to do no harm, yet this is increasingly challenging with today's competing forces of technology, shifting social morae's and the economics and legislation of health care; and

Whereas, Confronted/ burdened with the more complicated questions of when life begins and ends, physicians have not always been able to transition patients effectively from life to death, which has contributed to decreased use of tools such as palliative care and hospice care; and

Whereas, End-of-life care as defined by the World Health Organization (WHO) "is the term used to describe the support and medical care given during the time surrounding death"; and

Whereas, Palliative Care is the treatment of patients with serious illnesses and disease with the goal to help the patient feel better, prevent or alleviate symptoms and side effects of disease and treatment, treating the whole patient including the emotional, social, practical, and spiritual costs of that illnesses, striving to improve a patient's quality of life as they deal with serious illness; and

Whereas, Hospice is the treatment of patients at the end of life or with a terminal illness, generally for patients who have less than six months to live and which uses many elements of palliative care to keep patients comfortable during their transition from life to death; and

Whereas, Physicians need to educate themselves on what the treatment goals offer and the reasonableness of the outcome, while all physicians should understand what palliative and hospice care offer a patient in terms of treatment, palliative care is an appropriate bridge to care; and

Whereas, There needs to be more certificate programs for physicians on palliative care until such time as there are enough fellowship trained end of life physicians, education is critical with respect to hospice care which does not mean "no care" but should redefine the scope of care; and

Whereas, Currently, the delivery of end of life care is fragmented with services provided in the hospital, skilled nursing facility or community with each setting having different resources, definitions and protocols and no seamless way to transfer patients from one setting to the next and back again; and

Whereas, The current “one size fits all” approach does little to address the spectrum of end of life issues but reinforces the need for a centralized depository of end of life orders that is easily accessible; therefore be it

RESOLVED, That our American Medical Association develop educational resources for physicians, allied health professionals and patients on end of life care (Directive to Take Action); and be it further

RESOLVED, That our AMA work with all stakeholders to develop proper quality metrics to evaluate and improve palliative and hospice care. (Directive to Take Action)

Fiscal Note: Not yet determined

Received: 10/09/20

Reference Committee G

BOT Report(s)

17 Hospital Website Voluntary Physician Inclusion

CMS Report(s)

02 Mitigating the Negative Effects of High-Deductible Health Plans
04 Economic Discrimination in the Hospital Practice Setting

Resolution(s)

701 Degradation of Medical Records
702 Eliminating Claims Data for Measuring Physician and Hospital Quality
703 Medicare Advantage Record Requests
704 Government Imposed Volume Requirements for Credentialing
705 The Quadruple Aim - Promoting Improvement in the Physician Experience of Providing Care
706 Physician Burnout is an OSHA Issue
707 Physician Well-Being as an Indicator of Health System Quality
708 Reducing Prior Authorization Burden
709 Addressing Inflammatory and Untruthful Online Ratings
710 A Resolution to Amend the AMA's Physician and Medical Staff Bill of Rights
711 Prevent Medicare Advantage Plans from Limiting Care
712 Increase Insurance Company Hours for Prior Authorization for Inpatient Issues

REPORT OF THE BOARD OF TRUSTEES

B of T Report 17, November 2020

Subject: Hospital Website Voluntary Physician Inclusion (Resolution 819-I-19)

Presented by: Russ Kridel, MD, Chair

Referred to: Reference Committee G

At the 2019 Interim Meeting, the House of Delegates (HOD) referred Alternate Resolution 819-I-19, "Hospital Website Voluntary Physician Inclusion." Resolution 819 was sponsored by the Organized Medical Staff Section and asked the AMA to:

> advocate for regulation and/or legislation requiring that all credentialed physicians (employed and voluntary) of a hospital and/or other healthcare facility be equally included on the websites and physician search engines, such as Find a Doctor sites…

The resolution further asked the AMA to:

> study a requirement that all credentialed physicians (employed and voluntary) of a hospital and/or other healthcare facility be equally included on the websites and physician search engines, such as Find a Doctor sites with a report back at the 2020 Annual Meeting.

Testimony around Resolution 819 was supportive of having all credentialed physicians included in hospital and healthcare facility websites and search functions. Speakers recalled anecdotes of hospitals that only advertised employed physicians with the suggestion that this practice may be part of a plan to encourage voluntary physicians to consolidate with larger healthcare facilities. Additional testimony noted the practice of omitting non-employed physicians from websites and search functions was not transparent, making it hard to ascertain why a facility engaged in the practice. Testimony also reflected that omissions of physicians in this way could lead to a more confusing experience for patients who may have a more difficult time locating a physician for the first time or returning to one later.

Original iterations of Resolution 819 called more forcefully for the AMA to engage in the policymaking and regulatory process at the state and federal level to ensure that all credentialed physicians are included on healthcare facilities' websites. Some believed, however, that a fully engaged legislative and advocacy campaign was an inappropriate remedy for the problem and encouraged that the AMA do more to understand physician inclusion on websites first before committing to more involved action.

This report addresses the request to study requirements and practices around physician inclusion in hospital and healthcare facility websites and search functions with attention paid to recommendations for future action. For the purposes of this report, a "voluntary physician" can be understood to be any physician who is credentialed and privileged to practice at a hospital or health facility for any period of time but who is not employed or is otherwise financially independent on that hospital or health system.

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DISCUSSION

Resolution 819 follows the experiences of several voluntary physicians in New York who found that their names were not included in the "Find a Doctor" search functions of at least one, and in some cases more than one, healthcare facility they practiced in. By contrast, names and information for physicians who were employed by the facilities were listed. When the voluntary physicians reached out to understand why, they heard a variety of reasons, including that the website was being updated. In each of the anecdotal cases, the issue was resolved, and voluntary physicians were eventually also included in the web search function.

These incidents raised a few concerns: first, that credentialed physicians were being, intentionally or otherwise, deprived of potential new patients because they were harder to find online. Second, that patients themselves may lose out on needed care due to the difficulties of locating a physician or returning to one in the future. Third, that excluding voluntary physicians from facility websites may put undue pressure on voluntary physicians to consolidate their practices into larger systems or facilities.

To better understand this issue, we reached out to the ten largest hospitals in the United States by number of beds according to Becker's Hospital Review[1]. These hospitals were chosen simply as a sample of the kinds of facilities that could potentially have a wide variety of employed and voluntary physicians working in them and not due to any suspected bad policies or inappropriate actions. (In point of fact, the healthcare facilities that were mentioned in the New York physicians' anecdotes all tended to be much smaller facilities.) All ten had "Find a Doctor" search functions on their websites. We attempted to speak with someone who could explain how these hospitals make determinations about management of their web search functions; however, we did not receive responses.

In examining the current regulatory landscape, we again were unable to identify any significant body of work that directly governed how physicians were listed on websites from state, local, or federal sources. While some guidance exists for certain standards, such as listing credentials, disclosures, or conflicts of interest in a public forum, very little is codified as to when and in what manner physicians' general information should be included or presented. Likewise, the AMA itself has not, prior to the Interim Meeting in 2019, established any guiding principles or policy on the subject.

While it does not relate directly to web searches and "Find a Doctor" sites, it is worth mentioning that one area of public reporting that is seeing a significant amount of attention involves reporting of quality metrics and performance measures. Federal and state mandates about how physicians and health systems may rank against each other are increasingly becoming more searchable and easier to find. Voluntary physicians should pay special attention to how they are listed on hospital websites to ensure that they are presented with the same contact information and quality measures as all other providers.

[1] 50 Largest Hospitals in America. *Becker's Hospital Review*. Accessed June 25, 2020: https://www.beckershospitalreview.com/lists/50-largest-hospitals-in-america.html

CONCLUSION

With few standards and almost no regulation from professional bodies, or state, local, or federal governments, it is difficult to fully grasp the effect of listing physicians' names in search functions. It is a potentially fruitful area for further academic research, as it is currently difficult to fully articulate how hospital and healthcare facilities' internal practices could affect not only physicians but patients seeking care as well. Additionally, none of the hospitals examined during this research responded to any requests to better understand how physicians are included in their websites and search functions. This gap in policy and practice uniquely positions the AMA to provide leadership and establish best practices for all medical staff in healthcare facilities. In the absence of public regulations and policy, the AMA can proactively establish standards for medical staff inclusion in public-facing promotional efforts like websites.

Because it is difficult to demonstrate how widespread the practice of limiting voluntary physicians on hospital websites is, it is also difficult to draw conclusions about the harm or benefit. Regardless, promoting access to practicing physicians, whether they are employed by a facility or voluntary, should be considered a best practice by the AMA. Any actions the AMA can take to promote the availability of credentialed and practicing physicians in any practice setting should ultimately be considered for the benefit of all physicians and their patients.

RECOMMENDATIONS

The Board of Trustees recommends that the following be adopted in lieu of Resolution 819-I-19 and that the remainder of the report be filed:

1. That our AMA (1) work with relevant stakeholders to encourage decision-makers at all appropriate levels that all credentialed physicians be included in healthcare organizations' website listings and search functions in a fair, equal, and unbiased fashion; and (2) support efforts to ensure that physicians, through their medical staffs, are able to provide input on what information is published. (Directive to Take Action)

2. That our AMA work with relevant stakeholders to encourage healthcare organizations to notify credentialed physicians when a website is about to be changed if there is reason to believe that such a change could affect how physicians are listed or if they are listed at all. (Directive to Take Action)

3. That our AMA, through its Organized Medical Staff Section, produce and promote educational materials, trainings, and any other relevant components to help physicians advocate for their own inclusion on facilities' websites and search functions. (Directive to Take Action)

Fiscal Note: Moderate - between $5,000 - $10,000

REPORT 2 OF THE COUNCIL ON MEDICAL SERVICE (I-20)
Mitigating the Negative Effects of High-Deductible Health Plans
(Resolution 125-A-19)
(Reference Committee G)

EXECUTIVE SUMMARY

At the 2019 Annual Meeting, the House of Delegates referred the enclosed Resolution 125, which was sponsored by Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont. Resolution 125-A-19 directed the American Medical Association (AMA) to advocate for legislation or regulation specifying that codes for outpatient evaluation and management services, including initial and established patient office visits, be exempt from deductible payments. The Board of Trustees assigned this item to the Council on Medical Service for a report back to the House of Delegates at the 2020 Annual Meeting.

While increasing access to health insurance has been beneficial to patients, critical challenges persist regarding health care access. Even when a service is covered by a health plan, patients may incur significant costs in the form of copayments, coinsurance, and/or large medical bills that they must pay before meeting their deductibles. Such costs have been shown to cause people, especially those with low incomes and/or chronic conditions, to forgo necessary care, and these challenges can be exacerbated in the context of high-deductible health plans (HDHPs).

This report examines clinical and financial challenges associated with HDHPs, explores several potential strategies for improvement, and makes recommendations to mitigate the negative effects of HDHPs. Specifically, in addition to reaffirming highly relevant policy, this report recommends that the AMA encourage further research and advocacy to develop and promote innovative health plan designs; that employers be encouraged to provide robust education to help patients make good use of their benefits to obtain the care they need, collaborate with their employees to understand employees' health insurance preferences and needs, tailor benefit designs to employees' preferences and needs, and pursue strategies to help enrollees spread the costs associated with high out-of-pocket costs out across the plan year; and that state and national medical specialty societies be encouraged to actively collaborate with payers as they develop innovative plan designs to ensure that the health plans are likely to achieve their goals of enhanced access to affordable care.

REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 2, November 2020

Subject: Mitigating the Negative Effects of High-Deductible Health Plans (Resolution 125-A-19)

Presented by: Lynda M. Young, MD, Chair

Referred to: Reference Committee G

At the 2019 Annual Meeting, the House of Delegates referred the enclosed Resolution 125, which was sponsored by Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont. Resolution 125-A-19 directed the AMA to advocate for legislation or regulation specifying that codes for outpatient evaluation and management services, including initial and established patient office visits, be exempt from deductible payments. The Board of Trustees assigned this item to the Council on Medical Service (CMS) for a report back to the House of Delegates at the 2020 Annual Meeting. This report examines clinical and financial challenges associated with high-deductible health plans (HDHPs), explores several potential strategies for improvement, and makes recommendations to mitigate the negative effects of HDHPs.

BACKGROUND

HDHPs are insurance plans associated with lower premiums, higher deductibles, and greater cost-sharing requirements as compared with traditional health plans.[1] Both enrollment in HDHPs and the size of deductibles has increased dramatically in recent years. In 2019, approximately 30 percent of enrollees in employer-sponsored health plans were covered by HDHPs, compared to 4 percent in 2006.[2] The imposition of greater consumer cost-sharing is frequently described as a means of ensuring that those receiving health care services "have skin in the game," and used as a lever to minimize the growth of health insurance premiums.

However, while an HDHP's lower premium may be enticing, higher patient cost-sharing can lead to significant challenges. Reductions in health care spending achieved through HDHPs have been found to be due to patients simply receiving less medical care.[3] Moreover, HDHPs appear to reduce health care spending by decreasing the use of both appropriate care (such as recommended cancer screenings) and less appropriate care (such as low-severity emergency department visits).[4] Studies have found that families who have members with chronic disease and who are enrolled in HDHPs are more likely to go without care due to cost and/or face substantial financial burdens, such as trouble paying bills, than families enrolled in traditional plans.[5] Another study found that enrollment in an HDHP combined with a savings account led to significant increases in out-of-pocket (OOP) spending, with more than half of the enrollees with lower-incomes and more than one-third of the enrollees with chronic conditions facing "excessive financial burden."[6]

The challenges of underinsurance and cost-related nonadherence (CRN) which can negatively affect patient care in general can be exacerbated in the context of HDHPs. Rates of underinsurance (e.g. OOP costs that are high relative to income) have risen. Even when a service is covered by a health plan, patients may incur significant costs in the form of copayments, coinsurance, and/or

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large medical bills that they must pay before meeting their deductibles. Such costs have been shown to cause people, especially those with low incomes and/or chronic conditions, to forgo necessary care.[7] Similarly, CRN refers to a state in which patients are unable to pursue recommended medical care due to financial barriers.[8] CRN and sub-optimal patient use of evidence-based medical services can lead to negative clinical outcomes, increased disparities, and in some cases, higher aggregate costs.[9] CRN has been identified across the entire continuum of clinical care, including physician visits, preventive screenings, and prescription drugs,[10] and the challenges of CRN may be magnified by the COVID-19 pandemic as payers experience financial pressure and strive to lower medical spending.[11] CRN is especially problematic for vulnerable populations, such as those with multiple chronic conditions, lower socioeconomic status, and/or belonging to diverse racial or ethnic groups.[12] For example, a recent study found that HDHPs were associated with cost-related barriers to care for cancer survivors, and these barriers were significantly greater for Black patients.[13] Additionally, greater OOP costs for medication to treat certain chronic conditions has been found to reduce initiation and adherence, lower the likelihood of achieving desired health outcomes, and sometimes, increase utilization of acute care services.[14] At the same time, studies have demonstrated that reducing or eliminating cost-sharing leads to improvements in medication adherence[15] and reductions in health disparities based on socioeconomic status and race.[16]

In addition to increases in deductible spending, total patient OOP spending has also risen significantly in recent years. Total OOP spending, which includes pre-deductible spending, copayments, and coinsurance, increased by 54 percent between 2006 and 2016.[17] Intensifying this challenge is the fact that over the past decade, growth in OOP costs has outpaced increases in workers' wages.[18] The COVID-19 pandemic highlighted critical shortcomings, with many health plans not providing affordable coverage for services to treat many chronic conditions and COVID-19-related illness.[19] In fact, 68 percent of adults said that OOP costs would be very or somewhat important in their decision to get care if they had COVID-19 symptoms.[20]

To help offset the burdens of higher deductibles and greater cost-sharing that patients face when enrolled in HDHPs, plans and employers can make available one or more of several tax-advantaged savings accounts including: Health Savings Accounts (HSAs), Health Reimbursement Arrangements (HRAs), Flexible Spending Arrangements (FSAs), and for certain small employers or self-employed individuals, Medical Savings Accounts (MSAs).[21] Each of these savings accounts has unique benefits and drawbacks, and the "best option" is very case specific. However, many patients do not, or cannot, optimally utilize savings accounts to help them offset OOP costs associated with HDHPs.[22] In light of these significant financial concerns, more needs to be done to ensure access to necessary, high-value care.

POTENTIAL STRATEGIES FOR IMPROVEMENT

Resolution 125-A-19 recommended that outpatient evaluation and management services, including initial and established patient office visits, be exempt from deductible payments in an effort to improve patient health and decrease total health care costs. The AMA supports innovative benefit designs that could allow certain physician services and prescription drugs to be provided pre-deductible. Moreover, in CMS Report 1-I-20, the Council is recommending that health plans be incentivized to offer pre-deductible coverage including physician services in their bronze plans, to maximize the value of zero-premium plans to plan enrollees. This is similar to the requirement that catastrophic plans sold on health insurance exchanges must cover at least three primary care visits per year pre-deductible.[23] Pre-deductible coverage for certain physician visits in these specific contexts, however, is a significant departure from pre-deductible coverage for all physician visits in all contexts.

When health plans become more generous in exempting additional items and services from a deductible, other elements of benefit design become less generous (ie, more costly to the enrollee) to counterbalance the additional cost. In theory, over a long time horizon with a consistent enrollee base, a health plan might find long-term cost savings, such as through decreases in hospital admissions or emergency department visits, to offset short-term cost increases associated with increased generosity in services exempt from deductibles. However, when short-term costs are critical, such as in health insurance exchanges and among plans sponsored by employers in industries that experience high levels of employee turnover, short-term costs heavily influence benefit design. In the health insurance exchanges, increases in plan generosity cause an increase in actuarial value (AV) of a health plan, and the plan must become less generous in other domains to maintain its AV. For example, in a study designed to test how plans could provide more generous coverage for high-value services, the more generous coverage for some services had to be offset by less generous coverage of other services in order to maintain required AV.[24] Similarly, in the private market, health plans might increase premiums or impose greater cost-sharing on some items or services to compensate for decreased cost-sharing for other items and services.

While high deductibles and OOP costs pose a significant challenge to many, this challenge is not universal, so it is important to recognize that blunt instruments that simply cause health care costs to shift among deductibles, cost-sharing, and premiums will be reallocating the burden of health care costs among a general population with very disparate health care utilization. US health care spending is dramatically concentrated, with very few individuals incurring very large shares of spending, while other large portions of the population incur very little spending. In fact, in 2016, half of the population had health spending under $971, accounted for only 2.8 percent of total health spending in the US, and incurred average OOP health care spending of only $73.[25] In contrast, 10 percent of the population had health spending of at least $12,024, accounted for 66 percent of total US spending, and incurred average OOP spending of $2,380.[26]

Benefit Design Initiatives

Rather than applying a blunt instrument that categorically shifts health care costs, health plans could be designed with "clinical nuance," a principle of value-based insurance design (VBID). "Clinical nuance" recognizes that medical services may differ in the amount of health produced, and that the clinical benefit derived from a specific service depends on the person receiving it, as well as when, where, and by whom the service is provided.[27] The same service could be high-value to one patient and low-value to another, and the ability of patients and their physicians to make this determination on a case-by-case basis is critical and well-supported by AMA policy. Achieving truly nuanced plan design is a laudable goal and one that VBID researchers have been pursuing for over a decade[28] with some progress. For example, the US Department of Treasury recently released Notice 2019-45, allowing HSA-HDHP plans the flexibility to cover specified medications and services used to treat chronic diseases prior to meeting the plan deductible.[29] While the list of specified medications and services is limited, it is a decisive step in the direction of expanding health plan flexibility to improve affordable access to high-value care.

More recently, legislative and regulatory changes have further expanded HSA-HDHPs' capacity for clinical nuance in the context of COVID-19. Explicitly recognizing the potential administrative and financial barriers to care present for individuals enrolled in HSA-HDHPs, the Internal Revenue Service (IRS) issued Notice 2020-15 to remove those barriers in the context of the unprecedented public health emergency.[30] Specifically, Notice 2020-15 makes another limited exception to the general rules governing qualification for HSA-HDHPs to allow health plans the flexibility to cover testing and treatment of COVID-19 pre-deductible and without imposition of patient cost sharing. Many of the nation's leading insurance companies pursued this opportunity and waived patient

cost-sharing for COVID-19-related testing, but the scope and duration of these waivers varies across insurers.[31] IRS Notice 2020-29 further clarified that the testing and treatment of COVID-19 that can be provided pre-deductible includes the panel of diagnostic testing for influenza A & B, norovirus and other coronaviruses, and respiratory syncytial virus (RSV).[32] Additionally, the Coronavirus Aid, Relief and Economic Security (CARES) Act created a temporary safe harbor allowing HDHPs to cover telehealth services and other remote care without cost to participants before their deductibles are met.[33] The safe harbor is currently in effect until the end of 2021.[34] It is up to payers, though, to implement plan changes to take advantage of this legal flexibility, and it remains to be seen how much relief patients will experience. As understanding of the clinical impacts of COVID-19 continues to evolve and patients begin experiencing long-term impacts from the infection, patients have reported receiving medical bills totaling tens of thousands of dollars for treatment for COVID-19 and complications.[35]

A second key consideration is that to effectively enhance patients' access to high-value care, health plans must make high-value care across the clinical continuum affordable. Making physician visits more affordable is therefore a necessary, but insufficient, step toward achieving the improved access goal of Resolution 125-A-19. If only physician office visits are targeted for deductible exemption, some patients and physicians may be frustrated to realize that they can identify a problem but lack the resources to resolve it. For example, consider the scenario where patients can visit their physician and learn that they are at risk for diabetes without incurring costs under their health plan, but to pursue necessary testing, pharmaceuticals, and medical devices, they must pay OOP until reaching their deductibles. In fact, a recent study found that patients enrolled in an HDHP who received a prescription for a brand name antihyperglycemic medication were less likely to refill that prescription than were patients enrolled in non-HDHP plans who were prescribed the same medicine.[36] This study suggests that HDHP enrollment can impact the quality and delivery of care for patients with type 2 diabetes when branded antihyperglycemic medications offer optimal disease management.[37] Similarly, another study found that patients with diabetes experienced minimal changes in outpatient visits and disease monitoring after switching to an HDHP, but low-income, high-morbidity, and HSA-HDHP subgroups experienced major increases in emergency department visits or expenditures for preventable acute diabetes complications.[38]

However, VBID can be applied to reduce some of the negative impacts of HSA-HDHPs and reduce health care disparities. A recent study found that when HSA-HDHPs incorporate a preventive drug list (PDL) which exempts specific high-value classes of medications from deductibles, patients experienced substantial decreases in annual OOP costs, increased medication utilization, and lower barriers to initiating treatment.[39] The study authors emphasized the importance of these findings for patients with lower incomes and encouraged employers to consider tailoring their benefit designs to concentrate PDL coverage in lower-income employees who may benefit most from the subsidized coverage. Additionally, a recent study demonstrated that an "HDHP+," a hypothetical HSA-HDHP that would reduce cost-sharing for certain high-value items and services intended to treat chronic conditions, would likely save the federal government money, and at a minimum, be cost neutral.[40] Moreover, plans that apply VBID principles to HDHPs could improve health equity by ensuring that all enrollees can afford high-value services, even during the deductible phase of their coverage.[41] At the same time, especially with such complex benefit designs, active counseling to help enrollees understand the value of their benefits may be critical to the success of these programs.[42] Collectively, these studies reinforce the principle that mitigating the deleterious effects of HDHPs will require efforts from stakeholders from across the health care continuum.

Payer-Driven Initiatives

In addition to considering alternative benefit design strategies that incentivize use of high-value care, payers can adopt strategies to minimize the deleterious effects of high deductibles. Given the trend of increasing patient OOP spending, payers could nevertheless soften the burden of these increasing OOP costs on patients and their physicians. Two key variables add to the stress of increasing OOP patient spending – first, the extent to which health care expenditures may need to be paid in large lump sums, and second, the extent to which patients and their physicians are unable to anticipate how much a given item or service will cost a patient OOP. When deductibles reset every year on January 1, many patients, including the 60 percent of Americans living with at least one chronic condition, may face significant OOP costs.[43] Patients may delay or forgo necessary care early in the year when they are facing the full OOP burden of their deductibles and have not accumulated funds in health savings accounts. In fact, it has been shown that nearly all incremental reductions in high-deductible health care spending occur while patients are subject to their deductibles.[44] Moreover, for patients enrolled in plans with coinsurance, the cost of health care items and services often cannot be known in advance, even after they have met their deductibles. In contrast, plans designed with copayments allow patients and their physicians to anticipate patient OOP costs.

Copayments are the most common form of patient cost-sharing associated with physician visits,[45] but with the increasing use of HDHPs, increasing numbers of patients and physicians are facing high deductibles and unpredictable bills for coinsurance. From 2007 to 2017, among patients with large employer coverage, coinsurance, deductible, and patient OOP spending increased, and copayment spending decreased.[46] In 2019, approximately 15 percent of patients enrolled in an HDHP paired with a savings account were subject to copayments for a physician office visit, with 68 percent subject to coinsurance.[47] The opposite pattern is present for patients enrolled in non-HDHP plans – between 86 and 95 percent of patients in non-HDHP plans paid copayments for physician office visits, with only 4 to 11 percent paying coinsurance.[48] With patients bearing increasing OOP health care costs, health plans that allow patients to predict their OOP costs in advance and also spread their OOP expenses over time may present a more patient-friendly and physician practice-friendly benefit design.

Employers, in specific, play a unique role as designers of employee health care benefits, and employers can choose to deploy a variety of strategies to encourage patients to pursue the care they need. Benefit packages are increasingly important to employees, with employees seeking choice and personalization, and looking to their employers to provide the tools they need to make good decisions.[49] Employers can take a variety of actions to make the health insurance benefits they offer valuable and accessible to their employees. For example, in 2019, JPMorgan Chase provided employees with health plans that applied lower deductible and coinsurance maximum amounts to lower-income employees.[50] For 2020, some JPMorgan Chase and Amazon employees have even more innovative plan options via the Haven Healthcare program, the venture among JPMorgan Chase, Amazon, and Berkshire Hathaway. Few details are available, but reporting indicates that the JPMorgan Chase plans remove patient deductibles, and copayments for most services range from $15 to $110.[51] Employers have a variety of more incremental options for tailoring the health plans they offer to their employees' needs. Some potential options for employers to consider include:

- Seed and/or match employee contributions to one or more types of savings accounts that can be used for health care expenses to encourage savings and use of these savings accounts. Employers contributing to employees' HSAs can improve employee awareness, consideration, and ultimately adoption and self-funding of HSAs.[52] Research indicates that on average, employees contribute 10 percent more to their HSAs each year when their

employer seeds money to their HSAs, and 59 percent of employees would contribute more to their HSAs if their employer provides a matching contribution.[53] However, a recent study found that 55 percent of employers offering HSA-HDHPs do not make contributions toward their employees' HSAs.[54]

- When possible, grant employees access to the full annual employer and/or employee contribution to a savings account at the beginning of a plan year so that patients can pursue care as they need it, rather than delaying care until savings have accumulated.
- Provide, and perhaps incentivize employees to participate in, robust health insurance and financial literacy campaigns that give them tools to choose the plan that best meets their needs and identify affordable care options throughout the plan year. When making decisions about health care savings, patients must navigate a complex set of choices, and even those with high financial literacy have trouble deciding where to save and how to spend.[55] For example, a 2018 study found that 69 percent of employees who did not enroll in an HSA say they chose not to enroll because they did not see any benefits to an HSA, did not understand what HSAs do, or simply did not take the time to understand the HSA. Moreover, only 15 percent of employees with high financial literacy choose to save their HSA money for the future.[56] Educational campaigns could include practical information regarding which items and services are available without patient cost-sharing pre-deductible and information about how funds placed in an HSA, HRA, FSA, MSA, or other savings account can be used to pay for health expenses. Via online and in-person education, employers can provide decision support and care navigation tools to help their employees at the time of health insurance enrollment and throughout the year.[57]
- Consider how predictable copayments vs. variable coinsurance can influence patient tendencies to pursue necessary health care and provide patients with a variety of health plan design options whenever possible.
- Collaborate with organized medicine to ensure that their innovations in plan design are likely to achieve intended clinical goals, as well as enhanced access to affordable care.

Physician Practice Initiatives

Physician practice initiatives focused on helping patients with high deductibles can serve physicians and the patients in their care. High deductibles burden patients and their physicians when patient fears about cost of care impair joint patient-physician decision-making and care planning. High deductibles also pose billing and collection challenges for physician practices. Fortunately, there are tools available that can help physicians and their practices. The administrative simplification provisions of the Health Insurance Portability and Accountability Act (HIPAA) related to standard electronic transactions and associated operating rules empower health care providers to obtain real-time information regarding patients' health plan coverage and financial obligations. Specifically, the operating rules for the electronic eligibility standard transaction require health plans to respond in real-time (within 20 seconds)[58] to health care providers' electronic requests for information about patients' health plan benefits.[59] Implementation of this legal requirement has been imperfect[60] – challenges persist – but the eligibility operating rules provide physicians with an avenue to obtain necessary data to inform their practice and their physician-patient joint decision-making. Specifically, physician practices can ascertain the patient's portion of the financial responsibility, including copayment, coinsurance and patient-specific remaining deductible. This information can help practices estimate patient costs before treatment decisions are made, and in some cases, collect patient deductibles and/or coinsurance before patients leave the office.[61] To empower physicians to implement and exercise their rights under the HIPAA administrative simplification provisions and to streamline their practices' billing processes, the AMA has published several toolkits and educational resources,

including those entitled, "What you need to know about electronic eligibility verification," "Managing patient payments," and "Electronic transaction toolkits for administrative simplification, which includes a resource on Compliance in standard electronic transactions: Responsibilities of health plans and physicians."[62]

RELEVANT AMA POLICY

AMA policy strongly supports value-based care, VBID, and innovative insurance design. Policy H-185.939 broadly supports flexibility in the design and implementation of VBID programs and outlines a series of guiding principles including that VBID explicitly consider the clinical benefit of a given service or treatment when determining cost-sharing or other benefit design elements. Policy D-185.979 also supports clinical nuance in VBID to respect individual patient needs and supports legislative and regulatory flexibility to accommodate VBID, including innovations that expand access to affordable care, such as changes needed to allow HSA-HDHPs to provide pre-deductible coverage for preventive and chronic care management services. Policy D-185.979 also encourages national medical specialty societies to identify services that they consider to be high-value and collaborate with payers to experiment with benefit plan designs that align patient financial incentives with utilization of high-value services. Consistent with calls to remove legislative and regulatory barriers to innovative plan design, Policy H-165.856 states that the regulatory environment should enable rather than impede private market innovation in product development and purchasing arrangements and further states that benefit mandates should be minimized to allow markets to determine benefit packages and permit a wide choice of coverage options. Policy H-450.938 provides principles to guide physician value-based decision-making, and Policy H-155.960 supports value-based decision-making among other broad strategies for addressing rising health care costs. Moreover, this policy recognizes the role of physician leadership and collaboration among physicians, patients, insurers, employers, unions, and government in successful cost-containment and quality-improvement initiatives. The policy encourages third-party payers to use targeted benefit design, whereby patient cost-sharing is determined based on the clinical value of a health care service or treatment, with consideration given to further tailoring cost-sharing to patient income and other factors known to impact compliance. AMA policy also supports value-based pricing for pharmaceuticals (Policy H-110.986) and providing patients with information and incentives to encourage appropriate utilization of preventive services (Policy H-390.849).

Policy H-165.846 states that provisions must be made to assist individuals with low-incomes or unusually high medical costs in obtaining health insurance coverage and meeting cost-sharing obligations. Policy H-165.828 encourages the development of demonstration projects to allow individuals eligible for cost-sharing subsidies, who forego these subsidies by enrolling in a bronze plan, to have access to an HSA partially funded by an amount determined to be equivalent to the cost-sharing subsidy. That policy also supports education regarding deductibles, cost-sharing, and HSAs. Policy H-165.852 supports, as an integral component of AMA efforts to achieve universal access and coverage and freedom of choice in health insurance, legislation promoting the establishment and use of HSAs and allowing the tax-free use of such accounts for health care expenses. That policy also supports the enhancement of activities to educate patients about the advantages and opportunities of HSAs. In addition, Policy H-165.854 supports HRAs as a mechanism for empowering patients to have greater control over their health care decision-making.

DISCUSSION

The Council lauds the sponsors of Resolution 125-A-19 for highlighting key challenges that HDHPs present to both patients and physicians, and it shares the goal of reducing barriers to

necessary health care. The Council is committed to developing AMA policy to mitigate the negative impacts of HDHPs that is consistent with the broader context of AMA policy on health reform and value-based decision-making. To accomplish this goal, the Council believes that the AMA should encourage further research and advocacy to develop and promote innovative health plan designs, including designs that can recognize that medical services may differ in the amount of health produced and that the clinical benefit derived from a specific service can vary among patients. Such policy would be consistent with AMA policy regarding "clinical nuance" in VBID (Policy D-185.979) and policy encouraging private market innovation in product development and purchasing arrangements (Policy H-165.856). Recognizing that more than half of Americans under age 65 get their health insurance through an employer,[63] employers have a powerful role to play in designing health plans to meet their employees' needs and educating their employees about the benefits provided by the health plans. Accordingly, the Council recommends that employers should be encouraged to collaborate with their employees in ways that help them to better understand their employees' health insurance preferences and needs, tailor the benefits they offer to meet the preferences and needs of employees and their dependents, and provide robust education to help patients make good use of their benefits to obtain the care they need. Moreover, to ease the financial burden of large lump sum expenditures, the Council recommends that employers pursue strategies to help enrollees spread the costs associated with high OOP costs across the plan year. Additionally, consistent with Policy H-155.960, which highlights the importance of collaboration among physicians and employers in successful cost-containment and quality-improvement initiatives, the Council encourages state medical associations and state and national medical specialty societies to actively collaborate with payers as they develop innovative plan designs to ensure that the health plans are likely to achieve their goals of enhanced access to affordable care. In addition, to emphasize the importance of health plans designed with "clinical nuance," the need for legislative and regulatory flexibility to accommodate innovations in health plan design that expand access to affordable care, and the critical role of collaboration among national medical specialty societies and payers in designing innovative health plans, the Council recommends reaffirming Policy D-185.979. Similarly, to highlight the importance of robust education regarding deductibles, cost-sharing, and health care savings accounts, and to amplify the AMA's support for funding health savings accounts, the Council recommends reaffirming Policy H-165.828. Moreover, the Council notes that in CMS Report 1-I-20, it recommends incentivizing health plans to offer pre-deductible coverage, including physician services in bronze plans, to maximize the value of zero-premium plans to plan enrollees.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted in lieu of Resolution 125-A-19 and that the remainder of the report be filed:

1. That our American Medical Association (AMA) encourage ongoing research and advocacy to develop and promote innovative health plan designs, including designs that can recognize that medical services may differ in the amount of health produced and that the clinical benefit derived from a specific service can vary among patients. (New HOD Policy)

2. That our AMA encourage employers to: (a) provide robust education to help patients make good use of their benefits to obtain the care they need, (b) take steps to collaborate with their employees to understand employees' health insurance preferences and needs, (c) tailor their benefit designs to the health insurance preferences and needs of their employees and their dependents, and (d) pursue strategies to help enrollees spread the costs associated with high out-of-pocket costs across the plan year. (New HOD Policy)

3. That our AMA encourage state medical associations and state and national medical specialty societies to actively collaborate with payers as they develop innovative plan designs to ensure that the health plans are likely to achieve their goals of enhanced access to affordable care. (New HOD Policy)

4. That our AMA reaffirm Policy D-185.979, which supports health plans designed to respect individual patient needs and legislative and regulatory flexibility to accommodate innovations in health plan design that expand access to affordable care, and which encourages national medical specialty societies to identify services that they consider to be high-value and collaborate with payers to experiment with benefit plan designs that align patient financial incentives with utilization of high-value services. (Reaffirm HOD Policy)

5. That our AMA reaffirm Policy H-165.828, which supports education regarding deductibles, cost-sharing, and health savings accounts (HSAs), and encourages the development of demonstration projects to allow individuals eligible for cost-sharing subsidies, who forego these subsidies by enrolling in a bronze plan, to have access to an HSA partially funded by an amount determined to be equivalent to the cost-sharing subsidy. (Reaffirm HOD Policy)

Fiscal Note: Less than $500.

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REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 4, November 2020

Subject: Economic Discrimination in the Hospital Practice Setting (Resolution 718-A-19)

Presented by: Lynda M. Young, MD, Chair

Referred to: Reference Committee G

At the 2019 Annual Meeting, the House of Delegates referred Resolution 718, "Economic Discrimination in the Hospital Practice Setting," which was introduced by the Organized Medical Staff Section. The Board of Trustees assigned this item to the Council on Medical Service for a report back at the 2020 Annual Meeting. Resolution 718 asked that our American Medical Association (AMA) actively oppose policies that limit a physician's access to hospital services based on the number of referrals made, the number of procedures performed, the use of any and all hospital services or employment affiliation.

This report addresses concerns regarding the use of case and volume metrics to limit access to hospital services by private practice physicians on hospital staff, summarizes relevant AMA policy, and makes policy recommendations.

BACKGROUND

Relationships between hospitals and physicians have changed over the years as health care payment and delivery systems have evolved, more care has moved to outpatient settings, and physician practice ownership has shifted away from physician-owned practice and toward working for a hospital or hospital-owned practice. The shift toward hospital employment is evidenced by AMA's Physician Practice Benchmark Surveys, which show that 35 percent of physicians worked either directly for a hospital or in a practice at least partially owned by a hospital in 2018, up from 29 percent in 2012.[1]

Hospital care has similarly evolved over time, such that inpatients are now sicker, hospital stays are shorter, and the hospitalist model—which was introduced in the 1990s—is in place in a majority of hospitals. Although primary care physicians and other generalist physicians still serve as inpatient attendings, far fewer specialists do so,[2] and most inpatient care is managed by hospitalists.[3] Prior to these shifts and the advent of hospital medicine, physicians largely practiced independently and managed patient care across outpatient and inpatient settings. Although many private practice physicians remain members of hospital medical staffs and have clinical privileges, most hospitals (approximately 75 percent in 2016) utilize hospitalists.[4]

Recently, concerns have been raised in the House of Delegates regarding hospital-physician relationships and hospitals giving preference to their employed physicians to the detriment of private practice physicians and patient-physician relationships. Referred Resolution 718-A-19 focuses specifically on concerns regarding hospitals using case and volume metrics to limit access to hospital services by private practice physicians who are on staff. The *AMA Physician's Guide to Medical Staff Organization Bylaws* speaks to similar concerns:

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> In exclusive contracting situations, some hospitals argue that exclusive rights to use hospital resources, such as radiology equipment or operating rooms, can be awarded by contract to some holders of privileges, while others with the same privileges are barred from their use.[5]

Such actions by hospitals violate the intent of Policy H-230.982, which states that clinical privileges shall include access to those hospital resources essential to the full exercise of such privileges. To address these concerns, the *AMA Physician's Guide to Medical Staff Organization Bylaws* includes the following sample bylaw regarding clinical privileges:

> Clinical privileges or privileges means the permission granted to medical staff members to provide patient care and includes unrestricted access to hospital resources (including equipment, facilities and hospital personnel) which are necessary to effectively exercise those privileges.[6]

The Guide consists of sample bylaw language on self-governance and other issues relevant to hospital-medical staff relationships. A seventh iteration of the Guide was being developed at the time this report was written.

Physicians need full access to hospital services in order to provide high quality care to their patients. Additionally, physicians must have access to hospital services to maintain medical staff memberships and privileges. Case in point is The Joint Commission's Ongoing Professional Practice Evaluation (OPPE) requirements, which are factored into decisions to maintain existing privileges. Data used for the OPPE process must include physician activities performed at the hospital where privileges have been requested.

RELEVANT AMA POLICY

In addition to defining clinical privileges and addressing access to hospital resources, Policy H-230.982 states that privileges can be abridged only upon recommendation of the medical staff for reasons related to professional competence, adherence to appropriate standards of medical care, health status, or other parameters agreed upon by the medical staff.

An extensive collection of AMA medical staff policy aims to protect the rights of physicians who are members of hospital medical staffs. Policy H-225.942 delineates medical staff member rights and responsibilities, including fundamental rights that apply to individual medical staff members regardless of employment, contractual, or independent status. Policy H-225.950 includes principles for physician employment; Policy H-225.957 outlines principles for strengthening the physician-hospital relationship; and Policy H-225.997 addresses physician-hospital relationships. Policy H-220.951 requests The Joint Commission to require that conditions for hospital medical staff membership be based only on the physician's professional training, experience, qualifications, and adherence to medical staff bylaws. Policy H-230.953 encourages The Joint Commission to support alternative processes to evaluate competence, for the purpose of credentialing, of physicians who do not meet the traditional minimum volume requirements needed to maintain credentials and privileges. Policy H-225.984 encourages hospital medical executive committees to regularly examine hospital/corporate bylaws, rules and regulations for any conflicts with the medical staff bylaws, rules and regulations or practices. Policy H-230.987 supports the concept that individual medical staff members who have been granted clinical privileges are entitled to full due process in any attempt to abridge those privileges by granting exclusive contracts by the hospital governing body.

The AMA also has extensive policy on economic credentialing and volume discrimination. Policies H-230.975 and H-230.976 strongly oppose economic credentialing, defined in policy as the use of economic criteria unrelated to quality of care or professional competency in determining an individual's qualifications for hospital medical staff membership or privileges. Policy H-230.971 asks the AMA to work with The Joint Commission to assure that criteria used in the credentialing process are directly related to the quality of patient care. Under Policy H-225.949, medical staffs are encouraged to develop medical staff membership categories for physicians who provide a low volume or no volume of clinical services in the hospital, and also encourages medical staffs and hospitals to engage community physicians, as appropriate, in medical staff and hospital activities.

Policy H-285.964 states that hospitalist programs should be developed consistent with AMA policy on medical staff bylaws and implemented with the formal approval of the organized medical staff, and that hospitals and other health care organizations should not compel physicians by contractual obligation to assign their patients to hospitalists. This policy also opposes any hospitalist model that disrupts patient/physician relationships or continuity of care and jeopardizes the integrity of inpatient privileges of attending physicians and physician consultants.

As a benefit of membership, the AMA provides assistance, such as information and advice (but not legal opinions or representation) to employed physicians, physicians in independent practice, and independent physician contractors in matters pertaining to their relationships with hospitals, health systems, and other similar entities (Policy D-215.990).

DISCUSSION

Although the Council was unable to find more than anecdotal information regarding physicians being subjected to the discrimination discussed in referred Resolution 718-A-19, it agrees that new policy is needed. The Council also believes that economic discrimination may be based on the type, as well as number of referrals made. Accordingly, the Council recommends actively opposing policies that limit a physician's access to hospital services based on the number and type of referrals made, the number of procedures performed, the use of any and all hospital services or employment affiliation. Having heard broader concerns about fairness and the need to protect physicians serving on medical staffs, the Council also recommends new policy recognizing that physician onboarding, credentialing, and peer review should not be tied in a discriminatory manner to hospital employment status.

The Council acknowledges the strength of existing AMA medical staff policy and recommends reaffirmation of Policy H-230.982, which states that clinical privileges shall include access to those hospital resources essential to the full exercise of such privileges, and that privileges can be abridged only upon recommendation of the medical staff, for reasons related to professional competence, adherence to appropriate standards of medical care, health status, or other parameters agreed upon by the medical staff. To address the OPPE issue, the Council recommends reaffirmation of Policy H-230.953, which encourages The Joint Commission to support alternative processes to evaluate competence, for the purpose of credentialing, of physicians who do not meet the traditional minimum volume requirements needed to maintain credentials and privileges. Finally, the Council recommends reaffirmation of Policies H-230.975 and H-230.976, which strongly oppose economic credentialing.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted in lieu of Resolution 718-A-19, and the remainder of the report be filed.

1. That our American Medical Association (AMA) actively oppose policies that limit a physician's access to hospital services based on the number and type of referrals made, the number of procedures performed, the use of any and all hospital services or employment affiliation. (New HOD Policy)

2. That our AMA recognize that physician onboarding, credentialing and peer review should not be tied in a discriminatory manner to hospital employment status. (New HOD Policy)

3. That our AMA reaffirm Policy H-230.982, which states that clinical privileges shall include access to those hospital resources essential to the full exercise of such privileges, and that privileges can be abridged only upon recommendation of the medical staff, for reasons related to professional competence, adherence to appropriate standards of medical care, health status, or other parameters agreed upon by the medical staff. (Reaffirm HOD Policy)

4. That our AMA reaffirm Policy H-230.953, which encourages the Joint Commission to support alternative processes to evaluate competence, for the purpose of credentialing, of physicians who do not meet the traditional minimum volume requirements needed to maintain credentials and privileges. (Reaffirm HOD Policy)

5. That our AMA reaffirm Policy H-230.975, which strongly opposes economic credentialing and believes that physicians should attempt to assure provisions in hospital medical staff bylaws of an appropriate role of the medical staff in decisions to grant or maintain exclusive contracts. (Reaffirm HOD Policy)

6. That our AMA reaffirm Policy H-230.976, which opposes use of economic criteria not related to quality to determine a physician's qualification for the granting or renewal of medical staff membership or privileges. (Reaffirm HOD Policy)

Fiscal Note: Less than $500.

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[2] Wachter, RM. Zero to 50,000—The 20th anniversary of the hospitalist. The New England Journal of Medicine 375;11 September 2016.
[3] Stevens JP, Nyweide DJ et al. Comparison of hospital resource use and outcomes among hospitalists, primary care physicians, and other generalists. JAMA Internal Medicine. Vol. 177, No. 12: 1781-1787. Nov. 2017. Available online at: https://pubmed.ncbi.nlm.nih.gov/29131897-comparison-of-hospital-resource-use-and-outcomes-among-hospitalists-primary-care-physicians-and-other-generalists/.
[4] Wachter, RM. Zero to 50,000—The 20th anniversary of the hospitalist. The New England Journal of Medicine 375;11 September 2016.
[5] American Medical Association. Physician's guide to medical staff organization bylaws, Sixth Edition. Updated March 2017.
[6] Ibid.

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 701
(November 2020)

Introduced by: Illinois

Subject: Degradation of Medical Records

Referred to: Reference Committee G

Whereas, Medical records have traditionally served to help the physician in the care of patients; and

Whereas, The electronic health record (EHR) was initially viewed and welcomed as an asset assisting the care of patients; and

Whereas, EHRs have not been an asset in assisting in the care of patients because of the subsequently mandated and marked increase in documentation which effectively obliterated the intended benefit; and

Whereas, Adding the additional component of data entry to patient visits was apparently done without providing financial reimbursement for the required time to complete; and

Whereas, The reality is that the need for extra data entry often impairs the physician's ability to care for the patient given the time pressure of the appointments; and

Whereas, The burden of documentation impairs the doctor-patient relationship; and

Whereas, The doctor-patient relationship has been a major incentive to practice primary care medicine; and

Whereas, There is power in nomenclature and language; and

Whereas, Mandated EHR documentation now more accurately represents "insurance and government reports" rather than "medical records" in the traditional sense; therefore be it

RESOLVED, That our American Medical Association publish available data about the amount of time physicians spend on data entry versus direct patient care, in order to inform patients, insurers, and prospective primary care physicians about the real expectations of the medical profession. (Directive to Take Action)

Fiscal Note: Minimal - less than $1,000

Received: 07/17/20

RELEVANT AMA POLICY

D-478.966 - Understanding and Correcting Imbalances in Physician Work Attributable to Electronic Health Records
Our AMA will work with health care leaders and policymakers to use industrial engineering principles and evidence-based best practices to study and then propose systematic reforms to reduce physicians' electronic health record workload. Alt. Res. 716, A-17

H-478.981 - Health Information Technology Principles
Our AMA will promote the development of effective electronic health records (EHRs) in accordance with the following health information technology (HIT) principles. Effective HIT should:
1. Enhance physicians' ability to provide high quality patient care;
2. Support team-based care;
3. Promote care coordination;
4. Offer product modularity and configurability;
5. Reduce cognitive workload;
6. Promote data liquidity;
7. Facilitate digital and mobile patient engagement; and
8. Expedite user input into product design and post-implementation feedback.

Our AMA will AMA utilize HIT principles to:
1. Work with vendors to foster the development of usable EHRs;
2. Advocate to federal and state policymakers to develop effective HIT policy;
3. Collaborate with institutions and health care systems to develop effective institutional HIT policies;
4. Partner with researchers to advance our understanding of HIT usability;
5. Educate physicians about these priorities so they can lead in the development and use of future EHRs that can improve patient care; and
6. Promote the elimination of "Information Blocking."

Our AMA policy is that the cost of installing, maintaining, and upgrading information technology should be specifically acknowledged and addressed in reimbursement schedules. BOT Rep. 19, A-18 Reaffirmation: A-19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 702
(November 2020)

Introduced by: Oklahoma

Subject: Eliminating Claims Data for Measuring Physician and Hospital Quality

Referred to: Reference Committee G

Whereas, The US Centers for Medicare and Medicaid Services has been publishing mortality data of hospitalized patients since 2008; and

Whereas, Public reporting has been expanded to cover multiple quality measures by many entities over the past few years; and

Whereas, The debate rages over whether to focus on outcomes versus care processes when assessing quality; and

Whereas, The validity of outcomes measures is under scrutiny when the data used for reporting purposes is claims data; and

Whereas, Any models that are used for assessing quality should be reliable and valid; and

Whereas, Models using data on severity of illness consistently outperform models using only comorbidity data; and

Whereas, Factors associated with severity of illness are the strongest predictors of quality; and

Whereas, Data from hospital billing systems contain no factors associated with the severity of illness; and

Whereas, Because of the variability of information in the medical record, claims data cannot reliably code comorbid conditions; and

Whereas, It is time to eliminate measures based on claims data from public reporting and other programs designed to hold physicians and hospitals accountable for improving outcomes; therefore be it

RESOLVED, That our American Medical Association collaborate with the Centers for Medicare & Medicaid Services (CMS) and other appropriate stakeholders to ensure physician and hospital quality measures are based on the delivery of care in accordance with established best practices (Directive to Take Action); and be it further

RESOLVED, That our AMA collaborate with CMS and other stakeholders to eliminate the use of claims data for measuring physician and hospital quality. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000

Received: 08/27/20

Reference:
https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2757527?resultClick=1

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 703
(November 2020)

Introduced by: Georgia

Subject: Medicare Advantage Record Requests

Referred to: Reference Committee G

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1 Whereas, Medicare Advantage rules for plans do not stipulate how record requests are handled,
2 nor any limits to number or repetitiveness of these requests; and
3
4 Whereas, Complying with these record requests can require extensive staff time and other
5 associated costs; and
6
7 Whereas, Practices are not reimbursed by Medicare Advantage companies for the staff time
8 involved in complying with these requests; and
9
10 Whereas, Each Medicare Advantage plan has different rules for record requests governed by
11 the contract between the plan and provider; therefore be it
12
13 RESOLVED, That our American Medical Association advocate for the relevant agencies and
14 stakeholders to prevent Medicare Advantage plans from requesting records from practices
15 solely to data mine for more funds and limit requests to 2% of plan participants, and otherwise
16 advocate that the plan will reimburse the practices for their efforts in obtaining additional
17 requested information. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000

Received: 09/28/20

RELEVANT AMA POLICY

Limiting Access to Medical Records H-315.987
Our AMA: (1) will pursue the adoption of federal legislation and regulations that will: limit third party payers' random access to patient records unrelated to required quality assurance activities; limit third party payers' access to medical records to only that portion of the record (or only an abstract of the patient's records) necessary to evaluate for reimbursement purposes; require that requests for information and completion of forms be delineated and case specific; allow a summary of pertinent information relative to any inquiry into a patient's medical record be provided in lieu of a full copy of the records (except in instances of litigation where the records would be discoverable); and provide proper compensation for the time and skill spent by physicians and others in preparing and completing forms or summaries pertaining to patient records; and (2) supports the policy that copies of medical records of service no longer be required to be sent to insurance companies, Medicaid or Medicare with medical bills.
Citation: Sub. Res. 222, I-94; Appended: Res. 218, A-02; Reaffirmed: BOT Rep. 19, I-06; Reaffirmed: BOT Rep. 06, A-16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 704
(November 2020)

Introduced by: New York

Subject: Government Imposed Volume Requirements for Credentialing

Referred to: Reference Committee G

Whereas, The government will sometimes create volume requirements for credentialing; and

Whereas, Depending on the details, these requirements may or may not be appropriate and justified; and

Whereas, The AMA has no policy or guideline for determining whether such requirements would or would not be appropriate; therefore be it

RESOLVED, That our American Medical Association create guidelines and standards for evaluation of government-imposed volume requirements for credentialing that would include at least the following considerations:

(a) the evidence for that volume requirement

(b) how many current practitioners meet that volume requirement

(c) how difficult it would be to meet that volume requirement

(d) the consequences to that practitioner of not meeting that volume requirement

(e) the consequences to the hospital and the community of losing the services of the practitioners who can't meet that volume requirement

(f) whether volumes of similar procedures could also reasonably be used to satisfy such a requirement. (Directive to Take Action)

Fiscal Note: Moderate - between $5,000 - $10,000

Received: 10/09/20

RELEVANT AMA POLICY

Reentry into Physician Practice H-230.953
Our AMA encourages: (1) hospitals to establish alternative processes to evaluate competence, for the purpose of credentialing, of physicians who do not meet the traditional minimum volume requirements needed to obtain and maintain credentials and privileges; and (2) The Joint Commission and other accrediting organizations to support alternative processes to evaluate competence, for the purpose of credentialing, of physicians who do not meet the traditional minimum volume requirements needed to obtain and maintain credentials and privileges.
Res. 717, A-19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 705
(November 2020)

Introduced by: New York

Subject: The Quadruple Aim – Promoting Improvement in the Physician Experience of Providing Care

Referred to: Reference Committee G

Whereas, In 2008, Donald Berwick and the Institute of Healthcare Improvement provided a framework for the delivery of high value care in the USA, the *Triple Aim*, centered around three overarching goals: improving the individual experience of care; improving the health of populations; and reducing the per capita cost of healthcare; and

Whereas, The *Triple Aim*, adopted as a set of principles for health system reform within many organizations around the world, fails to acknowledge the critical role of physicians in healthcare transformation and ignores the threats of psychological and physical harm that are common in medical practice; and

Whereas, For decision makers in healthcare (hospital leaders, EMR and other medical vendors, lawmakers and insurance companies) to abide by the *Triple Aim* is to ignore the threats of psychological and physical harm that are common to [clinicians] and patients; and

Whereas, The focus on productivity and efficiency, fueled by the pressures of decreasing reimbursement, has reduced intimate caregiving relationships to a series of transactional demanding tasks; and

Whereas, That by ignoring the experience of providing care in our healthcare delivery framework, this has eliminated consideration of human limitations in the delivery of care and this deficit in the framework of healthcare delivery results in unreasonable expectations upon physicians that affects them personally and the patients they serve; and

Whereas, The *Triple Aim* framework perpetuates the high occupational stress environment currently experienced by physicians when this framework is followed by all decision makers in healthcare, be they hospital leaders, electronic medical record and other medical device vendors, as well as law makers; and

Whereas, Intimate caregiving relationships have been reduced to a series of transactional demanding tasks, with a focus on productivity and efficiency, fueled by the pressures of decreasing reimbursement; therefore be it

RESOLVED, That to the *Triple Aim* which was established by Dr. Berwick and the Institute of Healthcare Improvement, our American Medical Association adopt a fourth goal: namely the goal of improving physicians' experience in providing care. (Directive to Take Action)

Fiscal Note: Minimal - less than $1,000

Received: 10/09/20

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 706
(November 2020)

Introduced by: New York

Subject: Physician Burnout is an OSHA Issue

Referred to: Reference Committee G

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1 Whereas, Repetitive Strain (Stress) Injury or RSI is defined as a category of injuries "to the
2 musculoskeletal and nervous systems that may be caused by repetitive tasks, forceful
3 exertions, vibrations, mechanical compression, or sustained or awkward positions; and
4
5 Whereas, RSI is a known work-related injury which falls under the purview of the Occupational
6 Safety and Health Administration (OSHA); and
7
8 Whereas, Most RSI results from cumulative trauma rather than a single event; and
9
10 Whereas, Repeated exposure to work-related stressors can result in physician burnout; and
11
12 Whereas, Cerebral centers and activity are most certainly within the domain of the nervous
13 system; and
14
15 Whereas, Physician burnout resulting from work-related stressors should be regarded as RSI
16 and, as such, should fall under the aegis of OSHA; therefore be it
17
18 RESOLVED, That our American Medical Association seek legislation/regulation to add
19 physician burnout as a Repetitive Strain (Stress) Injury and subject to Occupational Safety and
20 Health Administration (OSHA) oversight. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000

Received: 10/09/20

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 707
(November 2020)

Introduced by: New York

Subject: Physician Well-Being as an Indicator of Health System Quality

Referred to: Reference Committee G

Whereas, Physician well-being is measurable and existing instruments can assess physician wellness at a system level; and

Whereas, The Triple Aim, now adopted as a set of principles for health system reform within many organizations around the world, fails to acknowledge the critical role of physicians in healthcare transformation and ignores the threats of psychological and physical harm that are common in medical practice; and

Whereas, Intimate caregiving relationships have been reduced to a series of transactional demanding tasks, with a focus on productivity and efficiency, fueled by the pressures of decreasing reimbursement; and

Whereas, These forces have led to an environment which exhibits a lack of teamwork, disrespect between colleagues, and lack of workforce engagement from the level of the front-line caregivers, doctors and nurses, who are burdened with non-caregiving work, to the healthcare leader with bottom-line worries and disproportionate reporting requirements; and

Whereas, By ignoring the experience of providing care in our healthcare delivery framework, this has eliminated consideration of human limitations in the delivery of care and this deficit in the framework of healthcare delivery results in unreasonable expectations upon physicians that affects them personally and the patients they serve; and

Whereas, The Triple Aim framework perpetuates the high occupational stress environment currently experienced by physicians when this framework is followed by all decision makers in healthcare, be they hospital leaders, electronic medical record and other medical device vendors, as well as law makers; and

Whereas, Physician burnout can be a drag on health system quality and outcomes; therefore be it

RESOLVED, That our American Medical Association support policies that acknowledge physician well-being is both a driver and an indicator of hospital and health system quality (New HOD Policy); and be it further

RESOLVED, That our AMA promote dialogue between key stakeholders (physician groups, health-system decision makers, payers, and the general public) about the components needed in such a quality-indicator system to best measure physician and organizational wellness (Directive to Take Action); and be it further

RESOLVED, That our AMA (with appropriate resources) develop the expertise to be available to assist in the implementations of effective interventions in situations of suboptimal physician wellness. (Directive to Take Action)

Fiscal Note: Minimal - less than $1,000

Received: 10/09/20

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 708
(November 2020)

Introduced by: New York

Subject: Reducing Prior Authorization Burden

Referred to: Reference Committee G

Whereas, A prescription drug may require an insurance prior authorization; and

Whereas, Patients on chronic therapy experience a change in the rules during the interval between office visits and this results in extra work for a physician to review forms, medical records, complete paperwork, provide documentation and create an entry in the medical record so that a patient's therapy not suffer interruption; and

Whereas, The documentation process can be as resource intensive as a patient encounter; and

Whereas, The prior authorization diverts physician time away from direct patient care, thereby diminishing patient access and physician job satisfaction; and

Whereas, Reducing prior authorizations can protect patients from unnecessary delays in care; therefore be it

RESOLVED, That our American Medical Association seek regulation or legislation that:

- restricts insurance companies from requiring prior authorizations for generic medications;
- contains disincentives for insurers demanding unnecessary prior authorizations, including payments to physicians' practices for inappropriate prior authorizations;
- requires payment be made to the physician practice for services related to prior authorization when those services do not coincide with a visit; and
- ensures a requirement for an independent external review organization to review disputes involving prior authorizations and require insurer payments be made to the practice when the review organization agrees with the physician practice. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000

Received: 10/09/20

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 709
(November 2020)

Introduced by: New York

Subject: Addressing Inflammatory and Untruthful Online Ratings

Referred to: Reference Committee G

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1 Whereas, More than 70 percent of consumers search for health information online, according to
2 Pew Research Center, and 77 percent of consumers say they use online reviews as the first
3 step in finding a new physician*; and
4
5 Whereas, Online reviews are an open public forum that allows patients to share their stories and
6 photos regarding their experiences with doctors; and
7
8 Whereas, Often these reviews are negative and accuse the doctors of complications or
9 mismanagement of medical visits, treatments and procedures that they have had; and
10
11 Whereas, Bad online ratings can wreak havoc on doctors' businesses, in extreme cases driving
12 physicians to leave a state to practice elsewhere; and
13
14 Whereas, Ratings sites will take down reviews that use profanity or can be proven fake, but they
15 typically won't edit or remove a review simply because a doctor (or any business) disputes what
16 is in it; and
17
18 Whereas, Critics of public airing of patient comments argue that it puts a doctor in an untenable
19 position because federal privacy laws such as HIPAA prohibit doctors from compromising
20 patient confidentiality by responding directly to a patient's complaint, leaving physicians with
21 limited ability to rebut complaints; and
22
23 Whereas, Physicians are uniquely vulnerable to public criticism and potential adverse publicity
24 regarding their professional abilities and find this extremely unfair and unjust; and
25
26 Whereas, Change.org (a petition website operated by for-profit Change.org, Inc., which hosts
27 sponsored campaigns for organizations and serves to facilitate petitions by the general public)
28 has posted a petition signed by over 42,000 physicians calling for an immediate end to online
29 reviews of ALL doctors and providers who are subject to HIPAA and medical privacy laws,
30 stating further that reviews should not be posted until physicians can defend themselves or
31 respond; and
32
33 Whereas, The problem of addressing unfair online reviews is faced by physicians throughout
34 the country transcending regions and states; therefore be it
35
36 RESOLVED, That our American Medical Association take action that would urge online review
37 organizations to create internal mechanisms ensuring due process to physicians before the
38 publication of negative reviews. (Directive to Take Action)

Fiscal Note: Minimal - less than $1,000

Received: 10/12/20

* 2015 survey of 1,438 patients by Software Advice, a software research and advisory firm.

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 710
(November 2020)

Introduced by: Virginia

Subject: A Resolution to Amend the AMA's Physician and Medical Staff Bill of Rights

Referred to: Reference Committee G

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1 Whereas, According to the *Washington Post*, approximately 77,800 health care workers have
2 tested positive for the coronavirus[1], but data collected by the Centers for Disease Control and
3 Prevention suggests higher rates of infection for HCP's at 142,946 cases and 705 deaths as of
4 August 23, 2020[2]; and
5
6 Whereas, The shortage of personal protective equipment, as a contributing factor to the
7 infection and deaths of frontline workers, has been noted on multiple occasions. Occurrences
8 where organizations and hospitals have disciplined health workers for failure to comply with
9 restrictions on the use of PPE mandated by limited supply have also been documented in
10 multiple cases including in Virginia. In the absence of adequate supplies of PPE health care
11 workers are struggling with ethical decisions about how to provide safe care for their patients,
12 themselves, their families and their communities. They should not have to make these in
13 isolation; and
14
15 Whereas, Beauchamp and Childress have articulated 4 principals of medical ethics; autonomy,
16 non-malfeasance, beneficence and justice[3]. The Emergency Medicine Society adds virtue and
17 teamwork. For the individual provider ethical questions include: What is my ethical duty to care
18 for patients during the pandemic and in the absence of having proper PPE? If I am in a high-risk
19 group due to age or medical history, should I continue to care for patients in the absence of
20 having proper PPE? If I live with family members who are in a high-risk group due to age or
21 medical history, should I continue to care for patients in the absence of having proper PPE? If I
22 believe that I might be spreading the virus to patients, patient family members, colleagues
23 and/or community members, should I continue to care for patients in the absence of having
24 proper PPE?; and
25
26 Whereas, The individual provider interfaces with, and is dependent on, organizations such as
27 hospitals and health plans that provide supplies and dictate standards for distribution. The
28 organizations are, in turn, dependent on governmental structures that establish legislation and
29 public health policy that can facilitate, or limit, the clinician's ability to provide necessary and
30 safe care to the patient and the community; and
31
32 Whereas, The IOM report of 2008 addressed issues altering adherence to PPE protocols
33 distinguishing 1. Individual factors (i.e. knowledge and beliefs) 2. environmental factors (i.e.
34 availability of equipment and negative pressure rooms) and 3. Organizational factors (i.e.
35 workplace policies); and

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[1] https://www.washingtonpost.com/graphics/2020/health/healthcare-workers-death-coronavirus/
[2] https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html
[3] Beauchamp T, Childress J. Principles of Biomedical Ethics, 7th Edition. New York: Oxford University Press, 2013.

Whereas, The ethics of governmental support via the public health, policy and legislative sectors has come to light recently as the glaring deficiencies have been revealed with the recent pandemic. OSHA has not set enforceable standards. Workers may refuse to work but have no guarantee of job protection if they refuse. State rules on unemployment insurance my limit rights of those who refuse to work; and

Whereas, CDC provided guidelines for optimizing supply in a period of shortage but logistics and supply lines were not in the purview of this agency. There was discussion of enactment the Defense Production Act without action. It is to be hoped that policies would be scientific and ethical as well as coherent, however, uncoordinated policies across multiple agencies have failed to provide required equipment and services. Physicians have had to resort to personal appeals for donations of equipment; therefore be it

RESOLVED, That our American Medical Association amend Policy H-225.942, “Physician and Medical Staff Member Bill of Rights” by addition to read as follows:

Physician and Medical Staff Member Bill of Rights H-225.942

Our AMA adopts and will distribute the following Medical Staff Rights and Responsibilities:

Preamble

The organized medical staff, hospital governing body and administration are all integral to the provision of quality care, providing a safe environment for patients, staff and visitors, and working continuously to improve patient care and outcomes. They operate in distinct, highly expert fields to fulfill common goals, and are each responsible for carrying out primary responsibilities that cannot be delegated.

The organized medical staff consists of practicing physicians who not only have medical expertise but also possess a specialized knowledge that can be acquired only through daily experiences at the frontline of patient care. These personal interactions between medical staff physicians and their patients lead to an accountability distinct from that of other stakeholders in the hospital. This accountability requires that physicians remain answerable first and foremost to their patients.

Medical staff self-governance is vital in protecting the ability of physicians to act in their patient’s best interest. Only within the confines of the principles and processes of self-governance can physicians ultimately ensure that all treatment decisions remain insulated from interference motivated by commercial or other interests that may threaten high-quality patient care.

<u>The AMA recognizes the responsibility to provide for the delivery of high quality and safe patient care, the provision of which relies on mutual accountability and interdependence with the health care organization’s governing body, and relies on accountability and inter-dependence with government and public health agencies that regulate and administer to these organizations.</u>

The AMA supports the right to advocate without fear of retaliation by the health care organization's administrative or governing body including the right to refuse work in unsafe situations without retaliation.

The AMA believes physicians should be continuously provided with the resources necessary to continuously improve patient care and outcomes and further be permitted to advocate for planning and delivery of such resources not only with the health agency but with supervising and regulating government agencies.

From this fundamental understanding flow the following Medical Staff Rights and Responsibilities:

I. Our AMA recognizes the following fundamental responsibilities of the medical staff:

a. The responsibility to provide for the delivery of high-quality and safe patient care, the provision of which relies on mutual accountability and interdependence with the health care organizations governing body.
b. The responsibility to provide leadership and work collaboratively with the health care organizations administration and governing body to continuously improve patient care and outcomes.
c. The responsibility to participate in the health care organization's operational and strategic planning to safeguard the interest of patients, the community, the health care organization, and the medical staff and its members.
d. The responsibility to establish qualifications for membership and fairly evaluate all members and candidates without the use of economic criteria unrelated to quality, and to identify and manage potential conflicts that could result in unfair evaluation.
e. The responsibility to establish standards and hold members individually and collectively accountable for quality, safety, and professional conduct.
f. The responsibility to make appropriate recommendations to the health care organization's governing body regarding membership, privileging, patient care, and peer review.

II. Our AMA recognizes that the following fundamental rights of the medical staff are essential to the medical staffs ability to fulfill its responsibilities:

a. The right to be self-governed, which includes but is not limited to (i) initiating, developing, and approving or disapproving of medical staff bylaws, rules and regulations, (ii) selecting and removing medical staff leaders, (iii) controlling the use of medical staff funds, (iv) being advised by independent legal counsel, and (v) establishing and defining, in accordance with applicable law, medical staff membership categories, including categories for non-physician members.
b. The right to advocate for its members and their patients without fear of retaliation by the health care organizations administration or governing body.
c. The right to be provided with the resources necessary to continuously improve patient care and outcomes.
d. The right to be well informed and share in the decision-making of the health care organization's operational and strategic planning, including involvement in decisions to grant exclusive contracts or close medical staff departments.
e. The right to be represented and heard, with or without vote, at all meetings of the health care organizations governing body.

f. The right to engage the health care organizations administration and governing body on professional matters involving their own interests.

III. Our AMA recognizes the following fundamental responsibilities of individual medical staff members, regardless of employment or contractual status:

a. The responsibility to work collaboratively with other members and with the health care organizations administration to improve quality and safety.
b. The responsibility to provide patient care that meets the professional standards established by the medical staff.
c. The responsibility to conduct all professional activities in accordance with the bylaws, rules, and regulations of the medical staff.
d. The responsibility to advocate for the best interest of patients, even when such interest may conflict with the interests of other members, the medical staff, or the health care organization.
e. The responsibility to participate and encourage others to play an active role in the governance and other activities of the medical staff.
f. The responsibility to participate in peer review activities, including submitting to review, contributing as a reviewer, and supporting member improvement.

IV. Our AMA recognizes that the following fundamental rights apply to individual medical staff members, regardless of employment, contractual, or independent status, and are essential to each members ability to fulfill the responsibilities owed to his or her patients, the medical staff, and the health care organization:

a. The right to exercise fully the prerogatives of medical staff membership afforded by the medical staff bylaws.
b. The right to make treatment decisions, including referrals, based on the best interest of the patient, subject to review only by peers.
c. The right to exercise personal and professional judgment in voting, speaking, and advocating on any matter regarding patient care or medical staff matters, without fear of retaliation by the medical staff or the health care organizations administration or governing body.
d. The right to be evaluated fairly, without the use of economic criteria, by unbiased peers who are actively practicing physicians in the community and in the same specialty.
e. The right to full due process before the medical staff or health care organization takes adverse action affecting membership or privileges, including any attempt to abridge membership or privileges through the granting of exclusive contracts or closing of medical staff departments.
f. The right to immunity from civil damages, injunctive or equitable relief, criminal liability, and protection from any retaliatory actions, when participating in good faith peer review activities. (Modify Current HOD Policy)

Fiscal Note: Minimal - less than $1,000

Received: 10/14/20

RELEVANT AMA POLICY

Physician and Medical Staff Member Bill of Rights H-225.942
Our AMA adopts and will distribute the following Medical Staff Rights and Responsibilities:
Preamble
The organized medical staff, hospital governing body and administration are all integral to the provision of quality care, providing a safe environment for patients, staff and visitors, and working continuously to improve patient care and outcomes. They operate in distinct, highly expert fields to fulfill common goals, and are each responsible for carrying out primary responsibilities that cannot be delegated.
The organized medical staff consists of practicing physicians who not only have medical expertise but also possess a specialized knowledge that can be acquired only through daily experiences at the frontline of patient care. These personal interactions between medical staff physicians and their patients lead to an accountability distinct from that of other stakeholders in the hospital. This accountability requires that physicians remain answerable first and foremost to their patients.
Medical staff self-governance is vital in protecting the ability of physicians to act in their patients best interest. Only within the confines of the principles and processes of self-governance can physicians ultimately ensure that all treatment decisions remain insulated from interference motivated by commercial or other interests that may threaten high-quality patient care.
From this fundamental understanding flow the following Medical Staff Rights and Responsibilities:
I. Our AMA recognizes the following fundamental responsibilities of the medical staff:
a. The responsibility to provide for the delivery of high-quality and safe patient care, the provision of which relies on mutual accountability and interdependence with the health care organizations governing body.
b. The responsibility to provide leadership and work collaboratively with the health care organizations administration and governing body to continuously improve patient care and outcomes.
c. The responsibility to participate in the health care organization's operational and strategic planning to safeguard the interest of patients, the community, the health care organization, and the medical staff and its members.
d. The responsibility to establish qualifications for membership and fairly evaluate all members and candidates without the use of economic criteria unrelated to quality, and to identify and manage potential conflicts that could result in unfair evaluation.
e. The responsibility to establish standards and hold members individually and collectively accountable for quality, safety, and professional conduct.
f. The responsibility to make appropriate recommendations to the health care organization's governing body regarding membership, privileging, patient care, and peer review.
II. Our AMA recognizes that the following fundamental rights of the medical staff are essential to the medical staffs ability to fulfill its responsibilities:
a. The right to be self-governed, which includes but is not limited to (i) initiating, developing, and approving or disapproving of medical staff bylaws, rules and regulations, (ii) selecting and removing medical staff leaders, (iii) controlling the use of medical staff funds, (iv) being advised by independent legal counsel, and (v) establishing and defining, in accordance with applicable law, medical staff membership categories, including categories for non-physician members.
b. The right to advocate for its members and their patients without fear of retaliation by the health care organizations administration or governing body.
c. The right to be provided with the resources necessary to continuously improve patient care and outcomes.

d. The right to be well informed and share in the decision-making of the health care organization's operational and strategic planning, including involvement in decisions to grant exclusive contracts or close medical staff departments.
e. The right to be represented and heard, with or without vote, at all meetings of the health care organizations governing body.
f. The right to engage the health care organizations administration and governing body on professional matters involving their own interests.

III. Our AMA recognizes the following fundamental responsibilities of individual medical staff members, regardless of employment or contractual status:

a. The responsibility to work collaboratively with other members and with the health care organizations administration to improve quality and safety.
b. The responsibility to provide patient care that meets the professional standards established by the medical staff.
c. The responsibility to conduct all professional activities in accordance with the bylaws, rules, and regulations of the medical staff.
d. The responsibility to advocate for the best interest of patients, even when such interest may conflict with the interests of other members, the medical staff, or the health care organization.
e. The responsibility to participate and encourage others to play an active role in the governance and other activities of the medical staff.
f. The responsibility to participate in peer review activities, including submitting to review, contributing as a reviewer, and supporting member improvement.

IV. Our AMA recognizes that the following fundamental rights apply to individual medical staff members, regardless of employment, contractual, or independent status, and are essential to each members ability to fulfill the responsibilities owed to his or her patients, the medical staff, and the health care organization:

a. The right to exercise fully the prerogatives of medical staff membership afforded by the medical staff bylaws.
b. The right to make treatment decisions, including referrals, based on the best interest of the patient, subject to review only by peers.
c. The right to exercise personal and professional judgment in voting, speaking, and advocating on any matter regarding patient care or medical staff matters, without fear of retaliation by the medical staff or the health care organizations administration or governing body.
d. The right to be evaluated fairly, without the use of economic criteria, by unbiased peers who are actively practicing physicians in the community and in the same specialty.
e. The right to full due process before the medical staff or health care organization takes adverse action affecting membership or privileges, including any attempt to abridge membership or privileges through the granting of exclusive contracts or closing of medical staff departments.
f. The right to immunity from civil damages, injunctive or equitable relief, criminal liability, and protection from any retaliatory actions, when participating in good faith peer review activities.

Citation: BOT Rep. 09, A-17; Modified: BOT Rep. 05, I-17; Appended: Res. 715, A-18; Reaffirmed: BOT Rep. 13, A-19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 711
(November 2020)

Introduced by: American Academy of Physical Medicine and Rehabilitation

Subject: Prevent Medicare Advantage Plans from Limiting Care

Referred to: Reference Committee G

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1 Whereas, There are Medicare guidelines for most treatments for patients including
2 appropriate diagnoses for admission to inpatient rehabilitation units and criteria for
3 procedures; and
4
5 Whereas, Medicare Advantage plans do not consistently follow Medicare guidelines
6 meaning that patients who are insured by Medicare Advantage plans do not receive the
7 same level of treatment as patients insured by standard Medicare; and
8
9 Whereas, When asked about denial of services, the Medicare Advantage plans state that
10 Medicare guidelines ALLOW them to approve a service but do not REQUIRE them to do
11 so; and
12
13 Whereas, Medicare Advantage plans often use proprietary criteria (such as Milliman and
14 InterQual) or NaviHealth algorithms to determine eligibility of Medicare beneficiaries for
15 procedures and admissions to hospitals and IRF's, which is an additional layer that limits
16 access to services and often does not agree with the professional judgement of the patient's
17 physician; therefore be it
18
19 RESOLVED, That our American Medical Association ask the Centers for Medicare and
20 Medicaid Services to more tightly regulate Medicare Advantage Plans so that Medicare
21 guidelines are followed for all Medicare patients and care is not limited for patients who chose
22 an Advantage Plan (Directive to Take Action); and be it further
23
24 RESOLVED, That our AMA advocate that applying proprietary criteria to determine
25 eligibility of Medicare patients for procedures and admissions should not overrule the
26 professional judgment of the patient's physician. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000

Received: 10/13/20

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 712
(November 2020)

Introduced by: American Academy of Physical Medicine and Rehabilitation

Subject: Increase Insurance Company Hours for Prior Authorization for Inpatient Issues

Referred to: Reference Committee G

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1 Whereas, Acute care hospitals are open 24 hours a day every day of the year, including
2 holidays and weekends; and
3
4 Whereas, Patients are admitted and discharged from hospitals 365 days a year; and
5
6 Whereas, Physicians working in hospitals are there to evaluate and treat patients 365 days a
7 year; and
8
9 Whereas, Prior authorization is required by most insurance companies to admit patients to
10 inpatient rehabilitation facilities and skilled nursing facilities for further rehabilitation before
11 returning home; and
12
13 Whereas, Insurance companies close their offices from Friday noon to Monday morning and
14 even longer around holidays (Thanksgiving from Wednesday noon until Monday morning); and
15
16 Whereas, These limited office hours adversely affect patient care as the delay in prior
17 authorization either keeps the patient in the acute hospital more days than necessary or causes
18 discharge to an inappropriate location due to pressures about length of stay; and
19
20 Whereas, Current House Bill, H.R. 3107: Improving Seniors' Access to Timely Care, provides
21 for the Medicare Advantage (MA) Prior Authorization Program to “provide real-time decisions
22 with respect to requests identified by the Secretary [...] if such requests contain all information
23 required by an MA plan; therefore be it
24
25 RESOLVED, That our American Medical Association advocate that all insurance companies
26 that require prior authorization for patients in acute care hospitals have prior authorization staff
27 available to do approvals for hospitalized patients every day of the year, including holidays and
28 weekends. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000

Received: 10/13/20

Informational Reports

BOT Report(s)

01 2019 Grants and Donations
02 Update on Corporate Relationships
03 AMA Performance, Activities and Status in 2019
04 Annual Update on Activities and Progress in Tobacco Control: March 2019 through February 2020
08 White House Initiative on Asian Americans and Pacific Islanders
11 Redefining AMA's Position on ACA and Healthcare Reform
12 2020 AMA Advocacy Efforts
15 Plan for Continued Progress Toward Health Equity (Center for Health Equity Annual Report)

CEJA Opinion(s)

01 Physician Competence, Self-Assessment and Self-Awareness

CME Report(s)

04 Preparedness for Pandemics Across the Medical Education Continuum

REPORT OF THE BOARD TRUSTEES

B of T Report 1, November 2020

Subject: 2019 Grants and Donations

Presented by: Russ Kridel, MD, Chair

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1 This informational financial report details all grants or donations received by the American
2 Medical Association during 2019.

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American Medical Association
Grants & Donations Received by the AMA
For the Year Ended December 31, 2019
Amounts in thousands

Funding Institution	Project	Amount Received
Agency for Healthcare Research and Quality (subcontracted through Northwestern University)	Midwest Small Practice Care Transformation Research Alliance	$ 4
Agency for Healthcare Research and Quality (subcontracted through RAND Corporation)	Health Insurance Expansion and Physician Distribution	49
Centers for Disease Control and Prevention	Engaging Physicians to Strengthen the Public Health System and Improve the Nation's Public Health	18
Centers for Disease Control and Prevention (subcontracted through American College of Preventive Medicine)	Building Healthcare Provider Capacity to Screen, Test, and Refer Disparate Populations with Prediabetes	182
Centers for Disease Control and Prevention (subcontracted through National Association of Community Health Centers, Inc.)	Preventing Heart Attacks and Strokes in Primary Care	117
Centers for Medicare & Medicaid Services	Transforming Clinical Practices Initiative — Support and Alignment Networks	467
Government Funding		**837**
American Heart Association, Inc.	Target: Blood Pressure Initiative	111
Atrium Health	American Conference on Physician Health	12
The Physicians Foundation, Inc.	American Conference on Physician Health	20
The Physicians Foundation, Inc.	Practice Transformation Initiative: Solutions to Increase Joy in Medicine	55
UNC Health Care System	American Conference on Physician Health	15
Nonprofit Contributors		**213**
Contributions less than $5,000	International Medical Graduates Section Reception	5
Other Contributors		5
Total Grants and Donations		**$ 1,055**

REPORT OF THE BOARD OF TRUSTEES

B of T Report 2, November 2020

Subject: Update on Corporate Relationships

Presented by: Russ Kridel, MD, Chair

PURPOSE

The purpose of this informational report is to update the House of Delegates (HOD) on the results of the Corporate Review process from January 1 through December 31, 2019. Corporate activities that associate the American Medical Association (AMA) name or logo with a company, non-Federation association or foundation, or include commercial support, currently undergo review and recommendations by the Corporate Review Team (CRT) (Appendix A).

BACKGROUND

At the 2002 Annual Meeting, the HOD approved revised principles to govern the American Medical Association's (AMA) corporate relationships, HOD Policy G-630.040 "Principles on Corporate Relationships." These "Guidelines for American Medical Association Corporate Relationships" were incorporated into the corporate review process, are reviewed regularly, and were reaffirmed at the 2012 Annual Meeting. AMA managers are responsible for reviewing AMA projects to ensure they fit within these guidelines.

YEAR 2019 RESULTS

In 2019, 85 new activities were considered and approved through the Corporate Review process. Of the 85 projects recommended for approval, 47 were conferences or events, 10 were educational content or grants, 23 were collaborations or affiliations, two were member programs, one was an American Medical Association (AMA) Alliance activity and two were American Medical Association Foundation (AMAF) programs (Appendix B).

CONCLUSION

The Board of Trustees (BOT) continues to evaluate the CRT review process to balance risk assessment with the need for external collaborations that advance the AMA's strategic focus.

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Appendix A

CORPORATE REVIEW PROCESS OVERVIEW

The Corporate Review Team (CRT) includes senior managers from the following areas: Strategy, Finance, Health Solutions Group (HSG), Advocacy, Federation Relations, Office of the General Counsel, Medical Education, Publishing, Ethics, Enterprise Communications (EC), Marketing and Member Experience (MMX), and Health and Science.

The CRT evaluates each project submitted to determine fit or conflict with AMA Corporate Guidelines, covering:

- Type, purpose and duration of the activity;
- Audience;
- Company, association, foundation, or academic institution involved (due diligence reviewed);
- Source of external funding;
- Use of the AMA logo;
- Editorial control/copyright;
- Exclusive or non-exclusive nature of the arrangement;
- Status of single and multiple supporters; and
- Risk assessment for AMA.

The CRT reviews and makes recommendations regarding the following types of activities that utilize AMA name and logo:

- Industry-supported web, print, or conference projects directed to physicians or patients that do not adhere to Accreditation Council for Continuing Medical Education (ACCME) Standards and Essentials.

- AMA sponsorship of external events.

- Independent and company-sponsored foundation supported projects.

- AMA licensing and publishing programs. (These corporate arrangements involve licensing AMA products or information to corporate or non-profit entities in exchange for a royalty and involve the use of AMA's name, logo, and trademarks. This does not include database or CPT licensing.)

- Member programs such as new affinity or insurance programs and member benefits.

- Third-party relationships such as joint ventures, business partnerships, or co-branding programs directed to members.

- Non-profit association collaborations outside the Federation. The CRT reviews all non-profit association projects (Federation or non-Federation) that involve corporate sponsorship.

- Collaboration with academic institutions only if there is corporate sponsorship.

For the above specified activities, if the CRT recommends approval, the project proceeds.

In addition to CRT review, the Executive Committee of the Board must review and approve CRT recommendations for the following AMA activities:

- Any activity directed to the public with external funding.

- Single-sponsor activities that do not meet ACCME Standards and Essentials.

- Activities involving risk of substantial financial penalties for cancellation.

- Upon request of a dissenting member of the CRT.
- Any other activity upon request of the CRT.

All Corporate Review recommendations are summarized annually for information to the Board of Trustees (BOT). The BOT informs the HOD of all corporate arrangements at the Annual Meeting.

Appendix B

SUMMARY OF CORPORATE REVIEW
RECOMMENDATIONS FOR 2019

Project No.	Project Description	Corporations	Approval Date
CONFERENCES / EVENTS			
34034	**2019 E-Health Conference –** Updated sponsorship with AMA name and logo to establish CPT in Canadian healthcare market.	E-Health Annual Conference and Trade Show	3/21/2019
34535	**Annual Celebrate Leaders Benefit Sponsorship 2019 –** Sponsorship with AMA name and logo.	Leadership Greater Chicago	1/15/2019
34542	**Women Business Leaders (WBL) 18th Annual Summit Gold Sponsorship –** Sponsorship with AMA name and logo.	Women Business Leaders (WBL) Amgen, Inc. UnitedHealth Group Tivity Health, Inc.	1/16/2019
34602	**The Demystification of Coding and the Digital Health Implementation Playbook** – Speaking engagement including sponsorship with AMA name and logo.	Tennessee Chapter of Healthcare Information and Management Systems Society (HIMSS)	1/22/2019
34716	**13th Annual RISE Summit Silver Sponsor –** Sponsorship with AMA name and logo.	Rise Health, Inc Advantasure, Inc. Babel Health, Inc. Ankura Consulting Group, LLC	2/12/2019
34717	**America's Health Insurance Plans (AHIP) Institute & Expo 2019 –** Speaking engagement and member sponsorship with AMA name and logo use.	America's Health Insurance Plans (AHIP)	3/18/2019
34810	**Arab Health 2020 Conference –** Sponsorship with AMA name and logo.	Arab Health (by Informa Markets)	2/25/2019
34835	**AMA sponsorship of The American Academy of Professional Coders (AAPC) Healthcon 2019** – Sponsorship with AMA name and logo.	American Academy of Professional Coders (AAPC) Optum360, LLC The Coding Network, LLC (TCN) Ultimate Medical Academy (UMA) Pinnacle Healthcare Consulting Wolters Kluwer N.V. HCTec	3/1/2019
34894	**Arizona Association of Medical Staff Services (AAMSS) and Michigan Association of Medical Staff Services (MAMSS) 2019 Annual Conferences** – AMA sponsorship with name and logo.	Arizona Association of Medical Staff Services (AAMSS)	3/7/2019

35036	**Association of Clinical Documentation Improvement Specialists (ACDIS) Clinical Documentation Integrity (CDI) Week Marketing Sponsorship** – Sponsorship with AMA name and logo.	Association of Clinical Documentation Improvement Specialists (ACDIS)	4/2/2019
35073	**National Minority Quality Forum Leadership Summit 2019 –** Sponsorship with AMA name and logo use.	The National Minority Quality Forum (NMQF)	4/3/2019
35169	**The Tenth Annual Patient Experience: Empathy & Innovation Summit –** AMA name and logo use to announce collaboration.	Cleveland Clinic Press Ganey Associates PricewaterhouseCoopers (PwC) Microsoft Corporation Sultan Bin Abdulaziz Humanitarian City International Business Machines Corporation (IBM) Siemens Healthineers, AG (Siemens Medical Solutions USA, Inc.) Wambi American Well Gozio Health (Gozio, Inc.) Verge Health (Verge Solutions, LLC) Baxter International, Inc. CEMOSoft Hill-Rom Services, Inc. Joint Accreditation Kyruus Medigate Oneview Healthcare The Continuous Ambient Relaxation Environment (C.A.R.E.) Channel Twistle, Inc. West – TeleVox Solutions Wolters Kluwer Financial Services, Inc.	4/29/2019
35186	**Rush University Medical Center - West Side Walks to Wellness –** Speaking engagement and sponsorship with AMA name and logo to encourage healthy physical activity and empower youth of color.	Rush University Medical Center	4/29/2019
35198	**American Health Information Management Association (AHIMA) World Congress Sponsorship** – Sponsorship with AMA name and logo.	American Health Information Management Association (AHIMA) World Congress (AWC)	5/3/2019
35268	**American Health Information Management Association (AHIMA) Clinical Coding Meeting –** Sponsorship of event dinner with AMA name and logo.	American Health Information Management Association (AHIMA) World Congress (AWC)	5/21/2019

35289	**Center for Healthcare Innovation Gold Level Sponsorship (2019) –** Sponsorship with AMA name and logo.	Center for Healthcare Innovation (CHI) AdvocateAuroraHealth Dunham Fund Otsuka Rush University Medical Center Cempa Community Care	5/24/2019
35344	**Celebrating Life Gala Sponsorship (2019)** – Sponsorship with AMA name and logo.	Metropolitan Chicago Breast Cancer Task Force	5/29/2019
35451	**Race, Bias, & Equity in Prenatal Care Beltway Briefing** – Sponsorship with AMA name and logo.	The Jennifer Bush-Lawson Foundation	6/8/2019
35453	**HLTH 2019** – Sponsorship with AMA name and logo.	HLTH, LLC	6/12/2019
35459	**Rock Health Summit 2019 –** Sponsorship with AMA name and logo use for summit on technologies transforming healthcare.	Rock Health	6/12/2019
35471	**National Association of Medical Staff Services (NAMSS) 2019 Sponsorship –** Sponsorship with AMA name and logo.	National Association of Medical Staff Services (NAMSS) MD-Staff (Applied Statistics & Management Inc.) Symplr Verity Health Intellisoft Group, LLC Verge Health (Verge Solutions, LLC) PreCheck, Inc. Hardenbergh Group, Inc. IntelliCentrics The Greeley Company	6/14/2019
35517	**Social Enterprise Alliance Summit 2019 –** Sponsorship with AMA name and logo for summit with national social enterprise leaders.	Social Enterprise Alliance (SEA) Airbnb, Inc. The Good Trade Wells Fargo & Company Catalyst Kitchens (FareStart) Classy Law Offices of Marc J. Lane The ICA (Industrial Cooperative Association) Group Catholic Charities USA Network for Good The Kresge Foundation UPS (United Parcel Service) BBVA (Banco Bilbao Vizcaya Argentaria) Compass (BBVA USA Bancshares, Inc. BBVA USA) Stanford Social Innovation Review (Stanford University) American Express Company Bank of America Corporation Northern Trust Corporation RSF Social Finance (Rudolf Steiner Foundation, Inc.) CiTTA Partnership, LLC Opendoor Advisors	6/27/2019

		Chicago Booth – Rustandy Center for Social Sector Innovation	
35575	**National Association of Black Journalists (NABJ) Annual Conference Sponsorship –** Sponsorship with AMA name and logo.	National Association of Black Journalists (NABJ)	7/5/2019
35620	**Institute of Electrical and Electronics Engineers (IEEE) Engineering in Medicine and Biology Society (EMBS) Conference 2019 –** Sponsorship with AMA name and logo of conference for physician, clinical and engineering innovation community.	Institute of Electrical and Electronics Engineers (IEEE) Engineering in Medicine and Biology Society (EMBS) National Institute of Health (NIH)	7/11/2019
35786	**Cardz for Kidz Event Sponsorship** – Sponsorship with AMA name and logo for event supporting hospitalized and traumatized children.	Cardz for Kidz!	8/8/2019
35800	**National Medical Fellowships' Champions of Health Awards (2019) –** Sponsorship with AMA name and logo.	National Medical Fellowships, Inc. Northwestern University Feinberg School of Medicine	9/4/2019
35838	**Stanford Medicine & National Academy of Medicine Artificial Intelligence (A.I.) Conference –** Sponsorship with AMA name and logo.	Gordon and Betty Moore Foundation National Academy of Medicine Regenstrief Institute, Inc. Stanford Presence Stanford Human-Centered AI Institute Vanderbilt University	8/5/2019
35928	**2019 Brady Action Awards –** Sponsorship with AMA name and logo.	The Brady Campaign to Prevent Gun Violence	8/8/2019
35936	**Genetic Health Information Network Summit (GHINS) sponsorship –** Sponsorship with AMA name and logo.	Genetic Health Information Network Summit (GHINS) Concert Genetics, Inc. Genome Medical, Inc.	8/28/2019
35945	**2019 Cook County Health Foundation Gala and Awards Event –** Sponsorship with AMA name and logo.	Cook County Health Foundation (CCHF)	9/3/2019
36014	**Congressional Black Caucus Foundation Annual Legislative Conference National Town Hall –** Sponsorship with AMA name and logo.	The Congressional Black Caucus The Procter and Gamble Company (P&G)	9/6/2019
36016	**Connected Health Conference (CHC19) –** Sponsorship with AMA name and logo.	The Connected Health Conference HIMSS (Healthcare Information and Management Systems Society) Teva Pharmaceuticals Industries Ltd. Conversa Health, Inc.	9/11/2019
36017	**Medical Organization for Latino Advancement (MOLA) Latino Health Symposium 2019 –** Sponsorship with AMA name and logo.	Medical Organization for Latino Advancement (MOLA)	9/6/2019

36022	**Systematized Nomenclature of Medicine (SNOMED) Clinical Terms Expo 2019 –** Sponsorship with AMA name and logo.	Systematized Nomenclature of Medicine (SNOMED) International TPP (The Phoenix Partnership) Goldblatt Systems, LLC CSIRO (Commonwealth Scientific and Industrial Research Organization)	9/4/2019
36048	**2019 Annual Hispanic Health Professional Student Scholarship Gala –** Sponsorship with AMA name and logo.	National Hispanic Medical Association National Hispanic Health Foundation United Health Foundation Davita, Inc. Fresenius Medical Care Amgen, Inc. Charles R. Drew University of Medicine and Science David Geffen School of Medicine at University of California, Los Angeles (UCLA) Adventist Health Southern California Huntington Memorial Hospital Montefiore Medical Center Latino Commission on AIDS Western University School of Pharmacy Children's Hospital of El Paso	9/9/2019
36094	**2019 Chicago United Bridge Awards Dinner –** Sponsorship with AMA name and logo.	Chicago United	9/19/2019
36156	**Special Olympics Illinois Sponsorship 2019 –** Sponsorship with AMA name and logo for Breakfast of Executive Champions to support inclusion and diversity.	Special Olympics Illinois	9/30/2019
36231	**Chicago Cares, Find Your Cause 2019 –** Sponsorship with AMA name and logo for social responsibility event.	Chicago Cares	10/8/2019
36280	**2020 National Rx Drug Abuse & Heroin Summit –** Sponsorship with AMA name and logo.	The National Rx Drug Abuse & Heroin Summit	10/9/2019
36281	**2019 National Addiction Treatment Week –** Sponsorship with AMA name and logo.	ASAM (American Society of Addiction Medicine) Advocates for Opioid Recovery Facing Addiction Faces and Voices of Recovery National Institute on Alcohol Abuse and Alcoholism (NIAAA) National Institute on Drug Abuse (NIDA) White Coats for Recovery National Association of Addiction Treatment Providers (NAATP) National Institute on Drug Abuse (NIDA) Bates Creative Group, LLC NACoA (National Association for Children of Addiction) Student Coalition on Addiction	10/9/2019

36290	**2019 Chicago Urban League, Annual Golden Fellowship Dinner** – Sponsorship with AMA name and logo.	Chicago Urban League	10/15/2019
36340	**International Association of Industrial Accident Boards and Commissions** – Sponsorship of breakfast meeting with AMA name and logo.	International Association of Industrial Accident Boards and Commissions (IAIABC)	10/9/2019
36384	**15th World Congress of Bioethics Conference Bags** – Sponsorship of conference bags with AMA name and logo.	2020 World Congress on Bioethics at Penn Penn State University	10/28/2019
36400	**2019 Juvenile Diabetes Research Foundation, 40th Annual One Dream Gala** – Sponsorship with AMA name and logo.	Juvenile Diabetes Research Foundation (JDRF) Illinois	10/28/2019
37016	**2020 International Conference on Physician Health** – Sponsorship with AMA name and logo.	The International Conference on Physician Health (ICPH) Canadian Medical Association (CMA) British Medical Association (BMA)	12/17/2019
37143	**American Academy of Professional Coders Healthcon 2020** – Sponsorship with AMA name and logo.	American Academy of Professional Coders (AAPC) Optum360 Simplify Compliance PGC Software (Professional Graphics Controller) Alpha II Duva Sawko Ohana Coding RSM Coding Solutions, LLC UMA (Ultimate Medical Academy)	12/26/2019
	AMA sponsorship of the 2019 Alliance for Health Policy Dinner – Sponsorship of event dinner with AMA name and logo.	Alliance for Health Policy	8/26/2019

EDUCATIONAL CONTENT OR GRANTS

30540	**AMA Ed Hub Gaples Institute Collaboration** – Gaples nutrition curriculum to be featured on the AMA Education Center with name and logo.	Gaples Institute	5/21/2019
34714	**Edge-U-Cate – Credentialing School Certification Study Sponsor** – Sponsorship with AMA name and logo listed on website as credentialing sponsor for education verification.	Edge-U-Cate, LLC American Board of Medical Specialties (ABMS) Solutions/CertiFACTS American Osteopathic Information Association (AOIA)	2/7/2019
34780	**What You Can Do Initiative** – AMA name and logo use on instructional video for health care workers to reduce firearm injury and death among high risk populations.	"What You Can Do to Stop Fire Violence" (WYCD) University of California (UC) Davis Heising-Simons Foundation California Wellness Foundation State of California American Academy of Pediatrics (AAP)	2/18/2019

		American College of Physicians (ACP) American Chemical Society (ACS)	
35571	**Becker's Healthcare Webinar Sponsorship 2019 –** Sponsorship with AMA name and logo for educational webinar on credentialing.	Becker's Healthcare Allscripts Healthcare, LLC Mercy Virtual Care Center Capella University Visitpay	7/5/2019
35585	**JAMA Network Content Licensing –** JAMA Network name and logo to be used in the educational section only of the Pfizer Pro website to identify JAMA content.	Pfizer, Inc.	7/9/2019
35745	**100&Change MacArthur Foundation Grant Application –** AMA submission to be a partial recipient of grant.	The MacArthur Foundation American Heart Association (AHA) World Hypertension League (WHL)	8/1/2019
36362	**Career Step Fulfillment Project –** AMA name and logo to be used with Career Step logo on limited use student book fulfillment form for AMA Current Procedural Terminology (CPT) Coding books.	Career Step, LLC Carrus	10/24/2019
36409	**PS2 Ambulatory Support Survey –** AMA name and logo use on collaborative survey including Amazon.com gift card.	Amazon.com Mayo Clinic (Mayo Foundation for Medical Education and Research) Stanford University	10/31/2019
36665	**Blood Pressure (BP) Measure Accurately Module Initiative –** Sponsorship with AMA and AHA names and logos for educational program on measuring blood pressure (BP) accurately.	American Heart Association (AHA)	11/14/2019
36666	**United States Pharmacopeia Convention (USP) Bicentennial Video –** AMA name and logo use on bicentennial video.	United States Pharmacopeia Convention (USP)	11/11/2019
COLLABORATIONS/AFFILIATIONS			
33627	**Health Care Organizations (HCOs) for the IHO Prevention Strategy Collaboration –** AMA name and logo will appear alongside these HCOs for the national diabetes prevention program.	Community Health Center of the New River Valley Louisiana Primary Care Association (LPCA) Start Corporation d/b/a/ Start Community Health Center Baystate Medical Practices Cook County Health Family Christian Health Center (FCHC) Mercy Health System Corp Valley Health Systems Bon Secours Hospital Care South Clinic	7/31/2019
34716	**America's Health Insurance Plans (AHIP) Sponsorship and Membership Agreement –** Repeat member sponsorship with AMA name and logo use.	America's Health Insurance Plans (AHIP)	2/12/2019

34737	**Social Enterprise Alliance Membership –** Member sponsorship with AMA name and logo use.	Social Enterprise Alliance (SEA)	2/12/2019
34849	**Healthcare Information and Management Systems Society (HIMSS) Interoperability Call to Action –** AMA name and logo to be listed on the webpage of pledge supporters.	Healthcare Information and Management Systems Society (HIMSS) Alliance for Nursing Informatics (ANI) National Association of County and City Health Officials (NACCHO) Riverside County Medical Association Bicgen Foundation, Inc. Integrating the Healthcare Enterprise (IHE) Institute for eHealth Policy Strategic Health Information Exchange Commission (SHIEC)	2/23/2019
34962	**2020 Census –** AMA name and logo with other supporters on the Census Bureau website.	The Census Bureau Uber Technologies, Inc. Major League Baseball United Way Worldwide National Domestic Workers Alliance Bird Rides, Inc. American Council on Education American Feed Industry Association No Kid Hungry (Share Our Strength) Children's Hospital Association League of Conservation Voters (LCV) Propel Water	3/18/2019
35034	**Building Provider Capacity to Screen, Test, and Refer Disparate Populations with Prediabetes Collaboration –** AMA name and logo use to support screening and referring high risk women to CDC – recognized Type Two diabetes prevention program.	Black Women's Health Imperative (BWHI) American College of Preventive Medicine (ACPM)	3/29/2019
35035	**AMA / Association of American Medical Colleges (AAMC) Residency Exploration Tool Collaboration –** AMA name and logo used in AAMC Residency Exploration Tool list of partners and collaborators.	Association of American Medical Colleges (AAMC)	4/2/2019
35111	**Omada – Chronic Disease Prevention Project –** Expansion of the AMA relationship with Omada for hypertension control.	Omada Health, Inc.	4/17/2019
35265	**Digital Bridge –** AMA name and logo use for Digital Bridge Membership.	Digital Bridge	5/16/2019
35318	**American Heart Association (AHA) and AMA – Measure Accurately Testing Organization –** AMA name and logo use with AHA to test e-learning module with healthcare organizations.	American Heart Association (AHA)	5/24/2019

35385	**IHMI Collaboration –** IHMI collaboration agreements with limited AMA name and logo use.	CloudDx United Healthcare (UHC) UnitedHealth Group Workgroup for Electronic Data Interchange (WEDI) Minnesota Mining and Manufacturing Company (3M) Carrot Health, Inc	5/31/2019
35406	**Chicago Area Public Affairs Group, Membership and Sponsorship (2019) –** Member sponsorship with AMA name and logo use.	Chicago Area Public Affairs Group (CAPAG)	6/6/2019
35719	**Validated Device Listing ("VDL") –** Independently developed criteria and program to provide physicians with a list of blood pressure devices demonstrating validation for clinical accuracy.	American Heart Association (AHA) National Opinion Research Center at University of Chicago (NORC) Association for the Advancement of Medical Instrumentation (AAMI) American Pharmacists Association Hypertension Canada Preventive Cardiovascular Nurses Association (PCNA) Food and Drug Administration	10/30/2019
35878	**Nuance IHMI Collaboration – Phase One –** IHMI collaboration agreement with limited AMA name and logo use for Phase One.	Nuance Communications, Inc.	9/4/2019
36018	**Physicians Foundation Practice Transformation Initiative –** AMA to receive grant with name and logo use.	The Physicians Foundation	9/11/2019
36020	**AMA Joy Recognition Program** – Sponsorship with AMA name and logo.	Southern California Permanente Medical Group Icahn School of Medicine at Mount Sinai University of Rochester Medical Center St. Vincent Medical Group/Ascension Medical Group Stanford University Medical Center Boston Medical Center Harvard Medical Faculty Physicians at Beth Israel Deaconess Medical Center Wake Forest School of Medicine Ascension, Ascension Medical Group University of North Carolina Health Care	9/11/2019
36021	**The Collaborative for Healing and Renewal in Medicine (CHARM) –** The AMA name and logo to be associated with the Charter and the "CHARM" friends" on AMA and Arnold P. Gold Foundation websites.	Ada County Medical Society American College of Cardiology Bayhealth Medical Center California Pacific Medical Center (CPMC) Emory Healthcare Henry Ford Health System SurgeonMasters Nurturing MDs	9/11/2019

36049	**AMA Physician Innovation Network (PIN) Collaborators –** AMA Physician Innovation Network (PIN) collaboration agreements with limited AMA name and logo use.	Junto Health Hofstra University MassChallenge HealthTech Doctorpreneurs, Ltd. Savvy Cooperative HealthXL, LLC HealthTech Arkansas Programs, LLC The Medical Futurist (TMF) University of California San Francisco (UCSF) Health Hub	9/12/2019
36120	**AMA/Dubai Health Authority Joint Press Release –** Joint press release with AMA name and logo use to announce five-year agreement.	Dubai Health Authority (DHA)	9/12/2019
36383	**"Partnership" with Time's Up Healthcare –** AMA name and logo use to announce collaboration.	Time's Up Healthcare Time's Up Foundation	10/22/2019
36385	**Healthcare Information and Management Systems Society (HIMSS) 2020 Collaborator Agreement –** Sponsorship with AMA name and logo.	Healthcare Information and Management Systems Society (HIMSS)	10/24/2019
36397	**Health Level Seven International (HL7) Benefactor Membership –** AMA name and logo use with HL7 to empower health data interoperability.	Health Level Seven International (HL7)	10/28/2019
36511	**Dietary Supplement Quality Collaborative (DSQC) –** AMA name and logo use to advance AMA's policies on improvement of dietary supplement quality and safety.	Dietary Supplement Quality Collaborative (DSQC) The United States Pharmacopeia Convention (USP)	11/8/2019
MEMBER PROGRAMS			
31370	**Mirador Financial, Inc. –** AMA Affinity program for small practice lending services, Mirador acquired by Credit Union National Association (CUNA) Mutual Group.	Mirador Financial, Inc. Credit Union National Association (CUNA) Mutual Group	2/6/2019
32694	**Laurel Road Bank / KeyBank (KeyCorp) –** AMA Affinity program for student loan refinance. Updated ownership to Key Bank (KeyCorp).	Laurel Road Bank (f/k/a Darien Rowayton Bank "DRB") Credible Labs, Inc. KeyBank (KeyCorp).	3/22/2019
AMA ALLIANCE			
	America's Opioid Epidemic: Know the Facts – AMAA / PTA collaboration with AMAA name and logo use for opioid epidemic education program.	Parent Teachers Association (PTA)	2/27/2019

AMA FOUNDATION

American Medical Association Foundation (AMAF) Corporate Donors – Corporate donors for 2019.	AbbVie, Inc. Amgen, Inc. Boehringer Ingelheim Bristol-Myers Squibb Company Eli Lilly Co. Genentech, Inc. GlaxoSmithKline, PLC Merck & Co., Inc. Novartis Pharmaceutical Corp Pfizer, Inc. Pharmaceutical Research and Manufacturers of America (PhRMA) Sanofi, S.A.	10/8/2019
American Medical Association Foundation (AMAF) Richard Allen Williams Event – Sponsors for Richard Allen Williams event.	American Heart Association (AHA) American College of Cardiology Anthem Blue Cross Arbor Pharmaceuticals Blue Shield of California California Endowment DaVita, Inc. Global Blood Therapeutics McGraw-Hill University of California, Los Angeles (UCLA) Health	5/17/2019

REPORT OF THE BOARD OF TRUSTEES

B of T Report 3, November 2020

Subject: AMA Performance, Activities, and Status in 2019

Presented by: Russ Kridel, MD, Chair

Policy G-605.050, "Annual Reporting Responsibilities of the AMA Board of Trustees," calls for the Board of Trustees to submit a report at the American Medical Association (AMA) Annual Meeting each year summarizing AMA performance, activities, and status for the prior year.

INTRODUCTION

The AMA's mission is to promote the art and science of medicine and the betterment of public health. As the physician organization whose reach and depth extends across all physicians, as well as policymakers, medical schools, and health care leaders, the AMA is uniquely positioned to deliver results-focused initiatives that enable physicians to answer a national imperative to measurably improve the health of the nation.

Removing obstacles that interfere with patient care

Insurer Practices

The AMA protected patients from unanticipated medical bills by working with state medical associations and national medical specialty societies to craft a common set of policies to guide advocacy efforts on surprise billing. The AMA also worked to ensure surprise billing legislation passed by Congress holds patients harmless for unanticipated medical bills and limited out-of-pocket expenses.

The AMA supported federal legislation to streamline prior authorization in Medicare Advantage plans and state legislation to improve the prior authorization process for patients and physicians in more than 15 states. Additionally, the AMA released new prior authorization physician survey data that highlighted the significant negative impact of this process on both patients and practices.

The AMA in partnership with state and specialty medical societies have helped remove prior authorization for medication assisted treatment for patients with opioid use disorder in the Medicaid and/or commercial markets in Arizona, Arkansas, Colorado, Delaware , the District of Columbia, Illinois, Iowa, Maine, Missouri, New Jersey, New York, Pennsylvania, Vermont, Virginia and Washington since the start of 2018.

Physician Payment

The AMA successfully urged CMS to adopt new physician payment models, including a set of primary care payment models and a model on emergency services, to help ease the transition to value-based care.

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CMS implemented the Current Procedural Terminology (CPT®) framework to simplify documentation and coding of office visits—as well as other regulatory relief changes championed by the AMA—further reducing administrative burdens and needless paperwork.

The Current Procedural Terminology (CPT®) Editorial Panel and AMA-convened Digital Medicine Payment Advisory Group advanced coverage and payment for digital medicine services by establishing new codes for remote self-measure blood pressure monitoring e-visits between patients and physicians.

The AMA and CMS worked to reduce physician documentation. The newly adopted approach represents the first overhaul of Evaluation & Management (E/M) guidelines and codes in more than 25 years, which will reduce burden and provide physicians more time with patients.

International adoption of Current Procedural Terminology (CPT®) extended to Cyprus, Abu Dhabi, Dubai, and Bahrain as part of an effort to improve the quality, efficiency, and access of their healthcare systems. In addition, other countries and provinces have expressed interest as the rigorous approach of the terminology continues to attract international interest.

Practice Transformation

The AMA is working diligently so that practicing physicians are integral partners in the movement towards a thriving value-based health care system. AMA created over 12 resources and tools for physicians and practice leaders that provide strategic guidance and education, implementation and decision support, and practice financial forecasting, among others. The AMA along with ReachMD developed a value-based care podcast series called "Reaching the Potential of Value-Based Care" to help physicians better understand emerging topics on Medicare Advantage and behavioral health integration into clinical practice.

The AMA has committed to expanding the body of "practice science research" on solutions that increase joy in medicine. The goal of the "Practice Transformation Initiative" with health systems is to improve patient care and clinician satisfaction by implementing evidence-based workflow improvements. Through this new line of research, we look to move from studying prevalence, causes, and impacts of physician burnout to evaluating comprehensive evidence-based solutions. The AMA has engaged with 10 health systems across the country. The AMA also partnered with the Physicians Foundation to sponsor 20 practice sites from three state medical societies (Washington, North Carolina and New Jersey) who will participate as a cohort in this important initiative. All sites will collaborate with the AMA on measurement, interventions, reporting and dissemination of findings.

The AMA offers physicians and health systems cutting-edge tools, information and resources to help rekindle a joy in medicine, including:

- STEPS Forward™ - a collection of more than 50 award-winning online tools that help physicians and medical teams make transformative changes to their practices, including topics on managing stress, preventing burnout and improving practice workflow. Six new modules were released in 2019:
    1. Medical Student Well-Being: Minimize Burnout and Improve Mental Health Among Medical Students
    2. Team-Based Care in Resident Clinics: Engage Residents to Lead in Team-Based Care
    3. Medicare Annual Wellness Visit (AWV): Streamline Workflow to Perform a Thorough AWV
    4. Hospitalist Well-Being: Maximize Engagement and Minimize Burnout for Hospitalists
    5. Getting Rid of Stupid Stuff: Reduce Unnecessary Daily Burdens for Clinicians

6. Medication Management: Save Time by Simplifying Your Prescribing and Refill Process

- Institutional Assessments - the AMA assesses burnout levels within medical organizations to provide a baseline metric for implementing solutions and interventions that reduce system-level burnout rates and improve physician well-being. AMA has measured burnout in over 60 organizations.
- American Conference on Physician Health - the AMA, Mayo Clinic and Stanford Medicine hosted the second American Conference on Physician Health in Charlotte, N.C. to promote health and well-being in the ranks of U.S. physicians. ACPH brought together nearly 500 physicians, researchers and other interested parties from across the country.
- Debunking Regulatory Myths - the AMA provides regulatory clarifications to physicians and their care teams to aid in their day-to-day practice environment. New myths debunked included information on pain assessments, specifically if clinicians are required to ask patients about pain during every visit.

The AMA brought to a close the four-year, grant-funded Transforming Clinical Practice Initiative, which supported more than 140,000 clinician practices and resulted in 20 new AMA STEPS Forward™ modules to help practices implement evidence-based quality improvement strategies.

Leading the charge to prevent chronic disease and confront health crises

The AMA partnered with the American Heart Association on a new e-learning module on proper blood pressure measurement, following results of an AMA-American Heart Association survey highlighting the need for such additional education. In addition, we expanded our M.A.P. Blood Pressure program with 25 additional health care organizations and more than 100 pilot sites that provide care for nearly one million patients with hypertension.

The AMA was among the leading voices nationally calling for regulation of e-cigarettes and vaping devices by the U.S. Federal Drug Administration and urging physicians to make sure their patients were aware of the dangers posed by these new products, especially among youth.

As part of our national push for common-sense gun laws, the AMA urged Congress to earmark spending for gun violence research and prevention. Congress ultimately did so, dedicating $25 million for gun violence research for the first time in more than 20 years.

The AMA kept physicians and medical students informed on important issues, such as the Title X lawsuit and the E/M rule change through AMA Morning Rounds, AMA social media and email newsletters. The AMA also launched content leveraging several new channels, such as Apple News, podcasts, Alexa skill, and AMA Moving Medicine, our quarterly digital magazine focused on showing how the AMA and its members are impacting the practice of medicine.

The AMA established the AMA Center for Health Equity (CHE) as the operational home to build, drive and sustain health equity efforts across the organization and our health system. In less than one year, CHE has created a vision, mission, and strategic direction, begun building a CHE team, and provided racial equity training to the senior management team and across the organization. Externally, CHE has begun to cultivate important relationships that will be critical in enabling AMA's work to improve health outcomes, close disparities gaps, and advance equity.

The AMA has advocated directly to the Administration several times demanding oversight of southern border detention facilities and calling for proper health care and safety for migrating children and families.

The AMA launched an Enterprise Social Responsibility program to engage AMA employees in public service work aligned with the organization's values and goals. The mission of AMA ESR is to produce value for the AMA's strategic work in a way that also produces value for society. Employees logged nearly 2,400 volunteer hours in the program's first seven months, supporting more than 70 local charities in Chicago, Washington, D.C. and South Carolina.

Driving the future of medicine

JAMA

The JAMA Network continued to expand into new channels and content types, publishing more high-quality, innovative content in more digital formats in more accessible ways than ever before. *JAMA*, the flagship journal in our portfolio, increased its impact factor to 51.3, and the impact factors of all the specialty journals rank in the top three of their specialty. *JAMA Network Open*, our open access journal launched in 2018, published more than 800 papers in 2019, and debuted the translation of article titles and key points into Spanish and Mandarin—the only journal in the world to make every published article this accessible to non-English speakers.

In addition, the JAMA Network has increased multimedia content, including videos, podcasts, and visual abstracts, and downloads of podcasts exceed 3 million in 2019. Overall, across the JAMA Network, downloads of content exceeded 130 million.

AMA Ed Hub™

AMA's new education delivery platform is a powerful vehicle providing physicians and other health care providers the education they need to improve care. During the inaugural year of operations, AMA Ed Hub™ is achieving significant increases in learner discovery and engagement with the education portfolio. The online physician education platform has secured more than 43,000 users in its first full year of operations.

AMA Ed Hub™ successfully welcomed its first specialty society content partner, the American College of Radiology (ACR). An expanding set of ACR content is now available on AMA Ed Hub™. Collaborations with additional medical societies and academic institutions will be introduced in the coming year.

We expanded our certification and licensure offerings in AMA Ed Hub™ to automatically transmit completed CME activities from the American Board of Pediatrics, American Board of Otolaryngology, and select state medical boards.

Health and Science

AMA convened thought-leaders with diverse expertise for a discussion about surveillance and data sharing to inform targeted drug-related prevention, treatment, policymaking and harm-reduction strategies industrywide. This initiative was prompted by AMA policy and broad interest from physicians for a public health approach and strategy. A white paper detailing the day, outlining best practices, barriers, and tools for surveillance implementation which lead to treatment and prevention, is under development. The white paper will identify opportunities with the greatest need and highest potential impact to inform AMA's future efforts.

Med Ed

The AMA awarded the first 11 grants through our Reimaging Residency Initiative, a five-year, $15-million grant program that builds on our Accelerating Change in Medical Education program by supporting innovations that will provide meaningful and safe transitions from undergraduate to graduate medical education.

The AMA launched our Health Systems Science Learning Series and our Health Systems Science Scholars Program, ensuring future physicians are well-equipped to care for patients in the modern health system. The 9 modules of the learning series have been accessed by hundreds of pre-med students, along with many physicians, providing basic education in Health Systems Science.

The AMA hosted ChangeMedEd in September. This premier medical education innovation conference brought together more than 500 stakeholders in the physician education continuum to disseminate and grow ideas about medical education transformation.

The AMA invested in the physician leaders of tomorrow by bringing 400 medical students to Capitol Hill to meet with government leaders; by bringing together our Board of Trustee members with more than 450 medical students at 30 medical schools; and by adding 10 new leadership positions at the AMA and developing a new leadership certificate program.

The AMA contributed the Physician Masterfile to support the establishment of an Accelerating Change in Education data warehouse in conjunction with NYU School of Medicine Institute for Innovations in Medical Education. The data warehouse will be used to answer important educational and research questions around workforce, clinical exposure, and quality of care as they relate to education and training.

Journal of Ethics

AMA Journal of Ethics received more than 3 million annual web visits. Monthly theme issues introduced the journal's medical student and physician readership to timely and important clinical, scientific, and public health topics ranging from ethics of artificial intelligence and human genome editing to access to prescription medication and caring for undocumented patients.

Digital Health

The AMA expanded our reach in digital health, working to scale solutions that are validated, effective and trusted through focused research and practice resources, such as the AMA Digital Health Implementation Playbook.

The startup we co-founded, Xcertia, released and widely circulated industry standards for the privacy, security, operability, content and usability of digital health applications.

More than 500 digital health organizations across the country submitted their new technology for consideration for the inaugural University of California, San Francisco (UCSF) Digital Health Awards. Finalists were selected across 14 categories by a team of expert judges from the health care industry. When choosing finalists, judges referenced the mHealth App Guidelines from Xcertia. Submissions were open to qualified, mature health tech companies with in-market products that have been used by thousands of patients and have been verified in a validation study or clinical trial. Each digital health company was judged on how its technology can reduce the health care costs while improving health care. Ten finalists per category were chosen for the UCSF

Digital Health Awards in collaboration with the AMA Physician Innovation Network and other organizations.

Our online digital health collaborative, the Physician Innovation Network (PIN), grew to more than 10,000 users and 20 partner organization across the industry, leveraging physician experience and expertise in the design of new digital heal technologies.

The Office of the National Coordinator (ONC) for Health Information Technology recently updated their Health IT Playbook to include an AMA-developed implementation guide to help physicians adopt and use digital health technology in their practice. ONC's Health IT Playbook is an easy-to-navigate resource designed by and for physicians. AMA's Digital Health Implementation Playbook complemented ONC's efforts by offering key steps, best practices and resources to accelerate the adoption and scale of remote patient monitoring services.

<u>IHMI</u>

The AMA positioned the Integrated Health Model Initiative (IHMI) as a key stakeholder in data interoperability by receiving founding-member status in the Gravity Project, the leading collaborative responsible for developing Social Determinants of Health data standards under HL7. Those data standards are under development in 2020.

IHMI is scheduled to beta release its first Self Monitored Blood Pressure app designed to assist providers in earning incremental revenue while better managing their hypertensive patients via new DMPAG CPT codes effective in 2020. This represents IHMI's first SMART on FHIR app with integrated support for the IHMI SMBP data standard as well as the AMA Validated Device List for home blood pressure devices.

IHMI has been recognized and asked to advise several leading interoperability projects, including the HL7 Da Vinci Project, which is focused on prior auth automation, as well as the USCDI Task Force, which advises the ONC on data interoperability. The sum of these efforts has re-positioned IHMI and the AMA as significant influencers within the national data interoperability space.

Membership

Membership grew for the 9th consecutive year, with a 3% increase in dues paying members in 2019. Growth was fueled by an innovative and award-winning campaign, "Membership Moves Medicine™," which celebrates the powerful work of physician members and showcases how their individual efforts - along with the AMA - are moving medicine forward.

EVP Compensation

During 2019, pursuant to his employment agreement, total cash compensation paid to James L. Madara, MD, as AMA Executive Vice President was $1,144,978 in salary and $1,125,032 in incentive compensation, reduced by $3,164 in pre-tax deductions. Other taxable amounts per the contract are as follows: $14,478 imputed costs for life insurance, $7,620 imputed costs for executive life insurance, $2,500 paid for health club fees, $2,760 paid for parking and $3,500 paid for an executive physical. An $81,000 contribution to a deferred compensation account was also made by the AMA. This will not be taxable until vested and paid pursuant to provisions in the deferred compensation agreement.

For additional information about AMA activities and accomplishments, please see the "AMA 2019 Annual Report."

REPORT OF THE BOARD OF TRUSTEES

B of T Report 4, November 2020

Subject: Annual Update on Activities and Progress in Tobacco Control: March 2019 through February 2020

Presented by: Russ Kridel, MD, Chair

This report summarizes American Medical Association (AMA) activities and progress in tobacco control from March 2019 through February 2020 and is written pursuant to AMA Policy D-490.983, "Annual Tobacco Report."

TOBACCO USE IN THE UNITED STATES: CDC MORBIDITY AND MORTALITY WEEKLY REPORTS (MMWR)

According to the Centers for Disease Control and Prevention (CDC) tobacco use remains the leading preventable cause of disease and death in the United States with an estimated 480,000 premature deaths annually, including more than 41,000 deaths resulting from secondhand smoke exposure. These data translate to about one in five deaths related to tobacco use annually, or 1,300 deaths every day. Each year, the United States spends nearly $170 billion on medical care to treat smoking-related disease in adults. From March 2019 through February 2020, the CDC released 12 MMWRs related to tobacco use. These reports provide useful data that researchers, health departments, community organizations and others use to assess and develop ongoing evidence-based programs, policies and interventions to eliminate and/or prevent the economic and social costs of tobacco use.

2019: https://www.cdc.gov/tobacco/data_statistics/mmwrs/byyear/2019/index.htm
2020: https://www.cdc.gov/tobacco/data_statistics/mmwrs/byyear/2020/index.html

Youth Tobacco Use: Analysis of 2019 National Youth Tobacco Survey (NYTS)

The December 6, 2019 MMWR published an analysis of tobacco product use patterns and associated factors from the 2019 National Youth Tobacco Surveys (NYTS). The NYTS is an annual survey that has been conducted since 1999. According to the report approximately one in four youths (23.0%) had used a tobacco product during the past 30 days. By school level, this represented approximately three in 10 high school students (31.2%) and approximately one in eight middle school students (12.5%). Among current tobacco product users, 55.5% reported use of e-cigarettes only. Among students who reported current tobacco use of two or more products, e-cigarettes were the most commonly used product in combination with other tobacco products.

Approximately one in three current tobacco product users (33.9%) reported using multiple tobacco products; youths who use multiple tobacco products are at higher risk for developing nicotine dependence and might be more likely to continue using tobacco into adulthood. The authors noted some encouraging news. More than half of current youth tobacco product users reported seriously thinking about quitting all tobacco products. By school level, 57.7% of high school students and 57.9% of middle school students reported they were seriously thinking about quitting.

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The authors' analysis of factors associated with tobacco product use included exposure to marketing and flavors, curiosity, perceptions about harms and cravings among current users. The percentage of students who reported that intermittent use of tobacco products causes "a lot of harm" was highest for cigarettes (54.9%), followed by smokeless tobacco products (52.5%), hookahs (44.9%), and e-cigarettes (32.3%). The percentage of students who reported that intermittent use causes "no or little harm" was highest for e-cigarettes (28.2%). The most commonly reported reason for usage among current exclusive e-cigarette users was curiosity (56.1%) followed by the fact that a friend or family member used them. Flavors such as mint, chocolate and candy were also reported by 23.9% as a reason for e-cigarette use and the ability to "do tricks" was reported by 12%.

Adult Smoking Rates

According to a study in the November 15, 2019 MMWR an estimated 13.7% of US adults were current cigarette smokers in 2018, the lowest prevalence recorded since 1965. However, no significant change in cigarette smoking prevalence occurred during 2017–2018. To assess recent national estimates of tobacco product use among US adults aged ≥18 years, the CDC, the Food and Drug Administration (FDA), and the National Institutes of Health's National Cancer Institute analyzed data from the 2018 National Health Interview Survey (NHIS). The NHIS is an annual, nationally representative in-person survey of the noninstitutionalized U.S. civilian population. The NHIS core questionnaire is administered to a randomly selected adult in the household (the sample adult).

According to the analysis, an estimated 49.1 million U.S. adults (19.7%) reported currently using any tobacco product, including cigarettes (13.7%), cigars (3.9%), e-cigarettes (3.2%), smokeless tobacco (2.4%), and pipes including water pipe or hookah (1.0%). Among current tobacco product users, 18.8% used 2 or more tobacco products.

Adults who use multiple tobacco product are also at increased risk for nicotine addiction and dependence. E-cigarettes were commonly used among multiple tobacco product users. Primary reasons for e-cigarette use among adults include curiosity, flavoring, cost, consideration of others, convenience, and simulation of cigarettes.

Medicaid enrollees have the highest rates of smoking compared to private insurance enrollees

The smoking prevalence for adults enrolled in Medicaid is 23.9% compared to 10.5% of privately insured adults, placing Medicaid enrollees at increased risk for smoking-related disease and death. The February 14, 2020 MMWR published American Lung Association's (ALA) surveillance data of Medicaid coverage for tobacco cessation and barriers to accessing treatment.

To monitor changes in state Medicaid cessation coverage for traditional Medicaid enrollees the ALA collected data on coverage of nine cessation treatments by state Medicaid programs during December 31, 2008–December 31, 2018: individual counseling, group counseling, and the seven FDA-approved cessation medications. As of December 31, 2018, 15 states covered all nine cessation treatments for all enrollees, up from six states as of December 31, 2008. Of these 15 states, Kentucky and Missouri were the only ones to have removed all seven barriers to accessing these cessation treatments. The barriers include co-payment, prior authorization, restrictions on prescribing medications, duration limits, stepped care therapy, and annual and lifetime limits.

Compared with smokers with private health insurance, smokers enrolled in Medicaid have been found to be more likely to have chronic diseases and to experience severe psychological distress.

The high smoking prevalence among Medicaid enrollees imposes a substantial health burden. State Medicaid programs can help reduce this health and financial burden by covering all evidence-based cessation treatments, removing coverage barriers, and promoting covered treatments to Medicaid enrollees and providers to increase their use.

TOBACCO CONTROL NEWS

States Take Action after Vaping Related Illnesses and Deaths

Public health officials and medical groups including the AMA have been concerned for years about the health consequences associated with the use of e-cigarettes especially by youth. As early as 2010, the AMA Council on Science and Public Health issued a report on e-cigarettes that outlined the known substances in the products and highlighted the lack of oversight of manufacturing and advertising.

In June 2019 state health officials noticed an increase in lung illnesses that seemed to be linked to e-cigarette use, many of them involving teens and young adults. The affected individuals have had symptoms including cough, shortness of breath and fatigue. Some also experienced vomiting and diarrhea. Symptoms worsened over a period of days or weeks before some required hospitalization. The first death from a vaping-related illness was reported August 23, 2019 in Illinois. National and state data from patient reports and product sample testing showed that vitamin E acetate and tetrahydrocannabinol (THC) were linked to this outbreak. CDC categorized these vaping-associated illnesses as E-cigarette, or Vaping, product use Associated Lung Injury or EVALI. In December, CDC attributed vitamin E acetate in black-market marijuana products as the strongest link to EVALI.

As of February 18, 2020, a total of 2,807 hospitalized EVALI cases or deaths have been reported to CDC from all 50 states, the District of Columbia, and two U.S. territories (Puerto Rico and U.S. Virgin Islands) with 69 deaths confirmed in 29 states. In response to the outbreak several states enacted policies to restrict access to e-cigarettes. Michigan became the first state to limit the sale of e-cigarettes followed by similar legislative actions in Massachusetts, New York, Washington and New Jersey. While no one e-cigarette manufacturer was identified as the cause of the outbreak, JUUL received wide-spread media attention for selling 1 million contaminated mint-flavored and outdated pods. Several states have filed suit against JUUL including Illinois, New York and California for deceptive marketing practices.

US House of Representatives Passes Comprehensive Bill to Address Youth Tobacco Use

On February 27, 2020, the US House of Representatives passed the Protecting American Lungs and Reversing the Youth Tobacco Epidemic Act of 2020. This bill would ban most flavored tobacco and vaping products, including mint and menthol, and imposes a tax on the nicotine in e-cigarettes. It also prohibits online sales of most tobacco products and requires the FDA to implement graphic warning labels on cigarette packs and advertising. This provision is required under the 2009 Tobacco Control Act but has been delayed due to lawsuits by the tobacco industry. The bill also includes funding to Community Health Centers to support tobacco cessation treatment and research to improve cessation treatments.

The bill isn't an outright ban on sales of flavored e-cigarettes. It includes an opportunity for FDA to authorize sales if a company can show that the flavor is necessary to help adult smokers switch from traditional cigarettes and doesn't have an adverse health impact or cause nonsmokers to take

up vaping. The sponsors acknowledge that it is unlikely that an e-cigarette manufacturer can meet this requirement.

AMA TOBACCO CONTROL ACTIVITIES

AMA Responds to Vaping Illnesses and Deaths from E-Cigarettes

As public health officials responded to the increase in vaping-related illnesses and death, the AMA moved quickly to urge the public to avoid the use of e-cigarette products. The AMA called on its physician members to make sure their patients are aware of the dangers of e-cigarettes, including toxins and carcinogens.

In a CNN interview, AMA President Dr. Patrice Harris reminded viewers that nicotine in any form should be avoided. She went on to specify that the AMA is very concerned around the increased use of e-cigarettes and vaping in teenagers. She reiterated the AMA's support for FDA's accelerated efforts to regulate e-cigarettes. There is no evidence that shows they are a safe alternative to combustible tobacco products.

AMA and Coalition of Public Health Organizations Believe FDA Needs to Take Stronger Efforts

In April 2019 the AMA joined with other physician groups and public health organizations including the American Academy of Family Physicians, American College of Physicians, American Heart Association and American Lung Association in responding to an FDA draft guidance on proposed modification to its compliance policy for certain deemed products.

The draft guidance outlined restrictions to youth access to flavored products but fell short of the forceful action needed. The AMA and others felt the guidance policies were an insufficient response to the current crisis of youth e-cigarette use, as well as to the continuing adverse public health consequences of youth cigar smoking. A particular area of concern was the FDA's reliance on the top five e-cigarette manufacturers to provide solutions to youth use of their products. The coalition believes the FDA must assert its own authority and not rely on voluntary action from manufacturers.

In 2009 the FDA was given the authority to regulate the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco products. The Tobacco Control Act also gave FDA the authority to issue regulations deeming other products that meet the statutory definition of a tobacco product. These products include but are not limited to electronic nicotine delivery systems, cigars, pipe and waterpipe tobacco, nicotine gels and dissolvables.

AMA calls for total ban on all vaping products not approved by FDA

At the 2019 Interim Meeting, the House of Delegates adopted tobacco control policies in response to increasing harms associated with e-cigarettes and youth-focused marketing by JUUL. The AMA adopted policies supporting banning the sale and distribution of all e-cigarette and vaping products, with the exception of those approved by the FDA for tobacco cessation purposes and advocating for research funding to study the safety and effectiveness of e-cigarette and vaping products for tobacco cessation purposes. The House of Delegates also called for a thorough study of the use of pharmacologic and non-pharmacologic treatment strategies for tobacco use disorder and nicotine dependence resulting from the use of non-combustible and combustible tobacco products in populations under the age of 18.

REPORT OF THE BOARD OF TRUSTEES

B of T Report 8, November 2020

Subject: White House Initiative on Asian Americans and Pacific Islanders

Presented by: Russ Kridel, MD, Chair

EXECUTIVE SUMMARY

This informational report is put forth in response to paragraph two of Policy H-350.954, "Disaggregation of Demographic Data Within Ethnic Groups", which directs that our AMA report back at the 2020 Annual Meeting on the issue of data disaggregation regarding Asian American and Pacific Islanders (AAPI) with regard to the ethnic subgroup disparities that exist in health outcomes and representation in medicine, including leadership positions in academic medicine. This report lays out an historical overview of the politicizing of the AAPI community for the purpose of distributing federal resources based on need as determined by federal data collection efforts. This report also outlines what current federal, state, local, as well as private and non-government associated data efforts entail, and the limitations associated with current efforts. It links to existing AMA policies, emphasizing where there can be greater coherence between policies. Finally, this report re-emphasizes the need for continued surveillance of data collection initiatives, and greater granularity of data collection, pertaining to AAPI communities in the U.S. and its territories.

BACKGROUND

At the height of the Vietnam War in 1968, a young Japanese graduate student at the University of California at Berkeley, Yuji Ichioka, banded with other students in an attempt to shut down the university in collective protest against the conflict. The demonstration was not only successful for five months, but Ichioka and his fellow students also successfully initiated a self-determination campaign against the derogatory term, "Oriental," then reserved for all persons of Asian descent, birthing the distinction, "Asian American,"[1] which we use to this day.

The United States Census Bureau's "Asian" racial category refers to "a person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent...," while "Native Hawaiian or other Pacific Islander" refers to "a person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.[2]" Asian Americans and Pacific Islanders (AAPI) collectively comprise the largest and fastest growing racial group in the U.S. Having ancestry from over 20 countries, they emigrated to the U.S. for myriad life opportunity and/or geo-political reasons, which are outlined in greater detail in the following sections below. Their health experiences in the U.S. are as diverse as their backgrounds and socio-political statuses within the U.S, yet our data systems infrastructure do not fully illustrate the rich complexity of their different experiences.

Prior to the 1997 Clinton Administration, the White House Office of Management and Budget (OMB) operationalized all public data according to its long-standing "Standards for the Classification of Federal Data on Race and Ethnicity." After signing Executive Order (EO) 13125, which intended to "improve the quality of life for Asian Americans and Pacific Islanders through

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increased participation in Federal programs where they may be underserved…”[3], President Clinton established the White House Initiative in June 1999. The grouping of AAPIs should therefore be understood as a socio-political construct, born from the Clinton White House Initiative in order to bring greater attention to the disparate life experiences that different Asian subgroups experience in the U.S.[4] The following year, the Clinton Administration revised the OMB standards, and declared:

> OMB is accepting the recommendations of the Interagency Committee for the Review of the Racial and Ethnic Standards with the following two modifications: (1) the Asian or Pacific Islander category will be separated into two categories – “Asian” and “Native Hawaiian or Other Pacific Islander,” and (2) the term “Hispanic” will be changed to “Hispanic or Latino.”
>
> The revised standards will have five minimum categories for data on race: American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White. There will be two categories for data on ethnicity: “Hispanic or Latino” and “Not Hispanic or Latino.”[5]

Since then, the Bush[6] and Obama[7] Administrations have also amended and/or extended the original EO, creating national statutes meant to recognize and redress the health and social inequities which AAPIs have historically experienced. President Trump re-established the White House Initiative on AAPIs in May 2019, during Asian Pacific American Heritage month[8].

Through these EOs, the previous Administrations also maintained a webpage, which featured AAPI health data, along with other considerable data points. The webpage operated under the purview of the Department of Education but has since come under the directorship of the Department of Commerce. On October 10, 2019, our AMA sent a letter to Secretary of Commerce, Wilbur Ross, advocating for the restoration of webpages on the Asian American and Pacific Islander initiative that specifically address disaggregation of health outcomes related to AAPI data, therefore successfully fulfilling that element of Policy H-350.954. On December 17, 2019, our AMA received notice from Secretary Ross’s office indicating that they are working on web page restoration. At the completion of this report, however, the web page had not yet been restored to the Department of Commerce website.

The dearth of racially and ethnically disaggregated data reflecting the health of AAPI persons and families underlies the struggles of the physician community to fully attend to, and be attuned to, the unique needs of their AAPI patients. Beyond the clinical setting, given that federal designations and distinctions yield variances in terms of resource distribution (i.e., public health programs supports, public benefits, etc.), it is imperative to hasten all efforts that disaggregate Asian American and Pacific Islander health outcomes and overall social needs. Without such granularity, clinical providers and researchers risk misunderstanding the unique characteristics that impact AAPI health behaviors, beliefs, uses of medical spaces, and the components that lead to their distinct health outcomes. In accordance with paragraph 2d of Policy H-350.954, “Disaggregation of Demographic Data Within Ethnic Groups”, the remainder of this report will focus on the current state of data disaggregation regarding AAPI health outcomes and representation in medicine.

ASIAN AMERICAN AND PACIFIC ISLANDERS (AAPIS) IN THE U.S.

Historical Considerations

The Asian and Pacific Islander presence, in the land that would become the United States, dates back to the 1850s. Life opportunity, economic promise, war, and/or colonialism and other cultural conflict, either pulled or pushed many individuals and families from their homelands to a new land.

The first groups to arrive were Chinese and Japanese men to work in California gold mines, or on the Transcontinental Railroad, or to cultivate new frontier lands. Over the course of almost a century, newly emigrated Asians in America faced severe economic hardship and social exclusion from mainstream society through racialized policies, including the Chinese Exclusion Act (1882), the Immigration Act (1917), the National Origins Act (1924), and the imprisonment of Japanese Americans at the start of World War II[9] (for which they received reparations in the form of restored property rights, $20,000, and a Presidential apology)[10]. Consequently, Asian communities were relegated to service industries-level occupations and de jure segregated ghettos. While Asians generally value work ethic and entrepreneurship, it was the seeds of social discrimination across generations that bred a practice of business ownership in America. This trend remains today: most major American cities with a large Asian-American population retain a Chinatown, an enclave of small, Asian-American owned restaurants, laundries, groceries, salons, and other such service-oriented businesses[11].

Current State of AAPI Community

Today, approximately 20 million Asian Americans hail from about 20 sovereign or American colonized countries across East Asia, South Asia, and Southeast Asia: more specifically, most are from China, India, or the Philippines[12]. Vietnamese, Korean, and Japanese descendants are also strongly represented in the U.S. To a lesser extent, there are American residents with ethnic roots to Pakistan, Cambodia, Thailand, Laos, Bangladesh, Burma, Nepal, Indonesia, Sri Lanka, Bhutan, Malaysia, and Mongolia. The Hmong people are technically country-less; many who are refugees (or mere generations removed) from the Laos region[13], also now call the U.S. home. Collectively, Asian Americans comprise the largest and fastest growing racial group in the U.S., burgeoning from 11.9 million to 20.4 million between 2000 and 2015[14]. They are slated to account for 11 percent of the U.S. population by 2050 [15] and "by 2065, the Asian American population alone is projected to almost triple to 62 million.[16]" Asian Americans make up almost 60% of the Hawaiian population. About half (45%) of the Asian American population in the U.S. live on the West Coast between California, Nevada, and Washington State. A quarter of Asian Americans live in the U.S. South, about the same proportion reside in the Northeast corridor, and about 12 percent live in the Midwest. Almost a third of Asians in America reside in multi-generational homes[17].

Altogether, the Asian American community represents well over 100 spoken languages, an aspect that lends astutely to the growing globalization rationale that all but necessitates that American-born citizens learn at least one Asian language, namely Mandarin Chinese[18]. About half of Asian American adults possess a bachelor's degree or higher, surpassing higher education rates of White Americans, and most are gainfully employed. More recent immigrants from South Asia are doctors and nurses, engineers, and financiers with greater means to come to the US[19]. Such high performance along socioeconomic indicators perpetuate the Asian "minority model" myth, where ostensibly, unlike other minoritized groups, Asians are lauded for having improved their collective status and social standing through hard work and exceptional educational performance, without asking for special considerations, or without reliance on public benefits[20]. This trope erringly gives the impression that AAPIs do not have needs to which governments, researchers, and physician bodies must pay especial attention. In fact, Asian Americans experience the highest language barriers compared to other racial and ethnic groups with Limited English Proficiency (LEP), and more than a third reside in linguistically isolated homes. Among a number of Asian American communities, Limited English Proficiency is highly correlated with medication non-compliance[21] and inconsistent engagement with Western health systems. Islamophobia, and other experiences of discrimination against non-Christian practicing Asians (many of whom practice Buddhism, Hinduism, Sikhism, Taoism, animism, or other religions) are harmful to the health of AAPIs. Furthermore, racial profiling of AAPIs—especially since 9/11—is associated with poorer health

outcomes[22]. Subsets of the Asian community have been hit hard by anti-immigrant rhetoric and U.S. Immigration and Customs Enforcement (ICE) raids in their communities, creating fear and isolation. Understanding their health and engendering their trust is critical for our public health. More recent xenophobia against Asians, spurred by the coronavirus outbreak and misinformation on the pandemic, only exacerbate these stressors.

Moreover, while they are collectively economically strong, existing data suppresses the wide education, economic, and overall health outcomes, in between ethnically Asian subgroups. For instance, Indian Americans, on average, have more education, and enjoy higher salaries[23] on account of attaining more lucrative occupations as physicians and scientists, compared to Laotian or Cambodian Americans, who historically work within service industries.

Clearly, due to wide sub-ethnic group representation, Asian America is by no means monolithic and is in fact comprised of the most diverse of minoritized populations.[24] This rich diversity is attributable to myriad languages spoken, religions practiced, and other cultural distinctions that set Indonesians apart from Indians, who are very different from Japanese and Koreans, and so on. Consequently, their health behaviors, beliefs, and challenges deserve distinct attention. Given the unique social positions they occupy—spanning from the "model minority" to the war-trauma refugee—documenting differences among such highly segmented communities is an essential starting point for implementing a wide array of policies and interventions to give credence to the potentially vastly different interventions needed to improve overall Asian American health.

AAPI Health Status & Public Health Implications

Before the implementation of the Patient Protection and Affordable Care Act (ACA) tenets mandating insurance coverage for all, and especially the protections afforded special populations under Section 1557[25], AAPI health research already cited the deep healthcare access barriers AAPIs faced[26], but existing data are limited for the reasons outlined below.

AAPIs experience tremendous health disparities among Asian and Pacific Islander groups and inequities compared to the non-AAPI or non-Hispanic White population. AAPIs are the sole group in which cancer—especially of the stomach and the liver[27]—is still the leading cause of death[28], and where rates of tuberculosis and Hepatitis B[29] are still exceedingly high (almost 30 times higher than non-Hispanic Whites). AAPIs experience higher rates of diabetes and obesity, as well as cardiovascular diseases compared to non-Hispanic Whites. Health screening (for HIV/AIDS, for example) and preventive health-seeking behaviors are also lower among AAPIs compared to non-Hispanic Whites.[30]

Under the auspices of the ACA, all federally funded health surveys must collect data disaggregated by seven Asian American categories: Chinese, Indian, Filipino, Vietnamese, Korean, Japanese, and 'other Asian'[31]. This 'other Asian' delineation collapses a more complex story. On the other hand, since the ACA, there has been an increase of insurance coverage among AAPIs; their insurance coverage rates are now similar to those of White Americans[32]. Yet, overall, AAPIs still experience difficulties with Medicaid enrollment due to language inaccessibility, although there is very little research that demonstrates the extent of this. The ACA has done much to advance data disaggregation efforts of the AAPI health experience, but more needs to be done. Extended and disaggregated data collection of these challenges would lend well toward creating a fuller and more accurate story and interventions to correct these issues.

EXISTING COLLECTION EFFORTS OF AAPI RACE & ETHNICITY DATA: STRENGTHS & LIMITATIONS

Data Collection: Existing Federal Efforts

Much of what we know about the health of the U.S. population comes from national surveys conducted by the federal government, such as the National Health and Nutrition Examination Survey (NHANES) and the National Health Interview Survey (NHIS). The significant role these scientific data repositories play in determining how national funds are appropriated in support of one program, often at the behest of another, or sets of others, cannot be overstated. Each year, Members of Congress on the Appropriations Committee assign monies to critical programs through a more or less objective process wherein they depend on existing data to rank programmatic, and thus, population need, for programs. The greater the severity of the issue that impacts a community, and/or the larger the community itself, the greater the odds that programming or resources supporting that issue and/or community's needs will be funded and funded well. Gone are the days of Congressional earmarking—Members no longer have the power to set aside specific monies for their constituent communities that may be in the direst of need. For these reasons, it is even more necessary that national data with respect to the health and social progress of Asian Americans and Pacific Islanders be distinguished and narratives clearly demonstrate the great inter-disparities between ethnic groups.

With Census 2020 upon us, reaching AAPI communities at the disaggregated level is crucial not only for determining accurate counts, but also for demonstrating the social strengths and, perhaps most importantly, the social vulnerabilities AAPI communities face and will face in this new decade. Without deriving adequately representative data of such special communities, it is likely that smaller AAPI communities will be counted out and their medical needs, unaccounted. For those most marginalized and socially isolated, the lack of data is also a lack of control, which often hinders communities from developing their narratives, health or otherwise, for which they can contend in current social structures, including both the right to have and analyze collected data.

Each national source provides a baseline sense of specific AAPI populations' health status. For instance, *Healthy People 2010* and *Healthy People 2020* both highlight the unique needs of Asian Americans by establishing baseline health outcomes data for AAPIs in infant mortality, cancer, heart diseases, HIV/AIDS, diabetes, and immunization rates[33]. However, neither fully encapsulates and conveys the heterogeneity of AAPIs, thus suppressing fundamental cultural differences between communities, as well as the health behaviors, beliefs, and outcomes differences that arise as a consequence of these inherent variances.[34] In processes of determining distribution of limited and critical monies for programs and policies that support health of highly diverse communities, there is limited utility associated with high-overview data.

Essentially, there are major limitations to the use of existing survey data, particularly for studying small populations such as AAPI subcommunities. In addition to the problems associated with smaller sample sizes, there are other weaknesses associated with federal race and ethnicity data. Federal data tend to be cross-sectional and do not capture more temporal sensitive phenomena that bear on health outcomes, such as stress associated with racial or ethnic discrimination. Federal data are dependent upon self-report, which may not always be corroborated with more objective methods, such as health records, and the like. There is also a lack of consistent race/ethnicity categories used in data collection.

The greatest of these data threats stem from the size of AAPI population segments relative to the total Asian population; there is a small likelihood that the data sets will adequately capture or

achieve robust representation of unique life experiences across the AAPI community. Apart from highly specialized studies, surveys generally obtain data from too few people to break out separate results for small populations. Even when these data are available, other unique characteristics, such as immigration status, confound outcomes and those groups need to be weighed comparably to U.S. born AAPIs. As a result, even valid inferences drawn about the population (or major segments thereof) based on well-designed survey samples may not apply to small populations. Challenges exist in obtaining sufficient sample sizes to conduct powerful analysis of Asian Americans overall, and even more for subpopulations. Researchers often attempt to correct for this by oversampling certain communities, but often, these segments are difficult to identify, hard-to-reach, and therefore hard-to-count, or may outright be less likely to participate in federal survey research for myriad reasons, including mistrust of American government and fear of retaliation from authority figures[35].

Data Collection: Existing State & Local Efforts

It is not surprising that the states and locales comprised of the largest AAPI populations are leading the force in disaggregated data collection. For this, we can look at efforts in California (at the state level), New York City, and Chicago.

The State of California is, by far, the most advanced state in disaggregated collection of data pertinent to the Asian American experience, delineated by AAPI ethnic community. Dating back to the mid-1990s, the state has required its agencies, boards and commissions to collect and disaggregate its public-facing data by race and ethnicity, specifically for AAPIs. More recently, under the auspices of 2016 state Assembly Bill No. 1726 (AB-1726), the decree is extended beyond the earlier law. It will take full effect in 2022, and will track major disease and mortality trends, pregnancy rates, and housing-related phenomena. More specifically,

> Existing law **requires any state agency, board, or commission that directly or by contract collects demographic data as to the ancestry or ethnic origin of Californians to use separate collection categories and tabulations for specified Asian groups and Pacific Islander groups**, and requires a state agency, board, or commission to include data on specified collection categories and tabulations in every demographic report on ancestry or ethnic origins of California residents that it publishes or releases. Existing law requires specified agencies to use additional separate collection categories and other tabulations for major Asian groups and Native Hawaiian and other Pacific Islander groups, and also requires those agencies to take additional actions, including, among other things, posting, and annually updating, the demographic data collected on their Internet Web sites, and updating the reporting categories to reflect these Asian and Pacific Islander groups as they are reported for the 2020 decennial census.[36]

However, even this measure is funding-dependent. So, while the edict is authorized, its lack of appropriated funds threatens the potential scope of the effort.

In March 2018, the New York City Department of Health and Mental Hygiene put forth a comprehensive data brief on the state of "Health Disparities Among Asian New Yorkers"[37]. Using Community Health Survey (CHS) data, the report highlighted health behaviors, health conditions, and healthcare utilization rates of the city's Chinese, Indian, Filipino, and Korean residents. It provides a sharp view of challenges the city is and will face without pointed public health interventions by racial/ethnic subgroup. So, it is disconcerting to also report that, in December 2019, New York Governor Andrew Cuomo vetoed a State Assembly Bill 677, citing budgetary constraints and implementation impediments as threats to the bill's longevity. Designed in a spirit

similar to California's Assembly Bill No. 1726, the New York equivalent, "would have required state agencies to collect demographic data for a wide number of Asian American ethnicities".[38]

Outside of formal data collection, local forums and community-based organizations have a major role to play with respect to supporting data collection of AAPI community residents. Due to the rapport and trust they have inculcated with AAPI communities over time, these organizations tend to have greater accessibility and entree into more esoteric or sacred spaces occupied by AAPIs than do government representatives. They often head up health-oriented interventionist programs. In Chicago, for example, the organization Cook County CARES (Cancer Alliance to Reignite and Enhance Screening), works with community-based organizations and with hospitals, and other health systems, to increase colorectal screening rates among low income residents, including Asian men aged 50 and older. In other cities throughout the U.S., the Asian Pacific Islander American Health Forum, the Association of Asian Pacific Community Health Organizations, and the National Asian Women's Health Organization are all examples of organizations pulling hefty weight to spread critical health messages to AAPI constituents, indirectly, yet substantially supporting the very purpose that disaggregated data sets out to achieve: telling a fuller story.

Data Collection: Academia & Private Institutional Initiatives

Countless researchers have shed light on the distinctions between AAPI communities and have used their research to call for granularity in data in order to identify medically underserved AAPI communities (MUACs)[39]. In 2009, the Institute of Medicine (IOM) released a report, titled "Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement"[40], which called for standardization for health care quality improvements, centered around training health care providers and implementing best practices for assessing patient race, ethnicity, and language proficiencies. Private grant-conferring institutions also rely on national data to help determine their grantee applications. Private philanthropy often relies on national data trends to determine funding allocations, and also uses data to prioritize and qualify applications. Applications that rely on AAPI data are arguably, then, at a disadvantage if they cannot demonstrate health phenomena at the subgroup level.

Data Collection: Our AMA Masterfile

To date, our AMA's efforts to eliminate health inequities and close existing health disparities gaps, through policy, education, and advocacy initiatives, have been firm steps forward. Our AMA has developed a *Working Together to End Racial and Ethnic Disparities: One Physician at a Time* toolkit for physicians that includes material used to improve awareness and skills in addressing the inequities in care that racial and ethnic minority patients receive. Even more so with the initiation of the Center for Health Equity, our AMA is well-positioned to internally guide our Business Units through processes of deeply embedding a health equity lens throughout all of our work and perpetuate greater leadership in the national health equity space.

Our AMA HOD policies around race and ethnicity data collection are broad in nature. For example, D-350.982, "Racial and Ethnic Identity Demographic Collection by the AMA", says:

> Our AMA will develop a plan with input from the Minority Affairs Section and the Chief Health Equity Officer to improve consistency and reliability in the collection of racial and ethnic minority demographic information for physicians and medical students.

Yet, our current internal system does not yet collect these data at all. Under the Division of Health Solutions and Data Management (HSDM), our AMA maintains the Physician Masterfile ("the

Masterfile"). Initially built in 1906, the Masterfile contains current and historical training and professional certification data for approximately 1.4 million physicians (MD and DO), residents, and medical students throughout the U.S., and the American territories, including Guam, the Northern Mariana Islands, and the American Samoa, all within the Pacific Islands. These records are maintained into perpetuity. Medical schools and other physician organizations, federal agencies, and research institutions rely on the Masterfile as a valid and reliable source of information about our nation's physician workforce and their competencies. However, beyond date of birth, mailing address, specialty area, and level of training, the Masterfile does not provide comprehensive demographic breakdown of our nation's physicians, the languages they speak, the patient communities to whom they deliver care, or other considerations from which entities can derive a cultural context that bears on the differential health needs of patients across diverse American communities. Moreover, other physician-oriented institutions, including the Association of American Medical Colleges (AAMC) and the Accreditation Council for Graduate Medical Education (ACGME), all utilize different racial and ethnic data sources, which presents standardization of data problems.

AAPI REPRESENTATION IN MEDICAL PATHWAYS PROGRAMMING & LEADERSHIP

The desire and/or inspiration to pursue a pathway to medical service and leadership often begins early in life. Yet the pathways are often uneven for minoritized populations for reasons outside of their individual control. In their 2001 study, Luzzo and McWhirter astutely noted, "for many ethnic minority adolescents, career decisions are not based on personal choice and interests but are instead bound to socioeconomic needs and cultural obligations."[41] Other historical issues, such as de facto segregation, and inequitable school resource distribution renders medical education unattainable for many minoritized students who would otherwise strive to become physicians[42]. AAPI students, who tend to value and are reared in households where interdependence and family obligations are paramount over self-aspirations[43], are underrepresented in medicine. This is particularly the case for lower-income AAPI adolescents, such as Laotians and Cambodians, compared to adolescents of higher socioeconomic standing, such as those of Japanese or Indian descent. Between 2002-2012, there was a surge of Asian applicants to American medical schools, but the data do not distinguish by subgroup[44], and in fact creates the impression that Asians as a bloc are overrepresented in medicine, where in fact the lack of data disaggregation contort the picture that certain Asian groups are more represented than others, who are not highly represented at all.

One current pathway for Asian physicians seeking to secure permanent residency or citizenship in the U.S., as well as guaranteed job placement, is through the Conrad 30 J-1 Visa Waiver Program. Conrad 30 "allows J-1 medical doctors to apply for a waiver for the 2-year residence requirement upon completion of the J-1 exchange visitor program.[45]" To qualify for the waiver, these physicians must deliver care in health professional shortage areas (HPSAs), or among patient populations that are deemed a part of a medically underserved populations (MUP). The implications of maintaining this program are significant: given the U.S. is already experiencing a physician shortage, especially in rural and underserved areas, these physicians cover crucial care delivery gaps. The program has yet to be extended, although several U.S. Senators have presented Congressional legislation—the Conrad State 30 and Physician Access Reauthorization Act[46]—to extend the program through 2021. Our AMA supports this legislation.

Research has shown that "demographic representation…improves health care access for underserved populations, improves the cultural effectiveness of the physician workforce as a whole, and improves medical research and innovation for all populations.[47]" As the racial and ethnic demographics of our nation shift, there is greater need for pathways and workforce opportunity programming that encourages a more representative physician workforce.

CONCLUSION

Beyond data disaggregation, our AMA will actively review existing AMA policy on disaggregated racial and ethnic data collection, and better coordinate existing efforts to standardize data production on the state of AAPI medical leadership and by ethnic community health outcomes. This will be a cross-enterprise effort between several AMA Business Units with expertise and experience in data collection, public health, and medical education. Undoubtedly, there is great need for both national as well as community-level disaggregated AAPI health data collection delineated by race and ethnicity, and also offered in languages native to the AAPI community. What is measured is what is valued; what is undercounted tends to be counted out. Precise investigative research disaggregated by ethnic subgroups is needed to yield accurate health outcomes trends for Asian Americans and Pacific Islanders. Current efforts are not robust enough to close the lid on this case. Surely, quantitative research will help researchers to visualize trends, but qualitative reports will add a density to the data that is currently missing. Without individual groups information, the physician community stands mired in serious knowledge gaps and may risk unintentionally perpetuating harms.

Moving forward, intentional efforts to support collection and evaluation of AAPI data as a whole and by subgroup will be a part of our AMA mission. The effort underscores each of our AMA Strategic Arc purviews in that supporting disaggregated AAPI data will (1) help create a clearer picture of medical education and ongoing training needs of AAPI student-physicians, current physicians, and aspiring doctors; (2) shed light on the prevalence of chronic conditions from which certain AAPI sub-populations suffer compared to others; and, (3) provide insight on how physicians may tailor their practices to better serve their AAPI patients from a culturally competent standpoint.

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REPORT OF THE BOARD OF TRUSTEES

B of T Report 11, November 2020

Subject: Redefining AMA's Position on ACA and Healthcare Reform

Presented by: Russ Kridel, MD, Chair

At the 2013 Annual Meeting of the House of Delegates (HOD), the HOD adopted Policy D-165. 938, "Redefining AMA's Position on ACA and Healthcare Reform," which called on our American Medical Association (AMA) to "develop a policy statement clearly outlining this organization's policies" on a number of specific issues related to the Affordable Care Act (ACA) and health care reform. The adopted policy went on to call for our AMA to report back at each meeting of the HOD. Board of Trustees Report 6-I-13, "Redefining AMA's Position on ACA and Healthcare Reform," accomplished the original intent of the policy. This report serves as an update on the issues and related developments occurring since the most recent meeting of the HOD.

IMPROVING THE AFFORDABLE CARE ACT

Our AMA continues to engage policymakers and advocate for meaningful, affordable health care for all Americans to improve the health of our nation. Our AMA remains committed to the goal of universal coverage, which includes protecting coverage for the 20 million Americans who acquired it through the ACA. Our AMA has been working to fix the current system by advancing solutions that make coverage more affordable and expanding the system's reach to Americans who fall within its gaps. Our AMA also remains committed to improving health care access so that patients receive timely, high quality care, preventive services, medications and other necessary treatments.

Our AMA continues to advocate for policies that would allow patients and physicians to be able to choose from a range of public and private coverage options with the goal of providing coverage to all Americans. Specifically, our AMA has been working with Congress, the Administration, and states to advance our plan to cover the uninsured and improve affordability as included in the "2020 and Beyond: AMA's Plan to Cover the Uninsured." The current COVID-19 pandemic has led to many people losing their employer-based health insurance. This has only increased the need for significant improvements to the Affordable Care Act. We also continue to examine the pros and cons of a broad array of approaches to achieve universal coverage as the policy debate evolves.

Our AMA has been advocating for the following policy provisions:

Cover Uninsured Eligible for ACA's Premium Tax Credits

- Our AMA advocates for increasing the generosity of premium tax credits to improve premium affordability and incentivize tax credit eligible individuals to get covered. Currently, eligible individuals and families with incomes between 100 and 400 percent federal poverty level (FPL) (133 and 400 percent in Medicaid expansion states) are being provided with refundable and advanceable premium tax credits to purchase coverage on health insurance exchanges.
- Our AMA has been advocating for enhanced premium tax credits to young adults. In order to improve insurance take-up rates among young adults and help balance the individual health insurance market risk pool, young adults ages 19 to 30 who are eligible for advance premium

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tax credits could be provided with "enhanced" premium tax credits — such as an additional $50 per month — while maintaining the current premium tax credit structure which is inversely related to income, as well as the current 3:1 age rating ratio.

- Our AMA has been advocating for an expansion of the eligibility for and increasing the size of cost-sharing reductions. Currently, individuals and families with incomes between 100 and 250 percent FPL (between 133 and 250 percent FPL in Medicaid expansion states) also qualify for cost-sharing subsidies if they select a silver plan, which leads to lower deductibles, out-of-pocket maximums, copayments and other cost-sharing amounts. Extending eligibility for cost-sharing reductions beyond 250 percent FPL, and increasing the size of cost-sharing reductions, would lessen the cost-sharing burdens many individuals face, which impact their ability to access and afford the care they need.

Cover Uninsured Eligible for Medicaid or Children Health Insurance Program

In 2018, 6.7 million of the nonelderly uninsured were eligible for Medicaid or Children Health Insurance Program (CHIP). Reasons for this population remaining uninsured include lack of awareness of eligibility or assistance in enrollment.

- Our AMA has been advocating for increasing and improving Medicaid/CHIP outreach and enrollment.
- Our AMA has been opposing efforts to establish Medicaid work requirements. The AMA believes that Medicaid work requirements would negatively affect access to care and lead to significant negative consequences for individuals' health and well-being.

Make Coverage More Affordable for People Not Eligible for ACA's Premium Tax Credits

In 2018, 5.7 million of the nonelderly uninsured were ineligible for financial assistance under the ACA, either due to their income, or because they have an offer of "affordable" employer-sponsored health insurance coverage. Without the assistance provided by ACA's premium tax credits, this population can continue to face unaffordable premiums and remain uninsured.

- Our AMA has been advocating for eliminating the subsidy "cliff," thereby expanding eligibility for premium tax credits beyond 400 percent FPL.
- Our AMA has been advocating for the establishment of a permanent federal reinsurance program, and the use of Section 1332 waivers for state reinsurance programs. Reinsurance plays a role in stabilizing premiums by reducing the incentive for insurers to charge higher premiums across the board in anticipation of higher-risk people enrolling in coverage. Section 1332 waivers have also been approved to provide funding for state reinsurance programs.
- Our AMA has been advocating for lowering the threshold that determines whether an employee's premium contribution is "affordable," allowing more employees to become eligible for premium tax credits to purchase marketplace coverage.

EXPAND MEDICAID TO COVER MORE PEOPLE

In 2018, 2.3 million of the nonelderly uninsured found themselves in the coverage gap – not eligible for Medicaid, and not eligible for tax credits because they reside in states that did not expand Medicaid. Without access to Medicaid, these individuals do not have a pathway to affordable coverage.

- Our AMA has been encouraging all states to expand Medicaid eligibility to 133 percent FPL.

TEXAS VS. AZAR SUPREME COURT CASE

The Supreme Court agreed on March 2, 2020 to address the constitutionality of the ACA for the third time, granting the petitions for certiorari from Democratic Attorneys General and the House of Representatives. Oral arguments will likely take place in the fall with a decision to follow before June 2021. The decision to hear the case now will avoid several years of delay while the case worked its way through the lower courts. Granting the petition also puts the ACA front and center in the presidential election. The AMA filed an amicus brief in support of the Act and the petitioners in this case.

The Trump Administration filed a brief with the Court, asking the justices to overturn the ACA in its entirety. The Administration clarified that the Court could choose to leave some ACA provisions in place if they do not harm the plaintiffs, but as legal experts point out, the entire ACA would be struck down if the Court rules that the law is inseparable from the individual mandate—meaning that there would be no provisions left to selectively enforce.

MERIT-BASED INCENTIVE PAYMENT SYSTEM AND ALTERNATIVE PAYMENT MODELS

The Medicare Access and CHIP Reauthorization Act (MACRA) represents an improvement over the flawed and now repealed sustainable growth rate payment methodology and legacy quality and cost reporting programs. The implementation of MACRA, though, has been a significant undertaking for the Centers for Medicare & Medicaid Services (CMS) and physicians. Our AMA continues to work closely with both Congress and CMS to promote a smooth implementation of the Merit-Based Incentive Payment System (MIPS) and alternative payment models (APMs).

The Bipartisan Budget Act of 2018 included improvements to MACRA that allowed for a more gradual transition into the program and helped many physician practices avoid penalties they likely would have otherwise incurred under the MIPS program. However, further refinements are needed to improve the program and ensure physicians can be successful going forward.

As physician practice expense payments fall increasingly below costs, patient access issues are expected to arise. Currently under MACRA, physicians are scheduled to receive a 0 percent payment update for 2020-2025. According to data from the Medicare trustees, Medicare physician pay has barely changed over the last decade and a half, increasing just seven percent from 2001 to 2019, or just 0.4 percent per year on average. In comparison:

- The cost of running a medical practice has increased 34 percent between 2001 and 2019, or 1.6 percent per year. Inflation in the cost of running a medical practice, including increases in physician office rent, employee wages and professional liability insurance premiums, is measured by the Medicare Economic Index or MEI.
- Economy-wide inflation, as measured by the Consumer Price Index, has increased 45 percent over this time period (or 2.1 percent per year, on average).

As a result, Medicare physician payment rates are insufficient. Adjusted for inflation in practice costs, Medicare physician pay has declined 20 percent from 2001 to 2019, or by 1.3 percent per year on average. Therefore, our AMA has been strongly urging Congress to replace the physician payment freeze with positive updates that allow physicians to sustain their practices and provide a margin to invest in practice improvements needed to transition to more efficient models of care delivery and better serve Medicare patients.

Extend the advanced APM incentive payments

One goal of MACRA was to provide physicians with a glide path to transition into more innovative payment models but changing the way physicians deliver care requires significant investment in new technologies, workflow systems, personnel and training.

To help physicians implement these changes, MACRA provided a 5 percent incentive payment for the first six years of the program for those who participate in advanced APMs, intended to create a margin for investing in care delivery improvements. However, the dearth of advanced APMs available for physicians limited their ability to take advantage of the APM incentive that Congress provided.

Therefore, our AMA has been strongly urging Congress to extend the advanced APM payments for an additional six years to provide physicians with an onramp to move to APMs once they become available as intended in the original legislation.

Implement Technical Improvements

Our AMA has also been very engaged with Congress and the Administration urging them to make additional technical changes to MACRA to reduce the burden of MIPS and make reporting more clinically meaningful for physicians.

Specifically, our AMA has been advocating for the following issues to be addressed including harmonizing the four MIPS reporting categories, setting multiple performance thresholds to even the playing field for practices of all sizes and locations, and aligning MIPS and Physician Compare measures, among others.

The primary goal should be to allow physicians to spend less time on reporting and more time with patients and on improving care, and to create a more sustainable MIPS program. Changes should also promote participation in APMs by adjusting the multi-payer thresholds and clarifying the role and responsibilities of the Physician-focused Payment Model Technical Advisory Committee.

CONCLUSION

Our AMA will remain engaged in efforts to improve the health care system through policies outlined in Policy D-165.938 and other directives of the House of Delegates.

REPORT 12 OF THE BOARD OF TRUSTEES (November 2020)
2020 AMA Advocacy Efforts
(Informational)

EXECUTIVE SUMMARY

Policy G-640.005, "AMA Advocacy Analysis," calls on the Board of Trustees (the Board) to provide a report to the House of Delegates (HOD) at each Interim Meeting highlighting the year's advocacy activities and should include efforts, successes, challenges, and recommendations/actions to further optimize advocacy efforts. The Board has prepared the following report to provide an update on American Medical Association (AMA) advocacy activities for the year. (Note: It was prepared in August based on approval deadlines and may be updated if legislative, regulatory, or judicial developments warrant.)

At the start of 2020, the AMA advocacy agenda focused on a wide range of health care issues with a major focus on removing obstacles to the provision of optimal patient care. Targeted issues included but were not limited to surprise billing, regulatory relief, excessive prior authorization, access to health care, health disparities, scope of practice, and public health issues such as gun violence, vaping, and drug overdose and death. Quickly though, the AMA had to pivot to address the COVID-19 pandemic which created not only a public health crisis, but an economic crisis as well. A few months later, the tragic deaths of George Floyd and several other Black Americans due to unnecessary police violence caused a national outrage. Both the COVID-19 pandemic and policing issues placed equity issues at the forefront of federal and state legislative debates. The AMA has relied on its policy to guide its legislative and regulatory efforts and has made significant progress on many of these issues in 2020.

On the COVID-19 front, the AMA successfully sought billions in emergency funding to help physician practices stay viable and keep providing needed care through the Coronavirus Aid, Relief, and Economic Security (CARES) Act and subsequent emergency supplemental legislation. At the AMA's urging, federal and state officials approved broad telehealth expansions to increase access to care and provide patients with a safer way to receive COVID-19 and non-COVID-19 care. The AMA has called for greater access to personal protective equipment (PPE) for physicians and other health care providers. The AMA has also urged policymakers to follow science and evidence in response to the pandemic. A more comprehensive list of AMA efforts is included in this report.

The AMA continued to call for health insurers to modify policies that inhibit optimal health care for patients. This included advocating for reform of the prior authorization process. The AMA has also had to fend off surprise billing legislation that creates unfair negotiating leverage for insurers and harms physician practices.

The AMA has urged federal lawmakers to work together to enact legislation on unnecessary police violence issues specifically asking them to support research into the public health consequences of violent police interactions with the public and to support a ban on the use of choke-holds among other recommendations.

The AMA will continue to work on these priority issues heading into the remaining months of 2020.

REPORT OF THE BOARD OF TRUSTEES

B of T Report 12, November 2020

Subject: 2020 AMA Advocacy Efforts

Presented by: Russ Kridel, MD, Chair

BACKGROUND

Policy G-640.005, "AMA Advocacy Analysis," calls on the Board of Trustees (the Board) to provide a report to the House of Delegates (HOD) at each Interim Meeting highlighting the year's advocacy activities and should include efforts, successes, challenges, and recommendations/actions to further optimize advocacy efforts. The Board has prepared the following report to provide an update on American Medical Association (AMA) advocacy activities for the year. (Note: The report was prepared in August based on approval deadlines and may be updated if legislative, regulatory, or judicial developments warrant.)

DISCUSSION OF 2020 ADVOCACY EFFORTS

At the start of 2020, the AMA advocacy agenda focused on a wide range of health care issues with a major focus on removing obstacles to the provision of optimal patient care. Targeted issues included but were not limited to surprise billing, regulatory relief, excessive prior authorization, access to health care, health disparities, scope of practice, and public health issues such as gun violence, vaping, and drug overdose and death. Quickly though, the AMA had to pivot to address the COVID-19 pandemic which created not only a public health crisis, but an economic crisis as well. A few months later, the tragic deaths of George Floyd and several other Black Americans due to unnecessary police violence caused a national outrage. Both the COVID-19 pandemic and policing issues placed equity issues at the forefront of federal and state legislative debates. The AMA has relied on its policy to guide its legislative and regulatory efforts and has made significant progress. However, much more work needs to be done on many of these issues. The following is a summary of the AMA's 2020 advocacy work to date.

COVID-19 Response

As the COVID-19 pandemic manifested in several regions of the country in early 2020, the AMA immediately turned its legislative and regulatory lobbying efforts to address this public health emergency as well as the financial fallout for physician practices stemming from it. With millions of infections and thousands of deaths nationwide, COVID-19 has been a public health nightmare, and the AMA thanks and applauds the physicians, nurses and other health care professionals on the frontlines taking care of America's COVID-19 patients. The AMA is also acutely aware of the effect that the suspension of elective procedures and other COVID-19-imposed restrictions have had on physician practices and is working extensively with federal and state leaders to mitigate the negative impact as much as possible. Key AMA efforts include:

- Successfully sought billions in emergency funding to help physician practices stay viable and keep providing needed care through the Coronavirus Aid, Relief, and Economic Security

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(CARES) Act and subsequent emergency supplemental legislation. Many practices qualified for loan-to-grant programs, advance payments and emergency payments;

- Sought and secured broad telehealth expansion at the federal and state levels to increase access to care and provide patients with a safer way to receive COVID-19 and non-COVID-19 care;
- Obtained changes to federal payment rules to allow for parity in payment for telehealth services whether provided by audio/video means or audio-only;
- Called for a "Manhattan Project" to provide Personal Protective Equipment (PPE) and other needed resources to frontline responders as the magnitude of this pandemic rapidly emerged;
- Urged the federal government to improve and expand testing and allow increased U.S. Food and Drug Administration (FDA) Emergency Use Authorizations to speed the process and lead to more informed policy decisions;
- Convinced FDA and the Centers for Disease Control and Prevention (CDC) to review and revise antibody tests and guidelines based on validity concerns, reflecting guidelines issued by the AMA to help ensure physicians and the public are aware of the limitations and potential uses of serological testing/antibody testing;
- Successfully sought temporary expansion of Medicaid eligibility to uninsured individuals for COVID-19 testing;
- Urged states to eliminate Medicaid cost-sharing for COVID-19 related care, simplify Medicaid enrollment and renewal processes, and eliminate barriers to Medicaid coverage such as work requirements;
- Called on the administration to collect and release demographic data to help address any potential race, sex and age disparities during the pandemic;
- Advocated for added liability protections for physicians in federal legislation, state executive orders and state legislation to provide safe harbors for physicians when faced with suboptimal treatment arrangements, guidelines and protocols, patient surges and postponement of elective procedures;
- Called on federal and state policymakers, and private payers, to ease extraneous administrative burdens for physicians, such as prior authorization, audits, data requests and quality reporting, and persuaded the Centers for Medicare & Medicaid Services (CMS) not to penalize physicians for failing to complete MIPS reporting this spring;
- Created three new Current Procedural Terminology (CPT®) codes for COVID-19 testing and antibody testing;
- Successfully urged the administration to open visa processing for international physicians during the pandemic; and
- Conducted a nationwide survey on the financial impact of the COVID-19 pandemic on physician practices.

As the COVID-19 pandemic continues to spread and infections rise, the AMA's work to mitigate its impact is far from over. The following are front burner issues that the AMA is actively advocating on at the federal and state levels.

- Advising Congress on the true scope of physician practice financial loss during the pandemic and ways to aid physician practices in the upcoming COVID-response legislative packages;
- Pressing for the continuation of temporary telehealth provisions that enable better patient care, greater alignment of telehealth coverage, payment and coding policies across all payers, and the continued suspension of further regulatory hurdles;
- Urging Congress to protect and expand high quality, affordable health care coverage during this unemployment crisis, including additional funding for Medicaid;
- Continuing to work with private insurers to mirror new Medicare telehealth flexibilities in the commercial markets and call on employers with self-funded plans to do the same;

- Urging the reduction of limitations for international medical graduates and those with Deferred Action for Childhood Arrival status to remain in the country and provide urgently needed care as appropriate;
- Calling on states to adopt, in-full, Drug Enforcement Administration (DEA) and Substance Abuse and Mental Health Services Administration (SAMHSA) increased flexibility in prescribing and treatment requirements for opioid use disorder and for patients with pain;
- Emphasizing the importance of prescribing naloxone to patients at risk of opioid-related overdose and urging states to increase availability of sterile needle and syringe services programs to help prevent spread of blood-borne infectious diseases;
- Calling on federal and state leaders to rely on science when considering reopening businesses, schools, and other institutions as well as potentially relaxing/reissuing stay-at-home orders;
- Collecting expenditure and practice data to help address the financial impact of COVID-19 and barriers to reopening practices; and
- In conjunction with the American Heart Association (AHA) urging CMS to take immediate action to cover validated home blood pressure monitors for use at home with self-measured blood pressure (SMBP) monitoring through Medicare and Medicaid which is imperative during the COVID-19 public health emergency.

A full compilation of AMA COVID-19 response efforts can be found at the AMA COVID-19 Resource Center. Lastly, proof of the AMA's strong efforts on the COVID-19 pandemic came when a research firm that focuses on federal advocacy efforts reached out to the AMA and stated that the AMA tied for first with one other association when senior federal policymakers were queried about which organizations were doing good work on the COVID-19 crisis. This information affirmed the ongoing work that the AMA's Advocacy, Health & Science, Enterprise Communications, Center for Health Equity, Marketing & Member Experience, and several other AMA units have accomplished to support patients and physicians during this public health emergency.

Scope of Practice

In 2006, the AMA created the Scope of Practice Partnership (SOPP), a collaborative effort staffed by the AMA and comprised of every state medical association, 34 state osteopathic medical associations and 14 national medical specialty societies. Since 2007, the SOPP has awarded over $2 million in grants to medical societies. In 2019 and 2020 alone, the SOPP awarded grants to 10 state medical and osteopathic associations to help with state advocacy efforts. Detailed information on all grants is available through the AMA's Advocacy Resource Center.

Since 2019, the AMA, in strong collaboration with state and national medical specialty societies defeated more than 70 scope of practice bills across the country, including defeating bills that would have expanded the scope of practice of nurse practitioners in more than 14 states. In March 2020 AMA focus quickly shifted to COVID-19. Scope of practice remained a top priority as the AMA sought to push back against attempts by non-physician groups who seized upon concerns over workforce capacity during the pandemic to expand their scope of practice, including nurse practitioners, physician assistants, pharmacists and podiatrists. In response, the AMA sought ways to expand the physician workforce by expanding telehealth, encouraging retired or inactive physicians to return to the workforce as appropriate, fighting prohibitive immigration restrictions, and supporting civil immunity protections. The AMA also implored state and federal lawmakers that now is not the time for broad scope expansions. Any measures to relax existing scopes of practice must be temporary and narrowly tailored to caring for COVID patients.

Although generally a state issue, scope of practice concerns have also arisen on the federal level. Waivers and additional flexibility for COVID-19 testing and other health care services have led to renewed calls for the federal government to adopt permanent policies allowing non-physician health professionals to "practice to the top of their license." The AMA organized a Federation letter cosigned by over 100 state and national physician organizations urging that scope of practice waivers be sunset when the public health emergency concludes.

A letter cosigned by 78 Federation groups was also sent to the Department of Veterans Affairs (VA) asking the department to rescind a directive and memorandum allowing non-physician health care professionals in 32 specialties to operate "within the full scope of their license, registration, or certification" as it relates to encouraging all VA medical facilities to allow CRNAs to practice without physician oversight during the national health emergency.

Insurer Practices

Prior Authorization

Two years ago, the AMA reached a consensus statement with insurers and other stakeholders to reform the arduous prior authorization (PA) process. Since then, insurers have lagged in implementing the principles, and this has led to continuing obstacles for patients and physicians. According to an AMA survey on this issue, physicians say prior authorization interferes with patient care and can lead to adverse clinical consequences—with 16% of physicians reporting that the process has led to a patient's hospitalization. Moreover, surveyed physicians see little, if any, progress toward easing agreed-upon burdensome barriers to patient care, highlighting the need for legislative action to address a problem affecting patients across the country.

In response at the federal level, the AMA is supporting the Improving Seniors' Timely Access to Care Act, H.R. 3107, which would require Medicare Advantage plans to abide by many of the PA reforms outlined in the consensus statement. The bill's sponsors include Representatives Suzan DelBene (D-WA), Mike Kelly (R-PA), Roger Marshall, MD (R-KS), and Ami Bera, MD (D-CA), and the bill has now gained support from a bipartisan majority of the House of Representatives. The AMA's FixPriorAuth grassroots campaign continues to garner social media attention and traction, including an "Echo Back Video" urging support for H.R. 3107. The AMA and state medical associations have made good progress on this issue in recent years in state legislatures. In 2020, state efforts focused on minimizing burdens related to COVID-19 care. To date, 14 states have eased administrative barriers (e.g., prior authorization and step therapy for COVID-19 care) and dozens of states have removed prior authorization for testing.

Surprise Billing

As federal lawmakers continue to debate surprise billing proposals, states are moving ahead with legislation. While over a dozen bills were introduced this past year/session, four major pieces of legislation have been enacted in Indiana, Maine, Virginia and Georgia. The new Indiana statute places a ban on surprise billing without establishing a complete or fair payment mechanism for physicians, and therefore was largely opposed by provider groups. However, the other states' statutes, while not perfectly in line with Federation principles or AMA policy, come much closer to comprehensive solutions that promote good-faith contracting while protecting patients. In fact, all three incorporate some form of baseball-style arbitration to be made available to physicians (under certain circumstances) when the rates paid by the health insurers are insufficient. As learned from other states' experiences, continued vigilance will be needed to ensure these statutes and subsequent regulations are implemented fairly and as intended.

On the federal level, the AMA and its Federation partners have so far been successful in blocking passage of harmful surprise billing proposals that would give unfair advantage to insurers in network contract negotiations and drive down in-network payment rates. Political pressure from employers, patient groups, the White House, and Members of Congress from both political parties have caused the issue to resurface several times during the year, most recently in the context of the COVID-19 4.0 relief proposal being drafted over the summer.

Insurer Accountability Campaign

In January and February of this year, the AMA targeted voters in early 2020 Democratic Presidential Primary/Caucus states (Iowa, New Hampshire, Nevada, and South Carolina) as well as key national and inside the beltway audiences in order to generate general awareness around negative health insurance practices. Through an integrated social media and digital online campaign the AMA reached over 61 million people and had an unmistakable impact as evidenced by:

- The social media conversation with a negative sentiment surrounding health insurance practices grew throughout the campaign;
- Other organizations increased ad spends in primary states following the AMA's campaign launch. Drafting off AMA core messaging points, these ads focused on problems with health insurance practices like coverage gaps and narrow networks that lead to surprise billing; and
- AMA campaign messaging helped contribute to presidential campaign messaging shifts.

Drug Overuse and Death

In 2014, the AMA established the Opioid Task Force with the Federation to provide concrete recommendations for physicians to stem the opioid overuse and death epidemic facing the U.S. The work of this Task Force, including additional policy recommendations issued in 2019, has contributed to AMA advocacy wins, including:

- More than 20 new state laws to reduce barriers to evidence-based treatment for opioid use disorder;
- At least a dozen new state laws and regulatory developments to help enforce mental health and substance use disorder parity; and
- All 50 states now having laws that increase access to naloxone and nearly every state having a law that allows for standing orders for persons to obtain naloxone without a patient-specific prescription.

In addition, physician efforts continue, as evidenced by the recently released Opioid Task Force 2020 Progress Report: https://end-overdose-epidemic.org/wp-content/uploads/2020/07/AMA-Opioid-Task-Force-2020-Progress-Report.pdf

- There has been a marked decrease in opioid prescriptions from 244.5 million in 2014 to 153.7 million in 2019;
- There were over 1 million naloxone prescriptions in 2019—up from only 6,588 in 2015;
- There has been a 64.4% increase in the use of state prescription drug monitoring programs —to 739M queries in 2019;
- Hundreds of thousands of physicians accessing continuing medical education and other courses on substance use disorders, treating and managing pain, and more; and
- 85,000+ physicians and health care professionals certified to prescribe buprenorphine in-office—an increase of nearly 50,000 since 2017.

While these are positive trends, the nation's continuing increase in illicit drug overdoses and deaths is fueling the evolution of a more dangerous and complicated epidemic. Illicitly manufactured fentanyl and fentanyl analogues and stimulants are now killing more Americans than ever with the CDC reporting over 70,000 deaths in 2019. The use of these illicit drugs has surged and their overdose rate increased by 10.1% and 10.8%, respectively. The COVID-19 stay-at-home period appears to have worsened this situation as well. Patients with pain continue to suffer from arbitrary restrictions on opioid therapy as well as limited access to non-opioid pain care.

The AMA's 2019 policy roadmap with Manatt health (https://end-overdose-epidemic.org/wp-content/uploads/2020/05/AMA-Manatt-National-Roadmap-September-2019-FINAL.pdf), and the newly-enhanced drug overdose microsite—www.end-overdose-epidemic.org—will help the AMA more comprehensively advance efforts by the AMA Opioid Task Force, the AMA Pain Care Task Force and place increased emphasis on the need for ensuring public health data collection and surveillance efforts implement systems to accurately track overdose and mortality trends to provide equitable public health interventions that include comprehensive, disaggregated, racial and ethnic data collection related to testing, hospitalization and mortality associated with opioids and other substances.

Medicare/MIPS

AMA advocacy has focused on numerous important Medicare issues in 2020:

- Replacing the multiyear Medicare payment freeze in the Medicare Access and CHIP Reauthorization Act (MACRA) with positive annual payment updates;
- Securing improvements in Medicare payments for office visits consistent with the recommendations of the AMA/Specialty Society RVS Update Committee (RUC);
- Waiving the budget neutrality adjustment for the office visit payment increases;
- Getting the office visit increases included in the global surgical packages;
- Extending the five percent incentive payment for physicians participating in Advanced Alternative Payment Models (APMs) for an additional six years;
- Improving Medicare APMs by implementing physician-focused models;
- Simplifying the scoring of the Merit-based Incentive Payment System (MIPS) and creating more clinically meaningful and less burdensome voluntary MIPS options for physician participants;
- Expanding MIPS exceptions and flexibilities during the COVID-19 pandemic; and
- Initiating a Practice Expense Pilot Project involving 32 specialty practices to evaluate the feasibility of a revised practice expense data collection methodology.

MACRA provided positive Medicare payment updates from 2015-2019 and for 2026 and beyond, but left a gap from 2020-2025 with no payment updates. The AMA is continuing to advocate for Congress to address this gap. In addition, MACRA limited the incentive payment for Advanced APM participants to the first six years of the program. As there have been so few Advanced APM opportunities available for physicians, the AMA is asking Congress to extend the incentive payment for an additional six years.

CMS adopted the significant changes in office visit coding definitions and guidelines made by the CPT Editorial Panel, as well as the RUC-recommended relative value recommendations for implementation in 2021. These coding changes and payment increases are a very substantial improvement. Unfortunately, under current law the payment increases must be implemented in a budget neutral manner which will lead to steep negative adjustments for many physicians and other health care professionals who report relatively few office visit codes. As physicians are already

facing severe economic hardship due to COVID-19, the AMA is urging Congress to waive the budget neutrality adjustment for the office visit increases. In addition, the AMA has advocated for CMS to fully adopt the RUC recommendations for the office visit codes by including the payment increases in the global surgical packages.

The AMA has also been advocating for new voluntary options within MIPS that would allow physicians to focus on a specific episode of care, clinical condition, or public health priority instead of fragmented and unrelated measures in four different categories. In its 2020 rulemaking process, CMS outlined a new approach called MIPS Value Pathways that is a step in this direction. The AMA is advocating for a number of improvements to the MIPS Value Pathways approach to make it less burdensome and more relevant to clinical practice. The AMA also has been working with CMS to address the need for MIPS flexibilities and hardship exemptions for 2019 and 2020 MIPS reporting due to COVID-19.

On August 3, CMS issued a proposed rule that includes updates to payment policies, payment rates and quality provisions for services furnished under the Medicare Physician Payment Schedule effective on or after January 1. The proposed CY 2021 PFS conversion factor is $32.26, almost 11% lower than in 2020. This is necessitated by proposed additional spending of $10.2 billion partly due to changes in coding and payment for evaluation and management (E/M) services provided in the office setting, as well as other changes made by CMS. The agency also proposed to permanently keep several codes that were temporarily added to the Medicare telehealth list during the COVID-19 Public Health Emergency (PHE), including the prolonged office or outpatient E/M visit codes and certain home visit services. The AMA will submit comprehensive formal comments on the proposal.

Telemedicine

During the COVID-19 pandemic, the need for patients, physicians, and practice staff to avoid all but essential travel and to practice social distancing as much as possible, combined with an acute shortage of personal protective equipment (PPE), made it necessary for many physician practices to temporarily close. Through AMA advocacy with Congress and federal officials in multiple agencies, waivers and other policy changes were secured to facilitate replacement of these in-person services with telehealth and telephone services. Adoption of telehealth by physicians increased exponentially and extremely rapidly. For Medicare patients, instead of telehealth being confined only to rural areas, it became available everywhere in the country, and instead of needing to go to a facility to obtain telehealth services provided by clinicians in a distant site, patients were able to obtain telehealth services in their own homes, often provided by physicians from their own homes. The DEA provided new flexibilities to allow Schedule II controlled substances and medications for treatment of opioid use disorder to be prescribed based on telehealth visits.

Following this rapid and widespread adoption of telehealth, the challenge is to preserve these new policies beyond the COVID-19 pandemic. To that end, the AMA has been engaged in advocacy with CMS and with Congress. The AMA is working to secure legislation that will prevent the geographic and originating site restrictions on Medicare telehealth services to be permanently removed, and to secure CMS support for retaining the coverage of audio-only services and retaining the many services, such as emergency department and critical care visits, that were newly added to the Medicare telehealth list. The AMA is also working to preserve changes made that allowed patients to use their smart phones for telehealth services while also ensuring that HIPAA requirements will be deployed to protect the privacy of patients' health information when they obtain telehealth services. Finally, whereas the AMA is working to preserve physicians' ability to provide supervision via telehealth as has been permitted during the public health emergency, the

AMA is opposed to permanently eliminating requirements for supervision of nonphysician health professionals as has been done by Medicare on a temporary basis during the pandemic.

The AMA has had a model state telehealth bill since 2017 and has worked with many states on telehealth legislation over the past three years; however, COVID-19 has prioritized the need to update telehealth laws to further expand access, coverage and payment by state regulated plans and Medicaid programs. Shortly after the pandemic hit, the AMA created COVID-19 policy recommendations to provide guidance to state lawmakers, regulators and other policymakers on many issues, including telehealth. The AMA also tracked and summarized changes to state telehealth laws through gubernatorial executive orders, insurance directives, legislation, and Medicaid bulletins. The AMA sent letters to National Governors Association (NGA), National Association of Insurance Commissioners (NAIC), and National Council of Insurance Legislators (NCOIL) outlining its position on telehealth. Finally, the AMA participated in multiple webinars and workgroups related to telehealth with leading state policymaking organizations, including NGA, NAIC, National Association of Attorneys General (NAAG), and the Uniform Laws Commission. These collective efforts have secured AMA's place at the table to make sure the physician's voice is part of these ongoing discussions.

In response to COVID-19, all 50 states took some action related to telehealth. For example, at least 45 states expanded coverage of telehealth for Medicaid patients by eliminating originating site restrictions or other restrictions on the type of care that can be provided via telehealth. While 30 states already had coverage parity for telehealth by state regulated payors, many states took additional steps to further expand coverage of telehealth. About a dozen states required insurers and/or Medicaid plans to pay for telehealth services at the same rate as in-person services. This was instrumental in making sure physicians were able to continue providing care to their patients during this pandemic.

Police Violence

After the deaths of George Floyd and several other African Americans due to unnecessary police violence, the AMA's then-Chair Jesse M. Ehrenfeld, MD, MPH, and then-President Patrice A. Harris, MD, MA, issued a statement calling on police brutality to stop. The statement further indicated "What's often not highlighted are the harmful health impacts that result, such as the connection between excessive police activity and health. Research demonstrates that racially marginalized communities are disproportionally subject to police force, and there is a correlation between policing and adverse health outcomes." Further, the AMA wrote to Congress detailing physician support for the following changes, among others:

- Research into the public health consequences of violent police interactions;
- States requiring the reporting of legal-intervention deaths and law-enforcement officer homicides to public health agencies;
- Banning the use of choke-holds;
- For appropriate stakeholders, including law enforcement and public health communities, to define "serious injuries" for the purpose of systematically collecting data on law enforcement-related nonfatal injuries among civilians and officers;
- Law-enforcement departments and agencies having in place specific guidelines, rigorous training and an accountability system for the use of conducted electrical devices, often called Tasers;
- Research into the health impacts of conducted electrical device use and development of a standardized protocol developed with the input of the medical community for the evaluation, management and post-exposure monitoring of subjects exposed to these devices;

- Increased use of body-worn cameras by law enforcement officers, as well as funding for the purchase of body-worn cameras, training for officers and technical assistance for law enforcement agencies;
- Training for law enforcement at all levels on implicit or unconscious bias and structural racism;
- School discipline policies that permit reasonable discretion and consideration of mitigating circumstances when determining punishments rather than "zero tolerance" policies that mandate out-of-school suspension, expulsion or the referral of students to the juvenile or criminal justice system;
- More research to identify programs and policies that are effective in reducing disproportionate minority contact across all decision points within the juvenile justice system; and
- Reauthorizing federal programs for juvenile justice and delinquency prevention, which should include incentives for community-based alternatives for youth who pose little risk to public safety, reentry and aftercare services to prevent recidivism and policies that promote justice to reduce disparities.

LGBTQ

The AMA opposes so-called "conversion therapy" and in 2020 two additional states—Utah and Virginia—banned the practice. The total number of states that have banned conversion therapy is now up to 20. The AMA has provided direct and indirect support for these laws. In addition, following a directive from the House of Delegates, the AMA has drafted model legislation banning conversion therapy. No additional activity related to conversion therapy is expected in 2020, but in 2021 the AMA will continue to work with state medical associations to pass laws in the remaining 30 states.

In close coordination with the South Dakota State Medical Association, the AMA worked to defeat harmful legislation that would have criminalized the provision of medically necessary care for transgender minors. The AMA opposed the bill as harmful to the health of transgender minors as well as a dangerous legislative intrusion into the practice of medicine. Similar bills were introduced in a handful of other states, but none advanced. The AMA will continue to monitor state activity and work with state medical associations if additional bills of this kind emerge.

Privacy

The AMA has been active on a variety of fronts related to privacy in 2020. Most notably, the organization developed and released to the public a set of Privacy Principles. The Principles were developed by AMA staff in tandem with the Council on Legislation and were approved by the Board of Trustees in April. They are derived primarily from AMA policy, and provide clarification in areas where AMA policy may be implied but not specific. They address (1) individual rights; (2) equity; (3) entity responsibility; (4) applicability; and (5) enforcement. The Principles will guide AMA advocacy efforts in light of ongoing discussions among Congress, the Administration, and stakeholders to address the growing concerns regarding patient privacy. The AMA has received favorable reaction to the Principles from Congressional offices and others in the health care and the privacy stakeholder community, and looks forward to continuing efforts to promote the importance of privacy in preserving trust between physicians and their patients.

The AMA has also been actively involved in multiple workgroups related to privacy including a steering committee that is seeking to develop a self-regulatory framework to protect patient health information not protected by HIPAA (e.g., health information created by wearables, stored and shared via smartphone apps, etc.) as a bridge until federal privacy legislation is passed by Congress. The AMA is also a lead participant in a workgroup seeking to protect privacy while

promoting interoperability, focused on data labeling and segmentation. This is an important strategy to encourage information sharing, while assisting physicians in using technology to support compliance with state and federal privacy laws. The workgroup recently proposed adopting a number of the AMA's Privacy Principles as foundational to the workgroup's mission. Additionally, the AMA is active within the standards development body Health Level 7 (HL7), and is incorporating AMA policy and the Privacy Principles in feedback on proposed implementation guides, particularly guides aimed at implementing the newly published regulations from the Office of the National Coordinator for Health Information Technology (ONC) and CMS on patient access, interoperability, and information blocking.

The AMA has also been active on privacy as related to COVID-19. For example, the AMA has provided behind-the-scenes technical assistance to multiple Congressional offices on bills seeking to address privacy concerns related to contact tracing technologies (e.g., smartphone apps). The AMA also partnered with the American Hospital Association (AHA) to develop a document for physicians working from home early in the pandemic to help them with proper privacy and security settings for their home networks and telemedicine platforms. Additionally, the AMA has shared information with the Federation about the federal government's notice of enforcement discretion related to HIPAA, including suggestions about the types of functionalities physicians should use to help protect the confidentiality of their patient information. Finally, the AMA is in the process of developing a second resource with the AHA to help educate physicians on technology considerations as they reopen their practices and prepare for a "second wave" of COVID in the coming months. This resource will include suggestions for how to prepare for the end of the government's HIPAA enforcement discretion.

International Medical Graduates

The AMA took several actions on behalf of International Medical Graduates (IMGs) to assist with various hurdles that arose in 2020. The AMA sent a letter to the Department of State (DoS) and the Department of Homeland Security (DHS) requesting that they open visa processing at embassies and consulates for physicians seeking to enter the U.S. to join residency programs on July 1. As a result of AMA advocacy, in concert with the Educational Commission for Foreign Medical Graduates (ECFMG), the DoS agreed to begin processing visa applications for foreign-born medical professionals and announced that J-1 physicians may consult with their program sponsor, to extend their programs in the U.S., and confirmed that J-1 physicians can engage in revised clinical training rotations/assignments in keeping with the Accreditation Council for Graduate Medical Education (ACGME) "Response to Pandemic Crisis."

On June 22, the President of the United States issued a second Presidential Proclamation. In response, on June 26, the AMA sent a letter urging the Administration to consider J-1 and H-1B International Medical Graduates (IMGs) and their families' entry into the U.S. to be in the national interest of the country. Moreover, the AMA spear-headed a sign-on letter for specialty societies. The letter urges DoS and DHS to issue clarifying guidance pertaining to the Proclamation by directing Consular Affairs to advise embassies and consulates that H-1B physicians and their dependent family members' entry into the U.S. is in the national interest of the country.

On July 6, the Student and Exchange Visitor Program (SEVP) announced that nonimmigrant F-1 and M-1 students attending schools operating entirely online could not take a full online course load and enter or remain in the U.S. In response, on July 9, the AMA sent a letter urging the Administration to withdraw its modifications to the temporary exemptions for nonimmigrant students taking online classes due to the pandemic for the fall 2020 semester, so that medical students seeking to study in the U.S. on an F-1 visa could enter or remain in the country. In part

due to the advocacy efforts of the AMA, on July 14, the Trump Administration rescinded the directive.

The AMA also created an IMG resource guide entitled "FAQs: Guidance for international medical graduates during COVID-19." This guide answers some of the questions that IMGs have surrounding their ability to practice, their visas, and available resources.

Immigration

The AMA was also very active on the immigration front in 2020. On July 14, the AMA submitted a comment letter to DHS and USCIS urging the Administration to withdraw Proposed Rule RIN 1125-AA94 which would change multiple aspects of the asylum immigration system and make it harder for worthy asylum seekers to find refuge in the U.S.

On June 18, the Supreme Court of the United States ruled in opposition of the U.S. Department of Homeland Security's attempt to rescind the Deferred Action for Childhood Arrivals (DACA) Program in a landmark decision. This decision aligns with the amicus brief that the AMA helped to write in conjunction with other leading health organizations, the letter the AMA signed onto urging regulatory or legislative action to retain DACA during the COVID-19 national emergency, and the AMA's advocacy supporting the American Dream and Promise Act of 2019 (H.R.6) and the Dream Act of 2019 (S.874).

CONCLUSION

The AMA has made significant progress on a challenging group of advocacy issues so far in 2020 and will continue to advocate powerfully for physicians and patients in the second half of the year. The situation is fluid with the COVID-19 pandemic worsening at the time of this report and protests over police violence occurring in many parts of the country. The November elections will be a major factor as well as many elected officials transition from legislating to campaigning. But the AMA will continue to press to advance AMA policy on these issues and others that arise.

REPORT 15 OF THE BOARD OF TRUSTEES (November 2020)
Plan for Continued Progress Toward Health Equity
(Center for Health Equity Annual Report)
(Informational)

EXECUTIVE SUMMARY

In accordance with Policy D-180.981, this informational report outlines the equity activities of our AMA from 2nd Quarter 2019 through the 3rd Quarter of 2020, with some projections into the 4th Quarter of 2020.

REPORT OF THE BOARD OF TRUSTEES

B of T Report 15, November 2020

Subject: Plan for Continued Progress Toward Health Equity (Center for Health Equity Annual Report)

Presented by: Russ Kridel, MD, Chair

BACKGROUND

This report is submitted for information to the House of Delegates. In June 2018, the House of Delegates adopted Policy D-180.981, "Plan for Continued Progress Toward Health Equity," directing our AMA to develop "an organizational unit, e.g., a Center or its equivalent, to facilitate, coordinate, initiate, and track AMA health equity activities." Subsequently, in April 2019, our AMA hired its inaugural Chief Health Equity Officer and Group Vice President, Dr. Aletha Maybank, and established the Center for Health Equity ("the CHE", "the Center"). Under the auspices of the Center for Health Equity, our AMA has outlined an internal equity strategy to be leveraged across each business unit toward overall elevation of our AMA Strategic Arcs, and an external equity strategy to maximize and normalize the embeddedness of equity in policy development and in health care delivery, altogether toward the betterment of public health. Policy D-180.981 also states "the Board will provide an annual report to the House of Delegates regarding AMA's health equity activities and achievements." As it is just over a year since the inception of the CHE, and the first full annual report of this nature, this document will expound on endeavors that were in development in the mid and latter parts of 2019, and are now in full-fledge operation or complete.

DISCUSSION

Stating the Case for Strategic Equity

Based on the premise of advancing optimal health for all, strategic equity is the re-aligning objective for health systems, whether under normal operating procedure or in the midst of public health crises, such as that which our world faces in 2020 with coronavirus SARS-CoV-2, COVID-19. Especially in the face of pandemic, the CHE considers equity the accelerant that focuses and prioritizes health practitioners' practice-wide goals to deliver high-level, comprehensive, equitable care to all, with thoughtful consideration of myriad lived experiences of patients. Equity considerations ought not fall by the wayside under grim conditions. This is where such principles are needed the most.

Center for Health Equity Quarter Successes and Milestones

<u>2nd Quarter, 2019</u>

(1) Hired in April 2019, Dr. Aletha Maybank leads the CHE as Chief Health Equity Officer, as well as AMA Group Vice President (initially Vice President). Having an extensive background at the intersection of public health, medicine, government, and equity enterprise establishment, Dr. Maybank brings with her a deep reservoir of know-how regarding embedding equity across a multi-tiered organization such as our AMA. Prior to

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joining the AMA, Dr. Maybank served as the Founding Deputy Commissioner for the Center for Health Equity at the NYC Department of Health and Mental Hygiene (2014). She was instrumental in infusing equity at the neighborhood level and advancing the Department's place-based approach to addressing health inequities. She also set precedence with groundbreaking work at the Office of Minority Health in the Suffolk County Department of Health Services (2006) while serving as the Founding Director. Dr. Maybank has taught medical and public health students on topics related to health inequities, public health leadership and management, physician advocacy, and community organizing in health. In 2012, along with a group of Black woman physician leaders, Dr. Maybank co-founded "We Are Doc McStuffins", a movement inspired by the Disney Junior character Doc McStuffins serving to shine light on the critical importance of diversity in medicine.

(2) Most of the time in the first quarter was spent learning AMA's culture and engagement with external partners. There was initial reach out and engagement with minoritized physician associations such as NMA and NHMA to start relationship building. Dr. Maybank provided in-depth AMA presence at NMA National Conference via participation in several panels. Also due to critical demand by business units (BU) across AMA, she began discussions BU by BU to share what she had learned in the past regarding institutional culture change as it related to equity as a way to start laying the foundation. She clearly articulated that AMA's approach needed to be an 'inside – outside' strategy in which the culture, practice, and policy within the management and membership was as equally critical to evolve as out external engagement in order to advance equity.

<u>3rd Quarter, 2019</u>

(1) By August 2019, Dr. Maybank hired Diana N. Derige, DrPH, as the CHE's Director of Health Equity Strategy and Development to focus on strategic planning, strengthen external partnerships such as West Side United, and identify external funding opportunities. In September 2019, Dr. Maybank hired Mia Keeys, MA, DrPH(c), as Director of Health Equity Policy and Advocacy to directly engage and support AMA Advocacy to center equity since advocacy is one of AMA's greatest assets. The Center is administratively supported by Executive Assistant Nish Wise, also hired within the 3rd quarter of 2019.

(2) Over the course of the 2019 3rd and 4th quarters, the CHE staff, with the guidance of an equity-in-practice consultant, developed strategic approaches, a vision, and a mission to guide the Center's work, which included embedding equity across the AMA enterprise. Internally, the CHE submitted its Strategic Roadmap for comment to AMA Management Team leadership at the end of 2019, listed below:

> CHE's vision is a nation where all people live in thriving communities where resources work well, systems are equitable and create no harm, and everyone has the power to achieve optimal health; and all physicians are equipped with the consciousness, tools, and resources to confront inequities as well as embed and advance equity within and across all aspects of the health care system.
>
> CHE's mission is to strengthen, amplify, and sustain the AMA's work to eliminate health inequities – improving health outcomes and closing disparities gaps – which are rooted in historical and contemporary injustices and discrimination.

Over the course of its development, the Center set about refining the Strategic Roadmap, informed by both internal and external stakeholder feedback, and have arrived at the tenets described in detail in a separate document, but, summarily, the CHE Strategies Approaches are:

- Embed health equity in practice, process, action, innovation and organizational performance and outcomes
- Build alliances and share power via meaningful engagement
- Ensure equitable opportunities and conditions in innovation for marginalized and minoritized people and communities
- Push upstream to address all determinants of health
- Create pathways for truth, reconciliation, and healing

(3) Also, in late 2019, CHE firmly established the Health Equity Workgroup building upon already exiting efforts with the AMA Management Team co- lead by Rodrigo Sierra and Michael Tutty. The Health Equity Workgroup ("HEW") is a conglomerate of AMA business unit representatives who are collectively tasked with building a community of equity learning and practice; supporting local and enterprise-wide accountability to equity principles; ensuring equity is explicit and infused during goal and objective setting; and better aligning and accounting for enterprise-wide health equity work. The HEW is a merger between AMA's Diversity and Inclusion and former Health Equity Workgroup. The CHE manages the Workgroup and coordinates its Steering Committee, which consists of leaders and members who are involved in planning, development, and implementation of Health Equity Workgroup and Business Action Team activities. Two persons per business unit have been appointed to work with their respective business units to create equity explicit metrics and goals. Following each HEW convening, those business unit representatives convey issues and decisions to supervisors, colleagues, and staff; appropriately escalate concerns; actively seek out, listen to, and incorporate other ideas and perspectives. They are heralded as accessible and open to discussing sensitive matters, and for bringing forth messages about health, race, gender, and social equity into communications with staff and stakeholders as it relates to their work.

Staff in these roles are voluntarily contributing significant time and talent to the development and implementation of health equity work and vision, at the behest of the enterprise-wide equity imperative. The HEW promotes inclusion of diverse voices (by gender/sexual identity, race, age), opportunity to build expertise around equity issues, and the implementation of an equity lens. The HEW gatherings and trainings are designed to focus on workforce equity, particularly at the leadership level, as well as to center equity in policy, practice, and programming.

(4) Since 2019, the Center has organized ongoing racial equity training for senior leadership and staff. Hosted by staff of the Racial Equity Institute (REI)—an organization dedicated to developing the equity capacity of organizations and its leaders—the training is a two-day immersive experience that features lessons tailored to organizational needs with respect to understanding, appreciating, and embedding racial equity across all goals and processes. For AMA, these trainings have included a deep review of organizational membership (by race), policies, and practices across its 175+ years existence. It has also included team-building and small-group discussions related to race, power, and how these constructs manifest within the context of our AMA. With the support of CEO Jim Madara, to date, 90% of Senior Management Group (SMG) have received REI training, and 17% of non-SMG staff have taken the REI training. Before the shelter-in-place and stay-at-home

orders went into effect, the Center had planned to hold additional trainings. The CHE plans to resume REI virtual trainings in the 4th Quarter of 2020, and in-person trainings in 2021 in accordance to AMA guidelines on in-person gatherings. The goal is to achieve 100% staff and SMG training by 2025.

1st Quarter, 2020

(1) In March 2020, the CHE hired and onboarded Hannah Seoh, Director of Health Equity Performance and Operations, and Diana Lemos, PhD, Senior Health Equity Program Manager.

(2) The Center for Health Equity is building sustainable and collaborative relationships with leading organizations likewise committed to an equity imperative. CHE has played a significant role in broadening the AMA's engagement with elected officials, with leaders throughout the fields of health care and public health, and also with non-traditional partners that have historically held rapport with marginalized and minoritized communities. Consequently, there is mounting evidence of the external environments' understanding and appreciation of AMA's Center for Health Equity, and for broader appreciation of the AMA's burgeoning practice of applying a strategic equity lens in relationship and alliance-building efforts. Table 1 in the Appendix further demonstrates identified cross-enterprise and external partners to date, and through 2025, thus far.

(3) Under the leadership of CHE, AMA is heavily investing in a nationwide effort to spread health equity messaging and community health resources across Black communities through *Essence*—the nation's leading lifestyle magazine brand for Black women—most notably through its internationally acclaimed annual July festival, and through its inaugural Wellness Houses in various cities with substantially large communities of Black women and their families. Immediate Past President, Dr. Patrice Harris, has participated in the *Essence Wellness House*, both in-person in Atlanta, GA, and, on March 31, 2020, virtually through the first broadcast of the *Essence Wellness House Live* during a session titled "Essence of the Matter: COVID-19's Impact on Black America".

The *Essence* partnership represents AMA's commitment to going to where trusted physician voices are needed and to building community trust through an established and time-honored brand. The Center's efforts also support the Improving Health Outcomes (IHO) business unit, build the AMA brand in health equity in the Black community, and demonstrate true partnership with the National Medical Association (NMA), the Association of Black Cardiologists (ABC), and the American Heart Association (AHA) to support community well-being.

(4) In February 2020, under the leadership of CHE, AMA partnered with notable hospitals, community health centers, and social organizations in Chicago in a $6 million collaborative social impact investment pact called West Side United (WSU). The investment in the collaborative is an investment in upstream improvements targeted at tackling social determinants of health (SDoH) and is a solid step forward toward closing the life expectancy gap between the loop and Chicago's westside neighborhoods through invigorating economic growth and improving educational outcomes.

For the first time, AMA is investing financially in our own backyard. In the first year, AMA is investing $2 million along with other health care institutions. This effort encourages investment in upstream work wherein health care institutions help to reduce burdens associated with SDoH. It also speaks to the awareness that health care institutions

and their leaders have a role in building community wealth and its impact on health. The WSU investment is a stellar example of how AMA can support upstream work, through social impact investing and a multi-tiered approach to planning, programming and assessment, while bringing together and leveraging the expertise of many AMA business units, including IHO (chronic disease management); Enterprise Communications—EC—(social responsibility); Finance (social impact investing) and coordinating human and financial resources to leverage impact.

2nd Quarter, 2020

(1) In May 2020, CHE also hired and onboarded Fernando De Maio, PhD, Director of Health Equity Strategic Data Use and Research, who brings experience in quantitative data analysis, social epidemiology and sociology. Dr. De Maio's role is a joint appointment with DePaul University, where he remains a tenured professor in the Department of Sociology. In May 2020, CHE also hired Alice Jones**,** Program Manager of Health Equity Performance and Operations. In June 2020, Aziza Jones and Joaquin Baca, MSPH**,** also joined the team as Marketing Manager and Senior Health Equity Policy Analyst, respectively. Formerly with the Environmental Intelligence and Strategic Analytics business unit, Chelsea Hanson also joined CHE as Director of Health Equity Innovation. Consequently, within a year of onboarding its first staff of four, the CHE has nearly tripled in size (see Figure 1 in the Appendix) with plans to hire a Director of Equitable Health Systems Integration by end of 3rd Quarter 2020.

(2) The CHE, in partnership with Enterprise Communications, drafted an online guide, titled Health Equity: A Guide on Concepts, Language and Narrative, which offers a selected glossary and analysis of key equity language and concepts. Its purpose is to enable readers to recognize, describe, think critically, and effectively engage in dialogue related to inequities and equity. It supports the value of ongoing dialogue as a method for advancing strategies for eliminating health inequities that undermine or diminish health. It is slated for full release at the beginning of the 3rd Quarter 2020.

(3) Early in 2020, the CHE launched the internal AMA Today site for staff, which includes learning modules on equity for staff edification; a reading list consisting of classic and contemporary texts and articles on various equity-related subjects; and videos/documentaries to aid self and business unit study of equity issues. At the onset of COVID-19, the equity in COVID-19 resource webpage for physician-members and staff was launched.

(4) On April 7, 2020, the *New York Times* published an article written by Dr. Maybank on the significance of race and ethnicity data in combating COVID-19. It contributed greatly to the national conversation and actions, received widespread attention on the issue, and elevated the role and growing importance and relevancy of the AMA Center for Health Equity. Demand from internal and external stakeholders for CHE's time, attention, and advice increased tremendously after this time.

(5) On Tuesday, April 14, 2020, via Apple TV+, Dr Maybank sat down (virtually), with international syndicate host Oprah Winfrey, during a special presentation, "Oprah Talks COVID-19 - The Deadly Impact On Black America". During this in-depth conversation, Dr. Maybank discussed the detrimental impact the COVID-19 pandemic is having on Blacks across the country. This too increased the demand for time and attention from CHE. It, like no other platform can do, elevated AMA as a serious contender in the fight for injustice in health.

3rd Quarter, 2020

(1) In just over a year, CHE has represented our AMA and its equity commitment in over 75 speaking engagements across the country. Table 2 in the Appendix describes speaking engagements at which CHE staff have represented the AMA since Interim 2019 to June 2020.

In addition to the physical and virtual speaking engagements, the CHE has solidified its online presence. In April 2020, the CHE, in collaboration with the Marketing and Member Experience (MMX) business unit, launched a YouTube-based conversation platform called **"**Prioritizing Health Equity**."** This series of conversation focuses on the experiences of marginalized and minoritized physicians, public health leaders, and medical students during the COVID-19 pandemic. The views have exceeded 50,000. Table 3 in the Appendix maps out the initiative to date.

(2) COVID-19 has shifted how CHE engages with AMA business units and with outside partners. At the time this report was written, CHE was in the process of refining the CHE Strategic Roadmap, informed both by internal and external feedback. In many ways, COVID-19 has enhanced engagement with external partners, and hastened output and collaboration across all AMA BUs while also looking to create both short-term, as well as sustainable endeavors to address the pandemic's impact on the AMA physician membership body, their patients, and on the greater public health environment.

The Center leads the AMA collection of emerging practices on Health Equity/Racial Equity COVID-19 strategic programs/policies. The collection and dissemination of the practices is meant to support best practice dissemination, innovation, and network development all in support of health equity. The Center will serve as repository of this information and will make the information available on the AMA website. Post COVID-19, the CHE will use the information to inform "after-action" conversations for planning and policy development.

Developed in response to the COVID-19 threat, this Equity COVID-19 Resource Page consists of articles, commentaries, resource lists, etc., produced by world health and public health leaders, as it relates to the pandemic. Not only are our AMA utilization analytics demonstrating its usefulness for physician-members—this is also a tool from which the general public is gaining utility. The Health Equity Resource Center for COVID-19 serves as a clearinghouse of sorts to ensure that communications from AMA have an equity framing and consideration of structural issues that contribute to, and could exacerbate, already existing inequities.

(3) In consultation with the National Council of Asian Pacific Islander Physicians, during Asian American Pacific Islander Heritage Month (May 2020), AMA released a public statement denouncing racism and xenophobia, particularly as it impacts Asian Americans and Asian-presenting persons in America. This document also publicly leverages a fuller report arguing for the discrete data disaggregation of Asian American and Pacific Islander health outcomes, which CHE also produced and release to the Board of Trustees in March 2020. A public version of the report is also available on the AMA website.

(4) One of the CHE's critical concerns related to COVID-19 is the dearth of publicly available granular data on the number of positive cases, hospitalizations, and mortality by race and ethnicity. Without these data, it is difficult to make sound decisions on resource allocation and to glean an overall understanding of how the virus has been impacting various

communities. Therefore, on April 3, 2020, in coordination with Advocacy business unit, the CHE submitted a letter to the Department of Health and Human Services (HHS) urging policymakers to require equitable demographic data collection and urging health systems/practices to collect data. The following physician and public health organizations signed onto this letter: the National Medical Association, the National Hispanic Medical Association, the National Council on Asian Pacific Islander Physicians, the Association of American Indian Physicians, the American Academy of Family Physicians, the American Academy of Pediatrics, and the American College of Gynecologists.

(5) On April 2, 2020, CHE, in coordination with the Advocacy business unit, submitted legislative language on equity considerations for inclusion consideration for a forthcoming COVID-19 legislative package. The bill, HR 6585, called the Equitable Data Collection and Disclosure Act, was introduced as a stand-alone bill by Representatives Kelly (D-IL), Pressley (D-MA), Bass (D-CA), and Lee (D-CA). Its Senate companion was introduced by Senators Booker (D-NJ), Harris (D-CA), Markey (D-MA), Merkley (D-OR), and Warren (D-MA).

The following are the provisions of the bill, which CHE submitted:

- Require HHS to use all available surveillance systems to post daily updates on the CDC website showing the testing, hospitalizations, treatment data disaggregated by race, ethnicity, sex, age, socioeconomic status, disability status, county, and other demographic information, including patients' preferred written and spoken language;
- Require HHS to take all necessary steps to protect privacy in releasing this data;
- Require HHS to provide a summary of the final statistics and a report to Congress within 60 days after the end of the public health emergency;
- Create a Commission on Ensuring Health Equity during the COVID-19 Public Health Emergency, including federal, state, local, and tribal officials along with independent experts, to provide guidance on how to better collect, develop and analyze racial and other demographic data in responding to future waves of the coronavirus;
- Authorize $50 million in emergency supplemental funding to the CDC, state public health agencies, the Indian Health Service, and other agencies to conduct or support data collection on racial, ethnic, and other demographic implications of COVID-19.

Not long after the bill had been introduced, the Centers for Disease Control and Prevention (CDC) announced it would adopt several the bill's provisions.

(6) Following the initial success of the equitable data bill, the Center convened a series of intimate virtual meetings with leading and representative minds in equity and ethics in public health, policy, and health care, throughout the months of April and May 2020. The purpose of these meetings was to gather additional ideas for legislative action to address inequities related to COVID-19. The following is a list of our contributive partners:

America's Essential Hospitals	Illinois Coalition for Immigrant & Refugee Rights
American Public Health Association	National Birth Equity Collaborative
Association of American Indian Physicians	National Council of Asian Pacific Islander Physicians
Civic Health Partners	National Hispanic Medical Association
CommonSpirit Health	National Medical Association
Commonwealth Fund	Trust for America's Health
Families USA	Unidos US

(7) At the behest of the United States Breastfeeding Committee, CHE serves as a leading organizational representative on the Infant and Young Child Feeding Constellation. This body is prompted to review and put forth guidance on the impact and related advantages and/or challenges associated with breastfeeding as the world uncovers additional information about the novel coronavirus, COVID-19.

(8) At the onset of COVID-19, the City of Chicago witnessed high numbers of positive cases, hospitalizations, and deaths due to complications of the virus. An overwhelming number of these cases were among marginalized and minoritized communities. In a valiant effort to quell the rapid spreading of the disease, Mayor Lori Lightfoot instituted a comprehensive, city-wide plan, which included a new mandatory race and ethnicity reporting requirement for all COVID-19 cases reported under the auspices of one of the nation's first Racial Equity Rapid Response efforts. In May 2020, CHE joined this effort, with the goal of (1) supporting data analysis to understand the burden of COVID-19 in Chicago and how that burden varies across the city by race/ethnicity, and (2) leveraging AMA's national reach to elevate this work and learn lessons from efforts in other cities. The WSU collaboration is also a critical component of Chicago Mayor Lori Lightfoot's Racial Equity Rapid Response Team.

<u>4th Quarter 2020 and early 2021 Projections</u>

(1) The COVID-19 pandemic demonstrates that the case for addressing patients' health-related social needs by integrating social care into health care delivery has never been stronger. Pandemics like COVID-19 highlight both the existing challenges in the current health system, lack of coordinated preparedness, and also the fragile state of the safety net health system that supports children, the elderly, people of color, Limited English Proficient persons, geographically challenged persons, people who identify as LGBTQ+, religious minorities, persons with disabilities, and individuals of low socioeconomic status. These communities are even more vulnerable to the uncertainty of the preparation, response, and events surrounding public health crises. This trend is playing out repeatedly—it is a trend that is becoming the clamoring, cacophonous tenor of the American health care system. These experiences expose the need for an evidence-based social determinants approach to maximize the public health of the nation, and the efficacy of this nation's physicians and other health care professionals.

However, health practitioners lack adequate support and training to lead this transformation into an equity-driven system, particularly as they are overwhelmed by the onslaught of COVID-19. As a simultaneous response to this dearth of strategic equity guidance, and in anticipation of the evolved needs of the nation's patient population in the wake of COVID-19, the Center for Health Equity has developed the first ever Centering Equity in Emergency Preparedness and Response: A Health care Institutions' Guide. In addition to the COVID-19 Equity Resource page, the Guide serves as an iterative, living document meant as a guide during public health crises, and also as health systems' transformative guide based on the tenets of applying an equity lens throughout all of a health systems' efforts to embed equity. CHE developed this guidance for physicians as they:

- Renew and refine practice's internal strategic equity preparedness for COVID-19 related care and for future health crises;
- Consider innovative integration of social determinant approaches across communities they service;

- Leverage the suggested resources to bolster the health of physicians, co-workers, and families;
- Access guides and resources that aid physicians in helping patient communities to recover from impacts of COVID-19.

This document has also been reviewed by other institutional partners and is slated for release in 4th Quarter 2020.

(2) In partnership with the Satcher Health Leadership Institute at Morehouse School of Medicine, the Health Equity Advocacy and Leadership (HEAL) Fellowship proposes to close the ever-widening health gap by training physicians who are best positioned to elevate health equity for communities in need. This fellowship—slated for initiation in 2021—will mobilize and engage AMA members in health equity-focused advocacy leadership to use their power and privilege to create positive changes that will address the structural determinants affecting health and implement health projects that will eliminate health disparities. The program will create a common platform for in-depth engagement in exploring a panoply of topics that will give participants concrete tools to enable effective engagement of multidisciplinary sectors and resources required to improve health and community well-being. The Health Equity Advocacy Leadership (HEAL) Fellowship will actualize health equity that is inclusive of the political determinants of health framework developed by the Morehouse School of Medicine's Satcher Health Leadership Institute.

APPENDIX

Figure 1: Current CHE Staff (As of 6/22/20)

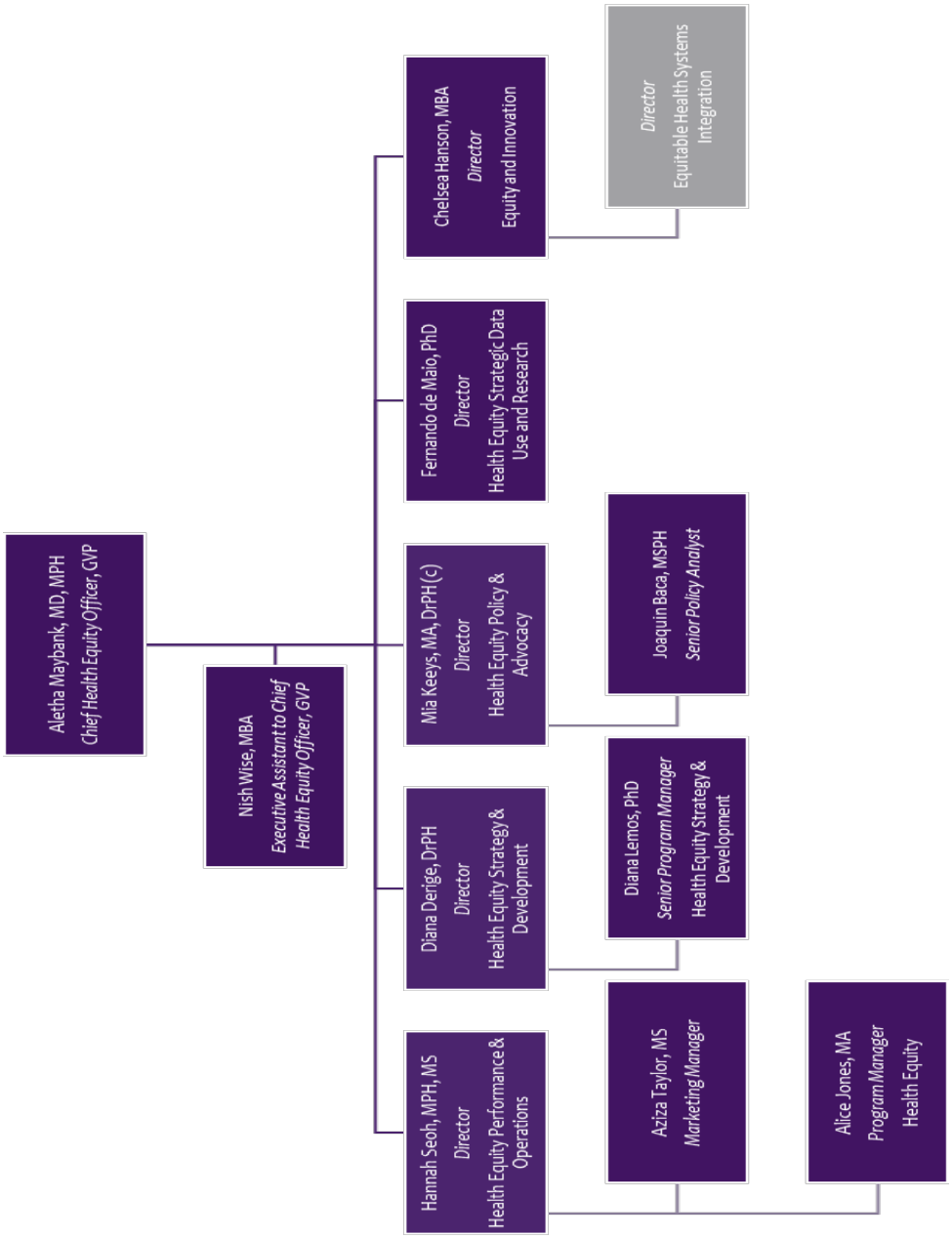

Table 1: AMA Center for Health Equity Supports & Partners (2020-2025)

	Identified Supports and Partners 2020-2025				
	Embed Equity	**Build Alliances & Share Power**	**Push Upstream**	**Ensure Equity in Innovation**	**Create Pathways for Healing**
Cross-Enterprise Partnerships	• All AMA management business units BUs co-creating opportunities and products • Human Resources • Enterprise Communications • EISAMR • Health Solutions • Advocacy • Publishing (Ed/Hub) • Marketing and Membership Experience (MMX) • AMA House of Delegates and Sections/Councils	• MMX[Ambassador Program, MAS (Minority Affairs Section), LGBTQ Advisory Committee, Womens Physicians Section (WPS)] • Advocacy [AMA PAC] • IHO (Improved Health Outcomes) • EISAMR • American Medical Association Foundation • AMA Federation	• IHMI • EISAMR • Health and Science • Med Ed • PS2 • Ed Hub • MMX	• EISAMR • PS2 • Health Solutions • Health & Science • IHMI • Health 2047	• AMA Archives • Health & Science [Ethics] • MMX
External Partnerships		• West Side United • Alliance for Health Equity • National Medical Association • National Hispanic Medical Association • Association of American Indian Physicians • National Council of Asian Pacific Islander Physicians • Congressional Black Caucus • Congressional Hispanic Caucus • Congressional Asian Pacific American Caucus • ESSENCE (Sponsorship) • REACH Media (Sponsorship) • Landmark Ventures (Sponsorship)	• West Side United • MEDICC • APHA (American Public Health Association) • American College of Preventive Medicine (ACPM) • NAACP • Academy of Nutrition & Dietetics	• AfroTech – Blavity • Landmark Ventures (Sponsorship) • HealthTech 4 Medicaid	• National Medical Association • National Hispanic Medical Association • Association of American Indian Physicians • National Council of Asian Pacific Islander Physicians • Harriet Washington – Author of American Apartheid • Meharry Medical College & Morehouse SoM
Consultants (paid)	• Race Forward • Morten Group • Racial Equity Institute • Interaction Institute for Social Change • OnBoard Health • Brandstage		• Health Begins • Advancing Health Equity (Uche Blackstock) • Jonathan Metzl (Vanderbilt)	• Onboard Health	• Kirwan Institute for the Study of Race and Ethnicity

Table 2: AMA Center for Health Equity National Speaking Engagements (November 2019- June 2020)

Table 2: American Medical Association Center for Health Equity National Speaking Engagements (Nov 2019-Present)				
EVENT	**DATE**	**LOCATION**	**PRESENTATION STYLE**	**AUDIENCE REACH**
Exponential	November 7, 2019	San Diego, CA		
Stanford University Artificial Intelligence in Health care: The Hope, The Hype, The Promise, The Peril	November 8, 2019	Stanford, CA	Solo	400
AMA I-19	November 12, 2019	San Diego, CA	Solo	NA
NHHF National Hispanic Health	November 21, 2019	Los Angeles, CA		NA
Brigham's Site Visit	December 12, 2019	Boston, MA		NA
Health Disparities Lecture at Rush	January 9, 2020	Chicago, IL	Solo	NA
MSS Standing Committee	January 12, 2020			NA
Chicago HS for AG Sciences	February 6, 2020	Chicago, IL	Solo	NA
Cook County	February 19, 2020	Chicago, IL	Panel	NA
Sojourner Truth Lecture	February 20, 2020	Claremont, CA	Solo	NA
University of Wisconsin–Madison's La Follette School of Public Affairs Inaugural Health Policy Conference	March 2, 2020	Madison, WI	Keynote Speaker	400+
Women's March/Moms Rising: Talking to Your Kids about Coronavirus	March 17, 2020	Zoom	Panel	1,129
AMA COVID-19 Update	March 25, 2020	Online	Panel	1,977
AMA COVID-19 Update	March 31, 2020	Online	Panel	582
AMA COVID-19 Update	April 2, 2020	Online	Panel	NA
ABA WEBINAR: Implications of the COVID-19 pandemic on African Americans	April 2, 2020	Zoom	Panel	NA
Prioritizing Equity: Physicians of Color and COVID-19	April 2, 2020	Online	Moderator	4,494
National Minority Quality Forum Webinar: (Every Friday since April 2020 to Present)	April 3, 2020 - Ongoing	RingCentral	Moderator	2,000+
AMA COVID-19 Update	April 6, 2020		Panel	550
COVID-19: MA's National Physician Townhall	April 9, 2020	Online	Panel	2,346

Oprah Talks COVID-19: The Deadly Impact of Black America	April 14, 2020		Solo	40,755
Cook County Commissioner Donna Miller's Virtual Town Hall - Our fight against COVID-19 in the southland focus on health equity	April 16, 2020	streamyard.com	Panel	2,900
University of N. Carolina Chapel Hill Class Lecture: Advocacy, Public Policy, & Health Reform: Improving Access to Quality Health Care	April 16, 2020	Zoom	Solo	25
Virtual - AMEC 2020 Speaker Invite	April 18, 2020	app.hopin.to	Solo	1,542
Birthright AFRICA Deep Dive Session	April 19, 2020	app.hopin.to	Panel	2,252
AMA COVID-19 Update	April 21, 2020		Panel	1,045
EPIDEMIC podcast Season 1 Episode 13: A Black Plague	April 21, 2020	Zoom	Solo	NA
AMA Moving Medicine Podcast - US Census 101 for Physicians, Part I	April 21, 2020		Panel	NA
Racial Disparities in the Pandemic, and what they mean for the Future of Medicine	April 23, 2020	Zoom	Solo	NA
Prioritizing Equity: Strengthening the Public Health Infrastructure to Battle Crises	April 23, 2020	Zoom	Moderator	558
COVID-19: The Battle to Save African American Lives Virtual Town Hall	April 30, 2020	Zoom	Panel	1200
National Minority Quality Forum Webinar (Every Friday since May 2020 to Present)	May 1, 2020	RingCentral	Moderator	1600+ to date
Black AZ COVID-19 Task Force	May 8, 2020	WebEX	Solo	100+
NewsOne Panel on COVID-19	May 13, 2020	Online	Panel	3,900
#ListenUpMBC Confab on Young Women's Metastatic Breast Cancer Disparities	May 29-30, 2020	Zoom	Keynote speaker & Moderator	100+
Northern CA Black Physicians Forum	June 12, 2020	TBD	Keynote speaker	NA

Table 3: AMA Center for Health Equity "Prioritizing Equity" YouTube Series (April – August 2020)

Date	Time	Title "Prioritizing Equity:…"	Panelists
4/2/2020	7 PM EDT/6 PM CDT	"Physicians of Color and COVID-19"	Dr. Patrice Harris Dr. Brian Thompson Dr. Elena Rios Dr. Winston F. Wong Dr. Siobhan Wescott
4/23/2020	7 PM EDT/6 PM CDT	"Strengthening the Public Health Infrastructure to Battle Crises"	Dr. Georges Benjamin Dr. J. Nadine Gracia Lori Tremmel Freeman
5/7/2020	7 PM EDT/6 PM CDT	"COVID-19 and the Experiences of Medical Students"	Alec Calac Alex Lindqwister Osose Oboh Sarah Mae Smith Yingfei Wu
5/14/2020	6 PM EDT/5 PM CDT	"COVID-19 and Latinx Voices in the Field"	Dr. Luis Seija Dr. Ricardo Correa Dr. Erica Flores Uribe Dr. Joaquín Estrada
5/21/2020	7 PM EDT/6 PM CDT	"COVID-19 and Native Voices in the Field"	Dr. Mary Owen Dr. Shannon Zullo Dr. Don Warren
5/28/2020	7 PM EDT/6 PM CDT	"The Root Cause"	Dr. Zinzi Bailey Dr. Joia Crear-Perry Dr. Camara Jones Dr. Jonathan Metzl Dr. Whitney Pirtle Dr. Brian Smedley
6/4/2020	1 PM EDT/12 PM CDT	"Police Brutality & COVID-19"	Dr. Rupa Marya Edwin G. Lindo Dr. Atheendar Venkataramani Dr. Mitchel Roger Jr. Dr. Rhea Boyd,
6/11/2020	1 PM EDT/12 PM CDT	"The Root Causes and Considerations for Healthcare Professionals"	LaShyra Nolen Dr. Michael Mensah Dr. Kamini Doobay Dr. Emily Cleveland Manchanda Dr. Brian Williams Dr. David Ansell
6/18/2020	2 PM EDT/1 PM CDT	"LGBTQ+ Health & COVID-19"	Dr. Jesse Ehrenfeld Dr. Blackstock Dr. Shilpen Patel Dr. Asa Radix Dr. David Malebranche
7/2/2020	1 PM EDT/12 PM CDT	"Moving Upstream"	Rishi Manchanda Lauren Powell David Zuckerman Sandra Hernandez
7/16/2020	1 PM EDT/12 PM CDT	COVID-19 & Asian American and Pacific Islander Voices	Dr. Julie Morita Dr. Raynald Samoa Dr. Jay Bhatt Dr. Manisha Sharma Ignatius Bau Dr. Ryan Huerto
8/6/2020	1 PM EDT/12 PM CDT	"Mental Health and COVID-19"	Dr. Patrice Harris Dr. Damon Tweedy
8/20/2020	1 PM EDT/12 PM CDT	"Political Determinants of Health"	Daniel Dawes Rep. Robin L. Kelly

OPINION OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Opinion 1, November 2020

Subject: Physician Competence, Self-Assessment and Self-Awareness

Presented by: Monique A. Spillman, MD, Chair

INTRODUCTION

At the 2019 Interim Meeting, the American Medical Association House of Delegates adopted the recommendations of Council on Ethical and Judicial Affairs Report 1-I-19, "Competence, Self-Assessment and Self-Awareness." The Council issues this Opinion, which will appear in the next version of AMA PolicyFinder and the next print edition of the *Code of Medical Ethics*.

E-8.1.3 – Physician Competence, Self-Assessment and Self-Awareness

The expectation that physicians will provide competent care is central to medicine. It undergirds professional autonomy and the privilege of self-regulation granted by society. To this end, medical schools, residency and fellowship programs, specialty boards, and other health care organizations regularly assess physicians' technical knowledge and skills.

However, as an ethical responsibility competence encompasses more than medical knowledge and skill. It requires physicians to understand that as a practical matter in the care of actual patients, competence is fluid and dependent on context. Each phase of a medical career, from medical school through retirement, carries its own implications for what a physician should know and be able to do to practice safely and to maintain effective relationships with patients and with colleagues. Physicians at all stages of their professional lives need to be able to recognize when they are and when they are not able to provide appropriate care for the patient in front of them or the patients in their practice as a whole.

To fulfill the ethical responsibility of competence, individual physicians and physicians in training should strive to:

(a) Cultivate continuous self-awareness and self-observation.

(b) Recognize that different points of transition in professional life can make different demands on competence.

(c) Take advantage of well-designed tools for self-assessment appropriate to their practice settings and patient populations.

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* Opinions of the Council on Ethical and Judicial Affairs will be placed on the Consent Calendar for informational reports, but may be withdrawn from the Consent Calendar on motion of any member of the House of Delegates and referred to a Reference Committee. The members of the House may discuss an Opinion fully in Reference Committee and on the floor of the House. After concluding its discussion, the House shall file the Opinion. The House may adopt a resolution requesting the Council on Ethical and Judicial Affairs to reconsider or withdraw the Opinion.

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(d) Seek feedback from peers and others.

(e) Be attentive to environmental and other factors that may compromise their ability to bring appropriate skills to the care of individual patients and act in the patient's best interest.

(f) Maintain their own health, in collaboration with a personal physician, in keeping with ethics guidance on physician health and wellness.

(g) Intervene in a timely, appropriate, and compassionate manner when a colleague's ability to practice safely is compromised by impairment, in keeping with ethics guidance on physician responsibilities to impaired colleagues.

Medicine as a profession should continue to refine mechanisms for assessing knowledge and skill and should develop meaningful opportunities for physicians and physicians in training to hone their ability to be self-reflective and attentive in the moment. (I, VII, VIII)

REPORT 4 OF THE COUNCIL ON MEDICAL EDUCATION (November 2020)
Preparedness for Pandemics Across the Medical Education Continuum
(Informational)

EXECUTIVE SUMMARY

As the coronavirus (COVID-19) spread throughout the United States, the nation's medical education community was forced to prepare for a variety of issues across the medical education continuum. While the 2017 Department of Health and Human Services Pandemic Influenza Plan offered guidance on how to respond to a pandemic, education, including medical education at all levels, was not included as a distinct domain that needed to be supported with planning. At the March 15, 2020, meeting of the Council of Medical Education, members decided to develop an informational report on preparedness for pandemics across the medical education continuum in the context of COVID-19 for the November 2020 House of Delegates meeting. This informational report provides a framework for preparedness for pandemics and other large-scale public health emergencies across medical education based on lessons learned from the COVID-19 pandemic.

This report provides an overview of COVID-19 in the United States and discusses the following:

- The impact of COVID-19 on U.S. undergraduate medical education (UME),
- The impact of COVID-19 on U.S. graduate medical education (GME),
- The impact on international medical graduates entering GME programs in the U.S.,
- The impact of COVID-19 on continuing medical education (CME) in the U.S.,
- The impact of COVID-19 on mental health of students, residents, and physicians, and
- Efforts by key stakeholders to address issues in medical education, training, licensure, and credentialing.

The Council on Medical Education is committed to best equipping individuals for success at various points in their medical career while ensuring patient safety. As such, the Council on Medical Education anticipates there will be evolving issues related to COVID-19 and will continue to monitor the evolution of these issues.

REPORT OF THE COUNCIL ON MEDICAL EDUCATION

CME Report 4, November 2020

Subject: Preparedness for Pandemics Across the Medical Education Continuum

Presented by: Liana Puscas, MD, MHS, Chair

INTRODUCTION

The first confirmed coronavirus (COVID-19) case in the United States was reported on January 21, 2020. As COVID-19 increasingly spread throughout the United States, the nation's medical education community was forced to prepare for a variety of issues across the medical education continuum, including, but not limited to:

- Conscientious oversight of the deployment of medical students;
- Recommended trajectory for medical students transitioning from graduation to residency;
- Student and trainee movement across geographic areas for interviews and clinical rotations;
- Field promotion of fellows to attending roles;
- Access to, and instruction in, the use of adequate personal protective equipment;
- Accreditation, licensure, examination, and certification requirements;
- Flexibility in graduate medical education reimbursements;
- Guidelines for volunteer clinical work;
- Maintaining standards for credentialing and competencies during this time of emergency;
- Continuing education offerings for practicing physicians.

Based on lessons learned from the COVID-19 pandemic, the Council on Medical Education offers this informational report to provide a framework for preparedness for pandemics and other large-scale public health emergencies across the medical education continuum.

OVERVIEW OF COVID-19 IN THE UNITED STATES

In late December 2019, officials in Wuhan, the capital of China's central Hubei province, confirmed dozens of cases of pneumonia from an unknown cause in the region.[1] In January 2020, the outbreak was confirmed as a new coronavirus, and on March 11, the World Health Organization declared the outbreak of coronavirus (COVID-19) to "be characterized as a pandemic."[2] The first confirmed COVID-19 case in the United States was reported on January 21, 2020.[3] The outbreak initially appeared contained through February; however, by mid-March, transmission of SARS-CoV-2, the virus that causes COVID-19, had accelerated, with rapidly increasing case counts indicating established transmission in the United States. Factors that contributed to the rapid acceleration of the spread of COVID-19 included continued importation of the virus by travelers infected elsewhere; attendance at professional and social events, which amplified the transmission of COVID-19 in the host locations and multistate spread; introduction of the virus into facilities or settings prone to amplification such as long-term care facilities and high-density urban areas; and challenges in virus detection, including limited testing, emergence

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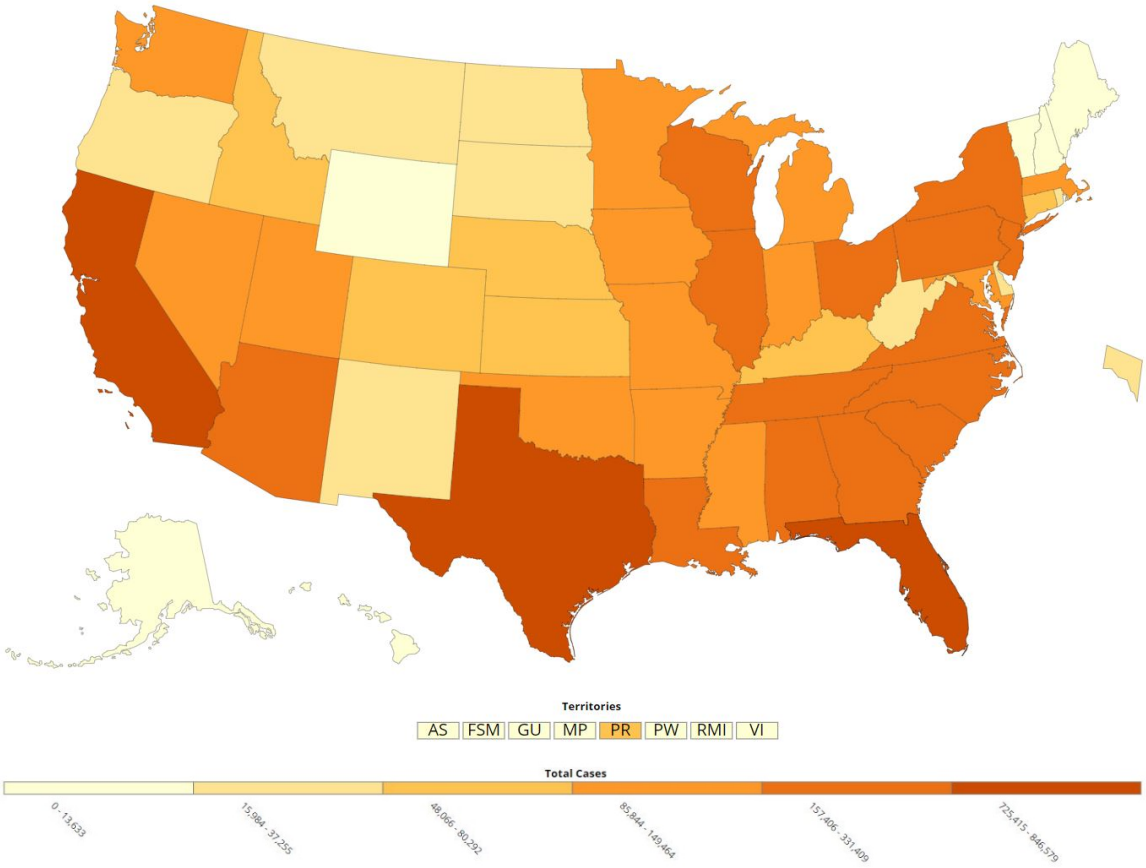
during the peak months of influenza circulation and influenza and pneumonia hospitalizations, and other cryptic transmission including from persons who were asymptomatic or presymptomatic.[3]

As of October 12, 2020, a total of 7,740,934 cases and 214,108 deaths in the United States were reported to the Centers for Disease Control and Prevention (CDC) since January 21, 2020. The states with the highest number of cases include California (846,579); Texas (792,478); Florida (725,415); New York (475,540) and Georgia (331,409). New York City leads the country in the number of total cases (251,618) in a city.[4] The map in Figure 1 highlights the total number of COVID-19 cases in the U.S. reported to the CDC by state/territory.

Figure 1 Total number of COVID-19 Cases in the US by state/territory reported to the CDC as of September 15, 2020



Source: CDC COVID Data Tracker, 2020

As the number of confirmed cases in the United States continued to grow, so did concern for the hospitals and health care facilities' capacity to respond to the pandemic. In 2005, the U.S. Department of Health and Human Services (HHS) developed the inaugural Pandemic Influenza Plan, which was most recently updated in 2017 to model the potential health care impact of moderate and severe influenza pandemics.[5] It suggested that a moderate pandemic would infect about 64 million Americans, with about 800,000 (1.25%) requiring hospitalization and 160,000 (0.25%) requiring beds in the intensive care unit (ICU). The plan also suggested that a severe pandemic would dramatically increase these demands. The 2017 Plan identified the following seven domains to support planning for the next decade:

- Surveillance, epidemiology, and laboratory activities;
- Community mitigation measures;
- Medical countermeasures: diagnostic devices, vaccines, therapeutics, and respiratory devices;
- Health care system preparedness and response activities;
- Communications and public outreach;
- Scientific infrastructure and preparedness; and
- Domestic and international response policy, incident management, and global partnerships and capacity building.

These domains expanded upon the original four key pandemic response elements of the original 2005 plan to reflect an end-to-end systems approach to improving the way preparedness and response are integrated across sectors and disciplines, while remaining flexible for the conditions surrounding a specific pandemic.[6] Of note, education, including medical education at all levels, was not included as a distinct domain that needed to be supported with planning, which complicated the development of a strategic response.

According to the American Hospital Association, there were 5,198 community hospitals and 209 federal hospitals in the United States in 2018. In community hospitals, there were 792,417 beds, with 3,532 emergency departments and 96,500 ICU beds, of which 23,000 were neonatal and 5,100 pediatric, leaving just under 68,400 ICU beds of all types for the adult population.[6] The extraordinary and sustained demands of responding to patients affected by COVID-19 on public health, health systems, and providers of essential community services created the need to ration medical equipment and interventions.[7] The earliest example was the near-immediate recognition that there were not enough high-filtration N-95 masks for health care workers, prompting contingency guidance on how to reuse masks designed for single use.[8] In addition, acute care hospitals in the United States currently have about 62,000 full-function ventilators and about 98,000 basic ventilators, with an additional 8,900 in the Office of the Assistant Secretary for Preparedness and Response Strategic National Stockpile.[9] While all hospitals have some lifesaving ventilators, that number of available ventilators is proportional to the number of hospital beds in the institution. As a surge of need develops in a particular community, all hospitals in the area then compete for a finite number of resources, which could lead to difficult decisions regarding who gets access to a ventilator and who does not.[10]

To prevent overburdening U.S. hospitals and health care facilities, immediate efforts were implemented to slow the spread of COVID-19. This was known as “flattening the curve.” These efforts included strict social distancing practices and stay-at-home orders. Social distancing has been identified as the most effective preventive strategy since the emergence of COVID-19 pending development of a vaccine, treatment, or both.[11] California Governor Gavin Newsom was the first governor to issue a stay-at-home order on March 19, and by early April many states had restrictions in place to mitigate the spread of the disease.[12]

THE IMPACT OF COVID-19 ON U.S. UNDERGRADUATE MEDICAL EDUCATION

Prior to COVID-19, most medical schools convened students in physical settings during the first 12 to 18 months of classes for interactive problem-solving or discussions in small groups, the students’ physical presence in both inpatient and outpatient settings being an accepted tenet of early clinical immersion experiences and the clerkship curriculum. The last 18 months of medical school may be individualized, with students participating in advanced clinical rotations, subinternships prior to residency, or scholarly projects. While efforts to provide individualized

instruction for asynchronous learning existed prior to COVID-19, students still convened in-person for small-group interactions, laboratory sessions, simulations, and technology sessions, as well as for clinical instruction with standardized patients and in authentic patient care environments.[13] The advent of strict social distancing altered undergraduate medical education in a multitude of ways. The traditional classroom experience shifted to virtual instruction, which severely limited on-campus activities and interactions, to minimize gathering in large groups and spending prolonged time in close proximity with faculty, staff, and students in spaces such as classrooms, learning studios, lecture halls, or small-group rooms. These changes also required faculty to rethink how they teach.

On March 17, 2020, the Association of American Medical Colleges (AAMC) issued a guidance document recommending that member schools suspend medical student participation in activities that involve patient contact.[14] The high probability that medical students in the hospital would be exposed to COVID-19 and the need to conserve personal protective equipment (PPE) seemed to outweigh the educational benefits of students' participation. By decreasing non-essential personnel in health care settings, including medical students, medical schools contributed to national and global efforts to "flatten the curve."[15]

With the removal of students from clinical sites, medical schools quickly developed curricula for their clinical students who were unable to see patients in person. For example, a teaching hospital affiliate of the University of Minnesota Medical School created a database of about 1,400 patients at risk of SARS-CoV-2 infection. The hospital implemented a system to send daily emails to these patients asking about COVID-19 relevant symptoms, such as fever, cough, and shortness of breath. Any patient who reported one or more of the symptoms would then receive a call from a third- or fourth-year medical student. The student would take a history and staff the patient with a supervising resident. Similarly, the Boonshoft School of Medicine in Ohio created an elective in which students worked through online modules on psychological first aid and behavioral activation. Each student was then paired with an isolated older adult in the community with whom they made weekly virtual social visits to ensure patient access to food, water, shelter, and medications, as well as the ability to pay bills. In another example, the Association of Professors of Gynecology and Obstetrics (APGO) at the University of Vermont Larner School of Medicine developed a two-week elective using APGO's medical student educational objectives and vast library of basic science videos. Students completed about six video cases per day in obstetrics and gynecology, sexuality, intimate partner violence, and sexual assault; with each requiring critical thinking and the development of differential diagnoses. An assessment of the student's knowledge was done through APGO-developed quizzes.[16] The AMA Medical Education Department curated a crowdsourced list of potential resources—both free and paid—for virtual or remote clinical and non-clinical learning (https://www.ama-assn.org/delivering-care/public-health/covid-19-resources-medical-educators). The AMA did not review or endorse any of the listings, aside from those created directly by the AMA. Rather, they were are provided as a resource to help medical educators determine the best ways to teach remote learners during the coronavirus pandemic.

Medical students also identified numerous ways to volunteer their time and efforts to support health care teams and patients during COVID-19. For example, medical students at the University of Texas Southwestern launched a wave of volunteerism as campus educational programs and research activities scaled back amid concerns over COVID-19. These students collaborated with institutional leadership to identify immediate as well as long-term needs to support and supplement the efforts of front-line clinical teams and staff; these efforts, which aligned with national guidelines for medical student volunteerism, allowed learners to provide maximum support while minimizing their own risk. Volunteer activities included helping to screen hospital visitors, answering phones, moving furniture, and delivering supplies.[17] In Chicago, students from

Northwestern University, Rosalind Franklin University of Medicine and Science, University of Chicago, Rush Medical College, Loyola University, Midwestern University, and University of Illinois at Chicago recruited more than 500 volunteers for the COVID Rapid Response Team Chicago to secure PPE and distribute them to the front lines of the epidemic, in addition to working to boost support for blood drives, performing laboratory tests, and organizing food drives for health care workers who did not have time to buy groceries.[18] Additionally, the AAMC established *iCollaborative (*https://icollaborative.aamc.org/collection/covid-19-student-service-projects*)* a compendium of student volunteer and relief initiatives

COVID-19 also prompted the creation of a process for early graduation of final-year medical students. On March 24, 2020, the Grossman School of Medicine at New York University (NYU) became the first medical school in the United States to announce an offer of early graduation to eligible students. The school's decision came as its hospitals were overwhelmed with an increasing number of COVID-19 patient cases, including in critical care.[19] Similar actions were taken by the medical schools at Tufts University, Boston University, and the University of Massachusetts following a request from the state of Massachusetts to help expand the medical work force. Massachusetts also provided 90-day provisional licenses for early graduates, allowing almost automatic entry into clinical work and making approximately 700 medical students in the state eligible to offer patient care at least eight weeks earlier than expected.[20]

While innovative efforts to respond to the health care demands of COVID-19 were rapidly and successfully implemented in some areas, uncertainty in other aspects of medical education proved problematic for medical students including administration of medical college admission and licensing examinations as well as the impact of testing center closures.

Aspiring premed college students were also impacted by disruptions to medical education. For example, the Medical College Admission Test (MCAT) is required by the AAMC to be taken in person. Due to COVID-19, the AAMC cancelled MCATs scheduled for March, April, and most of May, and the lack of communication regarding the cancellation of tests proved to be problematic. On May 7, the AAMC opened its MCAT scheduling system for applicants who needed to reschedule or make their initial testing appointment. However, the system was not prepared to handle the volume of individuals trying to schedule their exams, and it crashed. Additionally, those who needed special testing accommodations found the process to secure the necessary accommodations to be difficult. Additionally, MCAT test-taking stations were to be set up in accordance with social and physical distancing guidelines: Eight people can take the test together at one time and masks are required, among other changes. However, students expressed concern that the changes were insufficient to ensure safety or equality in taking the test and, in July, it was reported that three students had tested positive for COVID-19 from 2 to 7 days after taking the in-person MCAT exam.[20]

On March 18, 2020, Prometric, the private company that administers the United States Medical Licensure Examinations® (USMLE®) Step 1, Step 2 Clinical Knowledge (CK), and Step 3 exams closed its test centers in the U.S. and Canada through May 1, 2020. On May 1, 2020, Prometric resumed testing in a limited capacity in the U.S. and Canada for essential services programs and opened some of its locations for USMLE testing at 50% capacity. To accommodate this change, the company randomly selected thousands of appointments for cancellation.[21] On June 1, 2020, Prometric resumed testing, where possible, for all programs in numerous states and regions across North America. It is estimated that cancellations affected 17,000 medical students and residents through mid-May. Criticisms of Prometric's administration of the exams describe the process as "chaotic, poorly communicated, discriminatory, and outright harmful."[22] Inconsistent and often conflicting information from Prometric and the USMLE resulted in confusion and frustration for

test-takers. Last-minute cancellations of these exams continued through early June, sometimes just hours before exams were to start. Students also reported arriving at testing centers for exams, only to find them closed. In response to demand for increased testing capacity, USMLE developed a phased approached to expand testing centers. Phase one established a small number of testing sites in medical schools using Prometric equipment for different geographical regions across the U.S. Phase two sought to determine the school's level of interest and ability to participate in event-based testing to administer Step 1 and Step 2 CK among Liaison Committee on Medical Education (LCME)-accredited medical schools and American Osteopathic (AOA)-accredited medical schools.[22]

The situation also exposed inherent inequities in the system. Those who required testing accommodations were even further disadvantaged as they could not use the online system. People with learning disabilities, mobility impairments, type 1 diabetes, and anyone who was pregnant or breastfeeding was required to reschedule their exam by phone during business hours and often encountered hours-long waits. Additionally, equity concerns were raised when the National Board of Medical Examiners (NBME) announced that an abbreviated version of the examinations would be made available to those participating in event-based testing held at medical schools in July and August. The proposed changes would have cut approximately two hours from the total eight-hour test time. The shorter version also included the elimination of experimental questions, which are not scored but are used to determine whether they are valid indicators of a test-taker's performance. This plan met with an immediate backlash, and the USMLE announced on June 9, 2020, that a reduced-length test would not be offered to students taking Step 1 and Step 2 CK exams.[23]

Additionally, on May 26, 2020, the USMLE announced that Step 2 Clinical Skills (CS) exams would be suspended for a period of 12 to 18 months.[23] Step 2 CS aims to examine clinical skills in a performance-based setting; its primary purpose is medical licensure. Additionally, Step 2 CS is an important metric for international medical graduates looking to match into a U.S. residency program. Successful completion of Step 2 CS is a graduation requirement to begin the first year of residency. Suspension of the exam made meeting that requirement impossible for some medical students in the upcoming residency application cycle. A variety of factors influenced the suspension of Step 2 CS, including discouragement of non-essential travel as well as health and safety risks associated with using standardized patients.[24]

Similar to Prometric, the National Board of Osteopathic Medical Examiners' (NBOME) National Center for Clinical Skills Testing (NCCST), which administers the COMLEX-USA Level 2-Performance Evaluation, also temporarily closed its testing center due to COVID-19. On June 3, 2020, the NBOME announced its decision to postpone resumption of COMLEX-USA Level 2-PE testing until September 1, 2020. The scheduling change has complicated the ability of some students with 2021 graduation dates to complete examinations by the end of the 2020-21 academic year and has impacted DO students differently than their MD student counterparts. Following that decision, the Commission on Osteopathic College Accreditation (COCA) announced its decision to allow deans at colleges of osteopathic medicine to waive the requirement to pass the COMLEX Level 2-PE clinical skills exam for 2021 graduates.[25] Concerns have been raised by both DO and MD students regarding the differences in NBME & NBOME policies regarding testing during COVID-19.

The process for residency interview and selection was also impacted by COVID-19. The Coalition for Physician Accountability (CPA)—a national group of organizations concerned with the oversight, education, and assessment of medical students and physicians throughout their medical careers and of which the AMA is a member—issued recommendations concerning three major issues facing applicants and training programs as they prepare for the 2020-2021 residency

application cycle: away rotations, in-person interviews for residency, and the ERAS® (Electronic Residency Application Service) timeline. Specifically, the CPA recommended discouraging away rotations with limited exceptions; committing to online interviews and virtual visits for all applicants rather than in-person interviews for the entire cycle; and delaying both the opening of ERAS® for residency programs and the release of the medical student performance evaluation.[26]

These recommendations were not without consequences. For example, participation in away rotations is especially common within the competitive surgical subspecialties. In many of these fields, 50 percent or more of students completing away rotations match at a program where they rotated so suspension of these rotations could weaken students' applications.[27] Furthermore, as regions of the United States lift social distancing measures at different times throughout the coming year, a potential inequity could be created if some institutions accept external students for clinical rotations while other programs do not. Additionally, students attending school in an area where they must remain quarantined may be disadvantaged if students in other geographic areas are able return more quickly to clinical activities and travel to externship rotations.[27] Additional concerns were raised regarding the removal of financial constraints from in-person interviews, leading to a rise in qualified applicants over-applying for the limited number of available residency slots. Prior to COVID-19, the number of interviews an applicant could attend was limited by time and travel expense, but these constraints will be less relevant with virtual interviews. Students who are fearful of how their applications will be evaluated may respond by applying to even more programs and accepting more interview invitations which could lead to an increase in both the number of unmatched applicants and unfilled programs.[28]

To support and protect medical students during this time of uncertainty, the AMA Council on Medical Education developed guiding principles for conscientious oversight of the deployment of medical students. (see Appendix 2).

THE IMPACT OF COVID-19 ON U.S. GRADUATE MEDICAL EDUCATION

The process for onboarding early graduation medical students into residency programs was an evolving one beginning in April 2020. At NYU Langone Health, early graduates were initially anticipated to be supplemental to the teams caring for non-COVID-19 patients. However, due to the demand, these graduates were integrated into the health system's internal medicine and emergency medicine departments regardless of their match specialty. While both the current residents and early graduates expressed concerns about the transition from medical school to the wards during a national pandemic, NYU created a boot camp for them to address circumstances specifically related to COVID-19. The curriculum focused on the proper use of PPE, treatment protocols related to the virus, physician and patient isolation, and the moral distress physicians may feel treating COVID-19 patients. NYU also paired early graduates with residents who were not on service during the boot camp as part of the orientation.[29] To conform with their Match agreements, early graduates were not part of any specific residency program at NYU. Under an executive order from New York Governor Andrew Cuomo, graduates of medical schools accredited by the LCME and AOA, and matched into an Accreditation Council for Graduate Medical Education (ACGME)-accredited residency program in or outside New York, were eligible to temporarily practice medicine in New York under the supervision of a licensed physician prior to reporting to their matched program and did not have to apply for a license to do so.

Residents have been on the front lines during the COVID-19 response and like other health care workers, experienced some of the highest exposure risk situations and have the same need for PPE. Unfortunately, health care systems across the United States have reported substantial PPE shortages since the start of COVID-19 pandemic, compromising their ability to keep health care

professionals (including residents) safe while treating increasing numbers of patients.[30] The situation became so dire that some providers utilized social media with tags like #GetMePPE to raise public awareness. The Society for Healthcare Epidemiology of America (SHEA) conducted a survey in April 2020, among epidemiologists and infectious disease specialists at health care facilities in the United States, Canada, and abroad regarding how their facilities were adapting their PPE policies as shortages and knowledge about the coronavirus evolved. SHEA found that 52 percent of respondents said they had to ask health care workers in certain hospital units to use the same disposable N95 respirator for a whole day, 71 percent who reported PPE at "limited" or "crisis" levels practiced extended respirator use or reuse, and 48 percent said they reprocessed respirators. Some health care workers used surgical or cloth masks over their respirators and stored them in a paper bag to preserve them for reuse. Moreover, 59 percent of respondents who said their hospitals' supply of gowns was "limited" or "crisis-level" were having to wear gowns for an extended time or reuse them, and 13 percent said they were making their own PPE, including face shields, eye shields, coveralls, gowns, and surgical masks.[31]

Involvement of residents and fellows in COVID-19 care has varied by specialty and rapidly evolved. Some of these residents may have cared for patients with COVID-19 during assigned rotations. Others were asked to assume roles that were not a prescribed part of their specialty training, being deployed to medical units and emergency departments away from their roles in operating rooms and outpatient clinics. Residents may have been compelled to acquire skills on the job that were not an expectation when they began residency. Furthermore, time spent providing these services may not meet the requirements for graduation and certification in their discipline, leading to concerns that their training may need to be extended when routine clinical duties resume. Additionally, some subspecialty fellows were asked to serve in attending physician roles in their core disciplines (e.g., gastroenterology fellows serving as general internal medicine attending physicians). While they may have been board-certified in these specialties, their compensation and malpractice coverage were not guaranteed to be commensurate with the role. This is important, since resident salaries are low compared to those of other health care workers, particularly on an hourly basis. Given average resident salaries and an 80-hour work week, resident salaries equate to approximately $15 to $20 per hour. In addition, residents carry significant debt loads related to their undergraduate medical education. The average student loan burden at medical school graduation exceeds $200,000.

COVID-19 also highlighted the need for flexibility in GME reimbursement. Medicare GME affiliated group agreements are often in place at the beginning of the academic year (i.e., prior to July 1) to transfer cap slots between institutions and allow the host institution to claim the inbound rotator for reimbursement. If a rotation is canceled, the home hospital may find itself claiming more resident full-time equivalents (FTEs) than its cap allows, and the host hospital may find itself with more cap slots than resident FTEs it has to claim, impacting the GME reimbursement for both. It should be noted, however, that it is possible to amend a Medicare GME affiliated group agreement during the ongoing academic year (i.e., prior to June 30), provided that any changes are made only to the original parties to the agreement. Additionally, financial issues may arise if residents become "off cycle" and require additional time to complete their training. Residents are only eligible for funding for the accredited length of their program, and additional time is not reimbursed by the Centers for Medicare & Medicaid Services (CMS).

On top of the issues already presented, some residents who became ill and/or required quarantine while caring for COVID-19 patients learned that their residency program leave policies did not adequately account for these unplanned absences during the pandemic response. In response to the concerns of residents and fellows, the AMA developed guidance for residency programs to

adequately address the personal, physical, and economic stresses that trainees face. Some key points of the guidance include:

- Residents who become ill as a result of their participation in the COVID-19 response must not be required to use vacation or personal time off while ill or quarantined.
- Residents who require leave under these circumstances must continue to receive their salary and benefits.
- Residents deployed to clinical areas unfamiliar to them must receive appropriate training and supervision for the tasks they will be asked to perform.
- Clinical work that residents perform during the pandemic response should be considered in assessments of a trainee's qualifications for program completion. Where possible, credit should be given for the work residents are doing during this time.
- Bodies overseeing certification requirements should allow flexibility in assessments of the competence of trainees, in light of the pandemic. Where possible, these assessments should not delay program completion nor eligibility for certification.
- Fellows who assume attending physician roles in core disciplines in which they are licensed and certified should receive pay and benefits commensurate with these roles. The impact of this activity on progress toward completion of the training program must be openly discussed with fellows prior to them assuming these responsibilities.

The guiding principles to protect resident and fellow physicians responding to COVID-19 are featured in Appendix 3.

THE IMPACT OF COVID-19 ON INTERNATIONAL MEDICAL GRADUATES ENTERING GME PROGRAMS IN THE U.S.

As states called for more doctors to help meet the demand of the growing number of COVID-19 cases, non-U.S. citizen international medical graduates (IMGs) faced unique challenges that prevented them from responding due to visa limitations. Currently, non-U.S. citizen IMGs with H-1B visas and J-1 waivers face restrictions on where they can work.[32] Furthermore, the U.S. Citizenship and Immigration Services (USCIS) announced on March 20, 2020, its suspension of premium processing for all Form I-129, Petition for a Nonimmigrant Worker and I-140, Immigrant Petition for Alien Workers due to the coronavirus (COVID-19) pandemic.[33] This suspension was anticipated to exacerbate physician shortages, particularly in rural areas, and at the leading academic and research organizations that depend on health care provided by non-U.S. citizen IMGs. On April 9, 2020, U.S. Senators Dick Durbin (D-IL), Tammy Duckworth (D-IL), Amy Klobuchar (D-MN) along with colleagues in both the House and the Senate wrote a bipartisan, bicameral letter urging the Administration to resume premium processing for physicians seeking employment-based visas.[34] On May 29, 2020, USCIS announced it would resume premium processing for Form I-129 and Form I-140 in phases beginning June 1, 2020.[35] Moreover, USCIS announced that non-U.S. citizen IMGs can deliver telehealth services during the public health emergency without having to apply for a new or amended Labor Condition Application and that it is temporarily waiving certain immigration consequences for failing to meet the full-time work requirement.

On June 22, 2020, the President of the United States issued a Presidential Proclamation. As it pertains to physicians, the Proclamation states that there are exemptions for:

- Sec. 4(a)(i)… [individuals who] are involved with the provision of medical care to individuals who have contracted COVID-19 and are currently hospitalized; are

involved with the provision of medical research at United States facilities to help the United States combat COVID-19…

- Or Sec. 3(b)(iv) any alien whose entry would be in the national interest as determined by the Secretary of State, the Secretary of Homeland Security, or their respective designees.

J-1 physicians have been given an exemption from the June 22, 2020 Proclamation. However, the Proclamation still applies to most H-1B physicians. Per the AMA letter to Vice President Pence sent on May 4, 2020, urging the Administration to allow J-1, H-1B, and O-1 International Medical Graduates (IMGs) to be exempt from any future immigration bans or limitations, AMA has been aware of, and advocating against, any physician immigration bans since before this Proclamation was issued.

In response to the Proclamation, the Department of State (DOS) issued a statement that "as resources allow, embassies and consulates may continue to provide emergency and mission-critical visa services. Mission-critical immigrant visa categories include applicants who may be eligible for an exception under these presidential proclamations, such as…certain medical professionals." As such, on June 26, 2020, the AMA sent a letter to the Department of Homeland Security (DHS) and the Department of State strongly urging the Administration to consider J-1 and H-1B IMGs and their families' entry into the U.S. to be in the national interest of the country so that families can remain together and non-U.S. citizen IMG physicians can immediately begin to provide health care to U.S. patients. The AMA understands that every physician is mission critical, especially at this time. Moreover, the AMA spearheaded a sign-on letter for specialty societies. The letter urges the DOS and DHS to issue clarifying guidance pertaining to the Proclamation by directing Consular Affairs to advise embassies and consulates that H-1B physicians and their dependent family members' entry into the U.S. is in the national interest of the country.

On July 6, 2020, the Student and Exchange Visitor Program (SEVP) announced that nonimmigrant F-1 and M-1 students attending schools operating entirely online could not take a full online course load and enter or remain in the United States. In response, on July 9, 2020, the AMA sent a letter urging the Administration to withdraw its modifications to the temporary exemptions for nonimmigrant students taking online classes due to the pandemic for the Fall 2020 semester, so that medical students seeking to study in the U.S. on an F-1 visa could enter or remain in the country. In part due to the advocacy efforts of the AMA, on July 14, 2020, the Trump Administration rescinded the directive.

In addition to advocating for non-U.S. citizen IMGs, the AMA developed guidance to help ensure that visa-related issues do not prevent non-U.S. citizen IMGs from continuing to care for patients during COVID-19; this document is featured in Appendix 4.

THE IMPACT OF COVID-19 ON EFFORTS TO INCREASE DIVERSITY AMONG MEDICAL STUDENTS AND RESIDENTS

As medical school enrollment doubled over the past two decades, the percentage of entering under-represented students actually fell by 16%.[36] Even prior to COVID-19, national data suggested medical education was already losing ground with respect to racial and ethnic parity. Diversity efforts are particularly vulnerable during times of disruption; hence institutions must heighten their commitment of attention and resources. Current disruptions related to COVID-19 may amplify underlying inequities in our educational system, similar to the pandemic's role in exacerbating health inequities. Broader initiatives to foster long-term change in medicine and address inequities in the entire United States educational system are imperative and are underway. To support these

efforts, the AMA developed guidance to protect underrepresented students and residents during COVID-19; this document is featured in Appendix 5.

THE IMPACT OF COVID-19 ON CONTINUING MEDICAL EDUCATION IN THE U.S.

With the increased demand for physicians to respond to COVID-19 cases, many physicians who had left practice had a desire to return. Like many professionals, physicians take time off to raise children, care for sick family members, or recover from their own illnesses. Some also switch to non-clinical jobs. But efforts to return to medicine are more difficult than in most careers, as clinical change occurs quickly. Drugs, devices, and surgical techniques that were standard a decade ago may now be obsolete, and a returning doctor's skills may simply be outdated. The AMA defines physician re-entry as "a return to clinical practice in the discipline in which one has been trained or certified following an extended period of clinical inactivity not resulting from discipline or impairment." Re-entry is a complicated, time-consuming, and expensive process. While inactive physicians may not lose their licenses, they must complete a physician reentry program if they stop practicing for a certain length of time (it varies by state but averages about three years). Unfortunately, there is a dearth of training programs for physicians who have already completed residency training and need retraining.[37] Reentry programs also cost most returning physicians between $3,000 and $10,000 per month, not including travel and relocation costs for the duration of the training. While each program has different features, they all require some type of assessment to determine the physician's skill set and clinical competence. After completing a reentry program, physicians who have let their license lapse have to petition their state board to reactivate it. Once licensure is granted, reentering physicians can then obtain hospital privileges and insurance coverage.

Likewise, many senior and retired physicians may have either wanted to return to work or were called upon to do so during the COVID-19 outbreak, which raised additional considerations. For example, the licensure status of retired physicians varies by state. In some states retired physicians maintain their regular license, while others create a separate category for retired or inactive physicians, and still others have no license category for retired physicians. The path to reentry from a licensing perspective also varies. For senior and retired physicians who maintain active licenses, there are no licensure restrictions on re-entry to practice. For physicians who maintain an inactive, retired physician, or similar license, their state may have temporarily waived any barriers to re-entry due to COVID-19.

The issue of whether senior physicians should be providing direct patient care for COVID-19 patients is a complex one that must balance a number of factors, such as whether the age of the physician and their family members puts them in a high risk group, whether PPE is readily available, and whether they can contribute meaningfully in a non-direct patient care role.

The Federation of State Medical Boards (FSMB) has developed a repository of state-issued guidelines for expediting licensure for health care workers whose licenses are inactive or expired. As of June 9, 2020, 39 states issued guidelines waiving some of the requirements for physician reentry in response to COVID-19, though most require that physicians be recently retired (within the last two to five years).[38] Forty-nine state medical boards have policies or regulations that dictate what physicians need to do to reenter medicine after "an extended period of clinical inactivity." That period differs for each state but ranges from 1 to 10 years. After the designated time allotment, the board usually requires an evaluation before granting a license to practice medicine.

Additional factors that need to be considered for senior physicians looking to go back to work include professional and medical liability, clarification of roles, and the effect of income on

retirement status. The AMA developed a resource guide, featured in Appendix 6, to assist senior physicians as they consider these important issues.

THE IMPACT OF COVID-19 ON THE MENTAL HEALTH OF STUDENTS, RESIDENTS, AND PHYSICIANS

Critical stressors for medical students, residents, and physicians during COVID-19 are the uncertainty surrounding the pandemic; trauma associated with knowing there is a risk to one's own health; and concern for the safety and well-being of one's patients, as well as one's family and friends.[39] Many students reported moral distress associated with watching patients in isolation from loved ones and described feeling distant from patients while wearing PPE as well as disappointment and frustration about not being able to help. Safety concerns among residents and fellows are complicated by the recognition that their decisions had implications for their loved ones and others outside the hospital. Some worried about transmitting infection to others in their homes. Feelings of vulnerability were exacerbated by rapidly changing conditions and recommendations. The fear of potential PPE shortages was prominent. Trainees not providing COVID-19 care because of personal health issues expressed guilt that colleagues had to step in. These feelings of anxiety and vulnerability among students and trainees compete internally with a desire and commitment to serve the sick.[39] A recent study reported in *JAMA* found that front-line health care workers who have been exposed to COVID-19 have a high risk of developing unfavorable mental health outcomes and may need psychological support or interventions.[41] However, many students, residents, and physicians continue to do more than has been required of them for patient care and within the community, despite the risks and challenges of COVID-19.

The AMA developed a guide, "Caring for our caregivers during COVID-19," for health system leadership to consider when supporting their physicians and care teams during COVID-19. The guide provides practical examples and strategies to encourage well-being and improve physician satisfaction as well as valuable strategies that address workload redistribution, institutional policies, meals, childcare, attention to emotional and mental well-being, and connecting with others. This guide is featured in Appendix 7.

EFFORTS BY KEY STAKEHOLDERS TO ADDRESS ISSUES ACROSS THE CONTINUUM OF EDUCATION, TRAINING, LICENSURE, CERTIFICATION, AND CREDENTIALING

The LCME is officially recognized by the U.S. Department of Education to accredit medical school programs leading to the MD degree in the United States and Canada. It is jointly overseen by the AAMC and AMA but is an independent organization. To achieve and maintain accreditation, a medical education program must meet the LCME accreditation standards and is required to demonstrate that their graduates exhibit general professional competencies appropriate for entry to the next stage of their training and that serve as the foundation for lifelong learning and proficient medical care. The LCME developed and disseminated numerous resources to offer guidance to medical schools during COVID-19. The LCME guiding principles are featured in Appendix 8.

The COCA accredits medical school programs granting the DO degree in the United States. COCA is recognized by the U.S. Department of Education as the accreditor of colleges of osteopathic medicine. COCA accreditation signifies that a college has met or exceeded the Commission's standards for educational quality. COCA developed and disseminated numerous resources to offer guidance to colleges of osteopathic medicine related to COVID-19. The guidance developed by COCA can be found on its website (https://osteopathic.org/accreditation/coca-covid-19/).

The National Resident Matching Program® (NRMP®), or The Match®, is a private, non-profit organization established to provide an orderly and fair mechanism for matching the preferences of applicants for U.S. residency positions with the preferences of residency program directors. NRMP created Frequently Asked Questions (FAQs) to address questions regarding the applicant transition to GME during the COVID-19 crisis. FAQs developed by NRMP can be found on its website (http://www.nrmp.org/covid-faqs-2-2/)

The ACGME is an independent, not-for-profit, physician-led organization that sets and monitors the professional educational standards essential to preparing physicians who deliver safe, high-quality medical care to all Americans and monitors compliance with those standards. During COVID-19, the ACGME has monitored the needs of the GME community and provided guidance, clarification, and resources. ACGME resources specific to COVID can be found on its website (https://acgme.org/COVID-19/ACGME-Guidance-Statements).

The Educational Commission for Foreign Medical Graduates (ECFMG) assesses the readiness of IMGs to enter residency or fellowship programs in the United States that are accredited by the ACGME. The ECFMG also acts as the registration and score-reporting agency for the USMLE for IMGs. It conducts three examinations: Step 1, Step 2CK, and Step 2CS. The ECFMG certificate is issued to physicians who pass the three exams within seven years. The ECFMG developed resources and launched a COVID-19 specific newsletter during the pandemic. These resources are available on the ECFMG website (https://www.ecfmg.org/annc/covid-19-coronavirus.html).

The NBME is an independent, not-for-profit organization that serves the public through its high-quality assessments of health care professionals. The NBME is also a co-sponsor of the USMLE®. The NBME provided updates related to assessments during COVID-19 which can be found on its website (https://www.nbme.org/news/coronavirus-covid-19-assessment-information-and-updates)

The American Board of Medical Specialties (ABMS) is an independent, not-for-profit organization founded to set professional standards for physician practice and board certification. The ABMS and its 24 Member Boards aim to improve the quality of health care by elevating the discipline of specialty medicine through board certification. The ABMS developed numerous resources for diplomates and their fellow health care professionals which can be found on its website (https://www.abms.org/initiatives/covid-19-information/).

The FSMB is a national, non-profit organization that represents the state medical and osteopathic boards of the United States and its territories. FSMB also co-sponsors the USMLE®. The FSMB developed recommendations for medical license portability during COVID-19 and other resources which can be found on its website (https://www.fsmb.org/advocacy/covid-19/).

The CPA is a cross-organizational group of national medical education organizations, including the AMA, concerned with the oversight, education, and assessment of medical students and physicians throughout their medical careers. During COVID-19, the CPA created several work groups to develop common recommendations to address urgent issues related to the COVID-19 pandemic and physician education. “Maintaining Quality and Safety Standards Amid COVID-19” is a product of one of the work groups and offers guidance for health care administrators and credentialing staff members supporting the contributions of new or volunteer physicians during the COVID-19 pandemic. This product is featured in Appendix 9.

RELEVANT AMA POLICY

The AMA has developed several policies in response to addressing pandemics. These policies are featured in Appendix 1.

SUMMARY

The rapid spread of COVID-19 disrupted life, including medical education. Fortunately, the response of key stakeholders was equally rapid and multifactorial. Strategic planning for future pandemics needs to focus on equipping individuals at various points in their medical careers to redeploy while ensuring patient safety. As many of the issues presented in this report are interrelated, it will also be necessary for key stakeholders to collaborate to minimize negative unintended consequences for students, residents, physicians, and most importantly patients. The Council on Medical Education expects there to be evolving issues related to COVID-19 and will continue to monitor the evolution.

APPENDIX 1: RELEVANT AMA POLICY

9.2.1, "Medical Student Involvement in Patient Care"

Having contact with patients is essential for training medical students, and both patients and the public benefit from the integrated care that is provided by health care teams that include medical students. However, the obligation to develop the next generation of physicians must be balanced against patients' freedom to choose from whom they receive treatment.

All physicians share an obligation to ensure that patients are aware that medical students may participate in their care and have the opportunity to decline care from students. Attending physicians may be best suited to fulfill this obligation. Before involving medical students in a patient's care, physicians should:

(a) Convey to the patient the benefits of having medical students participate in their care.

(b) Inform the patients about the identity and training status of individuals involved in care. Students, their supervisors, and all health care professionals should avoid confusing terms and properly identify themselves to patients.

(c) Inform the patient that trainees will participate before a procedure is undertaken when the patient will be temporarily incapacitated.

(d) Discuss student involvement in care with the patient's surrogate when the patient lacks decision-making capacity.

(e) Confirm that the patient is willing to permit medical students to participate in care.

9.2.2, "Resident & Fellow Physicians' Involvement in Patient Care"

Residents and fellows have dual roles as trainees and caregivers. Residents and fellows share responsibility with physicians involved in their training to facilitate educational and patient care goals.

Residents and fellows are physicians first and foremost and should always regard the interests of patients as paramount. When they are involved in patient care, residents and fellows should:

(a) Interact honestly with patients, including clearly identifying themselves as members of a team that is supervised by the attending physician and clarifying the role they will play in patient care. They should notify the attending physician if a patient refuses care from a resident or fellow.

(b) Participate fully in established mechanisms in their training programs and hospital systems for reporting and analyzing errors. They should cooperate with attending physicians in communicating errors to patients.

(c) Monitor their own health and level of alertness so that these factors do not compromise their ability to care for patients safely. Residents and fellows should recognize that providing patient care beyond time permitted by their programs (for example, "moonlighting" or other activities that interfere with adequate rest during off hours) might be harmful to themselves and patients.

Physicians involved in training residents and fellows should:

(d) Take steps to help ensure that training programs are structured to be conducive to the learning process as well as to promote the patient's welfare and dignity.

(e) Address patient refusal of care from a resident or fellow. If after discussion, a patient does not want to participate in training, the physician may exclude residents or fellows from the patient's care. If appropriate, the physician may transfer the patient's care to another physician or nonteaching service or another health care facility.

(f) Provide residents and fellows with appropriate faculty supervision and availability of faculty consultants, and with graduated responsibility relative to level of training and expertise.

(g) Observe pertinent regulations and seek consultation with appropriate institutional resources, such as an ethics committee, to resolve educational or patient care conflicts that arise in the course of training. All parties involved in such conflicts must continue to regard patient welfare as the first priority. Conflict resolution should not be punitive, but should aim at assisting residents and fellows to complete their training successfully.

11.1.3, "Allocating Limited Health Care Resources"

Physicians' primary ethical obligation is to promote the well-being of their patients. Policies for allocating scarce health care resources can impede their ability to fulfill that obligation, whether those policies address situations of chronically limited resources, such as ICU (intensive care unit) beds, medications, or solid organs for transplantation, or "triage" situations in times of scarcity, such as access to ventilators during an influenza pandemic.

As professionals dedicated to protecting the interests of their patients, physicians thus have a responsibility to contribute their expertise to developing allocation policies that are fair and safeguard the welfare of patients.

Individually and collectively through the profession, physicians should advocate for policies and procedures that allocate scarce health care resources fairly among patients, in keeping with the following criteria:

(a) Base allocation policies on criteria relating to medical need, including urgency of need, likelihood and anticipated duration of benefit, and change in quality of life. In limited circumstances, it may be appropriate to take into consideration the amount of resources required for successful treatment. It is not appropriate to base allocation policies on social worth, perceived obstacles to treatment, patient contribution to illness, past use of resources, or other non-medical characteristics.

(b) Give first priority to those patients for whom treatment will avoid premature death or extremely poor outcomes, then to patients who will experience the greatest change in quality of life, when there are very substantial differences among patients who need access to the scarce resource(s).

(c) Use an objective, flexible, transparent mechanism to determine which patients will receive the resource(s) when there are not substantial differences among patients who need access to the scarce resource(s).

(d) Explain the applicable allocation policies or procedures to patients who are denied access to the scarce resource(s) and to the public.

H-140.900, "A Declaration of Professional Responsibility"

Our AMA adopts the Declaration of Professional Responsibility

DECLARATION OF PROFESSIONAL RESPONSIBILITY: MEDICINE's SOCIAL CONTRACT WITH HUMANITY

Preamble

Never in the history of human civilization has the well being of each individual been so inextricably linked to that of every other. Plagues and pandemics respect no national borders in a world of global commerce and travel. Wars and acts of terrorism enlist innocents as combatants and mark civilians as targets. Advances in medical science and genetics, while promising to do great good, may also be harnessed as agents of evil. The unprecedented scope and immediacy of these universal challenges demand concerted action and response by all.

As physicians, we are bound in our response by a common heritage of caring for the sick and the suffering. Through the centuries, individual physicians have fulfilled this obligation by applying their skills and knowledge competently, selflessly and at times heroically. Today, our profession must reaffirm its historical commitment to combat natural and man-made assaults on the health and well being of humankind. Only by acting together across geographic and ideological divides can we overcome such powerful threats. Humanity is our patient.

Declaration

We, the members of the world community of physicians, solemnly commit ourselves to: (1) Respect human life and the dignity of every individual. (2) Refrain from supporting or committing crimes against humanity and condemn any such acts. (3) Treat the sick and injured with competence and compassion and without prejudice. (4) Apply our knowledge and skills when needed, though doing so may put us at risk. (5) Protect the privacy and confidentiality of those for whom we care and breach that confidence only when keeping it would seriously threaten their health and safety or that of others. (6) Work freely with colleagues to discover, develop, and promote advances in medicine and public health that ameliorate suffering and contribute to human well-being. (7) Educate the public and polity about present and future threats to the health of humanity. (8) Advocate for social, economic, educational, and political changes that ameliorate suffering and contribute to human well-being. (9) Teach and mentor those who follow us for they are the future of our caring profession. We make these promises solemnly, freely, and upon our personal and professional honor.

H-295.860, "Promoting Transparency in Medical Education and Access to Training"

Our American Medical Association: (1) strongly encourages medical schools and graduate medical education training programs to communicate with current and prospective medical students, residents and fellows how affiliations and mergers among health care organizations may impact health care delivery, medical education and training opportunities at their respective institutions; and (2) will work with the Accreditation Council for Graduate Medical Education and other appropriate stakeholders to support transparency within medical education, recommending that medical schools and graduate medical education training programs communicate with current and prospective medical students, residents and fellows how affiliations and mergers among health care organizations may impact health care delivery, medical education and training opportunities.

H-295.868, Education in Disaster Medicine and Public Health Preparedness During Medical School and Residency Training

1. Our AMA recommends that formal education and training in disaster medicine and public health preparedness be incorporated into the curriculum at all medical schools and residency programs.

2. Our AMA encourages medical schools and residency programs to utilize multiple methods, including simulation, disaster drills, interprofessional team-based learning, and other interactive formats for teaching disaster medicine and public health preparedness.

3. Our AMA encourages public and private funders to support the development and implementation of education and training opportunities in disaster medicine and public health preparedness for medical students and resident physicians.

4. Our AMA supports the National Disaster Life Support (NDLS) Program Office's work to revise and enhance the NDLS courses and supporting course materials, in both didactic and electronic formats, for use in medical schools and residency programs.

5. Our AMA encourages involvement of the National Disaster Life Support Education Consortium's adoption of training and education standards and guidelines established by the newly created Federal Education and Training Interagency Group (FETIG).

6. Our AMA will continue to work with other specialties and stakeholders to coordinate and encourage provision of disaster preparedness education and training in medical schools and in graduate and continuing medical education.

7. Our AMA encourages all medical specialties, in collaboration with the National Disaster Life Support Educational Consortium (NDLSEC), to develop interdisciplinary and inter-professional training venues and curricula, including essential elements for national disaster preparedness for use by medical schools and residency programs to prepare physicians and other health professionals to respond in coordinated teams using the tools available to effectively manage disasters and public health emergencies.

8. Our AMA encourages medical schools and residency programs to use community-based disaster training and drills as appropriate to the region and community they serve as opportunities for medical students and residents to develop team skills outside the usual venues of teaching hospitals, ambulatory clinics, and physician offices.

9. Our AMA will make medical students and residents aware of the context (including relevant legal issues) in which they could serve with appropriate training, credentialing, and supervision during a national disaster or emergency, e.g., non-governmental organizations, American Red Cross, Medical Reserve Corps, and other entities that could provide requisite supervision.

10. Our AMA will work with the Federation of State Medical Boards to encourage state licensing authorities to include medical students and residents who are properly trained and credentialed to be able to participate under appropriate supervision in a national disaster or emergency.

11. Our AMA encourages physicians, residents, and medical students to participate in disaster response activities through organized groups, such as the Medical Response Corps and American Red Cross, and not as spontaneous volunteers.

12. Our AMA encourages teaching hospitals to develop and maintain a relocation plan to ensure that educational activities for faculty, medical students, and residents can be continued in times of national disaster and emergency.

H-295.939, Protecting Medical Trainees from Hazardous Exposure

1. Our AMA will encourage all health care-related educational institutions to apply the Occupational Safety and Health Administration (OSHA) Blood Borne Pathogen standard and OSHA hazardous exposure regulations, including communication requirements, equally to employees, students, and residents/fellows.

2. Our AMA recommends: (a) that the Accreditation Council for Graduate Medical Education revise the common program requirements to require education and subsequent demonstration of competence regarding potential exposure to hazardous agents relevant to specific specialties, including but not limited to: appropriate handling of hazardous agents, potential risks of exposure to hazardous agents, situational avoidance of hazardous agents, and appropriate responses when exposure to hazardous material may have occurred in the workplace/training site; (b) (i) that medical school policies on hazardous exposure include options to limit hazardous agent exposure in a manner that does not impact students' ability to successfully complete their training, and (ii) that medical school policies on continuity of educational requirements toward degree completion address leaves of absence or temporary reassignments when a pregnant trainee wishes to minimize the risks of hazardous exposures that may affect the trainee's and/or fetus' personal health status; (c) that medical schools and health care settings with medical learners be vigilant in updating educational material and protective measures regarding hazardous agent exposure of its learners and make this information readily available to students, faculty, and staff; and (d) medical schools and other sponsors of health professions education programs ensure that their students and trainees meet the same requirements for education regarding hazardous materials and potential exposures as faculty and staff.

H-310.912, Residents and Fellows' Bill of Rights

1. Our AMA continues to advocate for improvements in the ACGME Institutional and Common Program Requirements that support AMA policies as follows: a) adequate financial support for and guaranteed leave to attend professional meetings; b) submission of training verification information to requesting agencies within 30 days of the request; c) adequate compensation with consideration to local cost-of-living factors and years of training, and to include the orientation period; d) health insurance benefits to include dental and vision services; e) paid leave for all purposes (family, educational, vacation, sick) to be no less than six weeks per year; and f) stronger due process guidelines.

2. Our AMA encourages the ACGME to ensure access to educational programs and curricula as necessary to facilitate a deeper understanding by resident physicians of the US health care system and to increase their communication skills.

3. Our AMA regularly communicates to residency and fellowship programs and other GME stakeholders this Resident/Fellows Physicians' Bill of Rights.

4. Our AMA: a) will promote residency and fellowship training programs to evaluate their own institution's process for repayment and develop a leaner approach. This includes disbursement of funds by direct deposit as opposed to a paper check and an online system of applying for funds; b) encourages a system of expedited repayment for purchases of $200 or less (or an equivalent institutional threshold), for example through payment directly from their residency and fellowship programs (in contrast to following traditional workflow for reimbursement); and c) encourages training programs to develop a budget and strategy for planned expenses versus unplanned expenses, where planned expenses should be estimated using historical data, and should include trainee reimbursements for items such as educational materials, attendance at conferences, and entertaining applicants. Payment in advance or within one month of document submission is strongly recommended.

5. Our AMA encourages teaching institutions to explore benefits to residents and fellows that will reduce personal cost of living expenditures, such as allowances for housing, childcare, and transportation.

6. Our AMA will work with the Accreditation Council for Graduate Medical Education (ACGME) and other relevant stakeholders to amend the ACGME Common Program Requirements to allow flexibility in the specialty-specific ACGME program requirements enabling specialties to require salary reimbursement or "protected time" for resident and fellow education by "core faculty," program directors, and assistant/associate program directors.

7. Our AMA adopts the following 'Residents and Fellows' Bill of Rights' as applicable to all resident and fellow physicians in ACGME-accredited training programs:

RESIDENT/FELLOW PHYSICIANS' BILL OF RIGHTS

Residents and fellows have a right to:

A. An education that fosters professional development, takes priority over service, and leads to independent practice.

With regard to education, residents and fellows should expect: (1) A graduate medical education experience that facilitates their professional and ethical development, to include regularly scheduled didactics for which they are released from clinical duties. Service obligations should not interfere with educational opportunities and clinical education should be given priority over service obligations; (2) Faculty who devote sufficient time to the educational program to fulfill their teaching and supervisory responsibilities; (3) Adequate clerical and clinical support services that minimize the extraneous, time-consuming work that draws attention from patient care issues and offers no educational value; (4) 24-hour per day access to information resources to educate themselves further about appropriate patient care; and (5) Resources that will allow them to pursue scholarly activities to include financial support and education leave to attend professional meetings.

B. Appropriate supervision by qualified faculty with progressive resident responsibility toward independent practice.

With regard to supervision, residents and fellows should expect supervision by physicians and non-physicians who are adequately qualified and which allows them to assume progressive responsibility appropriate to their level of education, competence, and experience. It is neither feasible nor desirable to develop universally applicable and precise requirements for supervision of residents.

C. Regular and timely feedback and evaluation based on valid assessments of resident performance.

With regard to evaluation and assessment processes, residents and fellows should expect: (1) Timely and substantive evaluations during each rotation in which their competence is objectively assessed by faculty who have directly supervised their work; (2) To evaluate the faculty and the program confidentially and in writing at least once annually and expect that the training program will address deficiencies revealed by these evaluations in a timely fashion; (3) Access to their training file and to be made aware of the contents of their file on an annual basis; and (4) Training programs to complete primary verification/credentialing forms and recredentialing forms, apply all required signatures to the forms, and then have the forms permanently secured in their educational files at the completion of training or a period of training and, when requested by any organization involved in credentialing process, ensure the submission of those documents to the requesting organization within thirty days of the request.

D. A safe and supportive workplace with appropriate facilities.

With regard to the workplace, residents and fellows should have access to: (1) A safe workplace that enables them to fulfill their clinical duties and educational obligations; (2) Secure, clean, and comfortable on-call rooms and parking facilities which are secure and well-lit; (3) Opportunities to participate on committees whose actions may affect their education, patient care, workplace, or contract.

E. Adequate compensation and benefits that provide for resident well-being and health.

(1) With regard to contracts, residents and fellows should receive: a. Information about the interviewing residency or fellowship program including a copy of the currently used contract clearly outlining the conditions for (re)appointment, details of remuneration, specific responsibilities including call obligations, and a detailed protocol for handling any grievance; and b. At least four months advance notice of contract non-renewal and the reason for non-renewal.

(2) With regard to compensation, residents and fellows should receive: a. Compensation for time at orientation; and b. Salaries commensurate with their level of training and experience. Compensation should reflect cost of living differences based on local economic factors, such as housing, transportation, and energy costs (which affect the purchasing power of wages), and include appropriate adjustments for changes in the cost of living.

(3) With Regard to Benefits, Residents and Fellows Must Be Fully Informed of and Should Receive: a. Quality and affordable comprehensive medical, mental health, dental, and vision care for residents and their families, as well as professional liability insurance and disability insurance to all residents for disabilities resulting from activities that are part of the educational program; b. An institutional written policy on and education in the signs of excessive fatigue, clinical depression, substance abuse and dependence, and other physician impairment issues; c. Confidential access to mental health and substance abuse services; d. A guaranteed, predetermined amount of paid vacation leave, sick leave, family and medical leave and educational/professional leave during each year in their training program, the total amount of which should not be less than six weeks; e. Leave in compliance with the Family and Medical Leave Act; and f. The conditions under which sleeping quarters, meals and laundry or their equivalent are to be provided.

F. Clinical and educational work hours that protect patient safety and facilitate resident well-being and education.

With regard to clinical and educational work hours, residents and fellows should experience: (1) A reasonable work schedule that is in compliance with clinical and educational work hour requirements set forth by the ACGME; and (2) At-home call that is not so frequent or demanding such that rest periods are significantly diminished or that clinical and educational work hour requirements are effectively circumvented. Refer to AMA Policy H-310.907, "Resident/Fellow Clinical and Educational Work Hours," for more information.

G. Due process in cases of allegations of misconduct or poor performance.

With regard to the complaints and appeals process, residents and fellows should have the opportunity to defend themselves against any allegations presented against them by a patient, health professional, or training program in accordance with the due process guidelines established by the AMA.

H. Access to and protection by institutional and accreditation authorities when reporting violations.

With regard to reporting violations to the ACGME, residents and fellows should: (1) Be informed by their program at the beginning of their training and again at each semi-annual review of the resources and processes available within the residency program for addressing resident concerns or complaints, including the program director, Residency Training Committee, and the designated institutional official; (2) Be able to file a formal complaint with the ACGME to address program violations of residency training requirements without fear of recrimination and with the guarantee of due process; and (3) Have the opportunity to address their concerns about the training program through confidential channels, including the ACGME concern process and/or the annual ACGME Resident Survey.

H-310.929, Principles for Graduate Medical Education

Our AMA urges the Accreditation Council for Graduate Medical Education (ACGME) to incorporate these principles in its Institutional Requirements, if they are not already present.
(1) PURPOSE OF GRADUATE MEDICAL EDUCATION AND ITS RELATIONSHIP TO PATIENT CARE. There must be objectives for residency education in each specialty that promote the development of the knowledge, skills, attitudes, and behavior necessary to become a competent practitioner in a recognized medical specialty.
Exemplary patient care is a vital component for any residency/fellowship program. Graduate medical education enhances the quality of patient care in the institution sponsoring an accredited program. Graduate medical education must never compromise the quality of patient care. Institutions sponsoring residency programs and the director of each program must assure the highest quality of care for patients and the attainment of the program's educational objectives for the residents.
(2) RELATION OF ACCREDITATION TO THE PURPOSE OF RESIDENCY TRAINING. Accreditation requirements should relate to the stated purpose of a residency program and to the knowledge, skills, attitudes, and behaviors that a resident physician should have on completing residency education.
(3) EDUCATION IN THE BROAD FIELD OF MEDICINE. GME should provide a resident physician with broad clinical experiences that address the general competencies and professionalism expected of all physicians, adding depth as well as breadth to the competencies introduced in medical school.
(4) SCHOLARLY ACTIVITIES FOR RESIDENTS. Graduate medical education should always occur in a milieu that includes scholarship. Resident physicians should learn to appreciate the importance of scholarly activities and should be knowledgeable about scientific method. However, the accreditation requirements, the structure, and the content of graduate medical education should be directed toward preparing physicians to practice in a medical specialty. Individual educational opportunities beyond the residency program should be provided for resident physicians who have an interest in, and show an aptitude for, academic and research pursuits. The continued development of evidence-based medicine in the graduate medical education curriculum reinforces the integrity of the scientific method in the everyday practice of clinical medicine.
(5) FACULTY SCHOLARSHIP. All residency faculty members must engage in scholarly activities and/or scientific inquiry. Suitable examples of this work must not be limited to basic biomedical research. Faculty can comply with this principle through participation in scholarly meetings, journal club, lectures, and similar academic pursuits.

(6) INSTITUTIONAL RESPONSIBILITY FOR PROGRAMS. Specialty-specific GME must operate under a system of institutional governance responsible for the development and implementation of policies regarding the following; the initial authorization of programs, the appointment of program directors, compliance with the accreditation requirements of the ACGME, the advancement of resident physicians, the disciplining of resident physicians when this is appropriate, the maintenance of permanent records, and the credentialing of resident physicians who successfully complete the program. If an institution closes or has to reduce the size of a residency program, the institution must inform the residents as soon as possible. Institutions must make every effort to allow residents already in the program to complete their education in the affected program. When this is not possible, institutions must assist residents to enroll in another program in which they can continue their education. Programs must also make arrangements, when necessary, for the disposition of program files so that future confirmation of the completion of residency education is possible. Institutions should allow residents to form housestaff organizations, or similar organizations, to address patient care and resident work environment concerns. Institutional committees should include resident members.
(7) COMPENSATION OF RESIDENT PHYSICIANS. All residents should be compensated. Residents should receive fringe benefits, including, but not limited to, health, disability, and professional liability insurance and parental leave and should have access to other benefits offered by the institution. Residents must be informed of employment policies and fringe benefits, and their access to them. Restrictive covenants must not be required of residents or applicants for residency education.
(8) LENGTH OF TRAINING. The usual duration of an accredited residency in a specialty should be defined in the "Program Requirements." The required minimum duration should be the same for all programs in a specialty and should be sufficient to meet the stated objectives of residency education for the specialty and to cover the course content specified in the Program Requirements. The time required for an individual resident physician's education might be modified depending on the aptitude of the resident physician and the availability of required clinical experiences.
(9) PROVISION OF FORMAL EDUCATIONAL EXPERIENCES
Graduate medical education must include a formal educational component in addition to supervised clinical experience. This component should assist resident physicians in acquiring the knowledge and skill base required for practice in the specialty. The assignment of clinical responsibility to resident physicians must permit time for study of the basic sciences and clinical pathophysiology related to the specialty.
(10) INNOVATION OF GRADUATE MEDICAL EDUCATION. The requirements for accreditation of residency training should encourage educational innovation and continual improvement. New topic areas such as continuous quality improvement (CQI), outcome management, informatics and information systems, and population-based medicine should be included as appropriate to the specialty.
(11) THE ENVIRONMENT OF GRADUATE MEDICAL EDUCATION. Sponsoring organizations and other GME programs must create an environment that is conducive to learning. There must be an appropriate balance between education and service. Resident physicians must be treated as colleagues.
(12) SUPERVISION OF RESIDENT PHYSICIANS. Program directors must supervise and evaluate the clinical performance of resident physicians. The policies of the sponsoring institution, as enforced by the program director, and specified in the ACGME Institutional Requirements and related accreditation documents, must ensure that the clinical activities of each resident physician are supervised to a degree that reflects the ability of the resident physician and the level of responsibility for the care of patients that may be safely delegated to the resident. The sponsoring institution's GME Committee must monitor programs' supervision of residents and ensure that supervision is consistent with: (A) Provision of safe and effective patient care; (B) Educational needs of residents; (C) Progressive responsibility appropriate to residents' level of education, competence, and experience; and (D) Other applicable Common and specialty/subspecialty specific Program Requirements. The program director, in cooperation with the institution, is responsible for maintaining work schedules for each resident based on the intensity and variability of assignments in conformity with ACGME Review Committee recommendations, and in compliance with the ACGME clinical and educational work hour standards. Integral to resident supervision is the necessity for frequent evaluation of residents by faculty, with discussion between faculty and resident. It is a cardinal principle that responsibility for the treatment of each patient and the education of resident and fellow physicians lies with the physician/faculty to whom the patient is assigned and who supervises all care rendered to the patient by residents and fellows. Each patient's attending physician must decide, within guidelines established by the program director, the extent to which responsibility may be delegated to the resident, and the appropriate

degree of supervision of the resident's participation in the care of the patient. The attending physician, or designate, must be available to the resident for consultation at all times.
(13) EVALUATION OF RESIDENTS AND SPECIALTY BOARD CERTIFICATION. Residency program directors and faculty are responsible for evaluating and documenting the continuing development and competency of residents, as well as the readiness of residents to enter independent clinical practice upon completion of training. Program directors should also document any deficiency or concern that could interfere with the practice of medicine and which requires remediation, treatment, or removal from training. Inherent within the concept of specialty board certification is the necessity for the residency program to attest and affirm to the competence of the residents completing their training program and being recommended to the specialty board as candidates for examination. This attestation of competency should be accepted by specialty boards as fulfilling the educational and training requirements allowing candidates to sit for the certifying examination of each member board of the ABMS.
(14) GRADUATE MEDICAL EDUCATION IN THE AMBULATORY SETTING. Graduate medical education programs must provide educational experiences to residents in the broadest possible range of educational sites, so that residents are trained in the same types of sites in which they may practice after completing GME. It should include experiences in a variety of ambulatory settings, in addition to the traditional inpatient experience. The amount and types of ambulatory training is a function of the given specialty.
(15) VERIFICATION OF RESIDENT PHYSICIAN EXPERIENCE. The program director must document a resident physician's specific experiences and demonstrated knowledge, skills, attitudes, and behavior, and a record must be maintained within the institution.

H-440.835, "AMA Role in Addressing Epidemics and Pandemics"

1. Our AMA strongly supports U.S. and global efforts to fight epidemics and pandemics, including Ebola, and the need for improved public health infrastructure and surveillance in affected countries.
2. Our AMA strongly supports those responding to the Ebola epidemic and other epidemics and pandemics in affected countries, including all health care workers and volunteers, U.S. Public Health Service and U.S. military members. 3. Our AMA reaffirms Ethics Policy E-2.25, The Use of Quarantine and Isolation as Public Health Interventions, which states that the medical profession should collaborate with public health colleagues to take an active role in ensuring that quarantine and isolation interventions are based on science.
4. Our AMA will collaborate in the development of recommendations and guidelines for medical professionals on appropriate treatment of patients infected with or potentially infected with Ebola, and widely disseminate such guidelines through its communication channels. 5. Our AMA will continue to be a trusted source of information and education for physicians, health professionals and the public on urgent epidemics or pandemics affecting the U.S. population, such as Ebola. 6. Our AMA encourages relevant specialty societies to educate their members on specialty-specific issues relevant to new and emerging epidemics and pandemics.

H-440.847, Pandemic Preparedness for Influenza

In order to prepare for a potential influenza pandemic, our AMA: (1) urges the Department of Health and Human Services Emergency Care Coordination Center, in collaboration with the leadership of the Centers for Disease Control and Prevention (CDC), state and local health departments, and the national organizations representing them, to urgently assess the shortfall in funding, staffing, vaccine, drug, and data management capacity to prepare for and respond to an influenza pandemic or other serious public health emergency; (2) urges Congress and the Administration to work to ensure adequate funding and other resources: (a) for the CDC, the National Institutes of Health (NIH) and other appropriate federal agencies, to support implementation of an expanded capacity to produce the necessary vaccines and anti-viral drugs and to continue development of the nation's capacity to rapidly vaccinate the entire population and care for large numbers of seriously ill people; and (b) to bolster the infrastructure and capacity of state and local health department to effectively prepare for, respond to, and protect the population from illness and death in an influenza pandemic or other serious public health emergency; (3) urges the CDC to develop and disseminate electronic instructional resources on procedures to follow in an influenza epidemic, pandemic, or other serious public health emergency, which are tailored to the needs of physicians and medical office staff in ambulatory care settings; (4) supports the position that: (a) relevant national and state agencies (such as the

CDC, NIH, and the state departments of health) take immediate action to assure that physicians, nurses, other health care professionals, and first responders having direct patient contact, receive any appropriate vaccination in a timely and efficient manner, in order to reassure them that they will have first priority in the event of such a pandemic; and (b) such agencies should publicize now, in advance of any such pandemic, what the plan will be to provide immunization to health care providers; (6) will monitor progress in developing a contingency plan that addresses future influenza vaccine production or distribution problems and in developing a plan to respond to an influenza pandemic in the United States.

APPENDIX 2: AMA GUIDING PRINCIPLES TO PROTECT LEARNERS RESPONDING TO COVID-19

Updated May 1, 2020

This article is part of a series of COVID-19 articles and resources on medical education.
In their efforts to meet workforce demands in response to COVID-19, medical schools and health systems must make responsible decisions about engaging medical students. There are many opportunities for students to contribute to the clinical care of patients without engaging in direct physical contact with patients. However, in some institutions the workforce demands may be great enough that it is appropriate to consider including medical students in direct patient care.

Some students may be permitted to graduate early from medical school and may subsequently contribute as employed members of medical staffs prior to entering their planned residency training. Some students may be enlisted while retaining the status of student, on a voluntary basis, with appropriate supervision and with attention to infection control.

It is the responsibility of the AMA to support and protect medical students as we rely on them during this time. We stand with key stakeholders across the continuum of medical education, including but not limited to the Association of American Medical Colleges, Liaison Committee on Medical Education LCME), Accreditation Council for Graduate Medical Education, American Osteopathic Association, American Association of Colleges of Osteopathic Medicine and the Educational Commission for Foreign Medical Graduates in support of conscientious oversight of the deployment of medical students. The AMA Council on Medical Education recommends observance of the following principles:

For all institutions engaging medical students in physical contact with patients:

1. Thoughtful planning will allow the safe re-engagement of students in the direct care of patients and thus support the continuation of student training. For required coursework involving direct patient contact, schools should provide reasonable accommodations to learners who are unable to participate.
2. Medical students should be included in conversations as direct patient interaction activities are being explored, developed and implemented.
3. Medical students must be provided proper training and oversight in the use and reuse of personal protective equipment (PPE). This includes fit testing for N95 or other respirators, donning and doffing of enhanced PPE, and institutional policies related to the use of one's own PPE to augment hospital-supplied PPE.
4. Appropriate COVID-19 testing protocols for students and health care workers should be in place to reduce risk of transmission and to monitor trends in disease burden among students.
5. Each clinical environment in which students will come into direct contact with patients should be assessed for safety and educational readiness, including:
    - Burden of COVID-19 exposure
    - Stability of care protocols and clarity of roles
    - Appropriate patient mix to support learning goals
    - Faculty capacity to provide supervision, teaching and feedback
6. Health systems and medical schools should support the wellbeing of all providers and recognize that learners face an added stressor of uncertainty about their educational pathways.
7. Medical students should not be financially responsible for diagnosis and treatment of their own disease should they become ill due to care of COVID-19 patients through school-approved activities.
8. Medical schools should use a competency-based approach to redesign educational and assessment activities, considering alternatives to direct patient contact to meet desired learning outcomes.
9. Medical schools should work with the LCME to identify viable options to assess students' competency and meet curricular requirements in order to avoid, to the extent possible, any delay in medical students' graduation or progression in medical school.

Additionally, for institutions implementing early graduation to allow students to join the physician workforce:

10. Early graduation should be enacted on a voluntary basis and founded upon attainment of core competencies.
11. To the extent possible, early graduates should serve under the supervision of an approved graduate medical education program.
12. Medical school graduates should not be compelled to work for their matched residency institution prior to the intended date of employment.
13. Institutions deploying early graduates should grant these providers full status as health care employees with appropriate salary and benefits, while continuing efforts to mitigate their personal risk.
14. Institutions and medical school graduates should remain mindful of graduates' contractual obligations to their matched residencies, including consideration of the potential for quarantine and/or illness due to care of COVID-19 patients.
15. Financial institutions overseeing all loans, public and private, for medical school graduates deployed into the workforce between graduation and beginning residency should exercise forbearance and/or forgiveness of debt service during this time.

APPENDIX 3: GUIDING PRINCIPLES TO PROTECT RESIDENT & FELLOW PHYSICIANS RESPONDING TO COVID-19

Updated April 13, 2020

This article is part of a series of COVID-19 articles and resources on medical education.

Background
There are over 135,000 residents and fellows ("residents") working in graduate medical education (GME) programs in the United States. They are participating in supervised clinical experiences that will qualify them for certification and independent practice in a wide array of medical specialties. While acquiring this experience, residents are the frontline physician workforce in the health systems that employ them.

During the response to the COVID-19 pandemic, residents are experiencing personal, physical and economic stresses. Many of these stresses are common to all health care workers affected by the pandemic; some are unique to their status as employed trainees. These include the following:

- Residents are on the front lines during the COVID-19 response and like other health care workers, such as first responders and ED nurses, experience some of the highest risk situations for exposure and have the same need for personal protective equipment (PPE). They are at personal risk, and their work creates a risk to family members. Residents themselves may become ill and/or require quarantine while caring for COVID-19 patients, and residency program leave policies may not adequately account for these unplanned absences during the pandemic response.
- During the response to COVID-19, many residents are being asked to assume roles that are not a prescribed part of their specialty training, being deployed to medical units and emergency departments from their roles in operating rooms and outpatient clinics. Their preparation for these roles is variable, and residents may be compelled to acquire skills on the job that were not an expectation when they began residency. Furthermore, time spent providing these services may not meet the requirements for graduation and certification in their discipline, leading to concerns that their training may need to be extended when routine clinical duties resume.
- Some subspecialty fellows are being asked to serve in attending physician roles in their core disciplines (e.g., gastroenterology fellows serving as general internal medicine attending physicians). While they may be board certified in these specialties, their compensation and malpractice coverage may not be commensurate with the role.
- Resident salaries are low compared to those of other health care workers, particularly on an hourly basis. Given average resident salaries and an 80-hour work week, resident salaries equate to approximately $15 to $20/hour. In addition, residents carry significant debt loads related to their undergraduate medical education. The average student loan burden at medical school graduation exceeds $200,000.
- Residents are particularly vulnerable in their negotiating ability as a labor force. Although they are employed health care workers, their status as trainees makes them dependent upon their employer for their professional development. As such, their influence over the environment in which they work is limited.

Guiding principles
In managing the engagement of residents during the response to COVID-19, the AMA Council on Medical Education strongly supports observance of the following principles by programs, sponsoring institutions and national organizations:

1. Residents must be actively engaged in COVID-19 response planning regarding deployment of health care workers, including field promotion of fellows to attending roles, in order for the specific interests of trainees to be considered.
2. Residents must be free to raise concerns about their personal safety and the safety of those around them without recrimination or consequence to their employment and training.
3. Residents must have access to, and instruction in, the use of adequate personal protective equipment (PPE), as should all health care workers.
4. Residents deployed to clinical areas with which they are unfamiliar must receive appropriate training and supervision for the tasks they will be asked to perform.

5. Residents who become ill as a result of their participation in the COVID-19 response must not be required to use vacation and/or personal time off while ill and/or quarantined. Residents who require leave under these circumstances must continue to receive their salary and benefits.
6. Sponsoring institutions and residency programs must continue to comply with the Accreditation Council for Graduate Medical Education (ACGME) requirement to provide access to confidential, affordable mental health assessment, counseling and treatment, including access to urgent and emergency care 24 hours a day, seven days a week.
7. The clinical work that residents perform during the pandemic response must be considered in assessments of a trainee's qualifications for program completion. Where possible, credit should be given for the work residents are doing during this time.
8. The ACGME review committees (RCs), the American Board of Medical Specialties (ABMS) specialty boards and the American Osteopathic Association (AOA) specialty boards should consider their program and certification requirements, in light of the pandemic, to allow flexibility in assessments of the competence of trainees. Where possible, these assessments should not delay program completion nor eligibility for certification.
9. Residents must be permitted to remain in their programs to complete necessary requirements that qualify them for board certification. They must continue to receive salary and benefits and have access to necessary clinical experiences.
10. Residents should be candidates for hazard pay in a way that is equitable to other health care workers.
11. Residents should be granted forgiveness and/or forbearance for all or portions of their student loan debt to ease the financial stress they may experience in caring for themselves and their families. This is particularly important during this time of compromised access to opportunities to supplement their income, such as moonlighting.
12. Fellows who assume attending physician roles in core disciplines in which they are licensed and certified should receive pay and benefits commensurate with these roles. The impact of this activity on progress toward completion of the training program must be openly discussed with fellows prior to them assuming these responsibilities.
13. The Centers for Medicare & Medicaid Services (CMS) should ensure flexibility in GME reimbursements to hospitals to accommodate variations in training due to the COVID-19 response. This flexibility should lengthen the initial residency period (IRP) for residents to allow them to extend their training, if necessary, to meet program and board certification requirements. In addition, CMS should expand the residency funding cap at institutions where residents must extend their training, in order to support an increased number of residents, as new trainees begin, while existing trainees remain to complete their programs.
14. As hospitals and health systems confront the economic impact of the pandemic response, we urge early consideration of effects on the training environment and the sustainability of GME programs. Health systems should also proactively manage opportunities for residents to continue their professional development.
15. In the event of program contraction or closure that may result from the pandemic response, disruptions to resident education may be mitigated through active planning for resident relocation. In the event of closures, the AMA stands with other organizations ready to assist should the need arise.

APPENDIX 4: COVID-19 FAQS: GUIDANCE FOR INTERNATIONAL MEDICAL GRADUATES

Updated June 26, 2020

International Medical Graduate (IMG) physicians are a critical part of the U.S. health care workforce. During the COVID-19 pandemic, the AMA is advocating for IMG physicians, whether currently licensed to practice in the U.S. or seeking such licensure, and helping to ensure that visa-related issues do not stop their ability to continue to care for patients during this challenging time.

FAQs about the work the AMA is doing to support IMGs

How is the AMA working to ensure that I am supported after the COVID-19 pandemic subsides?
Ensuring that underserved and under-resourced communities have ample access to physicians is a chronic challenge in normal times, and the COVID-19 pandemic is expected to exacerbate this issue. Physicians practicing in underserved communities either via an H-1B visa or as part of the Conrad State 30 program play a key role in providing much needed health care to vulnerable populations. As such, we are supporting and working with U.S. Senator Amy Klobuchar, U.S. Representative Bradley Schneider, and the other bipartisan, bicameral Congressional members to pass legislation that will increase the number of doctors in rural and other medically underserved areas. Additionally, we are continuing to fight against a proposal by U.S. Immigration and Customs Enforcement (ICE) to modify the period of authorized stay for certain categories of nonimmigrants traveling to the United States by eliminating the availability of "duration of status" and by providing a maximum period of authorized stay with options for extensions for each applicable visa category. The AMA joined with other leading organizations in medical education and health care, to urge the Administration to not change duration of status, or to at the very least, exempt medical residents from such a proposal.

FAQs about visa processing

How will COVID-19 impact the processing of my visa?
Originally the U.S. had stopped processing visas. However, the U.S. Department of State (DoS) agreed to begin processing visa applications for foreign-born medical professionals after the AMA urged the DoS to expedite visa processing at U.S. embassies and consulates around the world.
The DoS encourages individuals with an approved U.S. non-immigrant or immigrant visa petition (I-129, I-140 or similar), or a certificate of eligibility in an approved exchange visitor program (DS-2019), to review the website of their nearest embassy or consulate for procedures to request a visa appointment. For any applicants who had an appointment scheduled with an Application Service Center (ASC) after their closure on March 18 or who have filed a Form I-765, Application for Employment Authorization, they will have their application processed using previously submitted biometrics. This announcement is consistent with U.S. Citizenship and Immigration Services' (USCIS) existing ability to reuse previously submitted biometrics. This will remain in effect until ASC resumes normal operations.
Is there premium processing for visas right now?
No. On March 20, 2020, USCIS announced that it will not accept any new requests for premium processing. This temporary suspension includes petitions filed for H-1B visas. The AMA is strongly urging USCIS to reconsider this suspension and to temporarily expand and expediate the premium processing option for H-1B physicians so they can provide health care to U.S. patients during this pandemic.

FAQs for IMG examinees and students

How will my medical licensing examination be affected?
The United States Medical Licensing Examination (USMLE) program is extending eligibility periods for all examinees who currently have a scheduling permit. The eligibility period ending in 2020 will be extended to have an end date of December 2020, regardless of the country in which examinees are testing. Extensions will be processed in order of expiration date, with all extension processing expected to be completed by the week of April 13. Examinees will receive a notification and new scheduling permit when their eligibility extension has been processed. Examinees will need to use the new permit once received. Extending the eligibility period for your Step 1, Step 2 CK, or Step 3 examination will not impact already scheduled

appointments. No fees will be charged for these eligibility extensions. Eligibility periods will be extended automatically, requiring no action from examinees. For more information, visit the USMLE program website which has published a COVID-19 page that includes information and FAQs about its responses to the pandemic.

Can special exceptions be made to allow exchange visitors to renew their J-1 visas without traveling back to their home country?

Exchange visitors currently on an exchange program whose visas have expired and who do not plan to travel outside of the U.S. do not need to renew their visa. If the exchange visitor does travel outside of the United States during their current exchange visitor program and after their J-1 visa has expired, they must apply for a new J-1 visa in their home country in order to re-enter the United States to continue their program. In addition, in accordance with AMA's letter, the State Department announced that J-1 physicians (medical residents) may consult with their program sponsor, to extend their programs in the United States, and confirmed that J-1 physicians can engage in revised clinical training rotations/assignments in keeping with the ACGME's "Response to Pandemic Crisis."

FAQs for IMGs currently practicing in the United States

As a physician on a H-1B visa, can I move to a different location to practice during the COVID-19 pandemic?

A physician on a H-1B visa must obtain a certified Labor Condition Application (LCA) covering each location where the physician will perform services as required under Department of Labor (DOL) regulations. The term "place of employment" means the worksite or physical location where an H-1B nonimmigrant worker actually performs his or her work.

The LCA will apply to any worksites within this "area of employment" meaning the area within normal commuting distance of the place (address) of employment, or worksite, where the H-1B nonimmigrant is, or will be, employed. However, in certain circumstances, an H-1B visa holder can temporarily work in a different geographic location without requiring a new LCA for up to 60 days in a one-year period. Moreover, the AMA is urging the Administration to permit H-1B physicians that are currently practicing in the U.S. with an active license and an approved immigrant petition, to apply and quickly receive authorization, to work at multiple locations and facilities with a broader range of medical services for the duration of the COVID-19 pandemic.

I am a foreign doctor not licensed in the U.S. but with practice experience in another country. How can I assist with the COVID-19 pandemic in my state?

The licensure requirements and steps to practice medicine in the U.S. remain the same. The licensure requirements and steps to practice medicine in the U. S. would require you to have additional years of residency training, pass the USMLE exams, become ECFMG certified and apply for licensure within the state that you want to practice medicine.

I'm an H-1B visa holder. What happens if I lose my job during the COVID-19 pandemic? How will this affect my H-4 visa family members?

An H-1B visa holder must remain employed for their visa to continue to be valid. If an H-1B visa holder loses their job they have a 60-day grace period within which they can remain in the U.S. and try to find a new job and sponsoring employer. If they are unsuccessful in finding a new position, then they must leave the country. The AMA understands how difficult losing a job is especially during this time, as such we are advocating to temporarily extend the 60-day grace period to 180 days to try and better accommodate IMGs during this time. An H-1B visa holder's spouse and unmarried children under 21 years of age may seek admission to the U.S. as H-4 nonimmigrants. However, the H-4 visa is completely dependent on the H-1B visa holder's status. As such, the H-1B visa holder must remain in compliance with all visa requirements, including meeting relevant employment requirements. If the H-1B visa holder loses their job due to COVID-19 and cannot find new employment within the grace period, the H-4 visa is no longer valid and the H-4 visa holder must leave the country.

Can I be removed from the United States if I overstay my H-1B visa due to COVID-19?
Yes. Deportation or removal is the same for H-1B visa holders as it is for all visa holders. In order to stay in status, an H-1B employee must continue working for the H-1B employer while in the United States. Generally, an H-1B employee must be in status in order to change, extend or adjust status. If an H-1B visa holder is terminated before the end of the period of authorized stay, the employer is liable for reasonable costs of the visa holder's return transportation unless the visa holder voluntarily resigns. As a matter of prosecutorial discretion, DHS may permit an H-1B visa holder who is present in the United States unlawfully, but who has pending an application that stops the accrual of unlawful presence, to remain in the United States while that application remains pending. In this sense, the H-1B visa holder's remaining can be said to be "authorized."
However, the fact that the H-1B visa holder does not accrue unlawful presence does not mean that their presence in the United States is lawful. If an H-1B visa holder accrues unlawful presence in the United States, they may be barred from reentering the U.S. for three years, ten years, or permanently depending on how long they overstayed the visa. For example, an H-1B professional who has been legally employed in the U.S. in H-1B status is permitted by federal regulation to continue living in the U.S. and working for the sponsoring employer for up to 240 days while an extension petition is pending – as long as the extension petition is filed prior to the expiration of the prior H-1B petition. However, due to significant processing backlogs, USCIS very often takes six months or longer to adjudicate H-1B extension petitions. During that time the previous H-1B petition may expire, leaving the H-1B professional solely dependent on the 240 days of work authorization permitted under the regulation – and without any underlying H-1B status unless/until the H-1B extension petition is approved. If the petition is ultimately denied, then such a person would be deemed unlawfully present as of the date of the denial and, a Notice To Appear would be issued. Petitions for nonimmigrant (temporary) visas may be filed up to six months in advance of the anticipated work start date. Extensions may be filed up to six months in advance of the expiration date of the current petition. Employers should plan to file petitions at the earliest possible moment.

AMA advocacy efforts supporting IMGs

- AMA June 26 letter: Urging the Administration to consider J-1 and H-1B IMGs and their families' entry into the U.S. to be in the national interest of the country so that families can remain together and IMG physicians can immediately begin to provide health care to U.S. patients.
- AMA May 8 letter: Supporting the Healthcare Workforce Resilience Act and to urging the Senate and House to quickly pass the legislation so that we could recapture 15,000 unused employment-based physician immigrant visas from prior fiscal years which would help enable our U.S. physicians to have the support they need and our U.S. patients to have the care they deserve.
- AMA May 4 letter: Urging Vice President Michael Pence to allow J-1, H-1B and O-1 IMGs to be exempt from any future immigration bans or limitations so IMGs can maintain their lawful non-immigrant status while responding to the COVID-19 pandemic.
- AMA April 14 letter: Urging U.S. Citizenship and Immigration Services (USCIS) to temporarily extend visas automatically for one year and expedite approvals of extensions and changes of status for IMGs.
- AMA April 3 letter: Asking Vice President Pence and USCIS to address the situation of thousands of IMGs in temporary status.
- AMA March 24 letter: Urging U.S. Department of State to let IMGs either continue, or begin, to serve a vital role in caring for patients during the COVID-19 pandemic.
- AMA March 24 letter: Petitioning USCIS to temporarily expedite extensions and changes of status for foreign national doctors currently in the U.S.

Additional federal guidance

- USCIS: Special situations
- Department of Homeland Security (COVID-19)
- Department of State:
    - Coronavirus disease 2019 (COVID-19)
    - Update on visas for medical professionals

APPENDIX 5: PROTECTING UNDERREPRESENTED STUDENTS AND RESIDENTS DURING COVID-19

Updated July 6, 2020

The current pandemic is impacting all segments of society—but not equally—and it has created significant disruptions in medical education. Even prior to the pandemic, national data suggested medical education was already losing ground with respect to racial and ethnic parity.[1]

Recent weeks have brought additional stressors to the fore as our society continues to grapple with structural racism. The medical education community must remain vigilant for potential inequities in educational outcomes across the medical education continuum. Diversity efforts are particularly vulnerable during times of disruption, hence institutions must heighten their commitment of attention and resources.
It is the responsibility of the AMA to advocate for medical students, to act to reverse the historic active exclusion of racially marginalized groups (specifically, Blacks, Latinx and Native Americans) from the practice of medicine and to drive advancement of multiple dimensions of diversity in the medical profession. Broader initiatives to foster long-term change in medicine and address inequities in the entire United States educational system are imperative and are underway.
Current disruptions related to COVID-19, however, may amplify underlying inequities in our educational system, similar to the pandemic's role in exacerbating health inequities. Recent societal unrest in response to ongoing public racist acts of violence further compounds immediate concerns. Detailed examples of pressing risks for inequity in educational outcomes are provided here.
Concerns span the continuum of pre-medical education, transition to medical school, performance during medical school, residency selection and performance in graduate medical education. Although this highlights immediate risks posed by current circumstances, these recommendations should be applied as long-term interventions.

Recommendations

Colleges, medical schools and residency programs should:

- Increase attention to structural determinants of academic success and provide a clear process by which students can report challenges and seek assistance.
- Engage students, residents and faculty from underrepresented backgrounds (particularly racial and socioeconomic) in the process of planning adjustments to curriculum, assessment and application processes in order to better consider the diverse circumstances of students.
- Amplify efforts to create inclusive learning and working environments across the continuum of pre-medical education, medical school, graduate medical education and practice.
- Heighten monitoring of learner well-being at all levels of medical education and minimize barriers to mental health care.
- Implement a systems approach to promoting well-being that serves to complement the resilience of individuals. Organizational-level efforts should be undertaken to provide:
    - Consistent and inclusive communication.
    - Clarity regarding changes in curriculum, performance expectations or administrative processes.
    - Allyship to address microaggressions in clinical and learning environments.
    - Responsiveness to student and resident concerns.
    - Processes for addressing student and resident grievances.
- Adjust medical school admissions and residency selection processes to:
    - Mitigate bias (e.g. review of applications blinded to academic metrics bias training for admissions committees and interviewers).
    - Apply novel screening practices (e.g. situational judgment tests).
    - Incorporate more holistic, inclusive selection criteria (e.g. distance traveled score).
    - Monitor outcomes for potential bias related to any newly implemented or modified approaches in admissions and selection.
- Improve communication in medical school admissions and residency selection processes by:

    - Implementing robust outreach to students from disadvantaged and underrepresented backgrounds.
    - Developing targeted platforms to foster bilateral exchange of information between applicants and medical schools or residency programs respectively.
    - Reducing complexity and improving transparency in application and selection processes.
    - Minimizing the disparities in candidates' access to coaching in selection processes, such as by providing tips for success at the level of the receiving medical school or graduate medical education (GME) program.
- Increase commitment to, and investment in, pathway and retention programs and other initiatives that intentionally promote equity, diversity and inclusion.

Examples of inequity in educational outcomes due to recent disruptions

Similar themes apply across the continuum of pre-medical education, transition to medical school, performance during medical school, residency selection and performance in GME.

- The shift to virtual platforms of educational delivery has revealed inequities that may further limit the academic achievement of students from under-resourced urban and rural communities, such as in:
    - Access to technology, including internet access and appropriate devices.
    - Home circumstances, including dedicated space and a quiet environment in which to work.
- Students are losing enrichment activities that carry particular importance to candidates who are from backgrounds underrepresented in medicine or who have perceived weaknesses in other aspects of their portfolios. Activities such as research, shadowing, global health experiences and clinical electives serve to instill confidence in pursuing a medical career, support exploration among medical disciplines, spur mentoring, and provide opportunities for distinction that contribute to successful advancement.
- Geographic inconsistency in administration of Medical Colleges Admissions Test (MCAT) and United States Medical Licensing Examination (USMLE) Step examinations has induced some students to consider travel for testing, which will amplify existing disparity in access and in completeness of application portfolios.
- Geographic variations in COVID-19 impact and response—such as physical distancing requirements, testing availability, and availability of personal protective equipment—will create inconsistency in recovery of medical student clinical activities among schools and may disproportionately impact under-resourced schools.
- Limited clinical activities may reduce medical students' access to advocacy in the residency application process (as in the form of letters of recommendation or other communication) which is particularly valuable to disadvantaged candidates.
- Limitations on medical student participation in away rotations, of particular importance for students to demonstrate their abilities to prospective GME programs and to assess the culture of those programs, may disproportionately disadvantage candidates who are underrepresented or who have perceived weaknesses in other aspects of their portfolios.
- The shift to virtual interviews for both medical school and residency selection may have disproportionately negative impacts on students from underrepresented groups or under-resourced communities, due to limitations in technology and appropriate dedicated space as well as less time and personal presence to overcome bias.
- Because people of color are experiencing COVID-19 disproportionately, there may be a corresponding emotional toll on students and residents who lose family and friends to the disease.
- The families of students and residents of color or those who are from lower socioeconomic status may be experiencing greater economic burden from COVID-19, perhaps due to losing employment or increased costs of essential goods. Students may prioritize the need to help support their families over school-related obligations.
- The current environment of racial and societal unrest may have disproportionately negative impacts on the well-being of students and residents from minority communities, impairing their ability to succeed in course work and to navigate application processes.

- Pathway and recruitment programs may suffer from disrupted opportunities to interact with students; and financial strain on many academic centers may result in decreased support to such programs, both in financial resources and in the engagement of participating faculty.

Additional resources
ACGME News: Increasing Graduate Medical Education Diversity and Inclusion, McDade
AAMC: Holistic Review in Medical School Admissions

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[1]Talamantes, et al. Closing the Gap - Making Medical School Admissions More Equitable. *NEJM* 2019. (As medical school enrollment doubled over the past two decades, the percentage of entering under-represented students actually fell by 16%)

APPENDIX 6: SENIOR PHYSICIAN COVID-19 RESOURCE GUIDE

Updated March 28, 2020

The AMA has curated a selection of resources to provide guidance to senior and retired physicians who may wish to return to work or are called upon to do so during the coronavirus (COVID-19) outbreak.

1. License considerations
The licensure status of retired physicians varies by state. In some states retired physicians maintain their regular license while others create a separate category for retired or inactive physicians, and still others have no license category for retired physicians. In response to COVID-19, many states have taken action to allow retired physicians to temporarily return to practice through an Executive Order, Department of Health Order or Board of Medicine directive. Often these actions specify the physician's license must have been in good standing at the time of retirement. Many states have also indicated the physician must have been in active practice within the last 2-5 years.
The path to reentry from a licensing perspective varies. For senior and retired physicians who maintain an active license, there are no licensure restrictions on re-entry to practice. For physicians who maintain an inactive, retired physician, or similar license, your state may have temporarily waived any barriers to re-entry. We encourage you to check the Federation of State Medical Boards' COVID-19 resource on state actions on license status for inactive/retired physicians for guidance: As this landscape continues to evolve, we strongly encourage physicians to check with their respective state medical boards for the latest information.

2. Providing assistance that does not involve direct patient care
Whether senior physicians should be providing direct patient care for COVID 19 patients is a complex issue that must balance a number of factors, such as whether the age of the physician and their family members puts them in a high risk group, whether personal protective equipment (PPE) is readily available, and whether they could contribute meaningfully in a non-direct patient care role. Below is a list of important contributions to consider:

- Many health systems are assigning senior physicians to telehealth and administrative activities, which may free up others to be on the front line.
- Contact your local or state health department. Many are keeping listings of needed roles for volunteer physicians and health care workers.
- Medical schools are using senior physicians for online teaching and mentoring of medical students. Contact your medical school's dean's office to find out how you can participate.
- Consider making an appointment at your local Red Cross to donate blood.
- Provide online outreach to residents of nursing homes or senior residential communities to combat isolation

Assist local practices in creating patient education materials and information sheets with local/regional resources.

3. Re-entering practice
Explore opportunities to provide mentoring or training in your practice location. Many institutions have developed algorithms for telephone triage and/or assessment of symptomatic patients.

4. Professional liability
Explore coverage with your local health system. If you are licensed and volunteer, the third federal economic COVID-19 stimulus package (H.R. 748) includes liability protections for volunteer health care professionals during COVID-19 emergency response. In addition, if you are authorized to prescribe and administer certain countermeasures to treat COVID-19, you may be immune from liability under the Public Readiness and Emergency Preparedness Act (PREP Act). Also check with your state medical association; you may have additional liability protections under state law, a recent Gubernatorial Executive Order, or other emergency response programs, such as the Uniform Emergency Volunteer Health Practitioners Act (UEVHPA) or the Emergency Management Assistance Compact (EMAC).

5. Retirement status
Some physicians are receiving retirement income that may be affected by a return to paid employment. Check the status of your retirement income according to the role you are being asked to perform.

6. Role clarification
Clarity on the following questions may be helpful if you are planning to volunteer your assistance.

- What are the activities I'm being asked to do?
- Do those activities align with my skill set?
- What types of training/refreshers/mentoring will be provided?
- Will I be provided with PPE?

7. COVID-19 resources

- *JAMA Network* Coronavirus disease 2019 resource center
- AMA COVID-19 resource center
- AMA licensure chart (PDF)

APPENDIX 7: CARING FOR OUR CAREGIVERS DURING COVID-19

Updated June 5, 2020

Resources for health care leadership
Amid the COVID-19 global outbreak, it's likely to be a stressful time for those who work on the front lines of health care.

Now more than ever, it's important for health systems and health care organizations to create and ensure an infrastructure and resources to support physicians, nurses and care team members.
The following lists provide practical strategies for health system leadership to consider in support of their physicians and care teams during COVID-19.
Note that any activities involving medical students or other health professions students should be part of a voluntary, student-led program overseen by their school in compliance with guidance from the LCME or other accreditor. No direct solicitation of individual students should occur.
Some items in the list are suggestions, while others have already been implemented by health systems.

Assess physician stress and identify specific drivers

- Surveys can be used to track trends in stress levels, identify specific drivers of stress, and develop supportive infrastructures based on these drivers. The American Medical Association is offering two no-cost surveys to help health care organizations monitor the impact COVID-19 has on their workforce during this pandemic.

Building a resilient organization

- The AMA's caregiver resource, Creating a Resilient Organization, provides 17 steps that health care organizations can take in order to effectively care for health care workers during times of crises. Successful organizations will take a systems approach and focus on becoming a resilient organization prior to times of crises, rather than limiting their efforts to a focus on individual resilience. Resilient organizations will need to rapidly reconfigure their well-being priorities to meet the biggest new drivers of stress in a crisis setting.

Workload redistribution

- Physicians/APPs who are at home (on quarantine or for childcare) manage the inboxes and phone calls of those who are at work and provide telemedicine care. Organizations have the ability to redirect or create physician work (wRVU) credit for this work.
    - Atlantic Medical Group has shifted their ambulatory practice care model to telephonic and telemedicine and has reduced office visits significantly. They are considering splitting their offices into teams of staff and physicians and rotating the teams in/out of the office. Rotating shifts would reduce staffing in the office such that everyone isn't in the same very close spaces together. Clinicians not in the office can do phone visits, telemedicine, answer patient questions or be deployed to call centers and testing centers.
- Retraining and/or enhancing the skills of who have not recently worked in the intensive care unit to increase workforce. AMA has curated guidance and resources for those who may wish to return to work or are called upon to do so during the coronavirus (COVID-19) outbreak.
- COVID Staffing provides and online resource to help hospitals understand and manage their staffing needs during the COVID-19 pandemic.
- Administrators and clinicians with extra time due to decreased regular services have offered assist with insurance needs (finding old claims, updating bad addresses, etc.).
- Set up triage hotline. Medical students at multiple states are providing extra staffing for the medical school call center. The purpose of this triage hotline is to provide students/staff/faculty who have traveled or have symptoms of COVID-19 with real-time information on protocol and next steps.
- Allow medical assistants and nurses to make contributions according to their ability, with physician or APP oversight and discretion. This may include nurses or MAs taking verbal orders, performing computerized order entry, doing medication reconciliation or assisting further with visit note documentation. This will alleviate some of the workload on physicians and APPs.

Institutional policies

- Ensure that paid time off and sick days remain unaffected for all employees for COVID-19 related illnesses.
- Ensure no out-of-pocket expenses for employees with COVID-19 related illnesses.
- CMS, Surgeon General, CDC and American College of Surgeons have called for cancellation of all elective surgeries and the rescheduling all non-urgent outpatient visits.
- CMS has implemented several blanket waivers (PDF) for COVID-19. This includes additional flexibility for verbal orders. View additional CMS policies and regulatory flexibilities.
- Six ways to address physician stress during COVID-19
- The Center for the Study of Traumatic Stress offers information for how health care teams notify families (PDF) after a COVID-19 death.

Meals

- SweetGreen will deliver free salads and bowls to hospitals in the cities they serve: DC, Philadelphia, Boston, New York City, San Francisco, Los Angeles, Chicago and Houston. To request free salads, please visit their site to order.
- GrubHub and DoorDash are now offering contact-free deliveries. Both companies have reduced or eliminated commission fees for local restaurants to support restaurants that are mandated to only have carry-out/delivery only service.
- Medical students at multiple states have volunteered to deliver supplies/meals and run errands on behalf of individuals in quarantine.
- A Denver community has reported the development of "Lunches for Clinicians" in which clinicians can order meals from local restaurants for delivery during shifts. Community members are raising funds to help pay for these meals. Many communities across the country have launched similar efforts.

Childcare and pet care

- Medical students in Minnesota, St. Louis (Washington University in St. Louis) and Chicago (Northwestern University) are offering childcare and pet care services for physicians and care teams. To facilitate logistics, both students and families register for services and students volunteer for shifts. Students are then matched with families based on need and availability. Students have reported that the need is overwhelming, with some systems reporting more than 100 families signed up for childcare or pet care services.
  Mount Sinai offers similar services through their Sinai Kids and Sinai Together initiatives. UW Health has partnered with Epic and Meriter to transform Epic's old headquarters into a 24/7 childcare center for children of clinicians that are working at local hospitals during COVID-19.
- Several organizations have partnered with their local YMCA to provide additional childcare for their health care workers.
- One system reported a program in which staff members who must stay home to care for their children are still paid their regular rate if they agree to care for children of two other staff members.

Personal protective equipment (PPE)

- American Dental Association and state dental associations are encouraging dentists to donate their PPE to local hospitals.
- Consider the use of Mask Match in order to request masks (if you are a health care professional) or to donate masks if you have extra. Masks are not for purchase or for sale. Those who are matched with a health care worker are expected to cover the cost shipping and handling.
- Mount Sinai has developed guidelines for health care workers to consider for keeping their family and friends safe when returning home from work.

Attention to emotional and mental well-being

- Headspace is a meditation and sleep app that can have a positive impact on health professionals' personal and professional lives.

- Organizations like Mount Sinai and UNC provide online toolkits where all well-being resources are centralized and easy for clinicians to access.
- Consider assigning therapists to strategic locations (e.g., cafeteria, staff lounges, emergency department) to provide easy access for staff. Several health systems offer drop-in hours with a psychologist onsite for their physicians and care teams. Several organizations are offering 24/7 emotional support through their behavioral health teams. In many cases, this includes emotional support for family members of clinicians as well.
- Continue to monitor the ability of the Employee Health and Well-Being Unit to meet workload demands, personnel health and safety, resource needs and documentation practices.
- Supervisors can conduct a 5-minute debrief at the end of every shift with their care team. Make debriefing a routine part of the day.
- Several wellness committees and Chief Wellness Officers have shared that intensive in-person rounding to frontline health care workers has proven enormously helpful. Rounding may include:
    - Supplying basic wellbeing needs (food, drinks, hygiene items)
    - Provide in the moment support, direct pathway for more intensive support needs through behavioral health teams, peer support, etc.
    - Elicit concerns/needs that require escalation and advocacy (has led to countless system changes, including prepaying of childcare, scrub service, transparency efforts, creation of a caregiver relief fund, etc)
    - Increase awareness of available support resources
- Consider making mental health resources available to families of clinicians (PDF), as traumatic experiences from COVID-19 will affect them as well.
- The Department of Psychiatry at SUNY Downstate Health Sciences Center has created a COVID-Stress Hotline that can be accessed by everyone at the medical center. The hotline can be accessed by SMS text, email, or call in and was set up using Updox. A second line was established for leadership to communicate about groups that might need help sessions or immediate group interventions.
- AMA offers strategies and resources to manage mental well-being while also caring for patients during the pandemic or any other crisis.
- With the goals of ensuring physicians and advanced practitioners receive the psychological support they need and of paving the way for them to successfully access existing resources through their Physician Assistance Program, the Washington State Medical Association called on Employee Assistance Programs/Physician Assistance Programs with clients in the health care industry to consider the following actions:
    - Change the pre-recorded greeting message on the 1-800 number to clearly communicate that all calls are confidential and HIPAA compliant.
    - Establish a triage system at entry that allows people to identify themselves as clinicians at the frontline of the COVID-19 response. Deploy your most highly trained and skilled staff to support this population, including the provision of cognitive behavioral therapy.
    - Develop custom communication materials targeted to clinicians at the frontline of the COVID-19 response that clearly explain that your mental health care professionals are equipped to help them navigate the COVID-19 crisis and that the services are completely confidential.
    - Work with each of your clients to provide just-in-time group and 1:1 sessions to frontline clinicians while protecting the health of your staff. For example, use telehealth technology to plant multiple virtual mental health professionals inside the most impacted hospitals and/or at health care provider quarantine facilities for easy on-demand access.
    - Ensure your organizations' emergency response plan includes strategies to adequately handle a surge in requests for services.

Social support

- Several organizations, including Methodist Hospital, UCSF and Mount Sinai, are using video conferencing tools to set up peer support "connection groups" in which physicians and care teams can support one another and discuss ongoing challenges. UCSF's anesthesia department provides virtual support sessions via Zoom for faculty and trainees. These sessions are held once per week—

one for faculty and one for trainees. Discussion questions for these sessions includes: What worries you? How are you feeling and what are you experiencing now? How are you processing all of this? Here are some Zoom and moderator tips provided by UCSF.

- **Virtual session tips:**
    1. Have everyone turn on their cameras (if possible)
    2. Open Zoom chat function so participants can bring up items and moderators can discuss with the group
    3. If more than 15 people consider using Zoom breakout rooms
    4. Acknowledge each person as they join the Zoom meeting
- **Moderator tips:**
    1. Psychological safety is key
    2. It may take time for participants to open up, resist the urge to "fill the silence" if there are lulls
    3. Let conversations unfold naturally
    4. Try to focus more on emotions vs. clinical details or how to fix the problem

Christiana Care is offering "COVID Conversations," topic-driven group support sessions. These sessions allow caregivers to connect with another and share thoughts, feelings and ideas about life during the pandemic.

PeerRxMed is a free, peer-to-peer program for physicians and others working in health care designed to provide support, connection, encouragement, resources and skill-building in order to help participants advance along the Burnout to Thriving Index toward optimal well-being, however you would define that state for yourself. This program provides regular reminders for weekly, monthly and quarterly check-ins with a peer. Reminders include exercises that provide structure for you to connect with a colleague or friend.

Jo Shapiro, MD (Harvard Medical School) discusses the importance of peer support, the fundamentals for operationalizing a peer-support system in health systems and practices and how it can potentially change organizational culture especially during the COVID-19 pandemic.

Nebraska Medicine offers 1:1 peer support through their Peers in Need of Support (PiNS) program. More than 120 volunteers were specifically trained for COVID-19 response using just-in-time training (PDF).

A new Slack channel, "Medical Students vs. COVID-19," allows medical students from across the country to connect and share helpful strategies for how students can continue to support physicians and care teams. Join the Slack channel.

An ambulatory care clinic in Arizona has set up games for clinicians and patients to play throughout the day to keep morale high.

AMA COVID-19 news coverage

Through interviews with health system leaders, the AMA highlights programs and initiatives from around the country that are supporting the health care workforce during the COVID-19 outbreak.

- COVID-19 front line: Mount Sinai keeps physician well-being in focus
- 6 ways to address physician stress during COVID-19 pandemic
- Peer support program strives to ease distress during pandemic
- COVID-19 physician well-being initiatives embrace family needs
- 5 wellness task force tactics designed to prioritize physician health
- 6 ways a health system attacks stress during the COVID-19 crisis

APPENDIX 8: LCME GUIDING PRINCIPLES

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Medical Students, Patients, and COVID-19: A Community Conversation about Education and Safety

March 12, 2020

LCME Guidance Principles

1. Your faculty has defined your school's **educational program objectives (EPOs) and graduation requirements** and the assessments you will use to ensure that those objectives and requirements are met. It is likely that you will need to change the mechanisms through which medical student learning occurs (e.g., online content delivery and/or interactive work) and is assessed (e.g., paper cases, simulation exercises when onsite clinical interactions might be limited). The LCME completely understands that, and while the LCME Secretariat is always happy to speak with, provide a sounding board to, or guide you, **you do not need to notify the LCME of these adjustments in instructional and assessment methods.**
2. The goal of accreditation is to assure all stakeholders (i.e., the public, medical students, medical schools, graduate medical education programs, health systems, licensing bodies, Department of Education) of educational program quality. This means that, together, **our goal is to provide that by ensuring that our graduates meet their school's EPOs, course and clerkship learning objectives, and required clinical experiences** in this most challenging of times. It is likely that the schools will face the greatest challenges in accomplishing this for students' required clinical experiences. From national data that you have shared, the LCME knows that most of our medical schools have several elective weeks/months in the last year or phase of the curriculum. **Should you need to interrupt or postpone clerkships or other required clinical experiences because of the real and important pressures and stresses of the clinical environment, these elective weeks are available to adjust your students' clinical training schedules without having to delay completion of these required experiences before graduation.** In other words, in looking at your own graduation requirements, you can and should be flexible with the elective weeks built into your curriculum; the LCME understands the need to repurpose elective time to achieve the required clinical experiences. The LCME also recommends that all changes in the required clerkships pass through the school's curriculum governance committee (e.g., Curriculum Committee) prior to implementation.
3. **The LCME is you.** Fifteen of its 19 members are deans and associate deans, perhaps at your school and at other LCME-accredited schools; there are two public and two medical student members. **It completely understands and is experiencing the exceptional pressures you are under,** as a result of both the national and local environment.
4. If you are contemplating **significant changes in the structure** (e.g., major shift in clinical training sites from the inpatient to outpatient setting); **timing** (e.g., delay in student progression to graduation); **duration** (e.g., below the 130-week expectation); or **location** (e.g., due to local variation in the spread of COVID-19), please email the Secretariat (lcme@aamc.org), and we will speak with and work with you to think through your particular situation and approach before you

notify the LCME of the major curriculum changes you are anticipating/making. Remember that any and all conversations you have with the Secretariat are completely confidential and are never shared with the LCME.

Know that we are being challenged along with you, learning from you, and thinking about this with you, every step of the way. We will be creating and updating a page on the LCME website for additional accreditation-related resources and information as they become available. This document, as well as the March 5, 2020 memo from Alison Whelan, Geoffrey Young, and Veronica Catanese will be posted there, and the AAMC COVID-19 resource site will contain links to this LCME resource collection.

APPENDIX 9: "MAINTAINING QUALITY AND SAFETY STANDARDS AMID COVID-19"

Coalition for Physician Accountability

Maintaining Quality and Safety Standards Amid COVID-19

May 11, 2020

The member organizations of the Coalition for Physician Accountability (www.physicianaccountability.org) have released the following statement and table of resources to provide guidance and support to healthcare administrators and credentialing staff who are supporting the contributions of new or volunteer physicians to patient care during the COVID-19 pandemic.

The Coalition for Physician Accountability (Coalition), a cross-organizational group including AACOM, AAMC, ABMS, ACCME, ACGME, AMA, AOA, CMSS (OPDA), ECFMG, FSMB, LCME, NBME, and NBOME, was established in 2009 to promote professional accountability by improving the quality, efficiency, and continuity of the education, training, and assessment of physicians. Its membership includes the national organizations responsible for the accreditation of medical education and training and the assessment, licensure and certification of physicians throughout their medical career, from medical school through practice. Our membership also includes members of the public and the profession. We share a strong commitment to protecting the public's health and safety through the delivery of quality health care.

The pandemic has created a public health emergency that is rapidly altering the provision of health care services across the country. Physicians and other clinicians have responded with offers to provide care outside of their previously licensed jurisdiction and beyond their typical scope of practice.

The Coalition members overseeing physician workforce and training have developed the following guidance and resources for the deployment of physicians, physicians in training (interns, residents and fellows), and retired or inactive physicians, to ensure the safe delivery of quality clinical care during this unprecedented emergency.

The Coalition's Guidance for Maintaining Quality and Safety Standards Amid COVID-19 Pandemic include:

- **Planning:** The pandemic poses a direct threat of over-burdening the health system. The stress to health systems is variable, but all health care facilities should be developing strategies for the optimal use of physician resources as the disease spreads and resource demands fluctuate.
- **Verification:** Acknowledging the additional flexibility that regulators have provided, administrators should access readily available licensing, credentialing, and certification data to verify the attestations of volunteers and new recruits.
- **Provision of Care:** The American Medical Association's *Code of Medical Ethics: Guidance in a Pandemic* states that physicians have an ethical obligation to "provide urgent medical care during disasters," an obligation that holds "even in the face of greater than usual risk to physicians' own safety, health or life." In a crisis, "(t)he risks of providing care to individual patients today should be evaluated against the ability to provide care in the future."
- **Protection:** Healthcare professionals must be equipped with appropriate Personal Protective Equipment (PPE) to safeguard their health and that of their patients, families, and the general public, and physicians must use this protection. The more transmissible the disease, and the higher the risk of occupational exposure, the more urgent the need for protection.
- **Training, Education, and Support:** Healthcare professionals who may be asked to practice outside their areas of training and expertise must have access to training and educational resources for the type(s) of care they are asked to provide during the COVID-19 pandemic to assure safe patient care. Appropriate mentorship, support, training, and supervision must also be available for healthcare professionals who are asked to provide care to which they are unaccustomed.
- **Maintenance of Safety Standards:** Health care facilities should have contingency plans to maintain customary safety standards in the face of a demand surge. Guidance for the adoption of crisis standards of care is available to help leaders make informed decisions that optimize resources while mitigating the risk of harm.

The following are some steps that can be taken to prepare for the arrival of a new volunteer:

	Action Step	Resource	Additional questions/resources
1	Check what licenses the physician has (and/or ECFMG certification if an international medical graduate)	www.Docinfo.org (free service) Physician Data Center www.fsmb.org/PDC/ ECFMG Certification Verification	Email: pdc@fsmb.org Email: cvsonline@ecfmg.org or call ECFMG at 215-386-5900
2	Determine applicable licensing waivers or exceptions (if licensed elsewhere)	FSMB COVID-19 Page for a summary of changes Please check applicable state or territorial medical board website	
3	Check Information on a volunteer's education and training	Physician Data Center www.fsmb.org/PDC/ ECFMG (for IMGS)	Email: pdc@fsmb.org Email: cvsonline@ecfmg.org or call ECFMG at (215) 386-5900
4	Determine if the volunteer has a valid controlled substance license	Obtain copy of existing license and see https://apps.deadiversion.usdoj.gov/webforms2/spring/dupeCertLogin?execution=e1s1	https://deanumber.com/default.aspx?relID=33637
5	Check a volunteer's board certification status	ABMS certification AOA certification https://certification.osteopathic.org/validate/	Call: ABMS Solutions at (800) 733-2267 with questions. Call: AOA at (888) 626-9262
6	Confirm: a) vaccination record b) malpractice insurance c) Review any history of malpractice	Recommended vaccinations for healthcare workers: https://www.cdc.gov/vaccines/adults/rec-vac/hcw.html Guidance on medical liability insurance during the COVID- 19 crisis available from the Medical Professional Liability Association	Call: CDC at (800) 232-4636 See also: The Coronavirus Aid, Relief, and Economic Security Act (CARES Act, H.R. 748), *Section 3215: Limitation on Liability for Volunteer Health Care Professionals During COVID-19 Emergency Response*

		National Practitioner Data Bank*: https://www.npdb.hrsa.gov/hcorg/howToSubmitAQuery.jsp	Email: help@npdb.hrsa.gov
7	Other Important Credentialing Resources	NAMSS COVID-19 Resources	Email: info@namss.org

**Only Accessible by Eligible Entities*

If the volunteer is a recently graduated physician, refer to the following resources:

8	Refer to guidance from AAMC, AACOM, ACGME and FSMB	AAMC guidance AACOM Coronavirus Resources ACGME guidance FSMB COVID-19 Page (for training license information)	

To support the volunteer as they start providing care:

9	Provide guidance to the physician	AMA volunteer guide AMA Code of Medical Ethics: Guidance in a Pandemic FSMB COVID-19 Page (for emergency licensure information) AOA COVID-19 Resources	
10	Provide training resources to the physician	ACCME training resources CDC guidance HHS COVID-19 Workforce Virtual Toolkit	Email: info@accme.org
11	Provide information on PPE	CDC guidance for PPE	

12	Share resources on managing telehealth	ACCME telehealth resources AMA Telehealth playbook HRSA Telehealth Website (hhs.telehealth.gov)	Email: info@accme.org

For more information on how to prepare for an anticipated surge in demand for scarce resources during an epidemic

13	Expand contingency plans to include a process for adopting crisis standards of care to manage scarce physician and other resources	National Academy of Medicine -Discussion Paper on Crisis Standards of Care in response to SARS-CoV-2 National Academy of Medicine -Systems framework for crisis standards of care	

Workgroup Members:

American Board of Medical Specialties (ABMS)
Accreditation Council for Continuing Medical Education (ACCME) Accreditation Council for Graduate Medical Education (ACGME) Council of Medical Specialty Societies (CMSS) Educational Commission for Foreign Medical Graduates (ECFMG) Federation of State Medical Boards (FSMB) National Resident Matching Program (NRMP) Public Member

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