Visit ama-assn.org/about-us/business-ama-house-delegates-2017-interim-meeting to access the handbook online.
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 to be considered by the House.

- 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.

- The Interim Meeting is focused on advocacy issues. A resolution committee (see AMA Bylaw 2.13.3) considers each resolution and recommends that the item be considered or not considered at the Interim Meeting. Items that meet the following definition of advocacy or that are considered urgent are recommended for acceptance:

  Active use of communication and influence with public and private sector entities responsible for making decisions that directly affect physician practice, payment for physician services, funding and regulation of education and research, and access to and delivery of medical care.

Resolutions pertaining to ethics should also be included in the agenda. Remaining items are recommended against consideration, but any delegate may request consideration when resolutions are presented for consideration (during Sunday’s “Second Opening” Session). A simple majority of those present and voting is required for consideration.

- 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.
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 Numbers are deleted and not reused when policies are rescinded.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
- CME – Council on Medical Education
- CEJA – Council on Ethical and Judicial Affairs
- CMS – Council on Medical Service
- CEJA – Council on Ethical and Judicial Affairs
- CSAPH – Council on Science and Public Health
- CLRPD – Council on Long Range Planning and Development

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.

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<th>10.000 Accident Prevention/Unintentional Injuries</th>
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LIST OF MATERIAL INCLUDED IN THIS HANDBOOK (I-17)

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 1, Reference Committee B begins with 201, etc.).

The informational reports contain no recommendations and will be filed on Sunday, November 12, 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 Allocation and Seating Chart for the House of Delegates

6. Hotel Maps

7. 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 Members

8. Note on Order of Business

9. Summary of Fiscal Notes

FOLLOWING COLLATED BY REFERRAL

10. Report(s) of the Board of Trustees - Gerald E. Harmon, MD, Chair
    01 Redefining AMA's Position on ACA and Healthcare Reform (Info. Report)
    02 2017 AMA Advocacy Efforts (Info. Report)
    03 Removing Restrictions on Federal Funding for Firearms Violence Research (Info. Report)
    04 Limitations on Reports by Insurance Carriers to the National Practitioner Data Bank Unrelated to Patient Care (Info. Report)
    05 Effective Peer Review (Amendments to C&B)
    06 Electronically Prescribed Controlled Substances Without Added Processes (B)
    07 Medical Reporting for Safety-Sensitive Positions (Amendments to C&B)
    08 2018 Strategic Plan (Info. Report)
    09 Parental Leave (Info. Report)
    10 High Cost to Authors for Open Source Peer Reviewed Publications (F)
    11* Anti-Harassment Policy (Info. Report)
11. Report(s) of the Council on Constitution and Bylaws - Colette R. Willins, MD, Chair
   01* Amended Bylaws - Specialty Society Representation - Five Year Review (Amendments to C&B)

12. Report(s) of the Council on Ethical and Judicial Affairs - Dennis S. Agliano, MD, Chair
   01* Competence, Self-Assessment and Self-Awareness (Amendments to C&B)
   02 Ethical Physician Conduct in the Media (Amendments to C&B)
   03 Supporting Autonomy for Patients with Differences of Sex Development (DSD) (Amendments to C&B)
   04* Mergers of Secular and Religiously Affiliated Health Care Institutions (Amendments to C&B)

13. Opinion(s) of the Council on Ethical and Judicial Affairs - Dennis S. Agliano, MD, Chair
   01 Amendment to E-2.3.2, "Professionalism in Social Media" (Info. Report)

14. Report(s) of the Council on Long Range Planning and Development - Glenn A. Loomis, MD, Chair
   01* Senior Physicians Section Five-Year Review (F)

15. Report(s) of the Council on Medical Education - Lynne M. Kirk, MD, Chair
   01* Promoting and Reaffirming Domestic Medical School Clerkship Education (K)
   02 A National Continuing Medical Education Repository (Info. Report)
   03* Impact of Immigration Barriers on the Nation's Health (Info. Report)

16. Report(s) of the Council on Medical Service - Paul A. Wertsch, MD, Chair
   01* Affordable Care Act Section 1332 Waivers (J)
   02* Hospital Surveys and Health Care Disparities (J)
   03 Non-Physician Screening Tests (J)
   04* Health Insurance Affordability: Essential Health Benefits and Subsidizing the Coverage of High-Risk Patients (J)
   05 Reaffirmation of AMA Policy Opposing Caps on Federal Medicaid Funding (J)

17. Report(s) of the Council on Science and Public Health - Robert A. Gilchick, MD, Chair
   01 Universal Color Scheme for Respiratory Inhalers (K)
   02 Targeted Education to Increase Organ Donation (K)
   03 Neuropathic Pain as a Disease (K)
   04 National Drug Shortages Update (K)
   05* Clinical Implications and Policy Considerations of Cannabis Use (K)

18. Joint Report(s)
   CMS/CSAPH 01* Payment and Coverage for Genetic/Genomic Precision Medicine (J)

19. Report(s) of the Speakers - Susan R. Bailey, MD, Speaker; Bruce A. Scott, MD, Vice Speaker
   01 Recommendations for Policy Reconciliation (Info. Report)

20. Resolutions
   001 Disaggregation of Data Concerning the Status of Asian-Americans (Amendments to C&B)
   002 Intimate Partner Violence Policy and Immigration (Amendments to C&B)
   003 Revision of AMA Policy Regarding Sex Workers (Amendments to C&B)
   004 Tissue Handling (Amendments to C&B)
   005* Protection of Physician Freedom of Speech (Amendments to C&B)
   006* Physicians' Freedom of Speech (Amendments to C&B)
   201 Improving FDA Expedited Approval Pathways (B)
   202 Sexual Assault Survivors’ Rights (B)
203 Bidirectional Communication for EHR Software and Pharmacies (B)
204 EHR Vendors Responsible for Health Information Technology (B)
205 Health Plan, Pharmacy, Electronic Health Records Integration (B)
206 Defending Federal Child Nutrition Programs (B)
207 Redistribution of Unused Prescription Drugs to Pharmaceutical Donation and Reuse Programs (B)
208 Increased Use of Body-Worn Cameras by Law Enforcement Officers (B)
209 Government Mandated Sequester (B)
210 Merit-Based Incentive Payment System and Small Practices (B)
211 Exclusive State Control of Methadone Clinics (B)
213 Barriers to Price Transparency (B)
214 APRN Compact (B)
215 Relieve Burden for Living Organ Donors (B)
216 Relationship with US Department of Health and Human Services (B)
217 Regulations Regarding Medical Tool and Instrument Repair (B)
218* Health Information Technology Principles (B)
219* Certified EMR Companies' Practice of Charging Fees for Regulatory Compliance (B)
220* Preserving Protections of the Americans with Disabilities Act of 1990 (B)
221* House of Representative Bill HR 2077, Restoring the Patient's Voice Act of 2017 (B)
222* The Clinical Use of a Home Sleep Apnea Test (B)
223* Treating Opioid Use Disorder in Correctional Facilities (B)
224* Modernizing Privacy Regulations for Addiction Treatment Records (B)
225* Oppose Inclusion of Medicare Part B Drugs in QPP / MIPS Payment Adjustment (B)
226* Prescription Drug Importation for Personal Use (B)
601 Physician Burnout and Wellness Challenges (F)
801 Chronic Care Management Payment for Patients Also on Home Health (J)
802 Opposition to Medicaid Work Requirements (J)
803 Air Ambulance Regulations and Reimbursements (J)
804 Prior Authorization (J)
805 A Dual System for Universal Health Care in the United States (J)
806 Mandate Transparency by Pharmacy Benefit Managers (J)
807 Structural Barriers to Achieving Better Health Care Efficiency and Outcomes: ACOs and Physician Employment by Hospitals (J)
808 Opposition to Reduced Payment for the 25 Modifier (J)
809 Expansion of Network Adequacy Policy (J)
810 Pharmacy Benefit Managers and Prescription Drug Affordability (J)
811 Update OBRA Nursing Facility Preadmission Screening Requirements (J)
812 Medicare Coverage of Services Provided by Proctored Medical Students (J)
813 Sustain Patient-Centered Medical Home Practices (J)
814* Appropriate Reimbursement for Evaluation and Management Services for Patients with Severe Mobility-Related Impairments (J)
815* Pediatric Representation for E/M Documentation Guideline Revision (J)
816* Social Determinants of Health in Payment Models (J)
817* Addressing the Site of Service Deferential (J)
818* On-Call and Emergency Services Pay (J)
819* Consultation Codes and Private Payers (J)
820* Elimination of the Laboratory 14-Day Rules Under Medicare (J)
821* Hormonal Contraception as a Preventive Service (J)
901 Harmful Effects of Screen Time in Children (K)
902 Expanding Expedited Partner Therapy to Treat Trichomoniasis (K)
903 Improving Screening and Treatment Guidelines for Domestic Violence Against Lesbian, Gay, Bisexual, Transgender, Queer/Questioning, and Other Individuals (K)
904 Educating Physicians About the Importance of Cervical Cancer Screening for Female-to-Male Transgender Patients (K)
905 Addressing Social Media Usage and its Negative Impacts on Mental Health (K)
906 Opioid Abuse in Breastfeeding Mothers (K)
907 Addressing Healthcare Needs of Foster Children (K)
908 Updating Energy Policy and Extraction Regulations to Promote Public Health and Sustainability (K)
909 Expanding Naloxone Programs (K)
910 Improving Treatment and Diagnosis of Maternal Depression Through Screening and State-Based Care Coordination (K)
911* State Maternal Mortality Review Committees (K)
912* Corrective Statements Ordered to be Published by Tobacco Companies for the Violation of the Racketeer Influenced and Corrupt Organizations Act (K)
913* Increased Death Rate and Decreased Life Expectancy in the United States (K)
914* Support of Training, Ongoing Education, and Consultation in Order to Reduce the Health Impact of Pediatric Environmental Chemical Exposures (K)
952 Implicit Bias, Diversity and Inclusion in Medical Education and Residency Training (K)
953 Fees for Taking Maintenance of Certification Examination (K)
954 Developing Physician Led Public Health / Population Health Capacity in Rural Communities (K)
955 Minimization of Bias in the Electronic Residency Application Service Residency Application (K)
956 House Physicians Category (K)
957 Standardization of Family Planning Training Opportunities in OB-BYN Residencies (K)
958 Sex and Gender Based Medicine in Clinical Education (K)
959* Lifestyle Medicine Education in Medical School Training and Practice (K)

21. Resolutions not for consideration
  212 Physician Identification (Not for consideration)
  602 Creation of LGBTQ Health Specialty Section Council (Not for consideration)
  603 A Guide for Best Health Practices for Seniors Living in Retirement Communities (Not for consideration)
  951 Financial Protections for Doctors in Training (Not for consideration)

* included in Handbook Addendum
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.
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**Audience Left**

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REFERENCE COMMITTEE HEARING LOCATIONS

SUNDAY, NOVEMBER 12
8:30 am-Noon

Ref Cmte Amendments to C&B 312
Reference Committee B 313C
Reference Committee F Kalakaua Ballroom
Reference Committee J 313A
Reference Committee K 311
2017 INTERM MEETING OF THE AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Official Call to the Officers and Members of the American Medical Association to attend the Interim Meeting of the House of Delegates in Honolulu, Hawaii, November 11-14, 2017.

The House of Delegates will convene at 2 p.m. on November 11, at the Hawaii Convention Center.

STATE ASSOCIATION REPRESENTATION IN THE HOUSE OF DELEGATES

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SPECIALTY SOCIETY REPRESENTATION IN THE HOUSE OF DELEGATES

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<td>Society of Thoracic Surgeons</td>
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Remaining eligible national medical specialty societies (96) 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 270
National Medical Specialty Societies 217
Professional Interest Medical Associations 2
Other National Societies (AMWA, AOA, NMA) 3
Medical Student Regional Delegates 27
Resident and Fellow Delegate Representatives 22
Sections 10
Services 5
Total Delegates 556

Registration facilities will be maintained at the Hawaii Convention Center.

David O. Barbe, MD, MHA  Susan R. Bailey, MD  Jesse M. Ehrenfeld, MD, MPH
President  Speaker, House of Delegates  Secretary
2017-2018

OFFICIALS OF THE ASSOCIATION

BOARD OF TRUSTEES (OFFICERS)

President - David O. Barbe .......................................................... Mountain Grove, Missouri
President-Elect - Barbara L. McAneny ............................................. Albuquerque, New Mexico
Immediate Past President - Andrew W. Gurman .......................... Hollidaysburg, Pennsylvania
Secretary - Jesse M. Ehrenfeld ..................................................... Nashville, Tennessee
Speaker, House of Delegates - Susan R. Bailey ................................ Fort Worth, Texas
Vice Speaker, House of Delegates - Bruce A. Scott .......................... Louisville, Kentucky

Willarda V. Edwards (2020) .......................................................... Baltimore, Maryland
Gerald E. Harmon, Chair (2021) ................................................. Pawleys Island, South Carolina
Patrice A. Harris (2019) ............................................................... Atlanta, Georgia
William E. Kobler (2020) ............................................................. Rockford, Illinois
Russell W.H. Kridel (2018) ........................................................... Houston, Texas
William A. McDade (2020) ......................................................... Metairie, Louisiana
S. Bobby Mukkamala (2021) ......................................................... Flint, Michigan
Albert J. Osbahr, III (2019) ............................................................. Hickory, North Carolina
Stephen R. Permut (2018) ............................................................. Lewes, Delaware
Jack Resneck, Jr, Chair-Elect (2018) ............................................. San Rafael, California
Ryan J. Ribeira (2019) ................................................................. Mountain View, California
Karthik V. Sarma (2018) ............................................................... Los Angeles, California
Carl A. Sirio (2018) ...................................................................... Pittsburgh, Pennsylvania
Georgia A. Tuttle (2019) ............................................................... Lebanon, New Hampshire
Kevin W. Williams (2020) .......................................................... Nashville, Tennessee

COUNCILS OF THE AMA

COUNCIL ON CONSTITUTION AND BYLAWS
Colette R. Willins, Chair, Westlake, Ohio (2019); Jerome C. Cohen, Vice Chair, Loch Sheldrake, New York (2021);
Naiim S. Ali, Burlington, Vermont (Resident) (2018); Patricia L. Austin, Alamo, California (2018); Madelyn E. Butler,
Tampa, Florida (2018); Pino D. Colone, Howell, Michigan (2020); Cyndi J. Yag-Howard, Naples, Florida (2018); Joy Lee,
Washington, District of Columbia (Student) (2018); Ex Officio, without vote: Susan R. Bailey, Fort Worth, Texas; Bruce
A. Scott, MD, Louisville, Kentucky.
Secretary: Janice Robertson, Chicago, Illinois.

COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS
Dennis S. Agliano, Tampa, Florida Chair (2018); David Fleming, Columbia, Missouri (2024); Marc Mendelsohn,
Brooklyn, New York (Resident) (2018); Kathryn L. Moseley, Ann Arbor, Michigan (2020); Alexander M. Rosenau,
Allentown, Pennsylvania (2022); James E. Sabin, Boston, Massachusetts (2019); Laurie Schleimer, Cambridge,
Massachusetts (Student) (2019); Peter A. Schwartz, Reading, Pennsylvania (2023); Monique A. Spillman, Dallas, Texas
(2021).
Secretary: Elliott Crigger, Chicago, Illinois.

COUNCIL ON LEGISLATION
E. Scott Ferguson, West Memphis, Arkansas, Chair (2018); Jerry D. Kennett, Columbia, Missouri, Vice Chair (2018);
David H. Aizuss, Encino, California (2018); Seyed H. Aleali, Bridgeport, Connecticut (2018); Hans C. Arora, Cleveland
Heights, Ohio (Resident) (2018); Mary S. Carpenter, Winner, South Dakota (2018); Christopher C. Clifford, Reno, Nevada
(Student) (2018); Gary W. Floyd, Keller, Texas (2018); Linda B. Ford, Bellevue, Nebraska (AMPAC Observer) (2018);
Marilyn J. Heine, Dresher, Pennsylvania (2018); Beth Irish, Bend, Oregon (Alliance Liaison) (2018); Heather A. Smith,
New York, New York (2018); David T. Tayloe, Jr., Goldsboro, North Carolina (2018); Willie Underwood, III, Buffalo,
Secretary: George Cox, Washington, District of Columbia.
COUNCIL ON LONG RANGE PLANNING AND DEVELOPMENT
Glenn A. Loomis, LaGrangeville, New York, Chair (2019); Alfred Herzog, Hartford, Connecticut, Vice Chair (2019); Mary T. Herald, Summit, New Jersey (2018) James Goodyear, North Wales, Pennsylvania (2021); Shannon Pryor, Washington, District of Columbia (2020); Clarence Chou, Milwaukee, Wisconsin (2020); Edmond Cabbabe, St. Louis, Missouri (2021); Gary Thal, Northbrook, Illinios (2021); Matthew Lecuyer, Providence, Rhode Island (Resident) (2019). Katherine Marsh (Student) (2018).
Secretary: Susan Close, Chicago, Illinois.

COUNCIL ON MEDICAL EDUCATION
Lynne M. Kirk, Dallas, Texas, Chair (2019); Carol D. Berkowitz, Torrance, California, Chair-elect (2019); Patricia L. Turner, Chicago, Illinois, Immediate Past Chair (2019); Jacqueline A. Bello, Bronx, New York, Member-at-large (2021); Robert B. Goldberg, New York, New York (2021); Arjun Gupta, East Hanover, New Jersey (Student) (2018); Cynthia A. Jumper, Lubbock, Texas (2020); Liana Puscas, Durham, North Carolina (2021); Niranjani V. Rao, New Brunswick, New Jersey (2018); Luke V. Selby, Denver, Colorado (Resident) (2020); Krystal L. Tomei, Cleveland, Ohio (2021); John P. Williams, Pittsburgh, Pennsylvania (2019).
Secretary: Carrie Radabaugh, Chicago, Illinois.

COUNCIL ON MEDICAL SERVICE
Paul A. Wertsch, Madison, Wisconsin, Chair (2018); James G. Hinsdale, San Jose, California, Chair-elect (2019); Meena Davuluri, New York, New York (Resident) (2020); Lisa Egbert, Dayton, Ohio (2021); W. Alan Harmon, Jacksonville, Florida (2020); Lynn Jeffers, Camarillo, California (2020); Peter Lavine, Washington, District of Columbia (2018); Asa Lockhart, Tyler, Texas (2018); Peter S. Lund, Erie, Pennsylvania, (2018); Thomas Madejski, Medina, New York (2019); Sarah Smith, Anaheim, California (Student) (2018); Lynda M. Young, Worcester, Massachusetts (2021).
Secretary: Val Carpenter, Chicago, Illinois.

COUNCIL ON SCIENCE AND PUBLIC HEALTH
Robert A. Gilchick, Los Angeles, California, Chair (2018); Robyn F. Chatman, Cincinnati, Ohio, Chair-elect (2019); John T. Carlo, Dallas, Texas (2021); Noel N. Deep, Antigo, Wisconsin (2019); Alexander Ding, Belmont, California (2020); Kira A. Geraci-Ciardullo, Mamaroneck, New York (2018); Christina Kratschmer, Brooklyn, New York (Student) (2018); Mary LaPlante, Cleveland, Ohio (2021); Michael Lubrano, San Francisco, CA (Resident) (2020); Michael M. Miller, Madison, Wisconsin (2018); Bruce M. Smoller, Chevy Chase, Maryland (2019); David J. Welsh, Batesville, Indiana (2020).
Secretary: Barry Dickinson, Chicago, Illinois.

AMERICAN MEDICAL ASSOCIATION POLITICAL ACTION COMMITTEE
Vidya S. Kora, Michigan City, Indiana, Chair; Lyle S. Thorstenson, Nacogdoches, Texas, Secretary: Grayson W. Armstrong, Boston, Massachusetts (Resident); Brooke M. Buckley, Annapolis, Maryland; Steven J. Fleischman, New Haven, Connecticut; Linda B. Ford, Bellevue, Nebraska; Benjamin Z. Galper, McLean, Virginia; Dev A. GnanaDev, Colton, California; Stephen A. Imbeau, Florence, South Carolina; Ashtin Jeney, Washington, District of Columbia (Student); James L. Milani, Libertyville, Illinois; Michael Suk, Danville, Pennsylvania.
Executive Director and Treasurer: Kevin Walker, Washington, District of Columbia.
EX OFFICIO MEMBERS OF THE HOUSE OF DELEGATES

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**

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<td>2005-2006</td>
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<tr>
<td>Robert R. McMillan</td>
<td>2002-2008</td>
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<td>Sandeep “Sunny” Mistry</td>
<td>2000-2001</td>
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<tr>
<td>Donald J. Palmisano</td>
<td>1996-2002</td>
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<td>Rebecca J. Patchin</td>
<td>1988-1989</td>
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<td>Rebecca J. Patchin</td>
<td>2003-2011</td>
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<td>Pamela Petersen-Cairn</td>
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<td>Dina Marie Pitta</td>
<td>2015-2016</td>
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<td>William G. Pledsted, III</td>
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<td>Stephen Pool</td>
<td>1995-1996</td>
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<td>Liana Puscas</td>
<td>1999-2001</td>
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<td>Thomas R. Reardon</td>
<td>1990-1998</td>
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<td>Kevin C. Reilly</td>
<td>2003-2005</td>
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<td>Ryan J. Ribeira</td>
<td>2013-2014</td>
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<td>Joseph A. Riggs</td>
<td>1999-2003</td>
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<td>J. James Rohack</td>
<td>2001-2008</td>
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<td>David A. Rosman</td>
<td>2002-2004</td>
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<td>Samantha L. Rosman</td>
<td>2005-2009</td>
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<tr>
<td>Raymond Scalaetar</td>
<td>1985-1994</td>
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<td>Bruce A. Scott</td>
<td>1998-2002</td>
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<td>Randolph D. Smoak, Jr.</td>
<td>1992-1999</td>
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<td>Steven J. Stack</td>
<td>2006-2014</td>
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<td>Lowell H. Steen</td>
<td>1975-1982</td>
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<td>Michael Suk</td>
<td>1994-1995</td>
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<td>Andrew M. Thomas</td>
<td>1997-1999</td>
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<tr>
<td>Jeffrey A. Towsdon</td>
<td>1998-1999</td>
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<tr>
<td>Jordan M. VanLare</td>
<td>2011-2012</td>
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<tr>
<td>Robert M. Wah</td>
<td>2005-2013</td>
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<tr>
<td>Peter Y. Watson</td>
<td>2001-2003</td>
</tr>
<tr>
<td>Monica C. Webby</td>
<td>2011-2013</td>
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<tr>
<td>Meredith C. Williams</td>
<td>2010-2011</td>
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<tr>
<td>Cecil B. Wilson</td>
<td>2002-2009</td>
</tr>
<tr>
<td>Percy Wootton</td>
<td>1991-1996</td>
</tr>
</tbody>
</table>
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.)

American Academy of Emergency Medicine ................................................................. Joseph Wood, MD, JD
American Society of Nuclear Cardiology ................................................................. David Winchester, MD
Society of Gynecologic Oncologists ........................................................................ Carol Brown, MD
National Lipid Association .................................................................................. Michael Davidson, MD
Society of Cardiovascular Computed Tomography ................................................ Dustin Thomas, MD
Korean American Medical Association ................................................................. John Yun, MD
Association of Professors of Dermatology .............................................................. Christopher R. Shea, MD
American Society for Reconstructive Microsurgery ............................................ Gregory R. D. Evans, MD
American Rhinological Society ............................................................................ Joseph B. Jacobs, MD
North American Neuromodulation Society .......................................................... Haroon Hameed, MD
North American Neuro-Ophthalmology Society ................................................ Thomas Mizen, MD
American Association of Endocrine Surgeons .................................................... Steven De Jong, MD
American College of Medical Toxicology ........................................................... Charles McKay, MD
Association of Academic Physiatrists ................................................................. Samuel Chu, MD
American Association of Hip and Knee Surgeons ................................................ Edward Tanner, MD
American Society of Neuroimaging ........................................................................ Vernon Rowe, MD
MEMBERS OF THE HOUSE OF DELEGATES - NOVEMBER 2017
The following is a list of delegates and alternate delegates to the House of Delegates as reported to the Executive Vice President

**Medical Association of the State of Alabama**

Delegate(s)
- Jorge Alsip, Daphne AL
- Steven P Furr, Jackson AL
- Beverly F Jordan, Enterprise AL
- George C Smith, Lineville AL

Alternate Delegate(s)
- Raymond Broughton, Theodore AL
- B Jerry Harrison, Haleyville AL
- Mark H LeQuire, Montgomery AL
- William Schneider, Huntsville AL

Regional Medical Student Delegate(s)
- Ben Bush, Mobile AL

**Alaska State Medical Association**

Delegate(s)
- Alex Malter, Juneau AK

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

**Arizona Medical Association**

Delegate(s)
- Daniel P Aspery, Phoenix AZ
- Veronica K Dowling, Show Low AZ
- Gary R Figge, Tucson AZ
- Thomas H Hicks, Tucson AZ
- M Zuhdi Jassar, Phoenix AZ

Alternate Delegate(s)
- Timothy Fagan, Tucson AZ
- Ross Goldberg, Phoenix AZ
- Michael Hamant, Tucson AZ
- Marc Leib, Phoenix AZ
- Katherine Marsh, Tucson AZ

Regional Medical Student Delegate(s)
- Daniel Hintze, Tucson AZ

**Arkansas Medical Society**

Delegate(s)
- E Scott Ferguson, West Memphis AR
- Michael Moody, Salem AR
- Alan Wilson, Crossett AR

Alternate Delegate(s)
- Omar Afiq, Little Rock AR
- Amy Cahill, Pine Bluff AR
- Chad Rodgers, Little Rock AR

**California Medical Association**

Delegate(s)
- David H Aizuss, Encino CA
- Mark Ard, Redlands CA
- Patricia L Austin, Alamo CA
- Edward Bentley, Santa Barbara CA
- J Brennan Cassidy, Newport Beach CA
- Thomas E Daglish, Visalia CA
- Kyle P Edmonds, San Diego CA
- Sidney Gold, Granada Hills CA
- James T Hay, Del Mar CA
- Robert Hertzka, Rancho Santa Fe CA
- James G Hinsdale, San Jose CA
- Vito Imbasciani, Los Angeles CA
- Steven E Larson, Riverside CA
- Arthur N Lurvey, Los Angeles CA
- Robert J Margolin, San Francisco CA
- Theodore Mazer, San Diego CA
- Helene Nepomuceno, Costa Mesa CA
- Albert Ray, San Diego CA
- Michael J Sexton, Novato CA
- Tatiana W Spirtos, Redwood City CA
- James J Strebig, Irvine CA
- Richard E Thorp, Paradise CA

Alternate Delegate(s)
- Barbara J Arnold, Sacramento CA
- Dirk Stephen Baumann, Burlingame CA
- Jeffrey Brackett, Ventura CA
- Peter N Bretan, Novato CA
- Lawrence Cheung, San Francisco CA
- Luther Cobb, Eureka CA
- Pooja Desai, Riverside CA
- Alexander Ding, Belmont CA
- Suparna Dutta, Oakland CA
- Gordon Fung, San Francisco CA
- Dev A GnanaDev, Colton CA

*This list does not reflect temporary changes for this meeting.*
### California Medical Association

**Alternate Delegate(s)**
- Poyin Huang, Los Angeles CA
- Alexandra Iacob, Loma Linda CA
- Scott Richard Karlan, West Hollywood CA
- Nikan Khatibi, Laguna Niguel CA
- Mark H Kogan, San Pablo CA
- Ramin Manshadi, Stockton CA
- Lisa S Miller, San Diego CA
- Richard Pan, Sacramento CA
- Sion Roy, Santa Monica CA
- Holly Yang, San Diego CA
- Marcy Zwelling, Los Alamitos CA

**Resident and Fellow Sectional Delegate(s)**
- Elizabeth Griffiths, San Francisco CA

**Resident and Fellow Sectional Alternate Delegate(s)**
- Ariel Anderson, San Diego CA

### Colorado Medical Society

**Delegate(s)**
- Katie Lozano, Centennial CO
- Alethia Morgan, Denver CO
- M Ray Painter, Thornton CO
- Lynn Parry, Littleton CO
- Brigitta J Robinson, Centennial CO

**Alternate Delegate(s)**
- David Downs, Denver CO
- Jan Kief, Highlands Ranch CO
- Tamaan Osbourne-Roberts, Denver CO
- Robert Yakely, Denver CO

**Resident and Fellow Sectional Delegate(s)**
- Luke Selby, Denver CO

This list does not reflect temporary changes for this meeting.
Florida Medical Association

Delegate(s)
  Michael L Patete, Venice FL
  Alan B Pillersdorf, Lake Worth FL
  Aaron Sudbury, Bradenton FL
  David Winchester, Gainesville FL

Alternate Delegate(s)
  Jose F Arrascue, Atlantis FL
  Ankush Bansal, West Palm Beach FL
  James Booker, Winter Haven FL
  Andrew Cooke, Orlando FL
  Aaron Elkin, Miami FL
  James Nathan Goldenberg, Atlantis FL
  Rebecca Lynn Johnson, Tampa FL
  Trachella Johnson Foy, Jacksonville FL
  Mark E Panna, Gainesville FL
  Jason J Pirozzolo, Winter Garden FL
  Sergio B Seoane, Barton FL
  James St Geroge, Ponte Verdra FL
  Michael Zimmer, St Petersburg FL

Resident and Fellow Sectional Alternate Delegate(s)
  Michelle Falcone, Miami FL

Regional Medical Student Delegate(s)
  Jessica Walsh O'Sullivan, Orlando FL

Regional Medical Student Alternate Delegate(s)
  Anna Beth West, Gainesville FL

Medical Association of Georgia

Delegate(s)
  S William Clark, Waycross GA
  Michael E Greene, Macon GA
  Billie Luke Jackson, Macon GA
  Joy Maxey, Atlanta GA
  Sandra B Reed, Atlanta GA

Alternate Delegate(s)
  John S Antalis, Dalton GA
  Jack Chapman, Gainesville GA
  John Goldman, Atlanta GA
  Gary Richter, Atlanta GA
  Steven M Walsh, Roswell GA

Guam Medical Society

Delegate(s)
  Insaf Ally, Tamuning GU

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

Delegate(s)
  Thomas M Anderson, Chicago IL
  Craig Alvin Backs, Springfield IL
  James Bull, Silvis IL
  Peter E Eupierre, Melrose Park IL
  Richard A Geline, Glenview IL
  Raj B Lal, Oak Brook IL
  Anne Langguth, Chicago IL
  Steve Malkin, Arlington Heights IL
  James L Milam, Libertyville IL
  Nestor Ramirez-Lopez, Champaign IL
  Shastri Swaminathan, Chicago IL

Alternate Delegate(s)
  Howard Axe, Arlington Heights IL
  Christine Bishop, Forest Park IL
  Kenneth G Busch, Chicago IL
  Scott A Cooper, Chicago IL
  Muhammad Padela, Edison NJ
  Laura Shea, Springfield IL
  Katherine Tynus, Chicago IL
  Piyush Vyas, Lake Forest IL

Resident and Fellow Sectional Delegate(s)
  Vanessa A Stan, Chicago IL

Resident and Fellow Sectional Alternate Delegate(s)
  Amar Kelkar, Peoria IL

This list does not reflect temporary changes for this meeting.
Illinois State Medical Society
Regional Medical Student Alternate Delegate(s)
Ajeet Singh, Forest Park IL

Indiana State Medical Association
Delegate(s)
Michael Hoover, Evansville IN
Vidya S Kora, Michigan City IN
William Mohr, Kokomo IN
Stephen Tharp, Frankfort IN
David Welsh, Batesville IN
Alternate Delegate(s)
Deepak Azad, Floyds Knobs IN
Heidi Dunniway, Indianapolis IN
Brent Mohr, South Bend IN
Fred Ridge, Linton IN
Thomas Vidic, Elkhart IN
Regional Medical Student Delegate(s)
Joshua Scantland, Indianapolis IN

Iowa Medical Society
Delegate(s)
Michael Kitchell, Ames IA
Robert Lee, Johnston IA
Victoria Sharp, Iowa City IA
Alternate Delegate(s)
Joyce Vista-Wayne, Des Moines IA

Kansas Medical Society
Delegate(s)
Terry L Poling, Wichita KS
Arthur D Snow, Shawnee Mission KS
Richard B Warner, Overland Park KS
Alternate Delegate(s)
Jennifer Bacani-McKenney, Fredonia KS
Robert Gibbs, Parsons KS
James H Gilbaugh, Wichita KS

Kentucky Medical Association
Delegate(s)
David J Bensema, Lexington KY
J Gregory Cooper, Cynthiana KY
Bruce A Scott, Louisville KY
Donald J Swikert, Edgewood KY
Alternate Delegate(s)
Robert Couch, Louisville KY
Shawn C Jones, Jr, Louisville KY
William B Monnig, Crestview Hills KY
Robert A Zaring, Louisville KY

Louisiana State Medical Society
Delegate(s)
Floyd Anthony Buras, Metairie LA
Dolleen Mary Licciardi, Jefferson LA
Lee Stevens, Shreveport LA
Ezekiel Wetzel, Metairie LA
Alternate Delegate(s)
Luis M Alvarado, Mandeville LA
William Clark, Baton Rouge LA
Myo Myint, New Orleans LA
Rachel Spann, New Orleans LA
Regional Medical Student Delegate(s)
Alexis Rudd, New Orleans LA

Maine Medical Association
Regional Medical Student Alternate Delegate(s)
Neal Dixit, New Orleans LA

MedChi: The Maryland State Medical Society
Delegate(s)
Habhajan Singh Ajrawat, Potomac MD
George H A Bone, Largo MD
Shannon Pryor, Washington DC
Stephen J Rockower, Rockville MD
Bruce M Smoller, Chevy Chase MD
Alternate Delegate(s)
Brooke M Buckley, Annapolis MD
Loralie Dawn Ma, Fulton MD
Gary Pushkin, Baltimore MD
Padmini Ranasinghe, Baltimore MD
Megan Srinivas, Baltimore MD

This list does not reflect temporary changes for this meeting.
**MedChi: The Maryland State Medical Society**

**Regional Medical Student Delegate(s)**
- James Ting, Baltimore MD

**Regional Medical Student Alternate Delegate(s)**
- Julia Rozier, Washington DC

**Massachusetts Medical Society**

**Delegate(s)**
- Maryanne C Bombaugh, Falmouth MA
- Theodore A Calianos, Mashpee MA
- Alain A Chaou, Boxford MA
- Alice Coombs-Tolbert, Richmond VA
- Ronald Dunlap, Norwell MA
- McKinley Glover, Boston MA
- Francis P Mac Millan, North Andover MA
- Mario E Motta, Salem MA
- Richard Pieters, Duxbury MA
- David A Rosman, Jamaica Plain MA
- Thomas E Sullivan, Beverly MA
- Lynda M Young, Worcester MA

**Alternate Delegate(s)**
- Nicolas Argy, Dover MA
- Dennis Dimitri, Worcester MA
- Henry Dorkin, Auburndale MA
- Melody J Eckardt, Milton MA
- Jessica Fortin, Worcester MA
- Christopher Garofalo, N Attleboro MA
- Kathryn Hughes, North Andover MA
- Lynda G Kabbash, Chestnut Hill MA
- Matthew Lecuyer, Providence RI
- Michael Medlock, Lexington MA
- Spiro Spanakis, Shrewsbury MA
- Ellana Stinson, Quincy MA

**Resident and Fellow Sectional Delegate(s)**
- Carl Streed, Boston MA

**Resident and Fellow Sectional Alternate Delegate(s)**
- Scott Resnick, Brookline MA

**Regional Medical Student Delegate(s)**
- Rohan Rastogi, Boston MA

**Regional Medical Student Alternate Delegate(s)**
- Corinne Carland, Cambridge MA
- Danny Vazquez, Boston MA

This list does not reflect temporary changes for this meeting.

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**Michigan State Medical Society**

**Delegate(s)**
- Cathy O Blight, Flint MI
- Michael D Chafty, Portage MI
- Betty S Chu, Bloomfield Hills MI
- Pino D Colone, Howell MI
- Kaitlyn Dobesh, Grosse Pointe MI
- James D Grant, Bloomfield Hills MI
- Mark C Komorowski, Bay City MI
- Bassam H Nasr, Port Huron MI
- Michael A Sandler, West Bloomfield MI
- Krishna K Sawhney, Bloomfield Hills MI
- Richard E Smith, Detroit MI
- David T Walsworth, East Lansing MI

**Alternate Delegate(s)**
- John G Bizon, Battle Creek MI
- Paul D Bozyk, Canton MI
- Cheryl Gibson-Fountain, Grosse Pointe MI
- Sarah A Gorgis, Detroit MI
- Venkat K Rao, Flint MI

**Minnesota Medical Association**

**Delegate(s)**
- David L Estrin, Plymouth MN
- David D Luehr, Barnum MN
- Paul C Matson, Mankato MN
- Sally J Trippel, Rochester MN

**Mississippi State Medical Association**

**Delegate(s)**
- Claude D Brunson, Ridgeland MS
- Jennifer Bryan, Flowood MS
- J Clay Hays, Jackson MS

**Alternate Delegate(s)**
- Sharon Douglas, Madison MS
- Daniel P Edney, Vicksburg MS
- Lee Voulters, Gulfport MS

**Regional Medical Student Alternate Delegate(s)**
- William Ross, Flowood MS

**Missouri State Medical Association**

**Delegate(s)**
- Edmond Cabbabe, St Louis MO
- James Conant, St. Joseph MO
- Rebecca Hierholzer, Leawood KS
Missouri State Medical Association
Delegate(s)
  William H Huffaker, Chesterfield MO
  Warren Lovinger, Nevada MO
Alternate Delegate(s)
  Elie Azrak, Saint Louis MO
  Joseph A Corrado, Mexico MO
  Michael L O’Dell, Kansas City MO
  Shannon Tai, Lisle IL
  Charles W Van Way, Fairway KS
Regional Medical Student Delegate(s)
  Ariel Carpenter, Columbia MO
Regional Medical Student Alternate Delegate(s)
  Jared Lammert, Columbia MO

Montana Medical Association
Delegate(s)
  Carter E Beck, Missoula MT
Alternate Delegate(s)
  Nicole C Clark, Helena MT

Nebraska Medical Association
Delegate(s)
  Kelly J Caverzagie, Omaha NE
  Kevin D Nohner, La Vista NE
Alternate Delegate(s)
  Robert Rhodes, Lincoln NE
Regional Medical Student Delegate(s)
  Karen Dionesotes, Baltimore MD
Regional Medical Student Alternate Delegate(s)
  Michael Visenio, Boston MA

Nevada State Medical Association
Delegate(s)
  Wayne C Hardwick, Reno NV
  Florence Jameson, Las Vegas NV
Alternate Delegate(s)
  Joseph A Adashke, Las Vegas NV
  Peter R Fenwick, Reno NV

New Hampshire Medical Society
Delegate(s)
  William J Kassler, Bedford NH

Medical Society of New Jersey
Delegate(s)
  Mary Campagnolo, Bordentown NJ
  Joseph P Costabile, Marlton NJ
  Joseph J Fallon, Woodbury NJ
  Nancy L Mueller, Englewood Cliffs NJ
  John W Poole, Ridgewood NJ
  Niranjan V Rao, New Brunswick NJ
  David Swee, Piscataway NJ
Alternate Delegate(s)
  Christopher Gribbin, Princeton NJ
  A. Ralph Kristeller, East Hanover NJ
  Soumen Samaddar, Pennington NJ
Regional Medical Student Delegate(s)
  Aakash Sheth, East Brunswick NJ
Regional Medical Student Alternate Delegate(s)
  Ilesha Sevak, Newark NJ

New Mexico Medical Society
Delegate(s)
  Steven Kanig, Albuquerque NM
  Stephen P Lucero, Santa Fe NM
Alternate Delegate(s)
  Patricia Lynn Bryant, Albuquerque NM
  William G Liakos, Roswell NM

Medical Society of the State of New York
Delegate(s)
  Abhimanyu Amamani, Brooklyn NY
  Rose Berkun, Buffalo NY
  Jerome C Cohen, Loch Sheldrake NY
  Joshua M Cohen, New York NY
  Frank G Dowling, Islandia NY
  Kira Geraci-Ciardullo, Harrison NY
  Robert B Goldberg, New York NY
  Robert J Hughes, Queensbury NY
  John J Kennedy, Schenectady NY
  Daniel J Koretz, Ontario NY
  William R Latreille, Malone NY
  Thomas J Madejks, Medina NY
  Leah S Mc Cormack, Middletown NJ
  Parag Mehta, Brooklyn NY
  Gregory L Pinto, Saratoga Springs NY
  Charles Rothberg, Patchogue NY

This list does not reflect temporary changes for this meeting.
Medical Society of the State of New York

Delegate(s)
Joseph Sellers, Cobleskill NY
Corliss Varnum, Oswego NY
Daniel M Young, Windsor NY

Alternate Delegate(s)
Mark Adams, Fairport NY
Howard Huang, Watertown NY
John A Ostuni, Freeport NY
Barry Rabin, Syracuse NY
Abdul Rehman, Staten Island NY

Resident and Fellow Sectional Alternate Delegate(s)
Moustafa Elsheshawy, Brooklyn NY

Regional Medical Student Delegate(s)
Brian Chernak, Brooklyn NY
Erin Duffy, Centereach NY
Moudi Hubeishy, Buffalo NY
Pratistha Koirala, Bronx NY

North Carolina Medical Society

Delegate(s)
Timothy M Beittel, Fayetteville NC
William E Bowman, Greensboro NC
Mary Ann Contogiannis, Greensboro NC
John R Mangum, Sanford NC
Liana Puscas, Durham NC
Charles F Willson, Greenville NC

Regional Medical Student Delegate(s)
Lauren Edgar, Winston-Salem NC

Regional Medical Student Alternate Delegate(s)
Lauren Benning, Littington NC

North Dakota Medical Association

Delegate(s)
Shari L Orser, Bismarck ND

Alternate Delegate(s)
A Michael Booth, Bismarck ND

Ohio State Medical Association

Delegate(s)
Robyn F Chatman, Cincinnati OH
Louito C Edje, Toledo OH
Lisa B. Egbert, Kettering OH
Richard R Ellison, Fairlawn OH
Charles J Hickey, Dublin OH
Gary R Katz, Dublin OH
William C. Sternfeld, Toledo OH
Donna A Woodson, Toledo OH

Alternate Delegate(s)
Brett Coldiron, Cincinnati OH
Shawn Cuevas, Columbus OH
Deepak Kumar, Dayton OH
Alisha Reiss, Columbus OH
Kara Richardson, Dublin OH
Regina Whitfield-Kekessi, West Chester OH

Regional Medical Student Delegate(s)
Michelle Knopp, Columbus OH
Kevin Qin, Toledo OH

Regional Medical Student Alternate Delegate(s)
Hari Iyer, Rootstown OH
Samantha King, Columbus OH
Theodore Rader, IV, Toledo OH

Oklahoma State Medical Association

Delegate(s)
Sherri Baker, Oklahoma City OK
Jack J Beller, Norman OK
Jay A Gregory, Muskogee OK
Bruce Storms, Chickasha OK

Alternate Delegate(s)
Peter Aran, Tulsa OK
Jenny Boyer, Tulsa OK
Julie Hager, Oklahoma City OK
Woody Jenkins, Stillwater OK

Resident and Fellow Sectional Alternate Delegate(s)
Eudy Bosley, Broken Arrow OK

Regional Medical Student Delegate(s)
Helga Skaftason, Tulsa OK

Regional Medical Student Alternate Delegate(s)
Chelsea McKenzie, Tulsa OK

This list does not reflect temporary changes for this meeting.
Oregon Medical Association
Delegate(s)
  Robert Dannenhoffer, Roseburg OR
  Sylvia Ann Emory, Eugene OR
Alternate Delegate(s)
  Peter A Bernardo, Salem OR
  Carla Mc Kelvey, Bandon OR

Pennsylvania Medical Society
Delegate(s)
  Theodore A Christopher, Maple Glen PA
  Stephen N Clay, Philadelphia PA
  James A Goodyear, North Wales PA
  Virginia E Hall, Hummelstown PA
  Marilyn J Heine, Dresher PA
  Daniel B Kimball, Wyomissing PA
  Peter S Lund, Fairview PA
  Anthony M Padula, Philadelphia PA
  Ralph Schmeltz, Pittsburgh PA
  Scott E Shapiro, Lower Gwynedd PA
  John W Spurlock, Bethlehem PA
  Martin D Trichtinger, Hatboro PA
  John P Williams, Gibsonia PA
Alternate Delegate(s)
  Erick Bergquist, Latrobe PA
  Michael A DellaVecchia, Berwyn PA
  Mark Friedlander, Nabeth PA
  John P Gallagher, Sharon PA
  Kevin Owen Garrett, Allison Park PA
  Aaron E George, Chambersburg PA
  Bruce A Mac Leod, Pittsburgh PA
  Jill M Owens, Bradford PA
  Evan Pollack, Bryn Mawr PA
  Erik Saka, Philadelphia PA
  John S Trickett Jr, Scranton PA
  John Michael Vasudevan, Philadelphia PA
Resident and Fellow Sectional Delegate(s)
  Raghuveer Puttagunta, Danville PA
Resident and Fellow Sectional Alternate Delegate(s)
  Tani Malhotra, York PA
Regional Medical Student Delegate(s)
  Neel Nabar, Philadelphia PA

This list does not reflect temporary changes for this meeting.
Tennessee Medical Association

Delegate(s)
- Richard J DePersio, Knoxville TN
- Donald B Franklin, Signal Mountain TN
- John J Ingram, Alcoa TN
- Lee R Morisy, Memphis TN
- BW Ruffner, Signal Mountain TN

Alternate Delegate(s)
- O. Lee Berkenstock, Memphis TN
- Wiley T Robinson, Memphis TN
- Nita Shumaker, Hixson TN
- Christopher E Young, Signal Mtn TN

Regional Medical Student Alternate Delegate(s)
- Anderson Webb, Smithville TN

Texas Medical Association

Delegate(s)
- Susan Rudd Bailey, Fort Worth TX
- Michelle A Berger, Austin TX
- Brad G Butler, Abilene TX
- Diana Fite, Tomball TX
- David C Fleeger, Austin TX
- William H Fleming, Houston TX
- Gary Floyd, Keller TX
- John T Gill, Dallas TX
- Robert T Gunby, Dallas TX
- David N Henkes, San Antonio TX
- Asa C Lockhart, Tyler TX
- Kenneth L Mattox, Houston TX
- Kevin H McKinney, Galveston TX
- Clifford K. Moy, Frisco TX
- Larry E Reaves, Fort Worth TX
- Leslie H Secrest, Dallas TX
- Lyle S Thorstenson, Nacogdoches TX
- E Linda Villarreal, Edinburg TX

Alternate Delegate(s)
- Justin Hensley, Corpus Christi TX
- Jessie Ho, Plano TX
- Cynthia Jumper, Lubbock TX
- Jennifer Rushton, Austin TX
- Habeeb Salameh, Galveston TX
- Jayesh Shah, San Antonio TX
- Elizabeth Torres, Sugar Land TX
- Roxanne Tyroch, El Pasco TX
- Arlo F Weltge, Bellaire TX
- Sherif Z Zaafran, Houston TX

Regional Medical Student Alternate Delegate(s)
- Michael Metzner, San Antonio TX

Regional Medical Student Delegate(s)
- Emily Dewar, Houston TX
- Luis Seija, Temple TX

Regional Medical Student Alternate Delegate(s)
- Hayley Rogers, College Station TX

Utah Medical Association

Delegate(s)
- Bryce Dee Allred, Holladay UT
- Mark Bair, Highland UT

Alternate Delegate(s)
- Richard Labasky, Sandy UT
- D Glenn Morrell, Layton UT

Vermont Medical Society

Delegate(s)
- Robert Block, Bennington VT

Alternate Delegate(s)
- Norman Ward, Burlington VT

Resident and Fellow Sectional Delegate(s)
- Naiim Ali, Burlington VT

Medical Society of Virginia

Delegate(s)
- Claudette E Dalton, Earlysville VA
- Thomas W Eppes, Forest VA
- Randolph J Gould, Norfolk VA
- Edward G Koch, McLean VA
- Hazle S Konerding, Richmond VA

This list does not reflect temporary changes for this meeting.
Medical Society of Virginia

Delegate(s)
Lawrence K Monahan, Roanoke VA
William Reha, Woodridge VA

Alternate Delegate(s)
Clifford L Deal, Henrico VA
Bhushan H Pandya, Danville VA
Sterling N Ransone, Deltaville VA

Regional Medical Student Delegate(s)
Thamolwan (Wan) Surakiatchanul, Philad

Regional Medical Student Alternate Delegate(s)
Carl Rudebusch, Richmond VA

Washington State Medical Association

Delegate(s)
Erin Harnish, Longview WA
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<table>
<thead>
<tr>
<th>Section</th>
<th>Delegate(s)</th>
<th>Alternate Delegate(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Academic Physicians Section</strong></td>
<td>Kenneth B Simons, Milwaukee WI</td>
<td>Donald G Eckhoff, Aurora CO</td>
</tr>
<tr>
<td><strong>Integrated Physician Practice Section</strong></td>
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<tr>
<td><strong>International Medical Graduates Section</strong></td>
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<td>Ronit Katz, Cupertino CA</td>
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<tr>
<td><strong>Medical Student Section</strong></td>
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<tr>
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Nestor Ramirez-Lopez, MD, Illinois

Chief Teller
James Bull, MD, Illinois

* Alternate Delegate
FIRST SESSION, Saturday, November 11, 2:00 – 6:00 pm

SECOND SESSION, Sunday, November 12, 8:00 – 8:30 am

THIRD SESSION, Monday, November 13, 2:00 – 6:00 pm

FOURTH SESSION, Tuesday, November 14, 8:30 am – noon
SUMMARY OF FISCAL NOTES (I-17)

**BOT Report(s)**
- 01 Redefining AMA's Position on ACA and Healthcare Reform: Informational report
- 02 2017 AMA Advocacy Efforts: Informational report
- 03 Removing Restrictions on Federal Funding for Firearms Violence Research: Informational report
- 04 Limitations on Reports by Insurance Carriers to the National Practitioner Data Bank Unrelated to Patient Care: Informational report
- 05 Effective Peer Review: Modest
- 06 Electronically Prescribed Controlled Substances Without Added Processes: Minimal
- 07 Medical Reporting for Safety-Sensitive Positions: Minimal
- 08 2018 Strategic Plan: Informational report
- 09 Parental Leave: Informational report
- 10 High Cost to Authors for Open Source Peer Reviewed Publications: n/a
- 11* Anti-Harassment Policy: Informational report

**CC&B Report(s)**
- 01* Amended Bylaws - Specialty Society Representation - Five Year Review: Minimal

**CEJA Opinion(s)**
- 01 Amendment to E-2.3.2, "Professionalism in Social Media": n/a

**CEJA Report(s)**
- 01* Competence, Self-Assessment and Self-Awareness: Minimal
- 02 Ethical Physician Conduct in the Media: Minimal
- 03 Supporting Autonomy for Patients with Differences of Sex Development (DSD): Minimal
- 04* Mergers of Secular and Religiously Affiliated Health Care Institutions: Minimal

**CLRPD Report(s)**
- 01* Senior Physicians Section Five-Year Review: Minimal

**CME Report(s)**
- 01* Promoting and Reaffirming Domestic Medical School Clerkship Education: Minimal
- 02 A National Continuing Medical Education Repository: Informational report
- 03* Impact of Immigration Barriers on the Nation's Health: Informational report

**CMS Report(s)**
- 01* Affordable Care Act Section 1332 Waivers: Minimal
- 02* Hospital Surveys and Health Care Disparities: Minimal
- 03 Non-Physician Screening Tests: Minimal
- 04* Health Insurance Affordability: Essential Health Benefits and Subsidizing the Coverage of High-Risk Patients: Minimal
- 05 Reaffirmation of AMA Policy Opposing Caps on Federal Medicaid Funding: Minimal

**CSAPH Report(s)**
- 01 Universal Color Scheme for Respiratory Inhalers: Minimal
- 02 Targeted Education to Increase Organ Donation: Minimal
SUMMARY OF FISCAL NOTES (I-17)

CSAPH Report(s)
03 Neuropathic Pain as a Disease: Minimal
04 National Drug Shortages Update: Minimal
05* Clinical Implications and Policy Considerations of Cannabis Use: Minimal

Joint Report(s)
CMS/CSAPH 01* Payment and Coverage for Genetic/Genomic Precision Medicine: Minimal

Report of the Speakers
01 Recommendations for Policy Reconciliation: Informational report

Resolution(s)
001 Disaggregation of Data Concerning the Status of Asian-Americans: Minimal
002 Intimate Partner Violence Policy and Immigration: Moderate
003 Revision of AMA Policy Regarding Sex Workers: Minimal
004 Tissue Handling: Modest
005* Protection of Physician Freedom of Speech: Minimal
006* Physicians’ Freedom of Speech: Minimal
201 Improving FDA Expedited Approval Pathways: Modest
202 Sexual Assault Survivors’ Rights: Modest
203 Bidirectional Communication for EHR Software and Pharmacies: Modest
204 EHR Vendors Responsible for Health Information Technology: Modest
205 Health Plan, Pharmacy, Electronic Health Records Integration: Minimal
206 Defending Federal Child Nutrition Programs: Minimal
207 Redistribution of Unused Prescription Drugs to Pharmaceutical Donation and Reuse Programs: Modest
208 Increased Use of Body-Worn Cameras by Law Enforcement Officers: Minimal
209 Government Mandated Sequester: Modest
210 Merit-Based Incentive Payment System and Small Practices: Modest
211 Exclusive State Control of Methadone Clinics: Modest
213 Barriers to Price Transparency: Modest
214 APRN Compact: Modest
215 Relieve Burden for Living Organ Donors: Minimal
216 Relationship with US Department of Health and Human Services: Modest
217 Regulations Regarding Medical Tool and Instrument Repair: Minimal
218* Health Information Technology Principles: Modest
219* Certified EMR Companies’ Practice of Charging Fees for Regulatory Compliance: Minimal
220* Preserving Protections of the Americans with Disabilities Act of 1990: Minimal
221* House of Representative Bill HR 2077, Restoring the Patient's Voice Act of 2017: Modest
222* The Clinical Use of a Home Sleep Apnea Test: Minimal
223* Treating Opioid Use Disorder in Correctional Facilities: Modest
224* Modernizing Privacy Regulations for Addiction Treatment Records: Modest
225* Oppose Inclusion of Medicare Part B Drugs in QPP / MIPS Payment Adjustment: Modest
Resolution(s)

226* Prescription Drug Importation for Personal Use: Minimal
601 Physician Burnout and Wellness Challenges: Minimal
801 Chronic Care Management Payment for Patients Also on Home Health: Modest
802 Opposition to Medicaid Work Requirements: Modest
803 Air Ambulance Regulations and Reimbursements: Modest
804 Prior Authorization: Modest
805 A Dual System for Universal Health Care in the United States: Modest
806 Mandate Transparency by Pharmacy Benefit Managers: Modest
807 Structural Barriers to Achieving Better Health Care Efficiency and Outcomes: ACOs and Physician Employment by Hospitals: Modest
808 Opposition to Reduced Payment for the 25 Modifier: Moderate
809 Expansion of Network Adequacy Policy: Minimal
810 Pharmacy Benefit Managers and Prescription Drug Affordability: Modest
811 Update OBRA Nursing Facility Preadmission Screening Requirements: Modest
812 Medicare Coverage of Services Provided by Proctored Medical Students: Modest
813 Sustain Patient-Centered Medical Home Practices: Modest
814* Appropriate Reimbursement for Evaluation and Management Services for Patients with Severe Mobility-Related Impairments: Minimal
815* Pediatric Representation for E/M Documentation Guideline Revision: None
816* Social Determinants of Health in Payment Models: Minimal
817* Addressing the Site of Service Deferential: Modest
818* On-Call and Emergency Services Pay: Modest
819* Consultation Codes and Private Payers: Modest
820* Elimination of the Laboratory 14-Day Rules Under Medicare: Modest
821* Hormonal Contraception as a Preventive Service: Modest
901 Harmful Effects of Screen Time in Children: Minimal
902 Expanding Expedited Partner Therapy to Treat Trichomoniasis: Minimal
903 Improving Screening and Treatment Guidelines for Domestic Violence Against Lesbian, Gay, Bisexual, Transgender, Queer/Questioning, and Other Individuals: Estimated cost to implement resolution is $85,500 to convene experts for 3 one-day session to determine Diagnostic and Treatment Guidelines on Domestic Violence. Estimate includes travel & meeting costs and promotion of guidelines.
904 Educating Physicians About the Importance of Cervical Cancer Screening for Female-to-Male Transgender Patients: Minimal
905 Addressing Social Media Usage and its Negative Impacts on Mental Health: Estimated cost to implement resolution is $375,000 for identification, treatment and referral of at risk individuals. Estimate includes costs to convene collaborator group and development of CME and effective clinical tools and protocols.
906 Opioid Abuse in Breastfeeding Mothers: Modest
907 Addressing Healthcare Needs of Foster Children: Minimal
908 Updating Energy Policy and Extraction Regulations to Promote Public Health and Sustainability: Minimal
909 Expanding Naloxone Programs: Modest
910 Improving Treatment and Diagnosis of Maternal Depression Through Screening and State-Based Care Coordination: Modest
911* State Maternal Mortality Review Committees: Modest
912* Corrective Statements Ordered to be Published by Tobacco Companies for the Violation of the Racketeer Influenced and Corrupt Organizations Act: Modest
913* Increased Death Rate and Decreased Life Expectancy in the United States: Modest
914* Support of Training, Ongoing Education, and Consultation in Order to Reduce the Health Impact of Pediatric Environmental Chemical Exposures: Minimal
952 Implicit Bias, Diversity and Inclusion in Medical Education and Residency Training: Modest
SUMMARY OF FISCAL NOTES (I-17)

Resolution(s)
953  Fees for Taking Maintenance of Certification Examination: Minimal
954  Developing Physician Led Public Health / Population Health Capacity in Rural Communities: Modest
955  Minimization of Bias in the Electronic Residency Application Service Residency Application: Minimal
956  House Physicians Category: Minimal
957  Standardization of Family Planning Training Opportunities in OB-BYN Residencies: Minimal
958  Sex and Gender Based Medicine in Clinical Education: Minimal
959*  Lifestyle Medicine Education in Medical School Training and Practice: Minimal

Resolutions not for consideration
212  Physician Identification: Minimal
602  Creation of LGBTQ Health Specialty Section Council: No significant fiscal impact
603  A Guide for Best Health Practices for Seniors Living in Retirement Communities: Modest
951  Financial Protections for Doctors in Training: Minimal

* contained in 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)
- 05 Effective Peer Review
- 07 Medical Reporting for Safety-Sensitive Positions

CC&B Report(s)
- 01* Amended Bylaws - Specialty Society Representation - Five Year Review

CEJA Report(s)
- 01* Competence, Self-Assessment and Self-Awareness
- 02 Ethical Physician Conduct in the Media
- 03 Supporting Autonomy for Patients with Differences of Sex Development (DSD)
- 04* Mergers of Secular and Religiously Affiliated Health Care Institutions

Resolution(s)
- 001 Disaggregation of Data Concerning the Status of Asian-Americans
- 002 Intimate Partner Violence Policy and Immigration
- 003 Revision of AMA Policy Regarding Sex Workers
- 004 Tissue Handling
- 005* Protection of Physician Freedom of Speech
- 006* Physicians' Freedom of Speech

* included in the Handbook Addendum
REPORT OF THE BOARD OF TRUSTEES

Subject: Effective Peer Review

Presented by: Gerald E. Harmon, MD, Chair

Referred to: Reference Committee on Amendments to Constitution and Bylaws
(Edmund R. Donoghue, Jr., MD, Chair)

INTRODUCTION

At the 2016 Interim Meeting, the House of Delegates adopted Policy D-375.987, “Effective Peer Review.”

[Our AMA study the current environment for effective peer review, on both a federal and state basis, in order to update its current policy to include strategies for promoting effective peer review by physicians and to consider a national strategy for protecting all physicians from retaliation as a result from participating in effective peer review.

Testimony spoke of the increasing number of physicians who are employed by, or affiliated with, large hospital systems or healthcare organizations, where physicians are concerned that they exert less and less control over their employment and/or practice situations and patient care. As a result, having effective, legitimate peer review processes in place is vital to safeguarding patient care and safety. Further, physicians in the peer review process need protection from retaliation by hospitals and other lay organizations that might be at odds with the role, actions, or decisions taken by those participants. Although the amended language above was originally contained in a resolution, the House of Delegates adopted this language as a “Directive to Take Action.” This report responds to the study requested by AMA Policy D-375.987.

DISCUSSION

AMA Definition of Peer Review

AMA Policy H-375.962, “Legal Protections for Peer Review,” defines peer review, in part, as:

. . . the task of self-monitoring and maintaining the administration of patient safety and quality of care, consistent with optimal standards of practice . . . Peer review goes beyond individual review of instances or events; it is a mechanism for assuring the quality, safety, and appropriateness of hospital services. The duties of peer review are: addressing the standard of care, preventing patient harm, evaluating patient safety and quality of care, and ensuring that the design of systems or settings of care support safety and high quality care . . .

Because peer review can involve close scrutiny of all aspects of patient care and safety, both with respect to organization-wide patient care and safety issues and issues concerning individual physicians and health care practitioners, the peer review process may bring to light serious patient care and safety issues that are systemic to a hospital or other lay organization. Exposure of such

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issues could damage the hospital’s or organization’s reputation in its community or its other
business interests. Consequently, a physician may be reluctant to participate in a peer review
proceeding for fear of retaliation if the physician believes that the hospital or lay organization will
take issue with the result of, or the physician’s role in, that proceeding. This fear is exacerbated if
the hospital or lay organization dominates the physician’s community. Thus, to ensure effective
peer review, physician peer review participants must be protected from the possibility of
retaliation.

Market Developments: Physician Employment by Hospitals and Non-physician Entities and
Increasing Hospital Consolidation

Physician concerns about retaliation against physician peer review participants have grown as
hospitals employ more physicians and hospital markets become more concentrated. Many
communities in the United States are dominated by only a few hospitals, or even by a single
hospital. As more physicians have become employed by, or affiliated with, dominant hospitals or
other powerful lay organizations, some physicians increasingly fear retaliation for expressing
patient safety or care concerns during a peer review proceeding, or otherwise participating in a peer
review process, that the hospital or organization perceives as being contrary to its financial
interests. For employed physicians, employment contract termination may be the greatest concern,
since termination may have an immediate and detrimental effect on the physician’s ability to
continue practicing medicine in the community, e.g., if the termination triggers a broad restrictive
covenant.

Independent physicians may also fear retaliation. Although retaliation against an independent
physician would not involve employment termination, retaliation could take other forms, e.g.,
ending other kinds of contracts with the physician, such as a medical directorship or co-
management agreement; attempting to reduce or withdraw the physician’s clinical privileges;
manipulating call, surgery, or procedure scheduling; or any other myriad means of making it
difficult, if not impossible, to fully and freely utilize hospital facilities and staff. If the hospital
dominates the physician’s community, these kinds of retaliatory conduct could make it difficult, if
not impossible, for even an independent physician to maintain his or her medical practice in the
community.


The Health Care Quality Improvement Act of 1986 (HCQIA), promotes peer review by
immunizing those who participate in the peer review process from damages. This immunity
applies if a decision by a professional review body, e.g., a decision to revoke hospital privileges, is
made using the following standards:

1. In the reasonable belief that the action was in the furtherance of quality health care;
2. After a reasonable effort to obtain the facts of the matter;
3. After adequate notice and hearing procedures are afforded to the physician involved or
   after such other procedures as are fair to the physician under the circumstances; and
4. In the reasonable belief that the action was warranted by the facts known after such
   reasonable effort to obtain facts and after meeting the requirement of paragraph (3).

Decisions made by a peer review body are presumed to have met standards (1) through (4) above,
although this presumption may be rebutted by a preponderance of the evidence.
HCQIA was enacted over 30 years ago, when most physicians practiced independently and hospital markets were not nearly as concentrated as they are today. HCQIA immunity is designed to protect peer reviewers and others who participate in the peer review process, e.g., those who provide information to peer review committees, from damage awards that might result from lawsuits filed by individuals who have been adversely affected by peer review decisions. HCQIA does not explicitly limit immunity from damages solely to lawsuits brought by adversely affected physicians. Consequently, it is possible that a court could interpret HCQIA immunity to extend to damages resulting from lawsuits filed by other parties, e.g., a hospital. However, court decisions have up to this point focused on damage claims by adversely affected physicians, so it is unclear if, and how, HCQIA immunity would apply in the context of lawsuits filed by other parties. Likely a greater concern within the context of AMA Policy D-375.987 is that HCQIA immunity applies when a lawsuit is involved. Consequently, immunity would seem not to apply to a wide variety of retaliatory actions that a hospital or other lay organization might take against a peer reviewer, for example, terminating an employment agreement or hindering an independent physician’s ability to fully and freely utilize hospital facilities or practice amenably in association with other physicians employed by, or affiliated with, the hospital or organization.

Amending HCQIA

Although it is possible that an attempt could be made to amend HCQIA to pursue the goals of AMA Policy D-375.987 your Board of Trustees does not, at this time, recommend attempting to amend HCQIA to address a peer review-related retaliation. First, Congressional attention is entirely taken up with a backlog of urgent “must pass” legislation. In this challenging and rapidly changing environment, it would be extremely difficult to draw Congressional attention to yet another major piece of health care legislation, particularly since amending HCQIA has not in recent years been an issue with which Congress has been actively interested. Second, pursuing a HCQIA amendment strategy at this time could have significant, negative unintended consequences, especially with respect to the National Practitioner Data Bank (NPDB). The enactment of HCQIA created the NPDB. In the past, some parties, whose interests are not aligned with those of organized medicine, have strongly urged Congress to amend HCQIA so that the information in the NPDB would be publicly available. Our AMA opposes such efforts. In fact, AMA Policy H-355.976, “National Practitioner Data Bank,” states in part:

. . . 3. Our AMA: (a) opposes all efforts to open the National Practitioner Data Bank to public access; (b) strongly opposes public access to medical malpractice payment information in the National Practitioner Data Bank; and (c) opposes the implementation by the National Practitioner Data Bank of a self-query user fee . . .

Our AMA has taken this position because information in the NPDB is often incomplete and inaccurate, not organized in a way that patients will understand, and is thus highly likely to be misunderstood or misinterpreted by patients. For these reasons, then, your Board of Trustees does not recommend attempting to amend HCQIA. However, while your Board does not believe that pursuing a HCQIA amendment would be appropriate at this time, your Board feels strongly that our AMA should provide assistance to any state medical association or national medical specialty society that wants to explore or pursue a state legislative strategy to protect physician peer review participants from retaliation.

Peer Review Immunity under State Law

The vast majority, if not all, states, have enacted peer review immunity laws. The conditions for immunity are usually less demanding or specific compared to HCQIA’s. HCQIA immunity is
available only if a decision by a peer review body satisfies standards (1) through (4) above. Under most state peer review laws, immunity is available to peer review participants who act in good faith. State peer review immunity extends to damages. In some circumstances, states go further, immunizing peer review participants from civil liability generally, which would also protect peer review participants from injunctions.

State peer review laws are designed to protect peer review participants from lawsuits by physicians or health care practitioners who feel that they have been aggrieved by a peer review decision. In many states, immunity protections may not be explicitly limited to lawsuits filed by these individuals. In such cases, like HCQIA, it is uncertain if, or to what extent, immunity would apply if a party other than the individual adversely affected by a peer review decision filed a lawsuit against one or more peer review participants. However, the more important issue with respect to AMA Policy D-375.987 is that, like HCQIA, state peer review immunity protections apply to lawsuits. Consequently, state peer review laws would likely not protect physician peer review participants from the gamut of retaliatory actions short of a lawsuit that might be taken against them for their role in, or a decision resulting from, a peer review proceeding.

Unlike HCQIA, most, if not all, states protect the confidentiality of peer review information. This means that peer review information, documents and records cannot lawfully be disclosed to anyone except those conducting the peer review and any other specific individuals or entities identified in the peer review statute. Similarly, states often privilege peer review information, documents and records of peer review proceedings, meaning that such information, documents and records are not admissible in lawsuits, such as those involving medical liability allegations.

**State Court Decisions**

Although state court decisions involving state peer review statutes have focused on lawsuits by persons adversely affected by a peer review decision, there is a reported case that does involve a situation where a hospital retaliated against a peer review participant. The New Mexico Supreme Court case of Yedidag, MD, v. Roswell Clinic Corp., 346 P.3d 1136 (2015) involved Emre Yedidag, MD, a surgeon employed by Eastern Medical Center (EMC) and his alleged conduct during a peer review proceeding. The proceeding focused on another physician’s role in a patient death. During the proceeding, Dr. Yedidag asked the physician a number of pointed questions to clarify the circumstances of the patient’s death, some of which the physician refused to answer. A staff assistant to the peer review committee, who was not a committee member, attended the meeting and later told hospital administration that Dr. Yedidag’s questioning had been inappropriately aggressive (even though physician peer review committee members found nothing untoward about Dr. Yedidag’s conduct). EMC subsequently fired Dr. Yedidag because of alleged “unprofessional behavior.” Dr. Yedidag sued EMC, claiming that EMC violated New Mexico’s peer review law. The New Mexico Supreme Court sided with Dr. Yedidag. The Court recognized that the New Mexico peer review law did not “explicitly preclude employer retaliation for peer review participation.” Nor did the statute explicitly authorize Dr. Yedidag to file a lawsuit for violations of the peer review law. However, the law did protect the confidentiality of peer review information. The law also permitted use and disclosure of such information only for specific reasons listed in the statute, and those reasons did not include the hospital’s acquisition and use of peer review information as part of its personnel decisions. Consequently, the Court ruled that the hospital violated Dr. Yedidag’s right to confidentiality under New Mexico’s peer review law.

Although Dr. Yedidag won his lawsuit, this decision does not sufficiently address the issues raised by D-375.987. First, the Yedidag case is a single decision under one state’s law. Although most, if not all, states protect the confidentiality of peer review information, state laws can vary
significantly in the scope of this protection. There is, therefore, no guarantee that other states would reach the same result. Second, hospitals and other lay organizations do not necessarily need access to confidential peer review information to retaliate against peer review participants. Thus, even if all states ultimately followed the Yedidag decision, doing so would probably not cover all of the instances in which a hospital or other lay organization could retaliate against a physician peer review participant. Consequently, physician advocates wanting to address the issues identified by D-375.987 may want to explore or pursue a state-based legislative strategy to ensure that physician peer review participants are protected from all forms of retaliation.

State Legislative Efforts to Protect Physician Peer Review Participants from Retaliation

While it is extremely unlikely that HCQIA could be successfully amended at this time, the prospects of amending a particular state’s laws might be more promising. Your Board of Trustees understands the serious concerns that AMA Policy D-375.987 raises. Your Board believes, therefore, that our AMA should make its Advocacy Resource Center staff and resources available to assist state medical associations and national medical specialty societies that may be interested in considering or pursuing a state legislative strategy to protect physician peer review participants from any retaliatory conduct by hospitals, lay organizations or other parties.

AMA Policy

AMA policies call for retaliation protections. The following is a list of relevant portions of AMA policies. First, AMA Policy H-225.950, “Principles for Physician Employment,” states, in part, that:

. . . 1.b. [e]mployed physicians should be free to exercise their personal and professional judgment in voting, speaking, and advocating on any matter 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 . . .

Next, AMA Policy H-225.952, “The Physician’s Right to Exercise Independent Judgement in All Organized Medical Staff Affairs,” states that:

[o]ur AMA supports the unfettered right of a physician to exercise his/her personal and professional judgment in voting, speaking and advocating on any matter regarding: [i] patient care interests; [ii] the profession; [iii] health care in the community; [iv] medical staff matters; [v] the independent exercise of medical judgment as appropriate interests to be incorporated into physician employment and independent contractor agreements; the right [vi] not to be deemed in breach of his/her employment or independent contractor agreement for asserting the foregoing enumerated rights; and [vii] not to be retaliated against by his/her employer in any way, including, but not limited to, termination of his/her employment or independent contractor agreement, commencement of any disciplinary action, or any other adverse action against him/her based on the exercise of the foregoing rights.

Further, AMA Policy H-230.965, “Immunity from Retaliation Against Medical Staff Representatives by Hospital Administrators,” states that:

[t]he AMA condemns any action taken by administrators or governing bodies of hospitals or other health care delivery systems who act in an administrative capacity to reduce or withdraw
or otherwise prevent a physician from exercising professional privileges because of medical
staff advocacy activities unrelated to professional competence, conduct or ethics.

AMA Policy H-225.942, “Physician and Medical Staff Member Bill of Rights,” asserts, in part,
that:

. . . II. Our AMA recognizes that the following fundamental rights of the medical staff are
essential to the medical staff’s ability to fulfill its responsibilities: . . .b. The right to advocate
for its members and their patients without fear of retaliation by the health care organization’s
administration or governing body . . .

AMA Policy H-225.942 also contains the following:

. . . 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 member’s ability to fulfill the responsibilities owed to his or her patients, the medical
staff, and the health care organization: . . .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 organization’s
administration or governing body . . .

In addition, AMA Policy H-225.957, “Principles for Strengthening the Physician-Hospital
Relationship,” states that:

. . . 6. The organized medical staff has inherent rights of self-governance, which include but are
not limited to: . . .c) Identifying the indications for automatic or summary suspension, or
termination or reduction of privileges or membership in the organized medical staff bylaws,
restricting the use of summary suspension strictly for patient safety and never for purposes of
punishment, retaliation or strategic advantage in a peer review matter . . .

Finally, it is notable that our AMA also has policies calling for peer review immunity, two of
which are most relevant to this report. First, AMA Policy H-375.962, “Legal Protections for Peer
Review,” states, in part, as follows:

. . . Peer Review Immunity. To encourage physician participation and ensure effective peer
review, entities and participants engaged in peer review activities should be immune from civil
damages, injunctive or equitable relief, and criminal liability . . .

Likewise, AMA Policy H-225.942, “Physician and Medical Staff Member Bill of Rights,” states, in
part, that the rights of individual medical staff members must include: “. . . f. The right to immunity
from civil damages, injunctive or equitable relief, and criminal liability when participating in good
faith peer review activities . . .”

Although protection from any kind of retaliation because of peer review participation might be
implied from AMA policies, AMA policies do not explicitly call for such protection in the context
of peer review participation. This report, therefore, recommends amending AMA Policies
H-225.942 and H-375.962 to explicitly include protection from any retaliatory conduct.
RECOMMENDATIONS

The Board of Trustees recommends that the following be adopted per AMA Policy D-375.987, and that the remainder of the report be filed:

1. That AMA Policy H-225.942, “Physician and Medical Staff Member Bill of Rights,” be amended by addition as follows:

   . . . IV. 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);

2. That AMA Policy H-375.962, “Legal Protections for Peer Review,” be amended by addition as follows:

   . . . Peer Review Immunity and Protection from Retaliation. To encourage physician participation and ensure effective peer review, entities and participants engaged in peer review activities should be immune from civil damages, injunctive or equitable relief, and criminal liability, and should be afforded all available protections from any retaliatory actions that might be taken against such entities or participants because of their involvement in peer review activities. (Modify Current HOD Policy); and

3. That our AMA will provide guidance, consultation and model legislation concerning protections from retaliation for physician peer review participants, upon request of state medical associations and national medical specialty societies. (Directive to Take Action)

Fiscal Note: $5000.
APPENDIX

D-235.984, “Medical Staff Non-Punitve Reporting Processes”
Our AMA will provide guidance, including but not limited to model medical staff bylaws language, to help medical staffs develop and implement reporting procedures that effectively protect medical staff members from retaliation when they report deficiencies in the quality, safety, or efficacy of patient care.

H-285.910, “The Physician’s Right to Engage in Independent Advocacy on Behalf of Patients, the Profession and the Community”
Our AMA endorses the following clause guaranteeing physician independence and recommends it for insertion into physician employment agreements and independent contractor agreements for physician services:
Physician’s Right to Engage in Independent Advocacy on Behalf of Patients, the Profession, and the Community
In caring for patients and in all matters related to this Agreement, Physician shall have the unfettered right to exercise his/her independent professional judgment and be guided by his/her personal and professional beliefs as to what is in the best interests of patients, the profession, and the community. Nothing in this Agreement shall prevent or limit Physician’s right or ability to advocate on behalf of patients’ interests or on behalf of good patient care, or to exercise his/her own medical judgment. Physician shall not be deemed in breach of this Agreement, nor may Employer retaliate in any way, including but not limited to termination of this Agreement, commencement of any disciplinary action, or any other adverse action against Physician directly or indirectly, based on Physician’s exercise of his/her rights under this paragraph.

REFERENCES

1 Unlike state peer review laws, HCQIA does not address the confidentiality of peer review information or records of peer review proceedings. Nor does HCQIA address the issue of whether, or to what extent, peer review information, documents, or records may be admitted into lawsuits or administrative proceedings. The Confidentiality and admission of peer review information is determined by courts on a case-by-case basis.
2 See 42 U.S.C. §§ 11101, et seq.
3 42 U.S. Code § 11112(a)
4 Id.
6 Id.
7 Yedidag, at 1143.
8 Id. at 1143-1144.
9 Id. at 1144.
10 Id. at 1151.
Board of Trustees Report 8-I-16, “Medical Reporting for Safety Sensitive Positions,” which sought to address Resolution 14-A-16 of the same title, was referred at the 2016 Interim Meeting of the AMA House of Delegates. Testimony indicated that the report content missed the resolution’s original intent. Although there are systems in place to screen pilots and others in safety sensitive positions for serious medical conditions, it was stated that these patients often look for medical care outside of these systems, and subsequently fail to be reported.

The Board of Trustees conferred with the authors to clarify the intent of Resolution 14-A-16. This report alerts physicians that they may have new responsibilities as a result of changes in regulations of the Federal Aviation Administration (FAA) regarding medical certification of pilots. It addresses the implications of these changes for pilot and public safety.

BACKGROUND

Effective May 1, 2017, pilots of certain small aircraft may elect to participate in the FAA’s new “BasicMed” program, which allows any licensed physician to evaluate a pilot’s medical fitness to fly. If pilots meet conditions for participating in BasicMed, they are no longer required to obtain third class medical certification specifically from an FAA-designated Aviation Medical Examiner (AME) [1]. Pilots in the designated category may continue to seek third class medical certification from an aviation medical examiner if they choose.

To be eligible for privileges in BasicMed, pilots must have a valid U.S. driver’s license, have held third class medical certification at some time since July 15, 2006 (which must not have been revoked, suspended or withdrawn), and not have been denied third class certification on their most recent application [2]. The individual must have documented completion of an FAA-approved online medical education course within the past 24 months; have had a physical examination by a licensed physician, who reviewed the FAA’s Comprehensive Medical Examination Checklist completed by the patient, within the past 48 months; and must consent to a National Driver Register check.

Individuals who have a medical history or clinical diagnosis of personality disorder repeatedly manifested by overt acts, psychosis, bipolar disorder, or substance dependence (within the previous two years) must obtain a “special issuance medical certification” from an aviation medical examiner before they may exercise privileges under BasicMed [2]. Similarly, a history or diagnosis of epilepsy or disturbance of consciousness or transient loss of control of nervous system function absent satisfactory medical explanation of cause entails that the individual obtain a special issuance medical certification.
medical certification before he or she may exercise privileges under BasicMed. Further these individuals must be under the care of a physician for the condition.

Individuals are prohibited from exercising privileges under BasicMed if their driver’s license has been revoked as a result of the diagnosed condition or if, “in the judgment of the individual’s state-licensed physician,” the individual is unable or “may reasonably be expected to be unable” to safely exercise those privileges as a result of the condition [2].

PILOT SAFETY — PUBLIC SAFETY

The goal of medical certification, for all classes of pilots, is to ensure public safety. Recent aviation incidents, notably the crash of Germanwings Flight 9525 in 2015, which killed 150 passengers and crew, have raised questions about whether oversight of pilots’ medical status and safety to fly is sufficiently rigorous. FAA requirements covering pilots who fly for commercial airlines, i.e., who hold transport pilot certification, or those who hold commercial pilot certification and may fly for hire, are not affected by the regulatory changes that created BasicMed. Even under the more stringent standards governing these classes of pilots there is concern that pilots with potentially impairing medical conditions may be permitted to fly when they are in fact unsafe [3]. These questions form the backdrop to challenges that BasicMed poses for physicians in the U.S.

Medical Certification of Aviators

Aviation Medical Examiners are specifically authorized by the FAA to carry out pilot medical examinations for purposes of protecting the public. To become an AME, physicians must apply to and complete training developed by the Aerospace Medical Education Division of the FAA Civil Aerospace Medical Institute [4]. Prospective AMEs are required to complete online course work as well as four and a half days of in-person training and to complete refresher training every 36 months [4]. Among other objectives, in-person training is intended to:

- Review the latest medical and technical information and clinical examination techniques in the various medical specialty fields that an AME will need to use to assure that aviators meet the medical certification standards for the class of aviator medical certificate applied for [and]
- Recognize the basis for disqualification of the aviator with a medical problem and the conditions necessitating deferral or denial as outlined in Federal Aviation Regulations [5]

In 2012, the Aerospace Medical Association Ad Hoc Working Group on Pilot Mental Health noted that “serious mental health issues involving sudden psychosis are relatively rare, and their onset is difficult to predict,” but that “more attention should be given to mental health issues during the aeromedical assessment of pilots” [6]. The group recommended that “physicians performing aeromedical assessments receive additional periodic training in aviation mental health issues” [6]. In a letter to the FAA of September 2015 following the report on the Germanwings incident, the working group reiterated its recommendation that more attention be given “to less serious and more common mental health conditions,” including grief, psychosocial stress, depression, anxiety, panic disorders, personality disorders, and substance misuse/abuse, noting that these conditions “show patterns that facilitate early detection, and have proven effective treatment strategies” [6,7].

The working group also reiterated and expanded on its previous recommendation to create a “safe zone” to encourage frank discussion of mental health issues [6], urging that “methods be used to build rapport and trust with the pilot in a nonthreatening environment” [7]. It also more explicitly identified barriers to frank discussion, noting that pilots are “highly independent, value control, and fear losing their medical certification.” The 2015 guidelines reiterated the call for additional
training in aviation mental health issues for physicians who conduct aeromedical assessments, and
called for training to include guidance for when the aeromedical examiner should consult with or
refer the pilot to “a mental health specialist provider or other aeromedical resource.”

The Challenge for Non-AME Physicians

When AMEs who are under contract to commercial air carriers or other commercial entities
conduct examinations of pilot-employees, they are required to report their findings to the pilot’s
employer as well as to the FAA. When they conduct examinations of aviator applicants
independently (i.e., not while under contract to the employer), AMEs must report all findings to the
FAA without fail. In the latter situation, individuals who do not receive medical certification are
expected to voluntarily refrain from piloting aircraft pending further evaluation by FAA medical
experts. On a few occasions the aviator applicants are permanently restricted from medical
certification and cannot legally fly any aircraft.

A pilot exercising the privileges of BasicMed may be examined by any physician licensed by any
U.S. state, territory or possession. The physician is required to report potentially impairing
conditions in keeping with state regulations governing the issuance of motor vehicle licenses. The
examining physician must review the individual’s completed FAA Comprehensive Medical
Examination Checklist with the pilot, but is not required to report to the FAA.

Questions have been raised about how well this process protects both pilots and the public interest.
Non-AME physicians may not be adequately prepared to fulfill this new responsibility. Non-AME
physicians need to be made aware of the responsibility itself and of resources available to them,
including consulting with or referring a patient to a regional Aviation Medical Examiner.

In addition, laws governing reporting of medical conditions that may impair an individual’s ability
to operate a motor vehicle safely vary from state to state. Whether pilots who are eligible for
privileges under BasicMed, but may be impaired, present a greater risk to safety than drivers who
may be impaired is not necessarily at issue. What is of concern are data suggesting that even in
jurisdictions where physicians are required to report potentially impairing conditions for motor
vehicle operators they do not uniformly do so [8].

Confidentiality & Trust

Effective patient-physician relationships require that patients be willing to share sensitive
information with their physicians. Patients must be able to trust that information they give to their
physicians in confidence will be protected, and physicians have a corresponding duty to protect the
confidentiality of patients’ personal information [9–12]. Patients who fear the consequences of
disclosure, particularly disclosure of stigmatizing conditions, may be reluctant to seek treatment.
However, the right to confidentiality is not without limits. In many situations, physicians may be
required to breach confidentiality for purposes of protecting the health or safety of the community,
as in mandatory reporting of infectious disease to public health authorities or required reporting of
potentially impaired drivers [13].

Physicians may also disclose personal health information without patients’ consent when in the
physician’s professional judgment there is a reasonably probability of serious harm to the patient or
serious harm to other identifiable individual(s) [15]. Industry-employed physicians and
independent medical examiners may likewise disclose to third parties [16]. In all instances,
however, physicians are expected to restrict disclosure to the minimum information necessary for
the specific purpose at hand and, whenever feasible, to notify the patient in advance of the disclosure.

RECOMMENDATION

In light of these considerations, the Board of Trustees recommends that the following be adopted and the reminder of this report be filed:

1. That our American Medical Association (AMA) promote awareness among all licensed physicians of the safety implications of mental health and other potentially impairing conditions for their patients who are aviator. Physicians need to be aware that for some patients the FAA’s BasicMed program now makes the treating physician a gatekeeper for pilot and public safety. Physicians who are not FAA Aviation Medical Examiners should be educated about when to seek guidance from colleagues with aeromedical expertise. Physicians should also recognize that the range of mental health conditions in particular that may compromise an aviator’s ability to fly safely is more extensive than the specific conditions identified in the FAA Comprehensive Medical Examination Checklist. (New HOD Policy)

2. That our AMA urge physicians to screen routinely for factors that may compromise pilot safety by the least intrusive means reasonable and take steps with the patient to mitigate identified risks. Physicians should be encouraged to consult with or refer the patient to the appropriate FAA Aviation Medical Examiner or FAA Regional Flight Surgeon. (New HOD Policy)

3. That our AMA advocate for adoption of a uniform mechanism for reporting aviators who have potentially compromising medical conditions. (New HOD Policy)

4. That the Council on Ethical and Judicial Affairs be encouraged to review implications for existing ethics guidance in light of the FAA’s alternative requirements for pilot physical examination and education codified in BasicMed. (New HOD Policy)

Fiscal Note: Less than $1000.
REFERENCES


At the 2017 Annual Meeting, the House of Delegates considered Board of Trustees Report 25, “Specialty Society Representation in the House of Delegates – Five-Year Review.” Among its recommendations was that two societies which failed to meet the requirements for continued representation after a year’s grace period to increase membership should not retain representation in the House of Delegates. Testimony at the Reference Committee on Amendments to Constitution and Bylaws, however, supported maintaining the inclusion of these two societies. Testimony lauded the groups’ growths in membership and their participation within the AMA, and maintained that the loss of these societies would be detrimental to the AMA. Both societies presented materials to the reference committee outlining their considerable efforts to increase membership. Based on the testimony presented, the Reference Committee on Amendments to Constitution and Bylaws recommended that the societies retain their representation.

The House of Delegates disagreed and chose to adopt amended language as follows, “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 [both societies]…. be allowed only one additional year to meet these requirements.” The following day, the House reconsidered this item of business because our current Bylaws do not contain an option for the House to extend a second one-year grace period. Ultimately, the House returned to the original BOT Report 25-A-17 recommendation to not retain the representation of these two societies in the House of Delegates. Although the AMA Bylaws do allow the House to continue the representation of a society that does not meet the current guidelines for representation, some testified that this is unfair to those societies that have faced similar membership challenges but succeeded in regaining membership during the one-year grace period. Lastly, a representative of the Specialty and Service Society (SSS) stated that, per the AMA Bylaws, each of the two societies, though they would not retain representation in the HOD, would continue as a member of the SSS and may apply for reinstatement in the House, through the SSS, when they believe they can comply with the guidelines for representation in the House of Delegates.

The Council on Constitution and Bylaws volunteered to look at the existing bylaws and bring forth a report back to the House.

HISTORICAL PERSPECTIVE/CURRENT STATUS

As part of its due diligence, the Council examined the origin of direct specialty society representation in the AMA House of Delegates. Specialty societies were first directly represented in the House of Delegates in 1977. Ten years later in 1987, there were major changes, including
guidelines for evaluating applications for representation and establishing a five-year review to ensure continued compliance with the guidelines.

The first instance of noncompliance arose in 1989. Subsequently the House, through the Council on Long Range Planning and Development (CLRPD), began to consider various options, including a grace period, automatic disqualification of the specialty organization, and a probationary period without voting privileges. It took three meetings for the House to ultimately agree on bylaw language that provided for an automatic one-year grace period to allow noncompliant societies time to become compliant, another review of the society a year later, and the following three options for House action on any society that remained noncompliant after the one-year grace period:

1) continued representation; 2) termination of representation; or 3) a year of probation defined as suspension from active representation, with the society on probation not having a voting delegate in the House or the privilege of the floor, but continued representation in the Specialty Section Council. During the probation period, one final review of the society’s compliance with the current guidelines would occur. If the specialty organization failed to bring itself into compliance, it then would automatically be terminated from representation in the House of Delegates.

In 1993, the House adopted CLRPD Report B-A-93, which provided substantive recommendations for restructuring the House of Delegates. This report also established the Specialty and Service Society (SSS) as the entity responsible for providing a process for: 1) granting specialty organization representation in the House; 2) periodic review of the qualifications of specialty organizations for retention of representation; and 3) a mechanism for terminating, when appropriate, the representation of a specialty organization in the House. The work of SSS is overseen by an 8-person governing council, which is elected by the SSS membership. CCB Report 2-A-94 provided the bylaw amendments to implement the mechanism by which specialty organizations were admitted to the House and by which they maintained their representation, but deleted the previous bylaw language providing for automatic termination after the one-year probationary period.

Under the current Bylaws, all specialty societies are reviewed on a five-year cycle to determine compliance with the current guidelines as stated in AMA policy (Policy G-600.020). The Bylaws provide noncompliant societies with a one-year grace period during which it is hoped that they are able to bring themselves into compliance. At the end of that period, the House has only two options for acting on societies that remain noncompliant after the one-year grace period: 1) continue the society’s representation; or 2) discontinue the society’s representation.

The appended chart shows the evolution of specialty society representation once the five-year review was put into place, offers more details regarding amendments over time to the AMA Bylaws to address noncompliant societies, and provides background on House actions on noncompliant societies. In short, since 1989 there have been 69 societies that did not meet the guidelines for continued representation, with House action characterized as follows:

- Society compliant after grace period – 38
- Society noncompliant/representation continued – 17
- Society noncompliant/representation terminated – 7 (two of these societies were subsequently readmitted)
- Other action – 7 (society dissolved, society merged with another, etc.)

It must also be noted that 10 years ago, a fairly large number of societies up for review were no longer able to meet the current guidelines for representation due to declining AMA membership among their own specialty society membership. The House placed a moratorium on loss of
representation, and in 2008 subsequently adopted modified membership criteria, which were again amended in 2012 and embodied in Policy G-600.020 (3).

DISCUSSION

The Council identified and discussed several elements it believed were not clearly addressed in current AMA Bylaws and convened a conference call with members of the SSS Governing Council. Discussion points included:

1) When does a specialty society’s termination from representation in the House of Delegates take effect?

Historically, the loss of representation has occurred at the conclusion of the meeting rather than immediately following the House’s action to unseat. This seems fair to the Council, as any organization with a one-year grace period that is invested enough in the outcome to send a representative without knowing the outcome in advance should not be penalized by immediately losing their seat or voting privileges. An amendment to the Bylaws to this effect has been proposed for House action.

2) When does the next five-year review occur for a noncompliant society when the House votes to continue its representation in the House after a one-year grace period?

Every specialty admitted to the House of Delegates is on a five-year review cycle. In the past, SSS has maintained the original five-year review schedule. Thus, when the House votes to continue the representation of a noncompliant society after a grace period, the specialty society retains representation in the House of Delegates until its next scheduled review with no additional scrutiny or reporting. The Council has proposed Bylaw language to make this clearer.

3) What actions, if any, beyond those in the current Bylaws should the House be empowered to take when faced with a society that remains noncompliant after its one-year grace period?

Both the Council and the SSS agree that it is the responsibility of the House to decide to either continue the membership with another review in 4 years or to terminate the society’s representation. In the past, the House has been inconsistent in its actions, often being swayed by passionate testimony during reference committee and again on the floor of the House on why a society should not lose its representation. In light of the recent parity in representation between constituent societies and specialty societies, essentially any nonconforming society whose representation is continued is taking a seat from another specialty society that has met all requirements for continued representation. SSS members expressed hopes that the House would be judicious in actions to continue the representation of any society that is noncompliant, reserving the vote for continuation only for extenuating circumstances. Also, per existing AMA Bylaw 8.5.3.2.2, if the House votes to terminate a specialty society’s representation in the House, they still remain members of the Specialty and Service Society. A society, which worked hard during its grace period but did not reach its goal but that continued its outreach efforts, likely would be without an HOD delegate seat for less than one year even recognizing that new societies are only admitted at the Annual Meeting. The Council believes the options currently provided in the Bylaws should remain as the only options.
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.

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. The next review will occur four years from the time of the House’s action to continue representation.

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 must 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. The next review will occur four years from the time of the House’s action to continue representation after a one-year grace period.

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 effective with the adjournment of the House of Delegate meeting at which action takes place. 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.
RELEVANT AMA POLICY

G-600.020, “Admission of Specialty Organizations to our AMA House”
The following guidelines shall be utilized in evaluating specialty society applications for representation in our AMA House of Delegates (new specialty organization applications will be considered only at Annual Meetings of the House of Delegates):
(1) The organization must not be in conflict with the Constitution and Bylaws of our AMA 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.

G-600.019, “Probationary Period for Specialty Societies”
The specialty organizations placed on one year probation are expected to work with AMA membership to develop a plan to increase their AMA membership and meet the responsibilities of National Medical Specialty Organizations as provided in Section 8.20 of the Bylaws.
Our AMA will work towards implementation of data licensing agreements with the specialty organizations seated in the House of Delegates that will provide them with the ability to view a portion of the AMA eprofile application for the sole purpose of AMA membership verification.
### History of Specialty Societies noncompliant with AMA-HOD Representation Criteria and House Action

<table>
<thead>
<tr>
<th>Society and Year of Initial Review for Compliance (and Year of Admittance)</th>
<th>Outcome/Comments</th>
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<tbody>
<tr>
<td><strong>Direct representation of specialty organizations was established in 1977. CLRPD Report A-I-77 recommended a set of criteria for determining such representation, and identified the societies that would be represented based on the criteria. CLRPD Report A-A-87 and subsequent CCB Report A-I-87 presented revised guidelines for representation and instituted a review process whereby specialty organizations represented in the House would have to reconfirm their qualifications for representation every five years. The review process was first initiated at the 1988 Annual Meeting.</strong></td>
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<td><strong>1989</strong></td>
<td>BOT Report DDD-A-89, in its review of the third group of specialty organizations seated in the HOD, noted the first society not in compliance. The Board was asked to develop a mechanism to address specialty society noncompliance and report back at I-89. CCB Report A-I-89, proposed a process, including a one-year grace period, to permit the House of Delegates to take direct action when a deficiency was discovered in the process of the five-year review, but it was referred back, as was CCB Report A-A-90. Ultimately adopted was CCB Report I-I-90 with its proposal that (1) there will be a verification of AMA membership of the specialty organization, and notification of the results of the review process provided to the specialty organization approximately one year prior to the BOT’s report to the House; (2) A specialty organization found to be noncompliant will have one year, from the time of the Board’s report to the HOD, to bring itself into compliance with the guidelines. At the end of the grace period of one year, the Board will submit another report advising the House as to the specialty organization’s compliance. If the organization is not in compliance, the House will have the option of voting to continue the representation of the specialty organization in the HOD, to terminate the representation in the HOD or to place the specialty organization on a probationary status for a period of one year. (Probationary status is defined as suspension from active representation. A society on probation would not have a voting delegate and would not have the privilege of the floor, but would be entitled to continue to have representation in the specialty Section Council.) If the HOD grants a one-year period of probationary status, the BOT shall report one year later, in an informational report, on the organization’s compliance with the guidelines for representation. If the organization has failed to bring itself into compliance, it will be automatically terminated from representation in the House. CCB Report E-A-91 with the bylaw amendments was adopted.**</td>
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<tr>
<td>American Association of Pathologists (1977)</td>
<td><strong>A-89: No “official probation,” but BOT reported it would again review membership data in 1990. BOT Report CCC-A-90 was adopted with the recommendation that AAP’s representation be suspended at the conclusion of the 1990 Annual Meeting for a 2-year period, during which the AAP may be readmitted to representation in the HOD if it cures the cited deficiency and brings itself into compliance with the Guidelines for Representation in the House. At the conclusion of said two year period if the cited deficiency has not been corrected the representation of the AAP will be terminated.</strong></td>
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<td>1991</td>
<td>American Society of Clinical Pharmacology</td>
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<td>and Therapeutics (1977)</td>
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<td>American Pediatric Surgical Association</td>
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<td>(1986)</td>
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<tr>
<td>1992</td>
<td>No noncompliant societies</td>
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<td>1993</td>
<td>No noncompliant societies</td>
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<tr>
<td>1994</td>
<td>National Association of Medical Examiners</td>
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<td>(1983)</td>
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<td>American College of Legal Medicine</td>
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<td>(1982) [Admitted as American Society of</td>
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<td>Year</td>
<td>Society Name</td>
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<td>1999</td>
<td>Association of University Radiologists (1989)</td>
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<td>2000</td>
<td>Association of University Radiologists (1989)</td>
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<td>2002</td>
<td>American College of Rheumatology (1987) [Admitted as the American Rheumatism Association]</td>
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<td>Organization</td>
<td>2006</td>
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<td>American College of Medical Genetics &amp; Genomics (1996) [Admitted as American College of Medical Genetics]</td>
<td>At A-06, the House adopted Resolution 603 that called for a moratorium on the loss of any organization’s current representation in the HOD for any society which does not meet the current AMA guidelines for representation requirements as it pertains to the percentage of AMA members; that the moratorium remain in place through December 31, 2007; and when the moratorium is lifted any organization which does not meet the required percentage of AMA members will have a one year grace period to meet the requirements for HOD representation.</td>
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<td>American Pediatric Surgical Association (1986)</td>
<td>A-06: Placed on a one-year grace period for review. &lt;br&gt; I-07: Representation retained at this time, but will be reviewed again at the end of the moratorium and will be required to comply with the membership requirements at that point, or be given one year to come into compliance. &lt;br&gt; I-08: Representation retained (compliant with new membership threshold).</td>
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<tr>
<td>American Society of Bariatric Physicians (2001)</td>
<td>A-06: Placed on a one-year grace period for review. &lt;br&gt; I-07: Representation retained at this time, but will be reviewed again at the end of the moratorium and will be required to comply with the membership requirements at that point, or be given one year to come into compliance. &lt;br&gt; I-08: Representation continued (compliant with new membership threshold).</td>
</tr>
<tr>
<td>American Society of Colon and Rectal Surgeons (1977)</td>
<td>A-06: Placed on a one-year grace period for review. &lt;br&gt; I-07: Representation retained at this time, but will be reviewed again at the end of the moratorium and will be required to comply with the membership requirements at that point, or be given one year to come into compliance. &lt;br&gt; I-08: Representation continued (compliant with new membership threshold).</td>
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<tr>
<td>American Society of Neuroimaging (1996)</td>
<td>A-06: Placed on a one-year grace period for review. &lt;br&gt; I-07: Representation retained at this time, but will be reviewed again at the end of the moratorium and will be required to comply with the membership requirements at that point, or be given one year to come into compliance. &lt;br&gt; I-08: Representation continued (compliant with new membership threshold).</td>
</tr>
<tr>
<td>American Society of Neuroradiology (1986)</td>
<td>A-06: Placed on a one-year grace period for review. &lt;br&gt; I-07: Representation retained at this time, but will be reviewed again at the end of the moratorium and will be required to comply with the membership requirements at that point, or be given one year to come into compliance. &lt;br&gt; I-08: Representation continued (compliant with new membership threshold).</td>
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<tr>
<td>Year</td>
<td>Organization</td>
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</table>
| 2007 | Academy of Pharmaceutical Physicians and Investigators (2002)                 | A-07: Did not submit materials (aware it will automatically be placed on probation at the end of the moratorium on December 31, 2007, and will be required to go through the five-year review process in 2008. Representation retained at this time, but will be reviewed again at the end of the moratorium and will be required to comply with the membership requirements at that point, or be given one year to come into compliance.  
I-08: Representation continued (compliant with new membership threshold). |
|      | Society of Nuclear Medicine (1979)                                            | I-07: Placed on a one-year grace period for review at the AMA’s 2008 Interim Meeting.  
I-08: Noncompliance noted but the House voted to continue their representation. |
| 2008 | Aerospace Medical Association (1977)                                          | I-08: Have a grace period of one year to bring themselves into compliance.  
A-09: Representation continued (noncompliant). |
|      | American Society of Addiction Medicine (1988)                                 | I-08: Have a grace period of one year to bring themselves into compliance.  
American Association for Hand Surgery (2003) | A-08: BOT report noted noncompliance and recommended a grace period of one year (Referred)  
I-08: Representation continued (compliant with new membership threshold) |
|      | American Clinical Neurophysiology Society (1998)                              | A-08: BOT report noted noncompliance and recommended a grace period of one year (Referred)  
I-08: Representation continued (compliant with new membership threshold) |
|      | American Society of Ophthalmic Plastic & Reconstructive Surgery (1998)        | A-08: BOT report noted noncompliance and recommended a grace period of one year (Referred)  
I-08: Representation continued (compliant with new membership threshold) |
|      | American Academy of Allergy, Asthma and Immunology (1977)                    | I-08: Noncompliance noted as well as a one-year grace period, but the House voted to continue representation. |
| 2009 | American College of Nuclear Medicine (1979)                                   | I-09: Did not submit information as it is in the process of merging with the College of Nuclear Physicians. The HOD voted to give it a one-year grace period to bring itself into compliance or be removed from the HOD.  
No further follow-up |
| 2010 | American Geriatrics Society (1978)                                            | I-10: Given a grace period of one year to meet the membership requirements to retain position in AMA HOD.  
I-11: Representation continued (compliant). |
<table>
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<tr>
<th>Organization</th>
<th>2011</th>
<th>2011</th>
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<tr>
<td>American College of Occupational and Environmental Medicine (1977) [Admitted as American Academy of Occupational Medicine]</td>
<td>I-10: Given a grace period of one year to meet the membership requirements to retain position in AMA HOD. I-11: Representation continued (compliant).</td>
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<tr>
<td>AMDA—Society for Post-Acute and Long-Term Care Medicine (1991) [Admitted as American Medical Directors Association]</td>
<td>A-11: Given a grace period of one year to meet the membership requirements to retain position in AMA HOD. A-12: Representation retained (noncompliant).</td>
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<tr>
<td>American Pediatric Surgical Association (1986)</td>
<td>A-11: Given a grace period of one year to meet the membership requirements to retain position in AMA HOD. A-12: Representation discontinued (did not submit materials and thus determined to be noncompliant; APSA notified they would no longer be participating).</td>
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<tr>
<td>American Society of Bariatric Physicians (2001)</td>
<td>A-11: Given a grace period of one year to meet the membership requirements to retain position in AMA HOD. A-12: Representation retained (noncompliant).</td>
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<tr>
<td>American Society of Neuroradiology (1996)</td>
<td>A-11: Given a grace period of one year to meet the membership requirements to retain position in AMA HOD. A-12: Representation retained (compliant).</td>
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<tr>
<td>Korean–American Medical Association (2006)</td>
<td>A-11: Given a grace period of one year to meet the membership requirements to retain position in AMA HOD. A-12: Representation discontinued (did not submit materials and thus determined to be noncompliant.</td>
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<tr>
<td>Renal Physicians Association (1986)</td>
<td>A-11: Given a grace period of one year to meet the membership requirements to retain position in AMA HOD. A-12: Representation retained (noncompliant).</td>
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<tr>
<td>Society of Interventional Radiology (1991)</td>
<td>A-11: Given a grace period of one year to meet the membership requirements to retain position in AMA HOD. A-12: Representation retained (compliant).</td>
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<tr>
<td>American Society of Radiation Oncology (1978) [Admitted as the American Society for Therapeutic Radiologists, later renamed ASTRO, American Society for Therapeutic Radiology and Oncology]</td>
<td>I-11: Given a grace period of one year to meet the membership requirements to retain position in AMA HOD. I-12: Representation continued (noncompliant).</td>
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<td>Organization</td>
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<td>American Society for Surgery of the Hand (1996)</td>
<td>I-11: Given a grace period of one year to meet the membership requirements to retain position in AMA HOD. I-12: Representation continued (noncompliant).</td>
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<tr>
<td>American Society of Cytopathology (1982) [Admitted as American Society of Cytology]</td>
<td>I-11: Given a grace period of one year to meet the membership requirements to retain position in AMA HOD. I-12: Representation continued (noncompliant).</td>
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<td>Society for Vascular Surgery (1996) [Admitted as International Society for Cardiovascular Surgery]</td>
<td>I-11: Given a grace period of one year to meet the membership requirements to retain position in AMA HOD. I-12: Representation continued (noncompliant).</td>
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<td>2012</td>
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<td>Society of Nuclear Medicine and Molecular Imaging (1979) [Admitted as Society of Nuclear Medicine]</td>
<td>I-12: Reported as noncompliant. Representation continued (noncompliant).</td>
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<tr>
<td>2013</td>
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<tr>
<td>American Academy of Hospice and Palliative Medicine (2003)</td>
<td>A-13: Given a grace period of one year to meet the membership requirements to retain position in AMA HOD. A-14: Representation continued (compliant).</td>
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<td>2014</td>
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<tr>
<td>American Society of Hematology (1989)</td>
<td>A-14: Given a grace period of one year to meet the membership requirements to retain position in the AMA HOD. A-15: Given a grace period of one year to meet the membership requirements to retain position in AMA HOD. A-16: Representation terminated (noncompliant). [Reapplied in 2017 and regained representation]</td>
<td></td>
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<tr>
<td>American College of Physician Executives (1989)</td>
<td>A-14: Representation terminated at the organization’s request.</td>
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<tr>
<td>Organization</td>
<td>Date</td>
<td>I-14: Given six months to submit materials for consideration for continued representation or risk loss of representation.</td>
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<tr>
<td>Organization</td>
<td>Date</td>
<td>Action</td>
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<tr>
<td>American Society of Plastic Surgeons (1977) [Admitted as American Society of Plastic and Reconstructive Surgeons]</td>
<td>I-16: Placed on probation and given one year to work withAMA membership staff to increase their AMA membership.</td>
<td></td>
</tr>
<tr>
<td>Academy of Physicians in Clinical Research (2002) [Admitted as American Academy of Pharmaceutical Physicians, later known as American Academy of Pharmaceutical Physicians and Investigators]</td>
<td>A-17: Placed on probation and given one year to work withAMA membership staff to increase their AMA membership.</td>
<td></td>
</tr>
<tr>
<td>American Society of General Surgeons (1997)</td>
<td>A-17: Placed on probation and given one year to work withAMA membership staff to increase their AMA membership.</td>
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EXECUTIVE SUMMARY

The expectation that physicians will provide competent care is central to medicine. It undergirds professional autonomy and the privilege of self-regulation granted to medicine by society.

The ethical responsibility of competence encompasses more than 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. Importantly, the ethical responsibility of competence requires that physicians at all stages of their professional lives 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.

Self-aware physicians discern when they are no longer comfortable handling a particular type of case and know when they need to obtain more information or need additional resources to supplement their own skills. They recognize when they should ask themselves whether they should postpone care, arrange to have a colleague provide care, or otherwise find ways to protect the patient’s well-being.

To fulfill their ethical responsibility of competence, physicians at all stages in their professional lives should cultivate and exercise skills of self-awareness and active self-observation; take advantage of tools for self-assessment that are appropriate to their practice settings and patient populations; and be attentive to environmental and other factors that may compromise their ability to bring their best skills to the care of individual patients. As a profession, medicine should provide meaningful opportunity for physicians to hone their ability to be self-reflective.
The expectation that physicians will provide competent care is central to medicine. This expectation shaped the founding mission of the American Medical Association (AMA) and runs throughout the AMA Code of Medical Ethics [1-4]. It undergirds professional autonomy and the privilege of self-regulation granted to medicine by society [5]. The profession promises that practitioners will have the knowledge, skills, and characteristics to practice safely and that the profession as a whole and its individual members will hold themselves accountable to identify and address lapses [6-9].

Yet despite the centrality of competence to professionalism, the Code has not hitherto examined what the commitment to competence means as an ethical responsibility for individual physicians in day-to-day practice. This report by the Council on Ethical and Judicial Affairs explores this topic to develop ethics guidance for physicians.

DEFINING COMPETENCE

A caveat is in order. Various bodies in medicine undertake point-in-time, cross-sectional assessments of physicians’ technical knowledge and skills. However, this report is not concerned with matters of technical proficiency assessed by medical schools and residency programs, specialty boards (for purposes of certification), or hospital and other health care organizations (e.g., for privileging and credentialing). Such matters lie outside the Council’s purview.

The ethical responsibility of competence encompasses more than 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. Importantly, the ethical responsibility of competence requires that physicians at all stages of their professional lives 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. For purposes of this analysis, competence is understood as “the habitual and judicious use of communication, knowledge, technical skills, clinical reasoning, emotions, values, and reflection in daily practice for the benefit of the individual and the community being served” and as “developmental, impermanent, and context dependent” [10].

Moreover, the Council is keenly aware that technical proficiency evolves over time—what is expected of physicians just entering practice is not exactly the same as what is expected of mid-
career physicians or physicians who are changing or re-entering practice or transitioning out of active practice to other roles. 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.

The concept that informs this report differs as well from the narrower legal definition of competence as the knowledge and skills an individual has to do a job. Rather, this report explores a broader notion of competence that encompasses deeper aspects of wisdom, judgment and practice that enable physicians to assure patients, the public, and the profession that they provide safe, high quality care moment to moment over the course of a professional lifetime.

SELF-ASSESSMENT & ITS LIMITATIONS

Health care institutions and the medical profession as a whole take responsibility to regulate physicians through credentialing and privileging, routinely testing knowledge (maintenance of certification, requirements for continuing education, etc.) and, when needed, taking disciplinary action against physicians who fail to meet expectations for competent, professional practice. However, the better part of the responsibility to maintain competence rests with physicians’ “individual capacity, as clinicians, to self-assess [their] strengths, deficiencies, and learning needs to maintain a level of competence commensurate with [their] clinical roles” [11].

Self-assessment has thus become “integral to many appraisal systems and has been espoused as an important aspect of personal professional behavior by several regulatory bodies and those developing learning outcomes for students” [12]. Undergraduate and graduate medical education programs regularly use self-assessment along with third-party evaluations to ensure that trainees are acquiring the knowledge and skills necessary for competent practice [5, 10, 13-16].

Yet how accurately physicians assess their own performance is open to question. Research to date suggests that there is poor correlation between how physicians rate themselves and how others rate them [5, 12, 13]. Various studies among health professionals have concluded that clinicians and trainees tend to assess their peers’ performance more accurately than they do their own; several have found that poor performers (e.g., those in the bottom quartile) tend to over-estimate their abilities while high performers (e.g., those in the top quartile), tend to under-estimate themselves [5, 12, 17].

The available findings suggest that self-assessment involves an interplay of factors that can be complicated by lack of insight or of metacognitive skill, that is, ability to be self-observant in the moment. Similarly, personal characteristics (e.g., gender, ethnicity, or cultural background) and the impact of external factors (e.g., the purpose of self-assessment or whether it is designed to assess practical skills or theoretical knowledge) can all affect self-assessment [12, 18]. The published literature also indicates that interventions intended to enhance self-assessment may seek different goals—improving the accuracy of self-assessors’ perceptions of their learning needs, promoting appropriate change in learning activities, or improving clinical practice or patient outcomes [12].

Self-assessment alone is not a reliable enough tool to ensure that physicians acquire and maintain the competence they need to provide safe, high quality care. Feedback from third parties is essential—or as one researcher has observed, “The road to self-knowledge may run through other people” [19]. However, physicians are often wary of assessment. They have indicated that while they want feedback, they are not sure how to use information that is not congruent with their self-appraisals [20]. Physicians can be hesitant to seek feedback for fear of looking incompetent or exposing possible deficiencies or out of concern that soliciting feedback could adversely affect
their relationships with those whom they approach [20]. They may also question the accuracy and
credibility of the assessment process and the data it generates [21].

To be effective, feedback must be valued both by those being assessed and by those offering
assessment [14]. When there is tension between the stated goals of assessment and the implicit
culture of the health care organization or institution, assessment programs can too readily devolve
into an activity undertaken primarily to satisfy administrators that rarely improves patient care [20].
Feedback mechanisms should be appropriate to the skills being assessed—multi-source reviews
(“360° reviews”), for example, are generally better suited to providing feedback on communication
and interpersonal skills than on technical knowledge or skills—and easy for evaluators to
understand and use [14]. High quality feedback will come from multiple sources; be specific and
focus on key elements of the ability being assessed; address behaviors rather than personality or
personal characteristics; and “provide both positive comments to reinforce good behavior and
constructive comments with action items to address deficiencies” [22]. Beyond such formal
mechanisms, physicians should welcome and seek out informal input from colleagues. They should
be willing to offer timely comments to colleagues as well.

EXPERTISE & EXPERT JUDGMENT

On this broad understanding of competence, physicians’ thought processes are as important as their
knowledge base or technical skills. Thus, understanding competence requires understanding
something of the nature of expertise and processes of expert reasoning, themselves topics of
ongoing exploration [23, 24, 25, 26]. Prevailing theory distinguishes “fast” from “slow” thinking;
that is, reflexive, intuitive processes that require minimal cognitive resources versus deliberate,
analytical processes that require more conscious effort [25]. Some scholars take expertise to
involve “fast” processes, and specifically decision making that involves automatic, nonanalytic
resources acquired through experience [23]. Others argue that expertise consists in using “slow,”
effortful, analytic processes to address problems [23]. A more integrative view argues that
expertise resides in being able to transition between intuitive and analytical processes as
circumstances require. On this account, experts use automatic resources to free up cognitive
capacity so that they maintain awareness of the environment (“situational awareness”) and can
determine when to shift to effortful processes [23].

Expert judgment is the ability “to respond effectively in the moment to the limits of [one’s]
automatic resources and to transition appropriately to a greater reliance on effortful processes when
needed” [23], a practice described as “slowing down.” Knowing when to slow down and be
reflective has been demonstrated to improve diagnostic accuracy and other outcomes [25]. To
respond to the unexpected events that often arise in a clinical situation, the physician must
“vigilantly monitor relevant environmental cues” and use these as signals to slow down, to
transition into a more effortful state [24]. This can happen, for example, when a surgeon confronts
an unexpected tumor or anatomical anomaly during a procedure. “Slowing down when you should”
serves as a critical marker for intraoperative surgical judgment [23].

INFLUENCES ON CLINICAL REASONING

Clinical reasoning is a complex endeavor. Physicians’ capabilities develop through education,
training, and experiences that provide tools with which to shape their clinical reasoning. Every
physician arrives at a diagnosis and treatment plan for an individual in ways that may align with or
differ from the analytical and investigative processes of their colleagues in innumerable ways.
When something goes wrong in the clinic, it can be difficult to discern why. Nonetheless, all
physicians are open to certain common pitfalls in reasoning, including relying unduly on heuristics and habits of perception, and succumbing to overconfidence.

Heuristics

Physicians often use various heuristics—i.e., cognitive short cuts—to aid decision making. While heuristics can be useful tools to help physicians identify and categorize relevant information, these time-saving devices can also derail decision making. For example, a physician may mistakenly assume that “something that seems similar to other things in a certain category is itself a member of that category” (the representative heuristic) [27], and fail to diagnose a serious health problem. Imagine a case in which a patient presents with symptoms of a possible heart attack or a stroke that the physician proceeds to discount as stress or intoxication once the physician learns that the patient is going through a divorce or smells alcohol on the patient’s breath. Or a physician may miscalculate the likelihood of a disease or injury occurring by placing too much weight “on examples of things that come to mind easily, . . . because they are easily remembered or recently encountered” (the availability heuristic) [27]. For example, amidst heavy media coverage of an outbreak of highly infectious disease thousands of miles away in a remote part of the world, a physician seeing a patient with symptoms of what is actually a more commonplace illness may misdiagnose (or over diagnose) the exotic condition because that is what is top of mind.

Clinical reasoning can be derailed by other common cognitive missteps as well. These can include misperceiving a coincidental relationship as a causal relationship (illusory bias), or the tendency to remember information transferred at the beginning (or end) of an exchange but not information transferred in the middle (primary or recency bias) [25, 27, 29].

Habits of Perception

Like every other person, physicians can also find themselves prone to explicit (conscious) or implicit (unconscious) habits of perception or biases. Physicians may allow unquestioned assumptions based on a patient’s race or ethnicity, gender, socioeconomic status, or health behavior, among other features, to shape how they perceive the patient and how they engage with, evaluate and treat the individual. Basing one’s interactions with a patient on pre-existing expectations or stereotypes demeans the patient, undermines the patient’s relationship with the physician and the health care system, and can result in significant health disparities across entire communities [30]. This is of particular concern for patients who are members of minority and historically disadvantaged populations [30]. Physicians may fall victim to the tendency to seek out information that confirms established expectations or dismiss contradicting information that does not fit into predetermined beliefs (confirmatory bias) [27]. These often inadvertent thought processes can result in a physician pursuing an incorrect line of questioning or testing that then leads to a misdiagnosis or the wrong treatment.

No matter how well a patient may seem to fit a stereotype, it is imperative that the physician look beyond categories and assumptions to investigate openly the health issues experienced by the patient. Although all human beings exhibit both conscious and unconscious habits of perception, physicians must remain vigilant in not allowing preconceived or unexamined assumptions to influence their medical practice.

Overconfidence

Finally, another obstacle to strong clinical reasoning that physicians may encounter is overconfidence. Despite their extensive training, physicians, like all people, are poor at identifying
the gaps in their knowledge [27, 29]. Physicians may consider their skills to be excellent, when, in fact, their peers have identified areas for improvement [29]. Overconfidence in one’s abilities can lead to suboptimal care for a patient, be it through mismanaging resources, failing to consider the advice of others, or not acknowledging one’s limits [27, 29].

To avoid falling into such traps, physicians must recognize that many factors can and will influence their clinical decisions [27]. They need to be aware of the information they do and do not have and they need to acknowledge that many factors can and will influence their judgment. They should keep in mind the likelihood of diseases and conditions and take the time to distinguish information that is truly essential to sound clinical judgment from the wealth of possibly relevant information available about a patient. They should consider reasons their decisions may be wrong and seek alternatives, as well as seek to disprove rather than confirm their hypotheses [27]. And they should be sensitive to the ways in which assumptions may color their reasoning and not allow expectations to govern their interactions with patients.

Shortcomings can be an opportunity for growth in medicine, as in any other field. By becoming aware of areas in which their skills are not at their strongest and seeking additional education or consulting with colleagues, physicians can enhance their practice and best serve their patients.

FROM SELF-ASSESSMENT TO SELF-AWARENESS

Recognizing that many factors affect clinical reasoning and that self-assessment as traditionally conceived has significant shortcomings, several scholars have argued that a different understanding of self-assessment is needed, along with a different conceptualization of its role in a self-regulating profession [31]. Self-assessment, it is suggested, is a mechanism for identifying both one’s weaknesses and one’s strengths. One should be aware of one’s weaknesses in order to self-limit practice in areas in which one has limited competence, to help set appropriate learning goals, and to identify areas that “should be accepted as forever outside one’s scope of competent practice” [31]. Knowing one’s strengths, meanwhile, allows a physician both to “act with appropriate confidence” and to “set appropriately challenging learning goals” that push the boundaries of the physician’s knowledge [31].

If self-assessment is to fulfill these functions, physicians need to reflect on past performance to evaluate not only their general abilities but also specific completed performances. At the same time, they must use self-assessment predictively to assess how likely they are to be able to manage new challenges and new situations. More important, physicians should understand self-assessment as an ongoing process of monitoring tasks during performance [32]. The ability to monitor oneself in the moment is critical to physicians’ ethical responsibility to practice safely, at the top of their expertise but not beyond it.

Expert practitioners rely on pattern recognition and other automatic resources to be able to think and act intuitively. As noted above, an important component of expert judgment is transitioning effectively from automatic modes of thinking to more effortful modes as the situation requires. Self-awareness, in the form of attentive self-observation (metacognitive monitoring), alerts physicians when they need to direct additional cognitive resources to the immediate task. For example, among surgeons, knowing when to “slow down” during a procedure is critical to competent professional performance, whether that means actually stopping the procedure, withdrawing attention from the surrounding environment to focus more intently on the task at hand, or removing distractions from the operating environment [24].
Physicians should also be sensitive to the ways that interruptions and distractions, which are common in health care settings, can affect competence in the moment [33, 34], by disrupting memory processes, particularly the “prospective memory”—i.e., “a memory performance in which a person must recall an intention or plan in the future without an agent telling them to do so”—important for resuming interrupted tasks [34, 35]. Systems-level interventions have been shown to help reduce the number or type of interruptions and distractions and mitigate their impact on medical errors [36].

A key aspect of competence is demonstrating situation-specific awareness in the moment of being at the boundaries of one’s knowledge and responding accordingly [32]. Slowing down, looking things up, consulting a colleague, or deferring from taking on a case can all be appropriate responses when physicians’ self-awareness tells them they are at the limits of their abilities. The capacity for ongoing, attentive self-observation, for “mindful” practice, is an essential marker of competence broadly understood:

Safe practice in a health professional’s day-to-day performance requires an awareness of when one lacks the specific knowledge or skill to make a good decision regarding a particular patient . . . . This decision making in context is importantly different from being able to accurately rate one’s own strengths and weaknesses in an acontextual manner. . . . Safe practice requires that self-assessment be conceptualized as repeatedly enacted, situationally relevant assessments of self-efficacy and ongoing ‘reflection-in-practice,’ addressing emergent problems and continuously monitoring one’s ability to effectively solve the current problem [31].

Self-aware physicians discern when they are no longer comfortable handling a particular type of case and know when they need to obtain more information or need additional resources to supplement their own skills [31]. Self-aware physicians are also alert to how external stressors—the death of a loved one or other family crisis, or the reorganization of their practice, for example—may be affecting their ability to provide care appropriately at a given time. They recognize when they should ask themselves whether they should postpone care, arrange to have a colleague provide care, or otherwise find ways to protect the patient’s well-being.

MAINTAINING COMPETENCE ACROSS A PRACTICE LIFETIME

For physicians, the ideal is not simply to be “good” practitioners, but to excel throughout their professional careers. This ideal holds not just over the course of a sustained clinical practice, but equally when physicians re-enter practice after a hiatus, transition from active patient care to roles as educators or administrators, or take on other functions in health care. Self-assessment and self-awareness are central to achieving that goal.

A variety of strategies are available to physicians to support effective self-assessment and help physicians cultivate the kind of self-awareness that enables them to “know when to slow down” in day-to-day practice. One such strategy might be to create a portfolio of materials for reflection in the form of written descriptions, audio or video recording, or photos of encounters with patients that can provide evidence of learning, achievement and accomplishment [16] or of opportunities to improve practice. A strength of portfolios as a tool for assessing one’s practice is that, unlike standardized examinations, they are drawn from one’s actual work and require self-reflection [15].

As noted above, to be effective, self-assessment must be joined with input from others. Well-designed multi-source feedback can be useful in this regard, particularly for providing information about interpersonal behaviors [14]. Research has shown that a four-domain tool with a simple response that elicits feedback about how well one maintains trust and professional relationships
with patients, one’s communication and teamwork skills, and accessibility offers a valid, reliable tool that can have practical value in helping to correct poor behavior and, just as important, consolidate good behavior [14]. Informal arrangements among colleagues to provide thoughtful feedback will not have the rigor of a validated tool but can accomplish similar ends.

Reflective practice, that is, the habit of using critical reflection to learn from experience, is essential to developing and maintaining competence across a physician’s practice lifetime [37]. It enables physicians to “integrate personal beliefs, attitudes, and values in the context of professional culture,” and to bridge new and existing knowledge. Studies suggest that reflective thinking can be assessed, and that it can be developed, but also that the habit can be lost over time with increasing years in practice [37].

“Mindful practice,” that is, being fully present in everyday experience and aware of one’s own mental processes (including those that cloud decision making) [38], sustains the attitudes and skills that are central to self-awareness. Medical training, with its fatigue, dogmatism, and emphasis on behavior over consciousness, erects barriers to mindful practice, while an individual’s unexamined negative emotions, failure of imagination, and literal-mindedness can do likewise. Mindfulness can be self-taught, but for most it is most effectively learned in relationship with a mentor or guide. Nonetheless, despite challenges, there are myriad ways physicians can cultivate mindfulness. Meditation, which may come first to mind, is one, but so is keeping a journal, reviewing videos of encounters with patients, or seeking insight from critical incident reports [38].

“Exemplary physicians,” one scholar notes, “seem to have a capacity for self-critical reflection that pervades all aspects of practice, including being present with the patient, solving problems, eliciting and transmitting information, making evidence-based decisions, performing technical skills, and defining their own values” [38].

RECOMMENDATION

The Council on Ethical and Judicial Affairs recommends that the following be adopted and the remainder of this report be filed:

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:

(a) Exercise 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;

(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.

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.

(New HOD/CEJA Policy)

Fiscal Note: Less than $500.
REFERENCES


Subject: Ethical Physician Conduct in the Media

Presented by: Dennis S. Agliano, MD, Chair

Referred to: Reference Committee on Amendments to Constitution and Bylaws
(Edmund R. Donoghue, Jr, MD, Chair)

Directive D-140.957 (1), “Ethical Physician Conduct in the Media,” adopted at the 2015 HOD Annual Meeting, calls for a report on the professional ethical obligations of physicians in the media. The following analysis by the Council on Ethical and Judicial Affairs (CEJA) addresses ethics concerns in this area and offers guidance for physicians who participate in the media.

PHYSICIANS IN THE PUBLIC SPHERE

Physicians’ knowledge is not confined to the clinical setting. Physicians have well-recognized responsibilities to use their knowledge and skills for the benefit of the community as a whole, whether it is by assisting a state health agency in identifying and tracing infectious disease during an epidemic, advocating for improved health care resources to lessen health disparities, or promoting behaviors that improve the health of communities [1]. Stepping into the media environment can serve as an extension of this public function.

However, the expectations held of physicians as members of the medical profession and of persons in the media are not always compatible. Participation in the media can have unintended consequences for the physician and the medical profession. Information in the public sphere can be sensationalized, misrepresented, or patently falsified, which can have potentially serious consequences if the benefits and drawbacks of medical advice are not appropriately conveyed [2]. Furthermore, physician recommendations may not always reflect the standard of care [3, 4].

A CONTINUUM OF ROLES

Physicians can engage the media in a number of roles. For example, they can serve as conveyors of information or advocates on behalf of public agencies or institutions; as expert consultants on medical science and practice; as commentators on health-related issues of interest to the public; or as journalists covering medicine-related stories. Imagine the following:

Dr. A is head of a health care agency in the federal government. A physician with two decades of public service experience, she is directly responsible for guiding the legislative goals of the agency and is supported by a staff of thousands of federal employees. Dr. A often gives statements to the press about matters under the agency’s jurisdiction, and has, from time to time, 

* Reports of the Council on Ethical and Judicial Affairs are assigned to the Reference Committee on Amendments to Constitution and Bylaws. They may be adopted, not adopted, or referred. A report may not be amended, except to clarify the meaning of the report and only with the concurrence of the Council.
time, participated in press conferences to speak on urgent matters of public health or to make
statements intended to garner greater legislative attention and support.

Dr. B works at an academic medical center. He is frequently approached by media outlets to
comment on recent breakthroughs in medicine or topical issues in medicine and public health
that are making their way through the news cycle. Dr. B also regularly contributes opinion
pieces about medicine and health care policy to news outlets.

Dr. C is a physician whose work has been lauded by practitioners, academics, and celebrities
alike. Recently, she has launched a daytime television program in which she discusses popular
subjects related to medicine, public health, and a general assortment of topics regarding
health and well-being. Dr. C maintains a practice where she sees patients, but the majority of
her time is now spent producing and appearing on her television show.

As a public official, Dr. A uses the media to further a political agenda regarding the health and
well-being of the American public, an agenda she has been tasked with upholding and protecting.
For her, the media is a vehicle to address the needs and concerns of the public, and to keep the
policy goals of her agency at the forefront of awareness among government and private actors
integral to the provision of medical care.

Dr. B is first and foremost an academic physician whose interactions with the media serve a more
consultative function. He generally offers his insight only when approached by the media, although
he may occasionally use his training and experience proactively to shed light on topics when he
feels the public may derive some educational benefit.

In contrast, Dr. C holds herself out to a national audience as a commentator on any number of
subjects falling under the general categories of medicine, health, and wellness—topics that are at
least in part developed by producers and pitched for their ability to boost ratings and increase
viewership. Her audience may or may not know the specifics of her training and experience,
although she uses her medical degree as a symbol of authority and credibility. Moreover, as a
media celebrity, the recommendations she makes on air may be especially persuasive [4].

Whatever role physicians adopt when they participate in the media is very different from that of a
clinical practitioner interacting with individual patients. Whether the medium is print, digital, or
social, physicians who take part in the media marketplace engage in what is fundamentally a
unidirectional relationship with the members of a vast audience who may regard themselves as
patients, but whom the physician will never encounter in person. When a video clip ends or a
reporter stops asking questions, the contact media physicians have with the audience ends. The
hundreds, if not millions, of individuals who have watched, listened, or read have no opportunity to
provide details about their unique medical histories, probe for more guidance about a treatment that
was discussed, or report back to the physician about what effect, if any, the physician’s advice has
had.

FIDELITY, TRUST, AND DIVIDED LOYALITIES

For physicians in the media, then, navigating successfully among the potentially overlapping roles
of clinician, expert consultant, journalist, or (for some) media personality poses challenges. Being
clear about what role(s) they are playing at any given time is crucial [3]. So is being aware of how
media content they create or the media presence they have blurs the lines of medicine, journalism,
and entertainment [3, 5].
For a physician who pursues a distinct career as a singer, a dancer, or a cook on the line in a restaurant kitchen, the new role is entirely different than that of a physician [6]. But when a media career involves depending on the inherent authority of their MD or DO degree rather than their training and skills, physicians in the media are taking advantage of the credibility and prestige bestowed by the public and the media on members of the medical profession [6, 7]. It may never occur to a cancer patient watching a physician on television that “someone highly credentialed might mix critical medical advice with a touch of ‘shock and awe’” even when such behavior might be condemned by other physicians and the medical profession as a whole [7].

Media entities themselves can have diverging interests and goals—winning a Pulitzer or an Emmy for excellence may compete with attracting advertising dollars, viewership, and ratings. Where the latter are the hallmarks of success, the qualifications of physicians who are media personalities, and the quality of the information they are disseminating, can be secondary for producers and audiences [6]. When there is temptation, or pressure, to attract an audience, it can be challenging for physicians to navigate the overlapping roles of health care professional and media personality, and to hold steady to the norms and values of medicine [7].

**Trustworthiness and Authoritativeness**

By using their medical expertise to reach out to an audience that is local, national, or even global in scale, physicians in the media carry with them heightened expectations as trusted resources, advisors, and representatives of the medical profession. Thus, like physicians in other roles that do not involve directly providing care for patients in clinical settings, physicians in the media should be expected to uphold the values and norms of medicine as a priority [8].

With respect to the recommendations or clinical perspectives a physician contributes to a media forum, such information must be acquired through practical clinical experience or supported by rigorous scientific research that has been carefully vetted within the peer-reviewed literature and presented accurately in the appropriate context [9, 10]. Physicians should likewise be transparent about the limitations of their knowledge or experience in a given area.

A message that is inaccurate, questionable, or false, may still be perceived as authoritative because it comes from a physician [2, 7]. Efforts to correct or recant misinformation from the public forum may prove futile. One contemporary example of this is the still pervasive but false public perception that childhood vaccines are linked to autism, despite the fact that this perception rests on a long-since discredited physician’s publication and there is overwhelming scientific consensus that no such relationship exists [11]. Material that is of poor quality and that does not meet expected standards of scientific rigor can mislead individuals who do not question the content of the message, while the promotion of such subpar work can erode the public’s trust in the larger medical community [7, 12].

**Maintaining Privacy in the Public Eye**

Physicians working in the media must be cognizant of their work’s impact on patient anonymity, the process of patient consent (concerns of inadvertent coercion), and the potential to exploit patients. They must also make decisions about whether they will present the outcome of a patient case as a fictional representation or as a story of true events [2, 13]. While journalism requires strict adherence to the facts and details of a story, physicians asked to recount a procedure or speak to media about a particular case have a responsibility to obscure or alter details that would reveal a patient’s identity unless the patient freely gave informed consent [13]. Physicians must also remain sensitive to how a story will affect patients under their care, and avoid situations where breaches of
privacy and confidentiality may occur [13, 14, 15]. In the media, physicians may at times need to emulate storytellers rather than journalists [13].

Physicians must exercise caution when they are asked to publicly diagnose celebrities, politicians, or private individuals currently caught in the media’s gaze. Physicians in the media must draw a careful line between using the media to educate the public versus providing a professional opinion when asked to comment on the physical or mental status of a public figure or someone else the physician has not had the opportunity to personally examine [3]. While a sound professional medical opinion reflects a thorough examination of a patient, the clinical history, and all relevant information under the protection of confidentiality, none of this occurs when physicians make casual observations about people [3]. There is a “critical distinction . . . between offering general information about a condition as it pertains to a public figure and rendering a professional opinion about an individual, involving a specific diagnosis, prognosis, or both” [3].

Moreover, physicians may be enticed into offering professional opinion that is outside their individual area of expertise. Physicians who offer expert testimony in court are expected to testify “only in areas in which they have appropriate training and recent, substantive experience and knowledge” [16]. The same expectations should apply to physicians who offer public commentary on health-related matters.

CONFLICTS AND DISCLOSURES

Competing interests are a fact of life for everyone, not only physicians in the media [17]. But as individuals in positions of public trust, media physicians should be especially sensitive to possible conflicts of interest. Even when there is no actual conflict, the appearance of influence or bias can compromise trust in the physician and the broader profession, with downstream consequences for patients and the public.

Taking steps to ensure transparency, independence, and accountability allows media consumers to make informed judgments about the comments or recommendations offered by physicians who are active in the media. Disclosing conflicts of interest is an essential first step [18, 19, 20]. Direct, substantial financial relationships that may influence a physician’s judgment, such as research funding, remuneration for advisory services or speaking engagements, or equity interests in featured products or services, should always be disclosed.

Nonfinancial relationships can also affect judgment and should be disclosed; for example, when a media physician has fiduciary responsibilities to a commercial entity that has an interest in the subject matter. Personal, political, ideological, or intellectual interests can also influence professional judgment in particular situations and media physicians should be prepared to disclose such interests [17, 21, 22].

Disclosure alone is not sufficient, however, and may have the perverse effect of inspiring false confidence on the part of media consumers and even discourage the media physician from rigorously ensuring that he or she is offering objective, unbiased information [23]. In some circumstances, the threat of actual or perceived conflicts of interest may be so great that the only way forward is for the physician to avoid the potential situation altogether.

Instituting measures to promote independent content is a further important step. For example, editorial review of proposed content and presentation can help identify possible bias or the appearance of bias or catch elements that media consumers might be expected to misinterpret. Prohibiting physicians who have clear, unresolved competing interests from being media
spokespersons on issues that involve those interests can likewise help ensure independence [24].
Making explicit to viewers the measures taken to address and mitigate the influence of conflicts of
interest will hold media physicians accountable to their peers and the public for exercising sound
professional judgment.

CONCLUSION

As trusted members of the community who regularly communicate with the public about health
and wellness, physicians have a responsibility to consider their ethical obligations to their patients,
the public, and the medical profession. In an increasingly technologically adept media marketplace
where the context and delivery of messages are shaped by any number of social and financial
forces, physicians must carefully delineate who they are and how they want to be perceived.
Equally important, physicians should give thought to how they want to frame and support their
messages, and how those messages should be consumed and utilized.

RECOMMENDATION

In light of the foregoing analysis, the Council on Ethical and Judicial Affairs recommends that the
following be adopted in lieu of D-140.957(1) and the remainder of this report be filed:

Physicians who participate in the media can offer effective and accessible medical perspectives
leading to a healthier and better informed society. However, ethical challenges present
themselves when the worlds of medicine, journalism, and entertainment intersect. In the
context of the media marketplace, understanding the role as a physician being distinct from a
journalist, commentator, or media personality is imperative.

Physicians involved in the media environment should be aware of their ethical obligations to
patients, the public, and the medical profession; and that their conduct can affect their medical
colleagues, other health care professionals, as well as institutions with which they are affiliated.
They should also recognize that members of the audience might not understand the
unidirectional nature of the relationship and might think of themselves as patients. Physicians
should:

(a) Always remember that they are physicians first and foremost, and must uphold the values,
norms, and integrity of the medical profession.

(b) Encourage audience members to seek out qualified physicians to address the unique
questions and concerns they have about their respective care when providing general
medical advice.

(c) Be aware of how their medical training, qualifications, experience, and advice are being
used by media forums and how this information is being communicated to the viewing
public.

(d) Understand that as physicians, they will be taken as authorities when they engage with the
media and therefore should ensure that the medical information they provide is:

(i) accurate

(ii) inclusive of known risks and benefits
(iii) commensurate with their medical expertise

(iv) based on valid scientific evidence and insight gained from professional experience

(e) Confine their medical advice to their area(s) of expertise, and should clearly distinguish the limits of their medical knowledge where appropriate.

(f) Refrain from making clinical diagnoses about individuals (e.g., public officials, celebrities, persons in the news) they have not had the opportunity to personally examine.

(g) Protect patient privacy and confidentiality by refraining from the discussion of identifiable information, unless given specific permission by the patient to do so.

(h) Fully disclose any conflicts of interest and avoid situations that may lead to potential conflicts.

(New HOD/CEJA Policy)

Fiscal Note: Less than $500
REFERENCES


At the 2016 Interim Meeting, the American Medical Association (AMA) House of Delegates referred Board of Trustees Report 7-I-16, “Supporting Autonomy for Patients with Differences of Sex Development (DSD),” responding to Resolution 3-A-16 of the same title introduced by the Medical Student Section, which had previously been referred. Resolution 3 asked:

That our AMA affirm that medically unnecessary surgeries in individuals born with differences of sex development are unethical and should be avoided until the patient can actively participate in decision-making.

Testimony regarding BOT 7-I-16 expressed concern about possible unintended consequences and lack of expert insight into the medical complexities in treating differences of sex development in pediatric patients. The Council on Ethical and Judicial Affairs was asked to prepare a report providing ethics guidance in this area.

BACKGROUND

The term “differences of sex development” (DSD), now preferred over “disorders of sex development,” is used to refer to congenital conditions “in which development of chromosomal, gonadal, or anatomic sex is atypical,” broadly encompassing five main groups [1]:

- 46,XX, classical congenital adrenal hyperplasia (CAH);
- 46,XY, a heterogenous set of conditions that includes abnormal androgen steroidogenesis and 5α reductase deficiency;
- varieties of sex chromosome mosaicism, such as mixed gonadal dysgenesis (45,X/46,XY DSD);
- ovo-testicular DSD in which patients present with both ovarian and testicular tissues and abnormally differentiated genital structures; and
- “nonhormonal/nonchromosomal” DSD, represented by abnormal genitalia.

The frequency of DSDs varies with etiology [2,3], but overall incidence of DSD is estimated to be one in 5,500 births [4]. Congenital adrenal hyperplasia accounts for approximately 60 percent of all DSDs [3]. Diagnosis of DSD is complex, encompassing family and prenatal history, physical examination (particularly of genital anatomy), and various laboratory tests, including determination of chromosomal sex. Diagnosis may also involve ultrasound or other imaging studies, hormonal stimulation tests (e.g., human chorionic gonadotropin or adrenocorticotropic stimulation), and, in
rare cases, laparotomy or laparoscopy [4]. Some 60 percent of affected children are now diagnosed prenatally [4].

DSD include potentially life-threatening developmental anomalies that may require immediate intervention, for example, hypotension resulting from salt-wasting nephropathy, which occurs in 75 percent of infants born with congenital adrenal hyperplasia. DSD also include “cosmetic” abnormalities for which elective interventions to normalize appearance can be undertaken at various stages in the child’s life [3,5].

Early diagnosis is essential to identify and intervene in life-threatening conditions. Historically, treatment for DSD also gave high priority to medically assigning gender in a newborn with ambiguous genitalia under what became known as an “optimal gender policy” intended to “facilitate stable gender identity and appropriate gender role behavior” [5]. This approach recommended early surgery to match genitalia to assigned gender, on the rationale that uncertain gender is distressing for the family, may adversely affect the child’s mental health, and can lead to stigmatization [4,5,6]. This view has been increasingly challenged [5,7]. DSD communities and a growing number of health care professionals have condemned such genital “normalizing,” arguing that except in the rare cases in which DSD presents as life-threatening anomalies, genital modification should be postponed until the patient can meaningfully participate in decision making [5,8,9,10].

In 2006, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) observed that “[m]uch of the clinical challenge intrinsic to pediatric urology rests in the need to discriminate between children at risk for severe long-term complications and requiring intervention and the larger group who are not. The report noted the lack of sufficient data to guide decisions about gender assignment and absence of clear guidelines for clinical practice, particularly in light of concerns about the irreversibility of surgical intervention and possible sensory damage to the genitalia [11]. The NIDDK cited the lack of “systematic outcome data about sexual function in individuals with disorders of sexual differentiation [sic]” and of data “pertaining to the association of sexual function with genital appearance and types of genital surgery.” It concluded that “it is unclear whether gender identity requires gender-consistent genital appearance” and urged prospective studies of gender identity, reproductive function, and quality of life for patients with DSD [11].

A decade later, outcomes data remain limited. A small study carried out in 2011–2012 among medical students in Zurich found that how physicians discussed treatment for a child with DSD influenced the choice for or against surgery [12]. Participants watched brief counseling videos that described DSD either as a condition that is static, has an inherent psychosocial component, and requires treatment, and for which predetermined treatment regimens focus on biological function, or as a dynamic disorder characterized by context-dependent impairment for which coping strategies should be fostered, with treatment geared to the individual’s interests and capabilities. Sixty-six percent of participants who viewed the medicalized video said they would choose early surgery for their child, compared to 23 percent of those who viewed the demedicalized video. In a systematic review of follow-up of psychological outcomes of intervention for patients with DSD published in 2015, Brazilian researchers found a lack of prospective long-term evaluations of psychological outcomes of sex assignment surgery [13]. They noted concerns about the quality of published studies, citing variable sample size, inconsistent methodologies, and poorly defined outcome measures.
NEW PARADIGMS FOR TREATMENT

In addition to the NIDDK report questioning the “optimal gender” policy, in 2006 both the Intersex Society of North America (ISNA) and the International Consensus Conference on Intersex released guidelines on the management of DSD that urged a more conservative approach [1,14]. ISNA guidelines note that gender assignment “is a social and legal process not requiring medical or surgical intervention” (original emphasis) [ISNA 2006]. The guidelines recommend delaying elective surgical and hormonal treatments until the patient can participate in decision making and caution that health care professionals must distinguish between offering medically needed treatment to benefit the child and offering treatment to allay parental anxiety. Like the ISNA, the consensus statement of the International Consensus Conference on Intersex recommended deferring elective interventions and similarly urged that care be provided by a multidisciplinary team. In 2016 the Global DSD Update Consortium reviewed developments over the preceding decade, noting particularly the important role that peer support can play in helping parents, and children, make informed decisions about elective treatment [15].

In its 2017 report on the rights of children in biomedicine, the Bioethics Committee of the Council of Europe observed that, based its review of on available scientific evidence, only three interventions meet criteria of being “medically necessary”: “(1) administration of endocrine treatment to prevent fatal salt-loss in some infants, (2) early removal of streak gonads in children with gonadal dysgenesis, and (3) surgery in rare cases to allow extrophic conditions in which organs protrude from the abdominal wall or impair excretion” [16]. However, these recommendations remain controversial and there is not yet consensus in the medical community. Recent interviews carried out by Human Rights Watch among individuals with DSD examine patient experience and underscore the value of organizing dedicated multidisciplinary care teams [17].

In educational material for parents, the American Academy of Pediatrics likewise stresses multidisciplinary care and notes that, if not medically necessary, “any irreversible procedure can be postponed until the child is old enough to agree to the procedure (e.g., genital surgery)” [18].

CURRENT AMA POLICY

Current AMA policy does not address treatment for patients with DSD directly. Rather, a limited number of ethics and House policies speak to decisions for minors more broadly, as well as to issues pertaining to gender identity, sexual orientation, transgender health, and discrimination toward sexual minority communities:

- **Opinion 2.2.1,** “Pediatric Decision Making,” encourages involving minor patients in decision making at a developmentally appropriate level, including decisions that involve life-sustaining interventions, and recommends that physicians work with parents or guardians to simplify complex treatment regimens for children with chronic health conditions.

- **Opinion 2.2.4,** “Treatment Decisions for Seriously Ill Newborns,” articulates the considerations that must be taken into account when addressing emotionally and ethically challenging cases involving newborns, including: the medical needs of the child; the interests, needs, and resources of the family; available treatment options; and respect for the child’s right to an “open future.” It calls on physicians to inform parents about available therapeutic options and the nature of those options and to discuss the child’s expected prognosis with and without intervention.
Opinion 2.2.5, “Genetic Testing of Children,” identifies conditions under which physicians may ethically offer genetic testing for minor patients. It observes that testing implicates important concerns about the autonomy and best interests of the minor patient and holds that medical decisions made on behalf of a child should not abrogate the opportunity to choose to know his or her genetic status as an adult.

DECISIONS FOR PEDIATRIC PATIENTS

Parents (or guardians) are granted the authority to make health care decisions for their minor children when the child lacks the ability to act independently or does not have the capacity to make medical decisions [19]. Parents are deemed to be in a better position than others to understand their child’s unique needs and interests, as well as their family’s, and thus to be able to make appropriate decisions regarding their child’s health care. Historically, the best interest standard has predominated as the appropriate decision-making standard for medical decisions for minors. Current consensus rests on a more nuanced view that encompasses not only the patient’s medical interests, but psychosocial and familial concerns as well [19].

The “harm principle” has been suggested as a further refinement on the decision-making standard, requiring not only that decision makers consider the patient’s best interests, broadly understood, but also that a threshold of harm be identified, below which decisions should not be tolerated [19]. Parents (or guardians) are also recognized to have a responsibility to foster their children’s autonomy and moral growth, a responsibility clinicians share. Providing information in a developmentally appropriate way that respects the minor patient’s cognitive ability, engaging the child in decision making to the extent possible, and seeking the child’s assent to proposed interventions helps to fulfill that responsibility [19].

With respect to DSD specifically, suggested broad principles to guide decisions about elective interventions have been suggested. Proposals emphasize the need to balance leaving future options open [9] and upholding the child’s right to participate in decision making [5] with respect for parents’ wishes and family relationships. Likewise, they concur that decisions for patients with DSD should focus on promoting the well-being of the child and future adult [5], including minimizing physical and psychosocial risks to the child, preserving potential for fertility, and preserving capacity for satisfying sexual relations [9].

In cases of DSD, decisions about a child’s best interests and appropriate interventions involve sensitive issues of sex, gender, and sexuality, and interventions that may be irreversible. Parents are often concerned about the future well-being of their child with regard to self-identity, relationships, and reproductive capacity [8]. Because of these concerns, they may be quick to want to establish sex and gender identity for their child in order to promote “normalcy” and reduce stigmatization. Moreover, when physicians perceive early intervention to be urgently needed or wholly beneficial, they may not fully recognize that there is a decision to be made, or the complexity of that decision for the family and patient.

A 2013 lawsuit, though unsuccessful, raised constitutional issues with respect to early surgical intervention and sex assignment. In 2013, the adoptive parents of a South Carolina child, MC, born with “ovotesticular DSD” filed suit in the US District Court for the District of South Carolina against physicians who had performed feminizing genitoplasty on the child at age 16 months. At the time of surgery, MC was under the legal custody of the South Carolina Department of Social Services, which authorized the intervention. Despite initially being raised as a girl by his adoptive parents, consistent with his surgically assigned sex, MC identified as a boy and at the time the lawsuit was filed was living as a boy. Because of the surgery, MC is now sterile. Although the
action was dismissed on appeal by the US Court of Appeals for the Fourth Circuit (in January 2015) [20], the lower court had denied the defendants’ request for dismissal on the grounds that the defendants may have violated MC’s constitutional right to procreate [21]. In July 2017, the Medical University of South Carolina denied all claims and liability, but agreed to a settlement with the family [22].

RECOMMENDATION

The Council on Ethical and Judicial Affairs recommends that Opinion E-2.2.1, “Pediatric Decision Making,” be amended as follows in lieu of Resolution 3-A-16 and the remainder of this report be filed:

Unlike health care decisions for most adult patients, decisions for pediatric patients usually involve a three-way relationship among the minor patient, the patient’s parents (or guardian), and the physician. Although children who are emancipated may consent to care on their own behalf, in general, children below the age of majority are not considered to have the capacity to make health care decisions on their own. Rather, parents or guardians are expected, and authorized, to provide or decline permission for treatment for minor patients. Nonetheless, respect and shared decision making remain important in the context of decisions for minors, and physicians have a responsibility to support the child’s emerging autonomy and should engage minor patients in making decisions about their own care to the greatest extent possible, including decisions about life-sustaining treatment.

Decisions made for pediatric patients should seek to foster the well-being of children and the adults they will become. Physicians should provide information and other resources to support parents or guardians in making decisions about their child’s care and should individualize treatment to promote the child’s best interest, which is determined by weighing many factors, including effectiveness of available appropriate medical therapies and the needs and interests of the patient and the family as the source of support and care for the patient.

Parents or guardians must also assess whether the decision made for a minor patient will abrogate a choice the future individual would want to make for him- or herself. Except when immediate treatment is medically necessary to preserve life or avert serious and irreversible harm, physicians should support parents’ efforts to make decisions that do not undermine the child’s right to an “open future.” When there is legitimate inability to reach no consensus in the field about what is in the best interest of the child, the wishes of the parents/guardian should generally receive preference.

For health care decisions involving minor patients, physicians should:

(a) Involve all patients in decision making at a developmentally appropriate level.

(b) Base recommendations for treatment on the likely benefit to the patient, taking into account the effectiveness of treatment, risks of additional suffering with and without treatment, available alternatives, and overall prognosis as indicated by the best available scientific evidence. Where there are questions about the efficacy or long-term impact of treatment alternatives, physicians should encourage ongoing collection of data to help clarify the value to patients of different approaches to care.
(c) For patients capable of assent, truthfully explain the medical condition, its clinical implications, and the treatment plan in a manner that takes into account the child’s cognitive and emotional maturity and social circumstances for patients capable of assent.

(d) Provide a supportive environment to promote the well-being of both the patient and the family and encourage parents to discuss their child’s health status with the patient. Offer to facilitate the parent-child conversation for reluctant parents.

(e) Recognize that for certain medical conditions, such as those involving HIV/AIDS, or inherited conditions, or developmental anomalies, may involve highly sensitive information. Disclosing the child’s health status may also reveal health information about biological relatives, or disrupt relationships within the family, or lead to stigma or discrimination. Physicians should offer education and support to help minimize the psychosocial impact of such conditions for the child and the family.

(f) Work with parents/guardians to simplify complex treatment regimens whenever possible and educate parents in ways to avoid behaviors that put the child or others at risk.

(g) When decisions involve life-sustaining interventions, ensure that patients have opportunity to be involved in keeping with their ability to understand decisions and their desire to participate. Physicians should ensure that the patient and parents/guardian understand the patient’s diagnosis, both with and without treatment. Physicians should discuss with the patient and parents/guardian the option of initiating an intervention with the intention of evaluating its clinical effectiveness after a specified amount of time to determine if it has led to improvement. Confirm that if the intervention has not achieved agreed-on goals it may be withdrawn.

(h) Respect the decisions of the patient and parents/guardian when it is not clear whether a specific intervention promotes the patient’s best interests.

(i) Seek consultation with an ethics committee or other institutional resource when:

   (i) there is a reversible life-threatening condition and the patient (if capable) or parents/guardian refuse treatment the physician believes is clearly in the patient’s best interest; or

   (ii) there is disagreement about what the patient’s best interests are. Physicians should turn to the courts to resolve disagreements only as a last resort.

(j) Provide compassionate and humane care to all pediatric patients, including patients who forgo or discontinue life-sustaining interventions.

(Modify Current HOD/CEJA Policy)

Fiscal Note: Less than $500
REFERENCES


Subject: Mergers of Secular and Religiously Affiliated Health Care Institutions

Presented by: Dennis S. Agliano, MD, Chair

Referred to: Reference Committee on Amendments to Constitution and Bylaws
(Edmund R. Donoghue, Jr, MD, Chair)

Policy D-140.956 “Religiously Affiliated Medical Facilities and the Impact on a Physician's Ability to Provide Patient Centered, Safe Care Services,” asks that the American Medical Association (AMA):

conduct a study of access to care in secular hospitals and religiously-affiliated hospitals to include any impact on access to services of consolidation in secular hospital systems and religiously-affiliated hospital systems.

The resolution on which this directive is based discussed the conflicts present in decision-making for health care professionals employed by religiously affiliated institutions. Given that the presence of religiously affiliated hospitals continues to grow, the resolution encouraged our AMA to conduct a study of access to care in secular hospitals and religiously affiliated hospitals to include any impact on access to services in the consolidation of systems.

RELIGIOUSLY AFFILIATED HEALTH CARE INSTITUTIONS

The concept of the hospital as a facility providing inpatient care for the sick originated with the Catholic Church, with the original and enduring dual mission of healing the body and promoting spiritual well-being [1]. The mission of today’s Catholic Health Association remains focused on the needs of those who are “poor, underserved, and most vulnerable” [2]. Although hospitals established by Protestant denominations and Jewish-identified facilities remain important segments of U.S. health care, Catholic facilities predominate among religiously affiliated institutions—U.S. Catholic Health Care is the largest nonprofit care provider in the country [2].

Since the 1990s, mergers between secular and religiously affiliated hospitals and health care institutions have been reshaping the landscape of health care in the United States, for both patients and physicians. Driven by economic considerations and changes in health policy, notably in recent years, emphasis on accountable care organizations and bundled payments [1,3], mergers have enabled facilities in some cases simply to survive and in others to thrive within their communities. Consolidation has enabled hospitals to control a greater share of their local markets and to negotiate effectively with insurers [4].

Religiously affiliated hospitals and facilities benefit from the tax-exempt status of the religious institutions they represent and from other tax subsidies that derive from their mission to serve the poor and provide charitable care [5]. Although the majority of religiously affiliated hospitals remain nonprofit, the number of for-profit hospitals affiliated with religious institutions increased by 22 percent between 2001 and 2016 [6]. Religiously affiliated health care facilities—which

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encompass clinics, hospitals, and long-term care facilities—are also important employers. According to the Catholic Health Association, as of 2017 member facilities employed more than 500,000 full-time and 200,000 part time staff [2].

In some communities, religiously affiliated health care institutions may be the only providers [6]—as of 2015, 132 of the nation’s approximately 1,300 critical access hospitals were members of U.S. Catholic Health Care [2]. In some areas, more than 40 percent of short-term, acute care beds are in Catholic facilities [6]. Nationwide, one in every six patients now receives care in a Catholic hospital [2].

THE DILEMMA OF MERGERS

The consolidation of a religiously affiliated institution with a secular health care facility raises challenges for all stakeholders—the facilities, their communities, their patients, and the physicians and other professionals who provide care. All religiously affiliated institutions seek to remain faithful to their defining mission and values, which can place them in tension with their secular counterparts. Catholic facilities, however, are embroiled in an increasingly public debate about the implications and effects of entering into arrangements with secular institutions as they seek to retain their identity and mission and still survive in the health care marketplace. Thus they offer a window through which to understand the ethical dimension of health care mergers.

As the Ethical and Religious Directives that govern care in Catholic health care facilities observe:

New partnerships can be opportunities to realign the local delivery system in order to provide a continuum of health care to the community; they can witness to a responsible stewardship of limited health care resources; and they can be opportunities to provide to poor and vulnerable persons a more equitable access to basic care.

On the other hand, new partnerships can pose serious challenges to the viability of the identity of Catholic health care institutions and services, and their ability to implement these Directives in a consistent way, especially when partnerships are formed with those who do not share Catholic moral principles (§VI)[7].

From this perspective, in the contemporary health care marketplace Catholic hospitals “are caught in an impossible bind” [1]. Like other hospitals, financial pressures drive them to consolidate with other institutions to become more economically efficient. Yet “competing in the aggressive world of the medical business industry” can put Catholic hospitals’ historical commitment to the poor at risk [1]. At the same time, gaining financial security may risk “imperceptibly compromising their traditional Catholic witness” when compromises are made with respect to Directives [1].

From the perspective of those they serve, a merger or consolidation may help guarantee the continued presence of health care in a community, but may also limit the range of services available to patients when the consolidated entity adheres to the Directives. Certain treatment choices for care at the end of life, reproductive health care services, and, by some reports, certain services for transgender individuals may all be affected [4, 8, 9]. Limitations on women’s health services have been a focus of concern for obstetricians and gynecologists associated with or employed by religiously affiliated hospitals [10], with reports of conflict over both elective and clinically indicated surgical sterilization [11, 12], and management of miscarriage [13]. Restricted access to services can have a disproportionate impact on poor women, and women in rural areas where religiously affiliated institutions are the only providers of care [14].
From the perspective of physicians and other health care professionals affiliated with or employed by the entity that results, a merger can challenge professional commitments. A merger that results in loss of access to services for the community and requires physicians to follow the religious guidelines embodied in the Directives may result in “conflict with prevailing medical standards of care and ethical principles of health care professional” [15]. Physicians and other health care professionals who are not members of the faith tradition may find themselves contractually prohibited from providing care that is otherwise legal and, in their professional judgment, clinically appropriate and ethically permissible under the norms of medical professionalism.

THE RESPONSIBILITIES OF LEADERSHIP

As challenging as mergers between secular and religiously affiliated health care facilities may be for individual patients and physicians, addressing dilemmas of mission is pre-eminently a responsibility of hospital leadership.

For Catholic facilities merging with secular facilities (or facilities associated with other religious traditions), a touchstone is the principle of cooperation [16, 17]. The principle, it is argued, is a necessity for business relationships in a pluralistic world, providing a way to address the reality that, for the faithful, “it is almost impossible to bring about good without brushing up against or even becoming somewhat involved in the wrongdoing of others” [16]. The principle of cooperation is understood “as a limiting principle, to avoid cooperating in evil” (original emphasis) [17].

The essential goal is to ensure that institutional arrangements allow the facility and its staff to “remain as removed as possible” from violations of the directives and “not [to] contribute anything essential to make possible the wrongdoing’s occurring” [16]—e.g., essential employed staff or equipment for the performance of what under the Directives is an immoral procedure [17]. Whether services that would be otherwise prohibited by the Directives will or may be available through the merged entity is importantly a function of how caregiving is organized in the resulting composite system. The approval of the diocesan bishop is required for mergers involving facilities subject to his governing authority, and the diocesan bishop has final authority for assessing whether a proposed merger constitutes morally licit cooperation (§VI) [7].

Analogous discussions of the ethics of trusteeship, such as that offered by The Hastings Center, offer secular insight for thinking about the responsibilities of leaders in health care institutions. Trustees of not-for-profit health care organizations “regularly make decisions that affect the lives and well-being of a large number of people who are relatively powerless, relatively vulnerable, and in need of services or assistance” [18]. In light of the mission of such organizations, service on a board of trustees entails fiduciary duties to the organization and responsibility to ensure that the organization realizes the public benefits for which it enjoys tax exempt status.

Trustees are held to principles of fidelity to mission; service to patients, ensuring that the care is high quality and provided “in an effective and ethically appropriate manner”; service to the community the hospital serves, deploying hospital resources “in ways that enhance the health and quality of life” of the community; and institutional stewardship. They have a further responsibility to ensure that when there is conflict over fundamental values and principles, “all points of view are heard and taken seriously, that reasonable compromise is explored, and that consensus has time to form” [18].

The Principles of Integrated Leadership for Hospitals and Health Care Systems, developed in collaboration by the American Hospital Association (AHA) and the AMA, address responsibilities of hospital leadership in the context of rapidly evolving models of integrated physician-hospital...
health care systems [19]. In addition to governance and management structure and leadership
development, guidance identifies “cultural adaptation” as a key element for success, observing that:

Culture is the way an organization, institution or integrated health system does business, in a
way that is predictable, known to all and consonant with the mission and values of the
organization, institution or integrated health system. The creation of a common shared culture
that includes an integrated set of values is important to serve as a guide to the entity and will
serve as a touch point to help resolve the inevitable conflicts that will arise [19].

The AHA-AMA principles urge integrated health systems to cultivate the characteristics of
adaptive institutional culture, including a focus on the health of the entire population served;
agreement to a common mission, vision, and values; mutual understanding and respect; and a sense
of common ownership of the entity and its reputation [19].

INSIGHT FROM THE CODE OF MEDICAL ETHICS

As frontline clinicians, physicians (and other health care professionals) regularly confront the
effects on patients’ lives and well-being of the institutional arrangements through which care is
delivered. They have a responsibility to advocate for the resources patients need, as well as to be
responsible stewards of the resources with which they are entrusted [20]. They must be able to
make treatment recommendations in keeping with their best judgment as medical professionals
[21]. And they are expected to uphold the ethical norms of medicine, including fidelity to patients
and respect for patients as moral agents and decision makers [22].

Existing guidance on exercise of conscience by individual physicians suggests essential
responsibilities of leadership in health care as well [22]. These include responsibility to engage in
thoughtful consideration of the implications of institutional arrangements—whether arrangements
sustain or risk undermining the personal and professional integrity of staff, cause moral distress, or
compromise the ability to provide care. Leaders in health care institutions must be mindful that
arrangements do not discriminate against or unduly burden individual patients or populations of
patients, and of the burden arrangements may place on fellow professionals. And they must accept
responsibility to take steps to ensure that services will be available to meet the needs of the patients
and community the institution serves.

RECOMMENDATIONS

In light of this analysis, the Council on Ethical and Judicial Affairs recommends:

1. That Policy D-140.956, “Religiously Affiliated Medical Facilities and the Impact on a
   Physician's Ability to Provide Patient Centered, Safe Care Services,” be rescinded. (Rescind
   HOD Policy)

2. That the following be adopted, and the remainder of this report be filed:

   The merger of secular health care institutions and those affiliated with a faith tradition can
   benefit patients and communities by sustaining the ability to provide a continuum of care
   locally in the face of financial and other pressures. Yet consolidation among health care
   institutions with diverging value commitments and missions may also result in limiting what
   services are available. Consolidation can be a source of tension for the physicians and other
   health care professionals who are employed by or affiliated with the consolidated health care
   entity.
Protecting 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, but challenging responsibility.

Physician-leaders within institutions that have or are contemplating a merger should:

(a) Seek input from stakeholders to inform decisions to help ensure that after a consolidation the range of services previously offered will continue to be available to the community.

(b) Be transparent about the values and mission that will guide the consolidated entity and proactively communicate to stakeholders, including prospective patients, physicians, staff, and civic leaders, how this will affect patient care and access to services.

(c) Negotiate contractual issues of governance, management, financing, and personnel that will respect the diversity of values within the community and at minimum that the same range of services remains available in the community.

(d) Recognize that physicians’ primary obligation is to their patients. Physician-leaders in consolidated health systems should provide avenues for meaningful appeal and advocacy to enable associated physicians to respond to the unique needs of individual patients.

(e) Establish mechanisms to monitor the effect of new institutional arrangements on patient care and well-being and the opportunity of participating clinicians to uphold professional norms, both to identify and address adverse consequences and to identify and disseminate positive outcomes.

Individual physicians associated with institutions that have consolidated or propose to consolidate should:

(f) Work to hold leaders accountable to meeting conditions for professionalism within the institution.

(g) Advocate for solutions when there is ongoing disagreement about services or arrangements for care.

(New HOD/CEJA Policy)

Fiscal note: Less than $500
REFERENCES

Whereas, The pan-ethnic, umbrella term "Asian-American" masks the significant disparities in health outcomes and socioeconomic realities as well as undermines efforts for increased inclusion and representation of students from under-represented Asian countries and cultures, especially in individuals from Laotian, Cambodian, Indonesian, and other backgrounds;1,2,3 and

Whereas, While Chinese American and Asian Indian Americans experience relatively low aggregate poverty rates, at 12.2% and 8.5% respectively, the ethnic groups with the most people in poverty in 2010 were Chinese Americans, with 449,356 people living in poverty, and Asian Indian Americans, with 246,399 people living in poverty, primarily due to the large size of their populations;4 and

Whereas, The 2006 to 2010 aggregate poverty rate by population group was reported as 65% of Bhutanese Americans, 27% for Hmong Americans, and 21% for Bangladeshi Americans;4,5,6 and

Whereas, AB-1726 became law in California, requiring that the Department of Public Health collect disaggregate demographic data to better expose disparities in health care for Pacific Islanders and Southeast Asians, serving as an example for other states to model;7,8 and

Whereas, Pursuant to AMA Policy H-350.966, the AMA urges existing federal agencies, commissions and Asian American and Pacific Islander health organizations to study how to improve the collection, analysis and dissemination of public health data on Asian Americans and Pacific Islanders; therefore be it

RESOLVED, That our American Medical Association support the disaggregation of data regarding Asian-Americans in order to reveal the within-group disparities that exist in health outcomes and representation in medicine. (New HOD Policy)

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Fiscal Note: Minimal - less than $1,000.

Received: 09/20/17

RELEVANT AMA POLICY

Health Initiatives on Asian-Americans and Pacific Islanders H-350.966
Our AMA urges existing federal agencies, commissions and Asian American and Pacific Islander health organizations to study how to improve the collection, analysis and dissemination of public health data on Asian Americans and Pacific Islanders.
Res. 404, A-00 Reaffirmed: CSAPH Rep. 1, A-10

See also:
Medical Education for Members in Underserved Minority Populations H-350.969
Underrepresented Student Access to US Medical Schools H-350.960
Reducing Racial and Ethnic Disparities in Health Care D-350.995
Diversity in Medical Education H-350.970
Improving the Health of Black and Minority Populations H-350.972
Racial and Ethnic Disparities in Health Care H-350.974
Minorities in the Health Professions H-350.978
Guiding Principles for Eliminating Racial and Ethnic Health Care Disparities D-350.991
Addressing Immigrant Health Disparities H-350.957
Improving the Health of Minority Populations H-350.961
Cancer and Health Care Disparities Among Minority Women D-55.997
Strategies for Eliminating Minority Health Care Disparities D-350.996
Whereas, Most states in the United States have enacted mandatory reporting laws regarding domestic violence, which require the reporting of specified injuries and wounds and suspected abuse or domestic violence for individuals being treated by a health care professional; and

Whereas, Reports have shown that stated goals of mandated reporting policy of enhancing patient safety, improving health care providers’ response to domestic violence, holding perpetrators accountable, and improving domestic violence data collection and documentation mitigate access to and quality of healthcare delivery; and

Whereas, The laws vary from state-to-state, but generally fall into four categories: states that require reporting of injuries caused by weapons; states that mandate reporting for injuries caused in violation of criminal laws, as a result of violence, or through non-accidental means; and

Whereas, Three states have exceptions for reporting injuries due to domestic violence (New Hampshire, Oklahoma, and Pennsylvania); and

Whereas, Our AMA opposes the adoption of mandatory reporting laws for physicians treating competent, non-elderly adult victims of intimate partner violence if the required reports identify victims; and

Whereas, Current AMA policy states if and where mandatory reporting statutes dealing with competent adults are adopted, the AMA believes the laws must incorporate provisions that: (a) do not require the inclusion of victims’ identities; (b) allow competent adult victims to opt out of the reporting system if identifiers are required; (c) provide that reports be made to public health agencies for surveillance purposes only; (d) contain a sunset mechanism; and (e) evaluate the efficacy of those laws; and

Whereas, It has been reported that immigrant women and girls are highly vulnerable to abuse and are statistically twice as likely as non-immigrant females to experience domestic violence; and

Whereas, There are reports that undocumented domestic violence victims are fearful of seeking healthcare due to concerns of immigration authority involvement; and

Whereas, Current AMA policy does not specify the use of mandated reporting policies with regard to immigration; and
Whereas, The AMA’s “Diagnostic and Treatment Guidelines on Domestic Violence”, which provided guidance for Interviewing, Diagnosis, Interventions, Documentation, and Risk management regarding domestic violence related care was last updated in 1992 and does not reflect current best practices; therefore be it

RESOLVED, That our American Medical Association encourage appropriate stakeholders to study the impact of mandated reporting of domestic violence policies on individuals with undocumented immigrant status and identify potential barriers for survivors seeking care (Directive to Take Action); and be it further

RESOLVED, That our AMA work with community based organizations and related stakeholders to clarify circumstances that would trigger mandated reporting of intimate partner violence and provide education on the implications of mandatory reporting on individuals with undocumented immigrant status. (Directive to Take Action)

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

Received: 09/28/17

RELEVANT AMA POLICY

Gender-Based Violence H-65.974
Our AMA: (1) opposes inhumane treatment of people of both genders; and (2) encourages the development of programs to educate and alert all cultures to remaining practices of inhumane treatment based on gender and promote recognition of abusive practices and adequate health care for victims thereof.
Citation: Res. 404, A-06; Modified: CSAPH Rep. 01, A-16

Patient and Physician Rights Regarding Immigration Status H-315.966
Our AMA supports protections that prohibit U.S. Immigration and Customs Enforcement, U.S. Customs and Border Protection, or other law enforcement agencies from utilizing information from medical records to pursue immigration enforcement actions against patients who are undocumented.
Citation: Res. 018, A-17

See also: Family and Intimate Partner Violence H-515.965; Preventing, Identifying and Treating Violence and Abuse E-8.10

References:
Whereas, The terms “prostitute” and “prostitution” are now considered pejorative labels for individuals who exchange sex for money or goods; and

Whereas, The medical, public health, and research communities currently utilize the terms “sex work” and “sex workers” to refer to the practice and individuals who exchange sex for money or goods;¹ and

Whereas, It remains important for our AMA to utilize the most current terminology accepted in the medical and public health communities; and

Whereas, Our AMA has policy discussing sex workers, but this policy utilizes terminology that is considered outdated and carries a negative connotation towards these individuals; and

Whereas, Sex work carries a significant stigma that requires continued attention from the medical and public health communities, and which acts as a strong deterrent against sex workers seeking appropriate and compassionate medical care; and

Whereas, Sex workers face numerous public health detriments, including, but not limited to, violence at the hands of clients and police personnel², psychiatric/mental health issues, sexually transmitted infections, drug abuse and addiction, personal hygiene, and poor access to health care;³ and

Whereas, Epidemiological and prevalence studies from varied urban and geographical centers report the number of sex workers with concurrent HIV infection to range from 9-33%, depending on the location and population studied;⁴,⁵,⁶,⁷ and

Whereas, It is predicted that aversion of up to 46% of new HIV infections worldwide could be attained by the decriminalization of sex work and the amelioration of stigma associated with this work;⁸ therefore be it

RESOLVED, That our American Medical Association amend the text of HOD Policy H-20.898, “Global HIV/AIDS Prevention,” by addition and deletion to read as follows:

H-20.898 Global HIV/AIDS Prevention
Our AMA supports continued funding efforts to address the global AIDS epidemic and disease prevention worldwide, without mandates determining what proportion of funding must be designated to treatment of HIV/AIDS, abstinence or be-faithful funding directives or grantee pledges of opposition to prostitution sex work (Modify Current HOD Policy); and be it further.

RESOLVED, That our AMA amend the text of HOD Policy H-20.922, “HIV/AIDS as a Global Public Health Priority,” by addition and deletion to read as follows:

H-20.922 HIV/AIDS as a Global Public Health Priority
In view of the urgent need to curtail the transmission of HIV infection in every segment of the population, our AMA:
(1) Strongly urges, as a public health priority, that federal agencies (in cooperation with medical and public health associations and state governments) develop and implement effective programs and strategies for the prevention and control of the HIV/AIDS epidemic;
(2) Supports adequate public and private funding for all aspects of the HIV/AIDS epidemic, including research, education, and patient care for the full spectrum of the disease. Public and private sector prevention and care efforts should be proportionate to the best available statistics on HIV incidence and prevalence rates;
(3) Will join national and international campaigns for the prevention of HIV disease and care of persons with this disease;
(4) Encourages cooperative efforts between state and local health agencies, with involvement of state and local medical societies, in the planning and delivery of state and community efforts directed at HIV testing, counseling, prevention, and care;
(5) Encourages community-centered HIV/AIDS prevention planning and programs as essential complements to less targeted media communication efforts;
(6) In coordination with appropriate medical specialty societies, supports addressing the special issues of heterosexual HIV infection, the role of intravenous drugs and HIV infection in women, and initiatives to prevent the spread of HIV infection through prostitutes commercial sex;
(7) Supports working with concerned groups to establish appropriate and uniform policies for neonates, school children, and pregnant adolescents with HIV/AIDS and AIDS-related conditions; and
(8) Supports increased availability of anti-retroviral drugs and drugs to prevent active tuberculosis infection to countries where HIV/AIDS is pandemic.
(9) Supports programs raising physician awareness of the benefits of early treatment of HIV and of "treatment as prevention," and the need for linkage of newly HIV-positive persons to clinical care and partner services (Modify Current HOD Policy); and be it further.
RESOLVED, That our AMA amend the title and text of HOD Policy H-515.958, “Promoting Safe Exit from Prostitution,” by addition and deletion to read as follows:

H-515.958 Promoting Safe Exit from Prostitution Sex Work
Our American Medical Association supports efforts to offer individuals opportunities to safely exit from prostitution safely if they choose to do so, as well as access to in pursuit of compassionate care and “best practices”-based services whether or not they choose to continue in sex work. Our American Medical Association also supports legislation for programs that prevent and divert prostitution rather than penalize them through criminal conviction and incarceration.

(Modify Current HOD Policy)

Fiscal Note: Minimal - less than $1,000.

Received: 09/29/17

RELEVANT AMA POLICY

Global HIV/AIDS Prevention H-20.898
Our AMA supports continued funding efforts to address the global AIDS epidemic and disease prevention worldwide, without mandates determining what proportion of funding must be designated to treatment of HIV/AIDS, abstinence or be-faithful funding directives or grantee pledges of opposition to prostitution.

HIV/AIDS as a Global Public Health Priority H-20.922
In view of the urgent need to curtail the transmission of HIV infection in every segment of the population, our AMA:

(1) Strongly urges, as a public health priority, that federal agencies (in cooperation with medical and public health associations and state governments) develop and implement effective programs and strategies for the prevention and control of the HIV/AIDS epidemic;

(2) Supports adequate public and private funding for all aspects of the HIV/AIDS epidemic, including research, education, and patient care for the full spectrum of the disease. Public and private sector prevention and care efforts should be proportionate to the best available statistics on HIV incidence and prevalence rates;

(3) Will join national and international campaigns for the prevention of HIV disease and care of persons with this disease;

(4) Encourages cooperative efforts between state and local health agencies, with involvement of state and local medical societies, in the planning and delivery of state and community efforts directed at HIV testing, counseling, prevention, and care;

(5) Encourages community-centered HIV/AIDS prevention planning and programs as essential complements to less targeted media communication efforts;

(6) In coordination with appropriate medical specialty societies, supports addressing the special issues of heterosexual HIV infection, the role of intravenous drugs and HIV infection in women, and initiatives to prevent the spread of HIV infection through prostitutes;

(7) Supports working with concerned groups to establish appropriate and uniform policies for neonates, school children, and pregnant adolescents with HIV/AIDS and AIDS-related conditions; and

(8) Supports increased availability of anti-retroviral drugs and drugs to prevent active tuberculosis infection to countries where HIV/AIDS is pandemic.

(9) Supports programs raising physician awareness of the benefits of early treatment of HIV and of “treatment as prevention,” and the need for linkage of newly HIV-positive persons to clinical care and partner services.

Promoting Safe Exit from Prostitution H-515.958
Our American Medical Association supports efforts to offer individuals a safe exit from prostitution in pursuit of compassionate care and best practices and supports legislation for programs that prevent and divert prostitution rather than penalize it through criminal conviction and incarceration.

Citation: Res. 14, A-15
Whereas, There appears to be a movement to pass laws requiring the handling of tissue obtained from the termination of a pregnancy differently than other tissues obtained during a medical procedure; and

Whereas, These laws propose to require the interment of fetal tissue obtained from the termination of a pregnancy; and

Whereas, The implementation of these laws has practical implications for patients, health care facilities, and physicians; and

Whereas, There appears to be no scientific basis for differing requirements; therefore be it

RESOLVED, That our American Medical Association adopt policy stating that fetal tissue obtained during the termination of a pregnancy should be handled no differently than other tissues obtained during a medical procedure (New HOD Policy); and be it further

RESOLVED, That our AMA strongly oppose any proposed laws or regulations that would require the handling of fetal tissue obtained during the termination of a pregnancy differently than other tissues obtained during a medical procedure. (Directive to Take Action)

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

Received: 09/29/17

RELEVANT AMA POLICY

Right to Privacy in Termination of Pregnancy H-5.993
The AMA reaffirms existing policy that (1) abortion is a medical procedure and should be performed only by a duly licensed physician in conformance with standards of good medical practice and the laws of the state; and (2) no physician or other professional personnel shall be required to perform an act violative of good medical judgment or personally held moral principles. In these circumstances good medical practice requires only that the physician or other professional withdraw from the case so long as the withdrawal is consistent with good medical practice. The AMA further supports the position that the early termination of pregnancy is a medical matter between the patient and the physician, subject to the physician's clinical judgment, the patient's informed consent, and the availability of appropriate facilities.
Citation: (Res. 49, I-89; Reaffirmed by Sub. Res. 208, I-96; Reaffirmed by BOT Rep. 26, A-97; Reaffirmed: Sub. Res. 206, A-04; Reaffirmed: CCB/CLRDP Rep. 2, A-14)

Pregnancy Termination H-5.983
The AMA adopted the position that pregnancy termination be performed only by appropriately trained physicians (MD or DO).
Citation: (Res. 520, A-95; Reaffirmed: CSA Rep. 8, A-03; Modified: CSAPH Rep. 1, A-13)
E-7.3.5 Research Using Human Fetal Tissue
Research with human fetal tissue research has led to the development of a number of important research and medical advances, such as the development of polio vaccine. Fetal tissue has also been used to study the mechanism of viral infections and to diagnose viral infections and inherited diseases, as well as to develop transplant therapies for a variety of conditions, for example, Parkinsonism.

However, the use of fetal tissue for research purposes also raises a number of ethical considerations, including the degree to which a woman's decision to have an abortion might be influenced by the opportunity to donate fetal tissue. Concerns have also been raised about potential conflict of interest when there is possible financial benefit to those who are involved in the retrieval, storage, testing, preparation, and delivery of fetal tissues.

To protect the interests of pregnant women as well as the integrity of science, physicians who are involved in research that uses human fetal tissues should:
(a) Abstain from offering money in exchange for fetal tissue.
(b) In all instances, obtain the woman's voluntary, informed consent in keeping with ethics guidance, including when using fetal tissue from a spontaneous abortion for purposes of research or transplantation. Informed consent includes a disclosure of the nature of the research including the purpose of using fetal tissue, as well as informing the woman of a right to refuse to participate.
(c) Ensure that when fetal tissue from an induced abortion is used for research purposes:
(i) the woman's decision to terminate the pregnancy is made prior to and independent of any discussion of using the fetal tissue for research purposes;
(ii) decisions regarding the technique used to induce abortion and the timing of the abortion in relation to the gestational age of the fetus are based on concern for the safety of the pregnant woman.
(d) Ensure that when fetal tissue is to be used for transplantation in research or clinical care:
(i) the donor does not designate the recipient of the tissue;
(ii) both the donor and the recipient of the tissue give voluntary, informed consent.
(e) Ensure that health care personnel involved in the termination of a pregnancy do not benefit from their participation in the termination, or from use of the fetal tissue for transplantation.

AMA Principles of Medical Ethics: I,II,IV,V

E-7.3.4 Maternal-Fetal Research
Maternal-fetal research, i.e., research intended to benefit pregnant women and/or their fetuses, must balance the health and safety of the woman who participates and the well-being of the fetus with the desire to develop new and innovative therapies. One challenge in such research is that pregnant women may face external pressure or expectations to enroll from partners, family members, or others that may compromise their ability to make a fully voluntary decision about whether to participate.

Physicians engaged in maternal-fetal research should demonstrate the same care and concern for the pregnant woman and fetus that they would in providing clinical care.

In addition to adhering to general guidelines for the ethical conduct of research and applicable law, physicians who are involved in maternal-fetal research should:
(a) Base studies on scientifically sound clinical research with animals and nongravid human participants that has been carried out prior to conducting maternal-fetal research whenever possible.
(b) Enroll a pregnant woman in maternal-fetal research only when there is no simpler, safer intervention available to promote the well-being of the woman or fetus.
(c) Obtain the informed, voluntary consent of the pregnant woman.
(d) Minimize risks to the fetus to the greatest extent possible, especially when the intervention under study is intended primarily to benefit the pregnant woman.

AMA Principles of Medical Ethics: I,II,V

Fetal Tissue Transplantation Research H-5.992
Our AMA (1) supports continued research employing fetal tissue obtained from induced abortion, including investigation of therapeutic transplantation; and (2) demands that adequate safeguards be taken to isolate decisions regarding abortion from subsequent use of fetal tissue, including the anonymity of the donor, free and non-coerced donation of tissue, and the absence of financial inducement.

Citation: (Res. 170, I-89; Reaffirmed by Res. 91, A-90; Modified: Sunset Report, I-00; Reaffirmed: CEJA Rep. 6, A-10)

Use of Fetal Tissue for Legitimate Scientific Research H-5.994
The AMA supports (1) the concept of the use of fetal tissue for legitimate scientific research, including transplantation; and (2) continued federal funding for such research.

Citation: (Res. 26, I-88; Reaffirmed: Res. 91, A-90; Reaffirmed: Sunset Report, I-00; Reaffirmed: CEJA Rep. 6, A-10)

Fetal Tissue Research H-5.985
The AMA supports the use of fetal tissue obtained from induced abortion for scientific research.

Citation: (Res. 540, A-92; Reaffirmed: CSA Rep. 8, A-03; Modified: CSAPH Rep. 1, A-13)
WHEREAS, Physicians have a First Amendment right to express their good faith views on medical therapies and other medical issues; and

WHEREAS, Physicians’ rights to express their good faith views on medical issues should not be lost because those views are expressed at seminars or other programs at which the physicians are paid by the sponsor; and

WHEREAS, Physicians have been, and increasingly are being, sued for doing nothing more than expressing their views on such topics as use of opioids in treating chronic pain and use of marijuana for medical treatment purposes; and

WHEREAS, Lawsuits challenging the expression of a physician’s opinion on medical issues are often directed against key opinion leaders in the particular medical specialty; and

WHEREAS, The defense of cases in which physicians are sued for expressing their good faith views on medical issues can be very expensive, can cost more than the available insurance coverage, can cause significant anxiety, and can divert the defendant physicians from their practices; and

WHEREAS, The mere bringing of these types of suits will exert a chilling effect on the willingness of physicians to speak out in good faith on such controversial issues as a woman’s right to choose termination of pregnancy, treatment of Attention Deficit Disorder, the role of marijuana in medical treatment, use of opioids to treat chronic pain, and the efficacy of annual mammograms and PSA screening; therefore be it

RESOLVED, That our American Medical Association strongly oppose litigation challenging the exercise of a physician’s First Amendment right to express good faith opinions regarding medical issues (New HOD Policy); and be it further

RESOLVED, That our AMA’s House of Delegates encourage the AMA Litigation Center to provide such support to a constituent or component medical society whose members have been sued for expressing good faith opinions regarding medical issues as the Litigation Center deems appropriate in any specific case. (New HOD Policy)

Fiscal Note: Minimal - less than $1,000.

Received: 10/11/17
References:

Luberda v. Purdue Frederick Corp Civil Action No 4:13-cv-00897 S District Court D. So Carolina, Florence Division, filed 4/3/13 (physicians expressing their views on the utilization of opioid medications in the treatment of chronic pain)

County of Suffolk v PurduePharma et al, State of New York Supreme Court Index# 613760/2016; filed 8/31/16 and numerous similar cases brought separately by different counties in New York (physicians expressing their views on the utilization of opioid medications in the treatment of chronic pain)

City of Lorain (Ohio) v. PurduePharma et al, Ohio Northern District Court Case #: 1:17-cv-01639, filed 8/4//17 (physicians expressing their views on the utilization of opioid medications in the treatment of chronic pain)

Conant v. Walters, 309 F.3d 629 (9th Cir. 2002), filed 9/7/00 (advocacy of use of marijuana for medical treatment purposes).
Whereas, The First Amendment of the U.S. Constitution states that “Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the government for a redress of grievances;” and

Whereas, There are over 3 billion active social media users around the world; and

Whereas, Studies indicate that Internet usage by physicians now exceeds 80% for professional communication, research, and networking; and

Whereas, Physicians have been disciplined or terminated by employers for expressing their personal viewpoints using their personal social media accounts; and

Whereas, AMA has existing policy that outlines the right of physicians to advocate for change in law and policy, in the public arena, and within their institutions; therefore be it

RESOLVED, That our American Medical Association encourage the Council on Ethical and Judicial Affairs to amend Ethical Opinion 1.2.10, “Political Action by Physicians,” by addition to read as follows:

E-1.2.10 Political Action by Physicians

Like all Americans, physicians enjoy the right to advocate for change in law and policy, in the public arena, and within their institutions. Indeed, physicians have an ethical responsibility to seek change when they believe the requirements of law or policy are contrary to the best interests of patients and community health. However, they have a responsibility to do so in ways that are not disruptive to patient care. Physicians who participate in advocacy activities should:

(a) Ensure that the health of patients is not jeopardized and that patient care is not compromised.
(b) Avoid using disruptive means to press for reform. Strikes and other collection actions may reduce access to care, eliminate or delay needed care, and interfere with continuity of care and should not be used as a bargaining tactic. In rare circumstances, briefly limiting personal availability may be appropriate as a means of calling attention to the need for changes in patient care. Physicians should be aware that some actions may put them or their organizations at risk of violating antitrust laws or laws pertaining to medical licensure or malpractice.
(c) Avoid forming workplace alliances, such as unions, with workers who do not share physicians’ primary and overriding commitment to patients.
(d) Refrain from using undue influence or pressure colleagues to participate in advocacy activities and should not punish colleagues, overtly or covertly, for deciding not to participate.

Furthermore, physicians:

(e) Should indicate they are expressing their personal opinions, which are guaranteed under the First Amendment of the U.S. Constitution, and should refrain from implying or stating that they are speaking on behalf of their employers;

(f) Should be allowed to express their personal opinions publicly without being subjected to disciplinary actions or termination. (Directive to Take Action)

Fiscal Note: Minimal - less than $1,000.

Received: 10/12/17

References:
Physicians and the First Amendment

RELEVANT AMA POLICY

E-1.2.10 Political Action by Physicians
Like all Americans, physicians enjoy the right to advocate for change in law and policy, in the public arena, and within their institutions. Indeed, physicians have an ethical responsibility to seek change when they believe the requirements of law or policy are contrary to the best interests of patients. However, they have a responsibility to do so in ways that are not disruptive to patient care.

Physicians who participate in advocacy activities should:
(a) Ensure that the health of patients is not jeopardized and that patient care is not compromised.
(b) Avoid using disruptive means to press for reform. Strikes and other collection actions may reduce access to care, eliminate or delay needed care, and interfere with continuity of care and should not be used as a bargaining tactic. In rare circumstances, briefly limiting personal availability may be appropriate as a means of calling attention to the need for changes in patient care. Physicians should be aware that some actions may put them or their organizations at risk of violating antitrust laws or laws pertaining to medical licensure or malpractice.
(c) Avoid forming workplace alliances, such as unions, with workers who do not share physicians' primary and overriding commitment to patients.
(d) Refrain from using undue influence or pressure colleagues to participate in advocacy activities and should not punish colleagues, overtly or covertly, for deciding not to participate.

E-2.3.4 Political Communications
Physicians enjoy the rights and privileges of free speech shared by all Americans. It is laudable for physicians to run for political office; to lobby for political positions, parties, or candidates; and in every other way to exercise the full scope of their political rights as citizens. Physicians may exercise these rights individually or through involvement with professional societies and political action committees or other organizations.

When physicians wish to express their personal political views to a patient or a patient's family, the physician must be sensitive to the imbalance of power in the patient-physician relationship, as well as to the patients' vulnerability and desire for privacy. Physicians should refrain from initiating political conversations during the clinical encounter.

Physicians must not allow differences with the patient or family about political matters to interfere with the delivery of professional care.

When expressing political views to a patient or a patient's family, physicians should:
(a) Judge both the intrusiveness of the discussion and the patient's level of comfort before initiating such a discussion.
(b) Discuss political matters only in contexts where conversation with the patient or family about social, civic, or recreational matters is acceptable.
(c) Refrain from conversation about political matters when the patient or family is emotionally pressured by significant medical circumstances.
(d) Work towards and advocate for the reform and proper administration of laws related to health care. Physicians should stay well informed of current political questions regarding needed and proposed reforms.

(e) Stay well informed about needed or proposed policies concerning health care access and quality, medical research, and promoting public health so as to be able to advocate for patients' needs.

**Free Speech Applies to Scientific Knowledge H-460.895**

Our AMA will advocate that scientific knowledge, data, and research will continue to be protected and freely disseminated in accordance with the U.S. First Amendment.

Citation: Res. 228, A-17

**Government Interference in Patient Counseling H-373.995**

1. Our AMA vigorously and actively defends the physician-patient-family relationship and actively opposes state and/or federal efforts to interfere in the content of communication in clinical care delivery between clinicians and patients.

2. Our AMA strongly condemns any interference by government or other third parties that compromise a physician's ability to use his or her medical judgment as to the information or treatment that is in the best interest of their patients.

3. Our AMA supports litigation that may be necessary to block the implementation of newly enacted state and/or federal laws that restrict the privacy of physician-patient-family relationships and/or that violate the First Amendment rights of physicians in their practice of the art and science of medicine.

4. Our AMA opposes any government regulation or legislative action on the content of the individual clinical encounter between a patient and physician without a compelling and evidence-based benefit to the patient, a substantial public health justification, or both.

5. Our AMA will educate lawmakers and industry experts on the following principles endorsed by the American College of Physicians which should be considered when creating new health care policy that may impact the patient-physician relationship or what occurs during the patient-physician encounter:
   A. Is the content and information or care consistent with the best available medical evidence on clinical effectiveness and appropriateness and professional standards of care?
   B. Is the proposed law or regulation necessary to achieve public health objectives that directly affect the health of the individual patient, as well as population health, as supported by scientific evidence, and if so, are there no other reasonable ways to achieve the same objectives?
   C. Could the presumed basis for a governmental role be better addressed through advisory clinical guidelines developed by professional societies?
   D. Does the content and information or care allow for flexibility based on individual patient circumstances and on the most appropriate time, setting and means of delivering such information or care?
   E. Is the proposed law or regulation required to achieve a public policy goal - such as protecting public health or encouraging access to needed medical care - without preventing physicians from addressing the healthcare needs of individual patients during specific clinical encounters based on the patient's own circumstances, and with minimal interference to patient-physician relationships?
   F. Does the content and information to be provided facilitate shared decision-making between patients and their physicians, based on the best medical evidence, the physician's knowledge and clinical judgment, and patient values (beliefs and preferences), or would it undermine shared decision-making by specifying content that is forced upon patients and physicians without regard to the best medical evidence, the physician's clinical judgment and the patient's wishes?
   G. Is there a process for appeal to accommodate individual patients' circumstances?

6. Our AMA strongly opposes any attempt by local, state, or federal government to interfere with a physician's right to free speech as a means to improve the health and wellness of patients across the United States.

Citation: Res. 201, A-11; Reaffirmation: I-12; Appended: Res. 717, A-13; Reaffirmed in lieu of Res. 5, I-13; Appended: Res. 234, A-15
Reference Committee B

BOT Report(s)

06 Electronically Prescribed Controlled Substances Without Added Processes

Resolution(s)

201 Improving FDA Expedited Approval Pathways
202 Sexual Assault Survivors’ Rights
203 Bidirectional Communication for EHR Software and Pharmacies
204 EHR Vendors Responsible for Health Information Technology
205 Health Plan, Pharmacy, Electronic Health Records Integration
206 Defending Federal Child Nutrition Programs
207 Redistribution of Unused Prescription Drugs to Pharmaceutical Donation and Reuse Programs
208 Increased Use of Body-Worn Cameras by Law Enforcement Officers
209 Government Mandated Sequester
210 Merit-Based Incentive Payment System and Small Practices
211 Exclusive State Control of Methadone Clinics
213 Barriers to Price Transparency
214 APRN Compact
215 Relieve Burden for Living Organ Donors
216 Relationship with US Department of Health and Human Services
217 Regulations Regarding Medical Tool and Instrument Repair
218* Health Information Technology Principles
219* Certified EMR Companies' Practice of Charging Fees for Regulatory Compliance
220* Preserving Protections of the Americans with Disabilities Act of 1990
221* House of Representative Bill HR 2077, Restoring the Patient's Voice Act of 2017
222* The Clinical Use of a Home Sleep Apnea Test
223* Treating Opioid Use Disorder in Correctional Facilities
224* Modernizing Privacy Regulations for Addiction Treatment Records
225* Oppose Inclusion of Medicare Part B Drugs in QPP / MIPS Payment Adjustment
226* Prescription Drug Importation for Personal Use

* included in the Handbook Addendum
REPORT OF THE BOARD OF TRUSTEES

BOT Report 6-I-17

Subject: Electronically Prescribed Controlled Substances without Added Processes (Resolution 216-A-17)

Presented by: Gerald E. Harmon, MD, Chair

Referred to: Reference Committee B (Ralph J. Nobo, Jr. MD, Chair)

INTRODUCTION

At the 2017 Annual Meeting of the House of Delegates (HOD), Resolution 216-A-17, "Electronically Prescribed Controlled Substances without Added Processes," was referred for report at the 2017 Interim Meeting. Resolution 216-A-17, sponsored by the Illinois Delegation Association, asks our American Medical Association (AMA) to advocate for full electronic prescribing of all prescriptions, without additional cumbersome electronic verification, including Schedule II-V controlled substances, eliminating the need for “wet signed” paper prescriptions and faxes for specific classes of prescriptions. The reference committee heard testimony strongly supportive of the intent of Resolution 216. The reference committee noted that current Drug Enforcement Administration (DEA) requirements for biometric devices limit user-friendly consumer electronics already found in physicians’ offices, such as fingerprint readers on laptop computers and mobile phones, from being used for two-factor authentication in Electronically Prescribed Controlled Substances (EPCS). The reference committee acknowledged the frustration heard in testimony regarding how two-factor authentication and other rules contribute to cumbersome workflows and applications and noted that EPCS uptake is slow precisely due to these barriers. The reference committee also heard testimony that our AMA continues to have discussions with key stakeholders to work toward improving the integration of EPCS and the interoperability of Prescription Drug Monitoring Programs (PDMP) and electronic health records into practice workflows and clinical decision-making. The reference committee noted that our AMA has made and continues to make these points at both the federal and state levels.

AMA POLICY

Current AMA policy provides:


Our American Medical Association will address with the Centers for Medicare & Medicaid Services and the Drug Enforcement Administration the contradictory guidance, issued respectively by those two federal agencies, relating to electronic transmission of physicians' prescriptions to pharmacies—commonly referred to as “e-prescribing”—for Schedules III, IV and V drugs, as those current guidelines add rather than reduce administrative paperwork and defeat the purpose of electronic handling of prescriptions.
Policy D-120.958, “Federal Roadblocks to E-Prescribing”

1. Our AMA will initiate discussions with the Centers for Medicare and Medicaid Services and state Medicaid directors to remove barriers to electronic prescribing including removal of the Medicaid requirement that physicians write, in their own hand, "brand medically necessary" on a paper prescription form. 2. Our AMA will initiate discussions with the Drug Enforcement Administration to allow electronic prescribing of Schedule II prescription drugs. 3. It is AMA policy that physician Medicare or Medicaid payments not be reduced for non-adoption of E-prescribing. 4. Our AMA will work with federal and private entities to ensure universal acceptance by pharmacies of electronically transmitted prescriptions. 5. Our AMA will advocate for appropriate financial and other incentives to physicians to facilitate electronic prescribing adoption. 6. Our AMA will: (A) investigate regulatory barriers to electronic prescription of controlled substances so that physicians may successfully submit electronic prescriptions for controlled substances; and (B) work with the Centers for Medicare & Medicaid Services to eliminate from any program (e.g., the Physician Quality Reporting System, meaningful use, and e-Prescribing) the requirement to electronically prescribe controlled substances, until such time that the necessary protocols are in place for electronic prescribing software vendors and pharmacy systems to comply. 7. Our AMA will work with representatives of pharmacies, pharmacy benefits managers, and software vendors to expand the ability to electronically prescribe all medications. 8. Our AMA will petition the Centers for Medicare & Medicaid Services and the federal government to have all pharmacies, including government pharmacies, accept e-prescriptions or to temporarily halt the e-prescribing requirements of meaningful use until this is accomplished.

Policy H-120.957, “Prescription of Schedule II Medications by Fax and Electronic Data Transmission”

Our AMA: (1) encourages the Drug Enforcement Administration to rewrite Section 1306 of Title 21 of the Code of Federal Regulations to accommodate encrypted electronic prescriptions for Schedule II controlled substances, as long as sufficient security measures are in place to ensure the confidentiality and integrity of the information. (2) Our AMA supports the concept that public key infrastructure (PKI) systems or other signature technologies designed to accommodate electronic prescriptions should be readily adaptable to current computer systems, and should satisfy the criteria of privacy and confidentiality, authentication, incorruptibility, and nonrepudiation. (3) Because sufficient concerns exist about privacy and confidentiality, authenticity, and other security measures, the AMA does not support the use of "hard copy" facsimile transmissions as the original written prescription for Schedule II controlled substances, except as currently allowed in Section 1306 of Title 21 of the Code of Federal Regulations.

DISCUSSION

The barriers to implementation of e-prescribing of controlled substances have been significant, but due to ongoing AMA advocacy a number of impediments have been addressed at the state and federal levels. The current challenge to streamlining adoption rests primarily with antiquated and burdensome DEA restrictions that the AMA continues to challenge. In addition, federal Medicaid regulations also drive state law impediments to electronic prescribing.

State Laws

All states allow electronic prescribing of controlled substances, and three go so far as to actively mandate it. New York mandated use of electronic prescribing of all prescriptions as of March 27, 2016. Maine’s mandate for e-prescribing of controlled substances went into effect July 1, 2017.
Virginia’s EPCS mandate, which does not go into effect until July 1, 2020, is limited to drugs containing opiates. Both New York and Virginia allow prescribers to apply for waivers. Also, at the time this report was drafted, several other states are considering legislation to mandate EPCS. However, in order for prescriptions to be reimbursable by Medicaid, a physician must certify in his or her own handwriting that a specific brand is medically necessary for a particular recipient. The state requirements are mandated by federal regulations. The state Medicaid programs must decide what certification form and procedure are used. Federal regulations provide that a checkoff box on a form is not acceptable, but a notation like “brand necessary” is allowable. Thus, there are state laws that require specifying “brand necessary,” particularly for Medicaid patients, and must be done in a physician’s handwriting.

Centers for Medicare & Medicaid Services (CMS)

CMS does not currently have a role in regulating EPCS. Beginning in 2009 there was a Medicare e-prescribing incentive program, but 2013 was the final program year for participating and reporting in this program. In addition, the CMS e-prescribing incentive program exempted EPCS, so controlled substance prescriptions were not an issue. CMS does have oversight responsibility for the Medicare Part D prescription drug benefit program, and it requires all Part D plan sponsors to support e-prescribing. Instead of developing its own e-prescribing standards, CMS adopted the standards developed by the National Council for Prescription Drug Programs (NCPDP), most recently the NCPDP Formulary and Benefits 3.0 transaction standards. In addition, CMS does have oversight of the Medicaid program, and as discussed above, federal regulations that require physicians to submit handwritten statements when a substitution is not permitted represent a barrier to electronic prescribing without a legitimate justification, as the information could be efficiently and securely transmitted through electronic prescribing.

U.S. Drug Enforcement Administration

The AMA continues concerted engagement to address barriers to e-prescribing of controlled substances due to overly burdensome DEA regulations. In 2010, the AMA provided comments as part of the DEA’s rulemaking process and raised concerns with a number of regulations and requirements that should be modified to facilitate widespread e-prescribing of controlled substances. More recently, the AMA again met with the DEA and reinforced and expanded on those recommendations that would enhance security (and decrease diversion) while streamlining the administrative burden. The AMA noted that many physicians have reported that a well-designed electronic medication prescription (eRx) system adds value to their practice of medicine and supports better patient care. The AMA stated that improving on the utility of EPCS to match that of current eRx capabilities will benefit physicians and patients alike. The AMA communicated the points below.

Two-factor authentication. While authentication through a combination of personal identification numbers (PINs), passwords, and biometrics increases the security of EPCS, it also contributes to frequent workflow disruptions and increases costs for many physicians. An AMA survey found that primary care physicians write up to 100 prescriptions per day. Other specialists usually write an average of 10 to 25 prescriptions per day. This volume of prescriptions makes compliance with two-factor authentication, particularly as a distinct process from e-prescribing of non-controlled substances onerous and a significant strain on practice workflows. Few health information technology (health IT) vendors currently support EPCS, and those that do often require physicians to purchase add-on modules or pay separate monthly service fees outside those of normal product maintenance. In speaking with many DEA-registered physicians, the AMA has found that many methods and processes health IT vendors utilize for EPCS are not well-aligned with normal eRx
workflows. In most instances, physicians must initiate an entirely new set of computer programs and windows each time they wish to use EPCS. The AMA shared with the DEA that cumbersome workflows and applications that do not take physician needs into account are the primary impediment to physician EPCS uptake and should be squarely addressed by system designers and product implementers. The DEA requirement that biometric devices comply with Federal Information Processing Standards (FIPS) compounds this problem by limiting many user-friendly consumer electronics already found in physicians’ offices from being utilized. The AMA asked that the DEA reexamine the scope of technology that is compliant with EPCS requirements and allow for lower-cost, high-performing biometric devices (e.g., fingerprint readers on laptop computers and mobile phones) to be leveraged in two-factor authentication.

Identity proofing. For individual physicians in private practice, identity proofing (verifying that the authenticated user is who he/she claims to be) must occur by an authorized third party that will, after verifying the physician’s identity, issue the authentication credential to the DEA registrant. The current identity proofing process is complex and must be performed for each location a physician wishes to employ EPCS. The AMA recommended that the DEA allow a physician’s hospital credentialing to be used for his or her EPCS identity proofing instead of requiring a separate process for EPCS. The AMA also suggested that DEA engage with initiatives like the Administration’s National Strategy for Trusted Identities in Cyberspace federated identity management program. Current regulations further require that, once the authentication credential has been issued to the DEA-registered physician, logical access controls must be established to verify that the authenticated user has the authority to perform the requested operation. The AMA communicated to the DEA that there is not a rational basis for requiring two-person access controls for EPCS on top of the other requirements and the AMA recommended that it be eliminated.

Audit requirements. The current DEA regulation provides that any person designated to set logical access controls is responsible for determining whether any identified auditable event represents a security incident that compromised or could have compromised the integrity of the prescription records (e.g., an unauthorized person attempting to sign or alter a prescription would be an auditable event; a pharmacist annotating a record to indicate a change to a generic version of a drug would not be). EPCS applications must run the internal audit function daily to identify any auditable events. When one occurs, the application must generate a readable report for the physician or pharmacist. If a physician or pharmacy determines that there is a potential security problem, it must be reported to the DEA within one business day. The AMA shared with the DEA that the one day requirement for physicians to report a compromised authentication protocol is impractical. Longer reporting timeframes, such as those required for HIPAA breaches, can be used as a precedent for revising this requirement. Additionally, the AMA urged the DEA to consider how health IT vendors may better support the review of audit logs and reduce the need for manual review by physicians.

PDMP. PDMPs have the promise to be an essential tool for physicians to help prevent drug misuse, diversion, and overdose. Currently, most PDMPs have limited or no ability to connect with and share information to third-party applications. The AMA urged the DEA to work with its state and federal partners to encourage the interoperability of PDMP databases, electronic health records, and other health IT products to improve the integration of data on controlled substance use into practice workflows and physicians’ clinical decision-making.

DEA fees and EPCS compliance costs. The AMA pointed out to the DEA that physicians often face excessive costs for complying with EPCS requirements. Many physicians—especially those in small and solo practices—face high fees associated with the extensive technical, security, and other standard requirements (e.g., costs for identity proofing, access control training and the setting of
access controls, hardware, software or application purchase and maintenance, reprogramming, and audit requirements), along with workflow adjustments needed for EPCS. In addition to the costs of compliance with EPCS, there are also monthly fees levied by health IT vendors. These fees and costs pose a significant barrier to EPCS adoption. As DEA registration fees ($731 for three years) are set to cover the costs of its diversion control program and a major purpose of EPCS is to lower the risk of drug diversion, the AMA urged the DEA to consider reducing registration fees for those who employ EPCS.

Clearer guidance. The AMA also shared with the DEA that the current regulations are difficult to comprehend. The AMA strongly urged the DEA to provide clarity and simplified guidance, including examples, to help physicians understand exactly what is required of them for EPCS compliance.

Recent Efforts

The AMA met with Surescripts, a health information network that connects health information technology (electronic health records, pharmacy systems) used by pharmacies, health care providers, and benefit managers, because Surescripts is often cited as one of the best examples of interoperability in the health care industry today. One of the meetings focused on EPCS where AMA staff reviewed the recommendations submitted to the DEA outlined above. Surescripts noted general agreement with the AMA concerns and AMA suggested solutions. More recently, on May 18, 2017, the AMA submitted comments to the President’s Commission on Combating Drug Addiction and the Opioid Crisis. The AMA again reiterated that the DEA requirements for biometric devices limit user-friendly consumer electronics already found in physicians’ offices, such as fingerprint readers on laptop computers and mobile phones, from being utilized for two-factor authentication in EPCS. The AMA noted that this and other rules contribute to cumbersome workflows and applications that do not take physician needs into account, which are an impediment to physician EPCS uptake. Furthermore, the AMA stated that encouraging EPCS uptake and interoperability of PDMP databases and electronic health records would improve the integration of controlled substance use data into practice workflows and clinical decision-making. AMA staff are preparing to follow-up directly with DEA.

CONCLUSION

During consideration of Resolution 216 there was consensus that it raised legitimate concerns. On the other hand, there was testimony in the reference committee urging reaffirmation of existing policy. In addition, during the HOD’s consideration of the Resolution and reference committee recommendation, a number of delegates noted that current AMA policy, while largely still relevant, should be updated.

RECOMMENDATIONS

The Board of Trustees recommends that the following policies be amended and the remainder of the report be filed.


Our American Medical Association will continue to advocate before relevant federal and state agencies and legislative bodies for the elimination of address with the Centers for Medicare & Medicaid Services and the Drug Enforcement Administration the contradictory, cumbersome, confusing, and burdensome requirements guidance, issued respectively by those two federal
agencies, relating to electronic transmission of physicians’ controlled substance prescriptions to pharmacies—commonly referred to as “e-prescribing”—Electronic Prescribing for Controlled Substances (EPCS). This includes for Schedules II, III, IV and V drugs, as those current guidelines add rather than reduce administrative paperwork and defeat the purpose of electronic handling of prescriptions (Modify Current HOD Policy).

2. That current AMA Policy D-120.958, “Federal Roadblocks to E-Prescribing,” Our AMA will initiate discussions work with the Centers for Medicare and Medicaid Services and states to remove or reduce barriers to electronic prescribing of both controlled substances and non-scheduled prescription drugs, including removal of the Medicaid requirement in all states that continue to mandate that physicians write, in their own hand, “brand medically necessary” or the equivalent on a paper prescription form.

2. Our AMA will initiate discussions with the Drug Enforcement Administration to allow electronic prescribing of Schedule II prescription drugs.

3. It is AMA policy that physician Medicare or Medicaid payments not be reduced for non-adoption of eE-prescribing.

4. Our AMA will work with the largest and nearly exclusive national electronic pharmacy network, all related state pharmacy regulators, and with federal and private entities to ensure universal acceptance by pharmacies of electronically transmitted prescriptions.

4. Our AMA will advocate for appropriate financial and other incentives to physicians to facilitate electronic prescribing adoption.

5. Our AMA will: (A) investigate work to substantially reduce regulatory burdens so that physicians may successfully submit electronic prescriptions for controlled substances; and (B) work with the Centers for Medicare & Medicaid Services to eliminate from any program (e.g., the Physician Quality Reporting System, meaningful use, and e-Prescribing) the requirement to electronically prescribe controlled substances, until such time that the necessary protocols are in place for electronic prescribing software vendors and pharmacy systems to comply.

6. Our AMA will work with representatives of pharmacies, pharmacy benefits managers, and software vendors to expand the ability to electronically prescribe all medications.

7. Our AMA will petition work with the Centers for Medicare & Medicaid Services and the federal government to have all pharmacies, including government pharmacies, accept e-prescriptions for prescription drugs or to temporarily halt the e-prescribing requirements of meaningful use until this is accomplished (Modify Current HOD Policy).

3. That current AMA Policy H-120.957, “Prescription of Schedule II Medications by Fax and Electronic Data Transmission,”

Our AMA: (1) encourages the Drug Enforcement Administration to rewrite Section 1306 of Title 21 of the Code of Federal Regulations to support two factor authentication that is easier to implement than the current DEA and EPCS security requirements accommodate encrypted electronic prescriptions for Schedule II controlled substances, as long as sufficient security measures are in place to ensure the confidentiality and integrity of the information. (2) Our AMA supports the concept that public key infrastructure (PKI) systems or other signature technologies designed to accommodate electronic using prescriptions should be readily adaptable to current computer systems, and should satisfy the criteria of privacy and confidentiality, authentication, incorruptibility, and. (23) Because sufficient concerns exist about privacy and confidentiality, authenticity, and other security measures, the AMA does not support the use of "hard copy" facsimile transmissions as the original written prescription for Schedule II controlled substances, except as currently allowed in Section 1306 of Title 21 of the Code of Federal Regulations (Modify Current HOD Policy).

Fiscal note: Less than $500.
Whereas, In the wake of the AIDS epidemic in the 1980s, the U.S. Food and Drug Administration (FDA) created pathways by which specialty drugs could be approved based on less rigorous data, including a “fast track” pathway for drugs that treat life-threatening or severely debilitating conditions, which allows approval on the basis of uncontrolled Phase II trials, and an “accelerated approval” pathway which lowers evidentiary requirements for drugs for serious or life-threatening conditions if the drug provides a meaningful therapeutic benefit not provided by existing treatment, both of which have reduced the time to approval for designated specialty drugs; and

Whereas, In the period of 2000-2013, 82 drugs were approved under the fast-track designation, representing 22% of all drugs including biologics approved by the FDA during that time period, yet only 49 of the 82 were specialty drugs; and

Whereas, In the same period of 2000-2013, 37 new drugs were granted accelerated approval (10% of all drugs including biologics), of which 26 were specialty drugs; and

Whereas, In 2012 the United States Congress created another expedited pathway for so-called “breakthrough therapies” which could be designated by FDA based on early clinical signs of promise, expected to be used only a few times a year but which received over 100 applications for designation in 2013; and

Whereas, These expedited pathways usually allow for drug approval some time during Phase III which lasts approximately from 1-4 years, and the standard drug approval process has a median approval time of 10.1 months from receipt of application, thereby resulting in expedited pathway approval approximately 5 years before said drug would be approved via the standard pathway; and

Whereas, These expedited approval pathways pose challenges to the evidence-based prescribing of approved drugs, since designations provide strong signals to the public about the clinical importance of the drugs entering these pathways and drugs that are approved after a shortened premarket period or drugs approved based on invalidated surrogate endpoints may later be found to have greater risks, or less certain benefits, than was initially believed to be the case; and

Whereas, Approval of an expensive new specialty drug based only on preliminary data suggesting that it might improve patient outcomes and resultant use by clinicians may divert resources away from other health care interventions that have been confirmed to be effective or that present greater value; and
Whereas, These expedited pathways require post-approval testing to confirm the drugs’ predicted benefit-risk profiles, yet one 2011 review of forty-seven oncology drugs approved through the “accelerated approval” pathway in the period 1992–2010 found that trials for eighteen had not been completed at the time of the review; and

Whereas, FDA has limited power to ensure that mandatory post-approval trials for drugs approved via these pathways be conducted in a timely and rigorous manner, being able to impose civil fines of up to $10 million, which is but a fraction of the enormous profit specialty drugs can generate; and

Whereas, Removing a drug from the market often draws criticism from physicians and patient-advocacy groups, even for drugs which lack data supporting their effectiveness or safety; and

Whereas, A system by which approval for drugs brought forward under these expedited pathways would be designated as temporary and have a set expiration date, with more permanent FDA approval given under the condition of further evidence supporting safety and efficacy, would shift the burden to the manufacturer to show that its drug should remain on the market; and

Whereas, Legislative action would be required to further modify the FDA expedited pathway processes; and

Whereas, Robert M. Califf, M.D., former FDA Commissioner noted that with the passage of the 21st Century Cures Act “great progress has been made towards our shared goal of advancing regulatory science so that we can continue to speed the discovery, development, and delivery of medical products to prevent and cure disease and improve health while sustaining the evidence framework that enables assurance to the public of the safety and effectiveness of medical products;” therefore be it

RESOLVED, That our American Medical Association work with U.S. Food and Drug Administration (FDA) and other interested stakeholders to design and implement via legislative action (including ensuring appropriate FDA staffing) a process by which drugs which obtain FDA approval via the Fast Track, Accelerated Approval, or Breakthrough Therapy pathways be granted FDA approval on a temporary basis not to exceed 5 years, pending further evidence of safety and efficacy that is at the level set for the standard drug approval process (Directive to Take Action); and be it further

RESOLVED, That our AMA work with the FDA and other interested stakeholders in improving the process by which drugs are selected for the expedited pathway to improve the prevalence of these drugs that are classified as “specialty drugs.” (Directive to Take Action)

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

Received: 09/06/17

RELEVANT AMA POLICY

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 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. (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)

Addressing the Exploitation of Restricted Distribution Systems by Pharmaceutical Manufacturers H-100.950
1. Our AMA will advocate with interested parties for legislative or regulatory measures that require prescription drug manufacturers to seek Food and Drug Administration and Federal Trade Commission approval before establishing a restricted distribution system.
2. Our AMA supports requiring pharmaceutical companies to allow for reasonable access to and purchase of appropriate quantities of approved out-of-patent drugs upon request to generic manufacturers seeking to perform bioequivalence assays.
3. Our AMA will advocate with interested parties for legislative or regulatory measures that expedite the FDA approval process for generic drugs, including but not limited to application review deadlines and generic priority review voucher programs. (Res. 809, I-16)

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. (Sub. Res. 548, A-92; BOT Rep. 32, A-95; BOT Rep. 32, A-95; BOT Rep. 32, 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)
Whereas, The Violence Against Women Reauthorization Act of 2013 requires state, tribal and local governments to offer medical forensic examinations to victims of sexual assault despite whether the victim participates in the criminal justice system;¹,² and

Whereas, The legal rights of a crime victim are not protected nor elucidated for sexual assault survivors in some states;³,⁴,⁵,⁶,⁷ and

Whereas, Sexual assault evidence collection kit storage policies vary across jurisdictions, resulting in (1) some kits being discarded in as little as 30 days or kits being discarded before the state-specific statute of limitations, (2) some survivors being charged for their own evidence collection kit or associated treatments, and (3) some sexual assault survivors are given no information about the testing or results of their kits;³,⁴,⁸,⁹ and

Whereas, Requiring sexual assault survivors to repeatedly request extensions for the preservation of their kits, especially if they remain undecided about pursuing legal action, places an undue burden on the survivor with consequences to their mental health and recovery;⁴,⁸ and

Whereas, The federal Survivors’ Bill of Rights Act of 2016 (SBRA) establishes that a survivor of sexual assault has the right to receive a medical forensic examination at no cost, that the evidence collection kit be preserved, without charge, for the duration of the statute of limitations or 20 years, that the survivor be informed of the results of the kit, that the survivor be notified of plans to destroy the kit, that the survivor be granted further preservation of the kit if requested, and that the survivor be informed of these rights;¹⁰,¹¹ and

Whereas, The federal government is limited in its ability to change law enforcement practices at the state level and since the provisions of SBRA involve elements of law enforcement, adopting the federal standards set by SBRA can only be accomplished by individual state legislation;¹² and

Whereas, Five states (MA, WA, VA, OR, MD) have passed legislation similar to the Survivors’ Bill of Rights Act of 2016, five additional states (VT, CA, MN, OK, WV) have introduced similar legislation, and twenty one states have ongoing advocacy efforts to consider similar legislation; and

Whereas, SBRA instructs the Attorney General and the Secretary of Health and Human Services to establish a joint working group, including the medical provider community, to develop, coordinate, disseminate and encourage implementation of best practices regarding the care of sexual assault survivors and the preservation of evidence among hospital administrators, physicians, forensic examiners, medical community leaders, and medical associations; and

Whereas, Pursuant to AMA policy H-80.998, the AMA supports the function and efficacy of rape victim services and AMA policy H-80.999, the AMA supports the preparation and dissemination of information intended to maintain and improve the skills needed by all practicing physicians involved in providing care to rape victims; and

Whereas, Existing AMA policy specifically addressing information for physicians on the medical-legal rights of sexual assault survivors would improve the care physicians can provide to victims of sexual assault who are their patients; and

Whereas, Collaboration between medical and legal communities on the rights of sexual assault survivors would improve health outcomes for these victims; therefore be it

RESOLVED, That our American Medical Association advocate for the legal protection of sexual assault survivors’ rights and work with state medical societies to ensure that each state implements these rights, which include but are not limited to, the right to: (1) receive a medical forensic examination free of charge, which includes but is not limited to HIV/STD testing and treatment, pregnancy testing, treatment of injuries, and collection of forensic evidence; (2) preservation of a sexual assault evidence collection kit for at least the maximum applicable statute of limitation; (3) notification of any intended disposal of a sexual assault evidence kit with the opportunity to be granted further preservation; (4) be informed of these rights and the policies governing the sexual assault evidence kit (New HOD Policy); and be it further

RESOLVED, That our AMA collaborate with relevant stakeholders to develop recommendations for implementing best practices in the treatment of sexual assault survivors, including through engagement with the joint working group established for this purpose under the Survivor’s Bill of Rights Act of 2016. (Directive to Take Action)

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

Received: 09/12/17

RELEVANTAMA POLICY


Rise. (2016) "Who We Are." Available at http://www.risenow.us/
Whereas, In 2017 physicians are increasingly required to send prescriptions electronically to pharmacies, also known as e-prescribing; and

Whereas, Physicians are also responsible for an accurate update in the Electronic Health Record (EHR) for their patient’s active current medications; and

Whereas, Many patients cannot recall their medications, prescribed dosage, route of administration, or how often they should take them; and

Whereas, The technology exists to have bidirectional communication between EHR software and pharmacies to keep patient medications in the Electronic Health Record accurate and current; therefore be it

RESOLVED, That our American Medical Association engage the American Pharmacy Association, and any other relevant stakeholders, to encourage both Electronic Health Record (EHR) and pharmacy software vendors to have bidirectional communication for an accurate and current medication list in the patient’s EHR. (New HOD Policy)

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

Received: 09/18/17
Resolution: 204
(I-17)

Introduced by: Virginia, North Carolina, American Urological Association, American Association of Clinical Urologists

Subject: EHR Vendors Responsible for Health Information Technology

Referred to: Reference Committee B
(Ralph J. Nobo, Jr., MD, Chair)

Whereas, For the 2017 Quality Payment Program (QPP) physicians have the option to use
Electronic Health Record (EHR) technology certified to the 2014 or 2015 edition, or a
combination of 2014 or 2015 editions; and

Whereas, Starting in 2018, physicians are required to use only 2015 Certified Electronic Health
Record Technology (CEHRT); and

Whereas, Very few vendor products meet the 2015 certification criteria required for approval by
the Office of the National Coordinator for Health Information Technology (ONC) Health IT
Certification Program; and

Whereas, Mandating use of EHR technology certified to the 2015 edition CEHRT by 2018 may
unfairly subject physicians to financial penalties under the QPP or force them to file for hardship
exceptions due to unavailable vendor products; therefore be it

RESOLVED, That our American Medical Association petition the Centers for Medicare and
Medicaid Services (CMS) to require Electronic Health Record (EHR) vendors, offering
technology for physician use, meet all current certification requirements as approved by the
ONC’s Health IT Certification Program (Directive to Take Action); and be it further

RESOLVED, That our AMA advocate that EHR vendors, not physicians, be financially penalized
for EHR technology not meeting current standards. (New HOD Policy)

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

Received: 09/18/17
Whereas, The multitude and ever-changing requirements of health plans and pharmacy benefit managers creates an enormous burden on physicians caring for their patients; and

Whereas, There are numerous similar medications for a prescribed class of pharmaceutical agent and different health plans mandate use of one or two due to contractual obligations and cost. In addition, these approved medications can change frequently within a single health plan; and

Whereas, Technology exists today to solve this problem; therefore be it

RESOLVED, That our American Medical Association advocate that health plans, pharmacies, and EHR vendors integrate their technology programs so that physicians have current and real time access to covered medications for patients within a specific health plan (New HOD Policy); and be it further

RESOLVED, That our AMA advocate that health plans make patient cost information readily available via this technology so that physicians and their patients may work together to choose the most cost-effective medically appropriate medication for patient care. (New HOD Policy)

Fiscal Note: Minimal - less than $1,000.

Received: 09/18/17
Whereas, The United States Department of Agriculture’s (USDA) child nutrition programs which include resources such as the National School Lunch Program (NSLP) and the School Breakfast Program (SBP) serve as vital lifelines in preserving and improving the general health of children in the United States;¹ with 58% of school-age children in the US utilizing NSLP and/or SBP on a given school day;² and

Whereas, The Healthy, Hunger-Free Kids Act (HHFKA) of 2010 updated nutrition standards for federal child nutrition programs and enabled the USDA to align school meal program resources with its Dietary Guidelines for Americans (DGA);³,⁴ and

Whereas, In 2012, the USDA issued updated nutritional guidelines for child nutrition programs which further compelled schools to add more fruits, vegetables, and legumes while reducing fat, sodium, and caloric content in provided foods;⁵ and

Whereas, In 2015, more than 13.1 million children were food insecure and thereby at increased risk for deficiencies in one or more nutrients, placing them at significantly higher risk for illness altered cognition, and decreased mental performance;⁶,⁷,⁸ and

Whereas, Early exposure to nutrition education and access to fruits and vegetables play a significant role on the shaping of good longitudinal dietary habits and mitigate the risk of developing early onset obesity and diseases associated with obesity such as diabetes and hyperlipidemia;⁹,¹⁰,¹¹ and

Whereas, Several recent studies indicate the USDA’s updated nutritional standards positively impact student fruit and vegetable consumption as well as food insecurity and its associated health and nutritional complications;\textsuperscript{9,12,13,14,15} and

Whereas, The US Senate Committee on Agriculture, Nutrition, and Forestry successfully persuaded the USDA in 2013 to grant flexibility on implementation of its 2012 school meal nutritional standards and under new administration in 2016, the USDA has granted even greater flexibility in implementation of these standards;\textsuperscript{16,17} and

Whereas, Our AMA currently has no policy efforts to reduce or eliminate federal child nutrition programs (AMA Policies H-150.944 and H-150.962); and

RESOLVED, That our American Medical Association oppose legislation that reduces or eliminates access to federal child nutrition programs (New HOD Policy); and be it further RESOLVED, That our AMA reaffirm Policy H-150.962, “Quality of School Lunch Program.” (Reaffirm HOD Policy)

Fiscal Note: Minimal - less than $1,000.

Received: 09/20/17

RELEVANT AMA POLICY

Quality of School Lunch Program H-150.962

See also:

\textsuperscript{16} Roberts P. Senator Roberts: USDA Grants Flexibility on School Meals; Waste and Cost Remain a Concern. United States Senate Committee on Agriculture, Nutrition, and Forestry.
WHEREAS, There is a surplus of unused medications in the US including long-term care facilities discarding $2 billion worth of medications already paid for by federal and state governments annually, leaving a potential $700 million to be saved by reusing these discarded medications;¹ ² while hospital pharmacies and other health care providers spend approximately $1 billion on unused medications annually;³ and

WHEREAS, Current Drug Enforcement Administration (DEA) standards of drug disposal include drug take-back programs, mail-back programs, and collection receptacles, with collected prescription drugs being destroyed by incineration;⁴ ⁵ and

WHEREAS, 38 states have passed pharmaceutical donation and reuse legislation for non-controlled substances, and 20 states have created operational pharmaceutical donation and reuse programs dedicated to collecting unused medications to redistribute to patients for little or no cost;⁶ ⁷ and

WHEREAS, The determination of recipients of legally redistributed prescription medications are determined by state regulations and the Department of Human Resources;⁶ and

WHEREAS, The safe return and reuse of prescription medications allows for increased access to prescription medications, as demonstrated by Oklahoma’s Drug Recycling Program, which has redistributed over 200,000 prescriptions worth $20 million to those in need since 2004;⁸ and

WHEREAS, A common obstacle to establishing a pharmaceutical donation and reuse program is the absence of funding, as depicted by Texas’s Drug Donation Pilot Program;⁹ and

Whereas, In a time of persistently rising prescription drug costs, establishing pharmaceutical donation and reuse programs not only allows for the proper recycling of these drugs, but also increased access to prescription drugs by the 35 million Americans who are unable to afford their medications;¹⁰ and

Whereas, The “AMA supports access to safe, convenient, and environmentally sound medication return for unwanted prescription medications” by working “with other national organizations and associations to inform, encourage, support and guide hospitals, clinics, retail pharmacies, and narcotic treatment programs in modifying their US Drug Enforcement Administration registrations to become authorized medication collectors and operate collection receptacles at their registered locations” (AMA Policies H-135.925, H-135.936); and

Whereas, The AMA Opioid Task Force encourages safe storage and disposal of opioids and all medications; therefore be it

RESOLVED, That our American Medical Association work with appropriate stakeholders to draft and promote model legislation aimed at developing better funding for drug donation programs on the state level provided these programs follow the quality assurance guidelines set by existing AMA Policy H-280.959. (Directive to Take Action)

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

Received: 09/20/17

RELEVANT AMA POLICY

Recycling of Nursing Home Drugs H-280.959
Our AMA supports the return and reuse of medications to the dispensing pharmacy to reduce waste associated with unused medications in long-term care facilities (LTCFs) and to offer substantial savings to the health care system, provided the following conditions are satisfied: (1) The returned medications are not controlled substances. (2) The medications are dispensed in tamper-evident packaging and returned with packaging intact (e.g., unit dose, unused injectable vials and ampules). (3) In the professional judgment of the pharmacist, the medications meet all federal and state standards for product integrity. (4) Policies and procedures are followed for the appropriate storage and handling of medications at the LTCF and for the transfer, receipt, and security of medications returned to the dispensing pharmacy. (5) A system is in place to track re-stocking and reuse to allow medications to be recalled if required. (6) A mechanism (reasonable for both the payer and the dispensing LTC pharmacy) is in place for billing only the number of doses used or crediting the number of doses returned, regardless of payer source. CSA Rep. 2, I-97 Reaffirmed: BOT Rep. 33, A-07 Modified and Reaffirmed: CSAPH Rep. 3, A-07 Reaffirmation A-09

See also:
Medications Return Program H-135.925
Contamination of Drinking Water by Pharmaceuticals and Personal Care Products D-135.993
Proper Disposal of Unused Prescription and Over-the-Counter (OTC) Drugs H-135.936

Whereas, “Police officers are more risk averse and cautious about their actions when wearing on-officer video technology,” with studies showing a 53% decrease in response-to-resistance incidents and a 59% decrease in use-of-force incidents;¹ ² ³ and

Whereas, Police officers using body-worn cameras are about half as likely to use force compared to officers who didn’t have body-worn cameras;⁴ and

Whereas, During the course of a study, police officers using body-worn cameras experienced a 47.7% decline in the number of complaints received, compared to a 7.4% decline in the number of complaints received by a control group of officers not wearing body-cameras;⁵ and

Whereas, After using body-worn cameras, most police officers agree that use of a body-worn camera “provides a more accurate account of an incident” and “improves the quality of evidence”;⁶ and

Whereas, Our AMA has affirmed 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” (AMA Policy H-515.955); and

Whereas, Existing AMA policy states that our AMA will “facilitate the development and implementation of a comprehensive, long-range, coordinated strategy to address issues and concerns affecting minorities, including minority health,” including the “development, coordination, and strengthening of AMA resources devoted to minority health issues” (H-350.971); therefore be it

RESOLVED, That our American Medical Association advocate for legislative, administrative, or regulatory measures to expand funding for (1) the purchase of body-worn cameras and (2) training and technical assistance required to implement body-worn camera programs. (New HOD Policy)

² Wesley G. Jennings, Mathew D. Lynch, Lorie A. Fridell, Evaluating the impact of police officer body-worn cameras (BWCs) on response-to-resistance and serious external complaints: Evidence from the Orlando police department (OPD) experience utilizing a randomized controlled experiment, Journal of Criminal Justice, 2015, Pages 480-486, ISSN 0047-2352
Fiscal Note: Minimal - less than $1,000.

Received: 09/20/17

**RELEVANT AMA POLICY**

- Research the Effects of Physical or Verbal Violence Between Law Enforcement Officers and Public Citizens on Public Health Outcomes H-515.955
- Initiatives Regarding Minorities H-350.971
- Use of Conducted Electrical Devices by Law Enforcement Agencies H-145.977
- Guns in Hospitals H-215.977
WHEREAS, EMR mandates do not increase relative value unit (RVU) values; and

WHEREAS, There are unfunded mandates for quality; and

WHEREAS, Funding was approved as appropriate before sequester; therefore be it

RESOLVED, That our American Medical Association advocate to remove the sequester provision for Part B Medicare reimbursement. (Directive to Take Action)

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

Received: 09/26/17
Whereas, The merit-based incentive payment system (MIPS) is a very complicated, burdensome payment system developed by the Centers for Medicare & Medicaid Services; and

Whereas, Small practices do not have the time and financing to understand and implement this program; and

Whereas, MIPS will essentially force small, independent practices out of business; therefore be it

RESOLVED, That our American Medical Association advocate for a policy that exempts self-employed small practices, defined as solo practitioners up to five physician providers, from the burdensome regulation of the merit-based incentive payment system (MIPS). (Directive to Take Action)

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

Received: 09/26/17
Whereas, States have some ability to approve and regulate methadone clinics. In Indiana, the federal government has ultimate control of methadone clinics location, size and operations; and

Whereas, Some federal methadone clinic policies contrast with the policies desired by the state. The best example of this is the rule that does not require participants of methadone clinics to be reported in the state controlled substances database. Therefore, some individuals have gone to two methadone clinics at the same time. They would take one clinic’s medication and sell the other’s take home medication. Another example relates to past issues with drug rehab and counseling at Indiana methadone clinics. In some cases, it was quite minimal with majority of the visits dedicated to the transaction of selling an opioid and collecting payment. Additionally, larger clinics don’t necessarily offer benefit to patients with size increasing the possibility of logistical problems and possibly making the visit process less personable and less therapeutic. Clark County Indiana is home to the largest methadone clinic in the country with over 1,600 active clients; and

Whereas, State control of the methadone clinics would allow local decisions about size, location, and operational rules and regulations; and

Whereas, Many recommendations have been made by the states over the years related to improving methadone clinic operations, and yet many of these have not been adopted by federal regulators; and

Whereas, A segment of the opioid-addicted population will never be able to be opioid abstinent. It is therefore acknowledged that methadone clinics provide a valuable service to opioid-addicted individuals; therefore be it

RESOLVED, That our American Medical Association support complete state control of all aspects of methadone clinic approval and operations; and, if deemed necessary, this control could be granted on a state by state basis. (Directive to Take Action)

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

Received: 09/26/17
Whereas, The lack of transparency of prices for medical services and drugs at point of service is a burden for both physicians and patients; and

Whereas, Prices for medical services vary greatly across the country; and

Whereas, Patients have the right to discuss with their physicians the benefits, risks, and costs of all treatment options; and

Whereas, Lack of transparency prevents physician and patient from discussing expected costs for services and treatments and can potentially foster a sense of distrust between the patient and physician; and

Whereas, In specific states insurers can have gag clauses in contracts preventing disclosure of pricing information and claims data; and

Whereas, These arrangements affect hospital-based and other employed physician’s ability to develop rational prices, price transparency, appropriately discount, and use customary price discrimination for services; and

Whereas, There is the opportunity for the AMA to take the lead on state level bills targeting this issue; therefore be it

RESOLVED, That our American Medical Association work with states and state medical societies to reduce health insurance contract provisions or gag clauses that restrict disclosure of pricing information to patients (Directive to Take Action); and be it further

RESOLVED, That our AMA work with states and state medical societies to ensure that health insurance contracts do not prohibit the application of discounts to uninsured or under-insured patients if such discounts are compliant with federal anti-kickback statutes (Directive to Take Action); and be it further

RESOLVED, That our AMA support access to real-time prescription drug pricing and cost transparency at the point of prescribing. (New HOD Policy)

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

Received: 09/29/17

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 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

Appropriate Hospital Charges H-155.958
Our AMA encourages hospitals to adopt, implement, monitor and publicize policies on patient discounts, charity care, and fair billing and collection practices, and make access to those programs readily available to eligible patients.
Citation: (CMS Rep. 4, A-09)

Physicians’ Freedom to Establish Their Fees H-380.994
Our AMA (1) affirms that it is a basic right and privilege of each physician to set fees for service that are reasonable and appropriate, while always remaining sensitive to the varying resources of patients and retaining the freedom to choose instances where courtesy or charity could be extended in a dignified and ethical manner; (2) supports the concept that health insurance should be treated like any other insurance (i.e., a contract between a patient and a third party for indemnification for expense or loss incurred by virtue of obtaining medical or other health care services); and (3) believes that the contract for care and payment is between the physician and patient.
Citation: (BOT Rep. JJ, I-83; Reaffirmed: CLRPD Rep. 1, I-93; Reaffirmed: Sub. Res. 704 and Reaffirmation A-01; Reaffirmation A-09)
AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 214
(I-17)


Subject: APRN Compact

Referred to: Reference Committee B
(Ralph J. Nobo, Jr., MD, Chair)

Whereas, Our AMA continues to advocate that physicians are best qualified by their education and training to lead the health care team; and

Whereas, In 2015, the National Council of the State Boards of Nursing (NCSBN) approved state model legislative language entitled the “APRN Compact,” which would create multistate licensure for APRNs (Advanced Practice Registered Nurses); and

Whereas, The APRN Compact would authorize APRNs with this multistate license to practice in other party states without going through state-by-state licensing; and

Whereas, The APRN Compact eliminates physician involvement requirements for APRNs practicing in a state under a multistate license through Article III, Section (h), which provides:

“An APRN issued a multistate license is authorized to assume responsibility and accountability for patient care independent of a supervisory or collaborative relationship with a physician. This authority may be exercised in the home state and in any remote state in which the APRN exercises a multistate licensure privilege.”; and

Whereas, The APRN Compact exclusively references the title “APRN” without defining the term allowing then a state that has granted the APRN title the Compact to authorize practice without physician involvement under a multistate license, regardless existing state law; and

Whereas, The APRN Compact requires only ten states to enact the Compact into law before it goes into effect. Two states (Idaho and Wyoming) passed this legislation into law in 2016, and North Dakota passed it into law in 2017; and

Whereas, The APRN Compact establishes an “Interstate Commission” that will take many licensing decisions away from state legislatures and state boards of nursing, creating rulemaking that is legally binding in all party states, including scope of practice and population foci; therefore be it
RESOLVED, That our American Medical Association convene an in-person meeting of relevant stakeholders to initiate a national strategy to address the APRN (Advanced Practice Registered Nurses) Compact. (Directive to Take Action)

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

Received: 09/29/17

REFERENCES

RELEVANT AMA POLICY

Support for Physician Led, Team Based Care D-35.985
Our AMA:
2. Will identify and review available data to analyze the effects on patients? access to care in the opt-out states (states whose governor has opted out of the federal Medicare physician supervision requirements for anesthesia services) to determine whether there has been any increased access to care in those states.
3. Will identify and review available data to analyze the type and complexity of care provided by all non-physician providers, including CRNAs in the opt-out states (states whose governor has opted out of the federal Medicare physician supervision requirements for anesthesia services), compared to the type and complexity of care provided by physicians and/or the anesthesia care team.
4. Will advocate to policymakers, insurers and other groups, as appropriate, that they should consider the available data to best determine how non-physicians can serve as a complement to address the nation's primary care workforce needs.
5. Will continue to recognize non-physician providers as valuable components of the physician-led health care team.
6. Will continue to advocate that physicians are best qualified by their education and training to lead the health care team.
7. Will call upon the Robert Wood Johnson Foundation to publicly announce that the report entitled, "Common Ground: An Agreement between Nurse and Physician Leaders on Interprofessional Collaboration for the Future of Patient Care" was premature; was not released officially; was not signed; and was not adopted by the participants.
Citation: BOT Rep. 9, I-11; Reaffirmed: CMS Rep. 1, A-12; Reaffirmed: CMS Rep. 07, A-17
Whereas, Studies have shown that direct costs to living organ donors average approximately $5,000.00, which is greater than one month’s wage for 76 percent of donors; and

Whereas, Between 25 to 30 percent of donors do not have sufficient medical leave and/or vacation time to accommodate their recovery; and

Whereas, Approximately 30 percent of living organ donors are persons of ethnic minorities who have been shown to be at greater risk of financial impacts both pre- and post-donation; and

Whereas, Financial burdens for living kidney donors have been shown to increase risk of depression and lower satisfaction of life scores after surgery; and

Whereas, 83 percent of living kidney donors surveyed in Canada reported an inability to perform household tasks after the surgery for an average of 33 days; and

Whereas, On average, living kidney donors report 252 hours of lost work due to donation; and

Whereas, It takes four to six weeks for a donor to make a full recovery, and during this time it is recommended they rest as much as possible; and

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4 Purnell TST. Advances in chronic kidney disease: Understanding and overcoming barriers to living kidney donation among racial and ethnic minorities in the United States. WB Saunders Company; 07/2012;19:244.
Whereas, Federal law grants federal employees seven days paid leave for bone marrow
donation and 30 days for organ donation in addition to annual and sick leave\(^{10}\); and

Whereas, The Living Donor Protection Act of 2016 (S.2584) would prevent the discrimination of
living organ donors in conferring insurance and rectify the Family and Medical Leave Act of
1993 to “include living organ donation as a serious health issue that entitles a covered
employee to leave...”\(^{11}\); and

Whereas, Laws in 31 states allow state employees some increment of paid leave for living
organ donation; laws in 20 states offer tax deductions to donors and in some cases private
employers; and, laws in eight states mandate paid leave from private employers\(^{12,13}\); therefore
be it

RESOLVED, That our American Medical Association amend Policy, H-370.965, “Removing
Financial Barriers to Living Organ Donation,” by addition and deletion as follows:

Our AMA supports federal and state laws that remove financial barriers to living organ
donation, such as: (1) provisions for expenses involved in the donation incurred by the
organ donor, (2) providing access to health care coverage for any medical expense
related to the donation, (3) prohibiting employment discrimination on the basis of living
donor status, and (4) prohibiting the use of living donor status as the sole basis for
denying health and life insurance coverage, and (5) provisions to encourage paid leave
for organ donation (Modify Current HOD Policy); and be it further

RESOLVED, That our AMA support legislation expanding paid leave for organ donation. (New
HOD Policy)

Fiscal Note: Minimal - less than $1,000.

Received: 09/29/17

RELEVANT AMA POLICY:

Removing Financial Barriers to Living Organ Donation H-370.965
Our AMA supports federal and state laws that remove financial barriers to living organ donation,
such as: (1) provisions for expenses involved in the donation incurred by the organ donor, (2)
providing access to health care coverage for any medical expense related to the donation, (3)
prohibiting employment discrimination on the basis of living donor status, and (4) prohibiting the
use of living donor status as the sole basis for denying health and life insurance coverage.
Citation: (BOT Rep. 15, A-12)

\(^{10}\) U.S. Office of Personnel Management. (2016) “Bone Marrow or Organ Donor Leave. 5 U.S.C. 6327” Available at:
Accessed December 1, 2016.

\(^{11}\) Living Donor Protection Act of 2016. S.2584. 114th Congress (2015-2016)

\(^{12}\) U.S. Department of Health & Human Services. (2010) “State Organ Donor Legislation” Available at:

\(^{13}\) National Kidney Foundation. (2016) “Donor Leave Laws and Tax Deductions/Credits for Living Donors” Available at:
Whereas, Medicine is undergoing unprecedented changes; and

Whereas, New care delivery and reimbursement models measure physicians on their population-level performance; and

Whereas, Physicians are best situated to lead the charge as the American health care system transitions into new era of enhanced clinical integration, collaboration, and system sophistication; therefore be it

RESOLVED, That our American Medical Association continue to consider and implement the most strategic and sustainable approaches to collaborate and engage with the US Department of Health and Human Services to: (1) advance and advocate for policies of importance to physicians and patients; (2) promote physician leadership in emerging health care organizational and reimbursement structures; and (3) enhance the opportunity for physician input. (Directive to Take Action)

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

Received: 09/29/17

RELEVANT AMA POLICY

Health System Reform Legislation H-165.838
1. Our American Medical Association is committed to working with Congress, the Administration, and other stakeholders to achieve enactment of health system reforms that include the following seven critical components of AMA policy:
   a. Health insurance coverage for all Americans
   b. Insurance market reforms that expand choice of affordable coverage and eliminate denials for pre-existing conditions or due to arbitrary caps
   c. Assurance that health care decisions will remain in the hands of patients and their physicians, not insurance companies or government officials
   d. Investments and incentives for quality improvement and prevention and wellness initiatives
   e. Repeal of the Medicare physician payment formula that triggers steep cuts and threaten seniors’ access to care
   f. Implementation of medical liability reforms to reduce the cost of defensive medicine
   g. Streamline and standardize insurance claims processing requirements to eliminate unnecessary costs and administrative burdens
2. Our American Medical Association advocates that elimination of denials due to pre-existing conditions is understood to include rescission of insurance coverage for reasons not related to fraudulent representation.
3. Our American Medical Association House of Delegates supports AMA leadership in their unwavering and bold efforts to promote AMA policies for health system reform in the United States.
4. Our American Medical Association supports health system reform alternatives that are consistent with AMA policies concerning pluralism, freedom of choice, freedom of practice, and universal access for patients.

5. AMA policy is 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.

6. Our AMA will actively and publicly support the inclusion in health system reform legislation the right of patients and physicians to privately contract, without penalty to patient or physician.

7. Our AMA will actively and publicly oppose the Independent Medicare Commission (or other similar construct), which would take Medicare payment policy out of the hands of Congress and place it under the control of a group of unelected individuals.

8. Our AMA will actively and publicly oppose, in accordance with AMA policy, inclusion of the following provisions in health system reform legislation:
   a. Reduced payments to physicians for failing to report quality data when there is evidence that widespread operational problems still have not been corrected by the Centers for Medicare and Medicaid Services
   b. Medicare payment rate cuts mandated by a commission that would create a double-jeopardy situation for physicians who are already subject to an expenditure target and potential payment reductions under the Medicare physician payment system
   c. Medicare payments cuts for higher utilization with no operational mechanism to assure that the Centers for Medicare and Medicaid Services can report accurate information that is properly attributed and risk-adjusted
   d. Redistributed Medicare payments among providers based on outcomes, quality, and risk-adjustment measurements that are not scientifically valid, verifiable and accurate
   e. Medicare payment cuts for all physician services to partially offset bonuses from one specialty to another
   f. Arbitrary restrictions on physicians who refer Medicare patients to high quality facilities in which they have an ownership interest

9. Our AMA will continue to actively engage grassroots physicians and physicians in training in collaboration with the state medical and national specialty societies to contact their Members of Congress, and that the grassroots message communicate our AMA's position based on AMA policy.

10. Our AMA will use the most effective media event or campaign to outline what physicians and patients need from health system reform.

11. AMA policy is that national health system reform must include replacing the sustainable growth rate (SGR) with a Medicare physician payment system that automatically keeps pace with the cost of running a practice and is backed by a fair, stable funding formula, and that the AMA initiate a "call to action" with the Federation to advance this goal.

12. AMA policy is that creation of a new single payer, government-run health care system is not in the best interest of the country and must not be part of national health system reform.

13. AMA policy is that effective medical liability reform that will significantly lower health care costs by reducing defensive medicine and eliminating unnecessary litigation from the system should be part of any national health system reform.

Citation: Sub. Res. 203, I-09; Reaffirmation A-10; Reaffirmed in lieu of Res. 102, A-10; Reaffirmed in lieu of Res. 228, A-10; Reaffirmed: CMS Rep. 2, I-10; Reaffirmed: Sub. Res. 222, I-10; Reaffirmed: CMS Rep. 9, A-11; Reaffirmation A-11; Reaffirmed: CMS Rep. 6, I-11; Reaffirmed in lieu of Res. 817, I-11; Reaffirmation I-11; Reaffirmation A-12; Reaffirmed in lieu of Res. 108, A-12; Reaffirmed: Res. 239, A-12; Reaffirmed: Sub. Res. 813, I-13; Reaffirmed: CMS Rep. 9, A-14; Reaffirmation A-15; Reaffirmed in lieu of Res. 215, A-15; Reaffirmation: A-17; Reaffirmed in lieu of: Res. 712, A-17;

Increasing Collaboration Between Physicians and the Public to Address Problems in Health Care Delivery H-160.904
Our American Medical Association will continue to consider and implement the most strategic and sustainable approaches to stay engaged with physician and non-physician stakeholders essential to our endeavor to improve the delivery of quality medical care.

Citation: Res. 612, A-15; Modified: BOT Rep. 18, A-16;
Whereas, The US Food and Drug Administration may be considering new rules regarding the repair of medical tools, equipment, and instruments; and

Whereas, There are indications that some individuals believe that the repair of medical tools, equipment, and instruments by non-factory authorized service personnel increases the risk of failure of the device; and

Whereas, There is no scientific data to show that medical tools, equipment, and instruments that have been repaired or refurbished by non-factory/manufacturer authorized service personnel pose any greater safety risk than those repaired by factory/manufacturer authorized personnel; and

Whereas, There have been suggestions that persons engaged in the repair and/or refurbishment of medical tools, equipment, and instruments should be licensed; and

Whereas, There is no evidence to show that licensing guarantees competency; and

Whereas, Additional rules and regulations regarding the repair and refurbishment of medical tools, equipment, and instruments could increase the cost of health care without offering any benefit to patients; therefore be it

RESOLVED, That our American Medical Association strongly oppose any rules or regulations regarding the repair or refurbishment of medical tools, equipment, and instruments that are not based on objective scientific data. (New HOD Policy)

Fiscal Note: Minimal - less than $1,000.

Received: 09/29/17
RELEVANT AMA POLICY

Medical Device Safety and Physician Responsibility H-480.972
The AMA supports: (1) the premise that medical device manufacturers are ultimately responsible for conducting the necessary testing, research and clinical investigation and scientifically proving the safety and efficacy of medical devices approved by the Food and Drug Administration; and (2) conclusive study and development of Center for Devices and Radiological Health/Office of Science and Technology recommendations regarding safety of article surveillance and other potentially harmful electronic devices with respect to pacemaker use..
Citation: (Res. 507, I-95; Res. 509, A-96; Appended Res. 504, A-99; Reaffirmed: CSAPH Rep. 1, A-09)

Medical Device Amendments of the FDA H-480.996
(1) The AMA reiterates its concerns regarding the implementation of the Medical Device Amendments to the Food and Drug Administration (FDA) and urges that regulations be promulgated or interpreted so as to: (a) not interfere with the physician-patient relationship; (b) not impose regulatory burdens that may discourage creativity and innovation in advancing device technology; (c) not change the character and mandate of existing Institutional Review Boards to unnecessarily burden members of the IRB’s and clinical investigators; (d) not raise the cost of medical care and new medical technology without any concomitant benefit or additional safeguards being provided the patients; and (e) not interfere with patient records’ confidentiality. (2) The AMA urges that existing mechanisms to assure ethical conduct be used to minimize burdensome reporting requirements and keep enforcement costs to a minimum for patients, health care providers, industry and the government.
Citation: (Res. 146, A-80; Reaffirmed: CLRPD Rep. B, I-90; Reaffirmed: Sunset Report, I-00; Reaffirmed: BOT Rep. 6, A-10)

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.
Whereas, The American Medical Association has numerous and extensive policy on electronic health records (EHRs) that support current advocacy efforts to improve EHRs and advance health information technology (HIT); and

Whereas, This body of existing policy has helped the AMA make progress in persuading policy-makers and other stakeholders that greater attention is needed on issues such as flexibility, EHR usability, and security; and

Whereas, While AMA policy on HIT continues to guide current and ongoing efforts, the AMA’s fundamental principles on information technology have never been codified in their entirety as AMA policy; and

Whereas, Clear and concise principles should be set forth to outline what HIT should seek to accomplish and give voice to what physicians feel is missing from current technology-enabled solutions; therefore be it

RESOLVED, That our American Medical Association adopt and promote the development of effective electronic health records in accordance with the following health information technology principles:

1. Whenever possible, physicians should have direct control over choice and management of the information technology used in their practices.

2. Information technology available to physicians must be safe (e.g., electronically secure, and in the case of distributed devices, physically so), effective and efficient.

3. Information technology available to physicians should support the physician’s obligation to put the interests of patients first.

4. Information technology available to physicians should support the integrity and autonomy of physicians.

5. Information technology should support the patient’s autonomy by providing access to that individual’s data.

6. There should be no institutional or administrative barriers between physicians and their patients’ health data.

7. Information technology should promote the elimination of health care disparities.

8. The cost of installing, maintaining and upgrading information technology should be specifically acknowledged and addressed in reimbursement schedules on an ongoing basis; payments should ensure sustainability of such systems in practice.

(New HOD Policy)

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

Received: 10/02/17
RELEVANT AMA POLICY

National Health Information Technology D-478.995
1. Our AMA will closely coordinate with the newly formed Office of the National Health Information Technology Coordinator all efforts necessary to expedite the implementation of an interoperable health information technology infrastructure, while minimizing the financial burden to the physician and maintaining the art of medicine without compromising patient care.
2. Our AMA: (A) advocates for standardization of key elements of electronic health record (EHR) and computerized physician order entry (CPOE) user interface design during the ongoing development of this technology; (B) advocates that medical facilities and health systems work toward standardized login procedures and parameters to reduce user login fatigue; and (C) advocates for continued research and physician education on EHR and CPOE user interface design specifically concerning key design principles and features that can improve the quality, safety, and efficiency of health care.; and (D) advocates for more research on EHR, CPOE and clinical decision support systems and vendor accountability for the efficacy, effectiveness, and safety of these systems.
3. Our AMA will request that the Centers for Medicare & Medicaid Services: (A) support an external, independent evaluation of the effect of Electronic Medical Record (EMR) implementation on patient safety and on the productivity and financial solvency of hospitals and physicians’ practices; and (B) develop minimum standards to be applied to outcome-based initiatives measured during this rapid implementation phase of EMRs.
4. Our AMA will (A) seek legislation or regulation to require all EHR vendors to utilize standard and interoperable software technology components to enable cost efficient use of electronic health records across all health care delivery systems including institutional and community based settings of care delivery; and (B) work with CMS to incentivize hospitals and health systems to achieve interconnectivity and interoperability of electronic health records systems with independent physician practices to enable the efficient and cost effective use and sharing of electronic health records across all settings of care delivery.
5. Our AMA will seek to incorporate incremental steps to achieve electronic health record (EHR) data portability as part of the Office of the National Coordinator for Health Information Technology’s (ONC) certification process.
6. Our AMA will collaborate with EHR vendors and other stakeholders to enhance transparency and establish processes to achieve data portability.
7. Our AMA will directly engage the EHR vendor community to promote improvements in EHR usability.
8. Our AMA will advocate for appropriate, effective, and less burdensome documentation requirements in the use of electronic health records.

Information Technology Standards and Costs D-478.996
Our AMA will:
(1) encourage the setting of standards for health care information technology whereby the different products will be interoperable and able to retrieve and share data for the identified important functions while allowing the software companies to develop competitive systems;
(2) work with Congress and insurance companies to appropriately align incentives as part of the development of a National Health Information Infrastructure (NHII), so that the financial burden on physicians is not disproportionate when they implement these technologies in their offices;
(3) review the following issues when participating in or commenting on initiatives to create a NHII: (a) cost to physicians at the office-based level; (b) security of electronic records; and (c) the standardization of electronic systems;
(4) continue to advocate for and support initiatives that minimize the financial burden to physician practices of adopting and maintaining electronic medical records; and
(5) continue its active involvement in efforts to define and promote standards that will facilitate the interoperability of health information technology systems.

Principles for Hospital Sponsored Electronic Health Records D-478.973
1. Our AMA will promote electronic health record (EHR) interoperability, data portability, and health IT data exchange testing as a priority of the Office of the National Coordinator for Health Information Technology (ONC).
2. Our AMA will work with EHR vendors to promote transparency of actual costs of EHR implementation, maintenance and interface production.
3. Our AMA will work with the Centers for Medicare and Medicaid Services (CMS) and ONC to identify barriers and potential solutions to data blocking to allow hospitals and physicians greater choice when purchasing, donating, subsidizing, or migrating to new EHRs.
4. Our AMA will advocate that sponsoring institutions providing EHRs to physician practices provide data access and portability to affected physicians if they withdraw support of EHR sponsorship.

Citation: (BOT Rep. 1, I-15)
AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 219
(I-17)

Introduced by: Maryland

Subject: Certified EMR Companies' Practice of Charging Fees for Regulatory Compliance

Referred to: Reference Committee B
(Ralph J. Nobo, Jr., MD, Chair)

Whereas, Physician practices acquire EMR systems which have demonstrated the technological capability, functionality, and security requirements required by the Secretary of Health and Human Services and have received certification by the Office of the National Coordinator; and

Whereas, Acquisition of the hardware and EMR software are a significant expense to the practice; and

Whereas, Physician practices are required to use certified EMR systems for participation in various government programs and with third party payors; and

Whereas, Government changes the requirements for participation in the various programs requiring updates in EMR software; and

Whereas, In many cases, EMR vendors pass on the cost of these updates to the physician practice; therefore be it

RESOLVED, That our American Medical Association advocate for policy requiring EMR vendors to absorb the cost of software updates required for compliance and participation in government and third-party programs, instead of passing on these expenses to physicians. (New HOD Policy)

Fiscal Note: Minimal - less than $1,000.

Received: 10/09/17
Resolved, That our American Medical Association support legislative changes to the Americans with Disabilities Act of 1990, to educate state and local government officials and property owners on strategies for promoting access to persons with a disability (New HOD Policy); and be it further...
RESOLVED, That our AMA oppose legislation amending the Americans with Disabilities Act of 1990, that would increase barriers for disabled persons attempting to file suit to challenge a violation of their civil rights. (New HOD Policy)

Fiscal Note: Minimal - less than $1,000.

Received: 10/10/17

References
H.R. 620: The ADA Education and Reform Act of 2017

RELEVANT AMA POLICY

Threats Against Physicians Based on Americans With Disabilities Act D-90.994
Our AMA encourages AMA members who are threatened with non-meritorious lawsuits, supposedly founded on the Americans with Disabilities Act, to contact the AMA's Private Sector Advocacy Group for assistance. The AMA will post a notice on its web site, informing physicians how to report such incidents.
Citation: BOT Rep. 6, I-05; Reaffirmed: BOT Rep. 10, A-15

Enhancing Accommodations for People with Disabilities H-90.971
Our AMA encourages physicians to make their offices accessible to patients with disabilities, consistent with the Americans with Disabilities Act (ADA) guidelines.
Citation: Res. 705, A-13
Whereas, It has been our AMA policy to support the doctor-patient relationship; and

Whereas, The goal of prescription benefit managers is to reduce the use of costly medications without respect to the patient’s condition or the judgment of the patient’s doctor; and

Whereas, The doctor who has evaluated the patient and relies on years of experience and ongoing education is the best one to judge the optimum, most cost effective approach for the patient; and

Whereas, Many of the most useful medications for the treatment of some grave diseases such as ulcerative colitis and Crohn’s disease require the use of advanced technology for their development and result in costly medications; and

Whereas, It is best to use the most effective medications in the care of seriously ill patients at an early stage of their treatment before there is irreparable harm; and

Whereas, Such considerations have led the Crohn’s & Colitis Foundation, the Digestive Disease National Coalition, American Academy of Dermatology, the Arthritis Foundation, Epilepsy Foundation, Lupus and Allied Diseases Association, US Pain Foundation, American Gastroenterological Association, and Digestive Disease National Coalition to advocate for this bill on Capitol Hill this year; therefore be it

RESOLVED, That our American Medical Association support HR 2077, a bill to amend the Employee Retirement Income Security Act of 1974 to require a group health plan (or health insurance coverage offered in connection with such a plan) to provide an exceptions process for any medication step therapy protocol, and for other purposes (New HOD Policy); and be it

further

RESOLVED, That our AMA further support, as part of this legislation, that such a request shall be granted as quickly as the disease or condition of the participant or beneficiary requires, but no later than three days after the day of receipt of the request. For circumstances in which the applicable medication step therapy protocol may seriously jeopardize the life, health, or ability to regain maximum function of the participant or beneficiary, such a request shall be granted on an expedited basis, and no later than 24 hours after receipt of such request. (New HOD Policy)

Fiscal Note: Modest - between $1,000 - $5,000.
Received: 10/12/17
Whereas, For the purposes of this resolution, the term “physician” refers to a medical provider who is licensed to practice medicine; and

Whereas, Obstructive sleep apnea (OSA) is a chronic medical disease that involves the collapse or near-collapse of the upper airway during sleep despite an ongoing effort to breathe; and

Whereas, OSA afflicts nearly 30 million U.S. adults, and the prevalence of OSA has increased substantially over the last two decades and is likely to continue rising in tandem with an escalation in obesity and the aging of our population; and

Whereas, Untreated OSA is a potentially lethal disease that has a detrimental impact on health and well-being, increasing the risk of high blood pressure, cardiovascular disease, stroke, Type 2 diabetes, depression and mortality; and

Whereas, A home sleep apnea test (HSAT) is a medical assessment that may be used for the diagnosis of OSA in uncomplicated adults presenting with signs and symptoms that indicate an increased risk of moderate to severe OSA; and

Whereas, Most HSAT studies, including randomized controlled trials that are most generalizable to clinical practice, have involved accredited sleep centers and the clinical expertise of board-certified sleep medicine physicians; and

Whereas, Data suggest that sleep medicine accreditation and certification are associated with higher quality care for patients with OSA; therefore be it

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RESOLVED, That it be the policy of our American Medical Association that: (1) the diagnosis of obstructive sleep apnea (OSA) or primary snoring constitutes the practice of medicine; (2) that the need for, and appropriateness of, a home sleep apnea test (HSAT) for purposes of diagnosing OSA or primary snoring or evaluating treatment efficacy must be based on the patient’s medical history and a face-to-face examination by a physician, either in person or via telemedicine; and (3) that an HSAT is a medical assessment that must be ordered by a physician to diagnose OSA or evaluate treatment efficacy in the practice of medicine (New HOD Policy); and be it further

RESOLVED, That it be our AMA’s policy that (1) an HSAT should not be used for general screening of asymptomatic populations for OSA; (2) diagnosis of OSA, assessment of treatment efficacy, and treatment decisions must not be based solely on automatically scored HSAT data, which could lead to sub-optimal care that jeopardizes patient health and safety; and (3) for purposes of diagnosing OSA or evaluating treatment efficacy, the raw data from the HSAT device must be reviewed and interpreted by a physician who is either board-certified in sleep medicine or overseen by a board-certified sleep medicine physician (New HOD Policy); and be it further

RESOLVED, That our AMA support the legislative and regulatory efforts of interested state and specialty medical societies in opposing policies that would allow an HSAT to be ordered by a non-physician and distributed or used for purposes of diagnosing OSA or evaluating treatment efficacy without the oversight of a physician. (New HOD Policy)

Fiscal Note: Minimal - less than $1,000.

Received: 10/11/17
Whereas, The opioid epidemic has become a critical threat to public health in the U.S., with drug overdoses now the leading cause of accidental death and opioids being responsible for 61 percent of those deaths; and

Whereas, Approximately one-third of heroin users pass through correctional facilities annually and up to 60 percent of the incarcerated population has a substance use disorder; and

Whereas, Individuals recently released from prison have a high risk of overdose death, particularly during the first two weeks after release when their risk is 130 times greater than that of the non-incarcerated population; and

Whereas, Correctional facilities rarely treat opioid withdrawal with opioid agonist therapy, which is the most effective, evidence-based treatment for this condition, and rarely provide opioid agonist therapy even to inmate-patients who have been stabilized on it prior to entry, resulting in unnecessary suffering and sometimes death; and

Whereas, Effective treatment for opioid use disorder, including pharmacotherapy, improves medical and mental health outcomes and reduces spread of infectious diseases and, in the incarcerated population, reduces deaths during incarceration, reduces deaths immediately following release, and reduces recidivism; and

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Whereas, The National Commission on Correctional Health Care in a 2016 position paper\textsuperscript{12} established that evidence-based treatment of substance use disorders, including use of opioid-agonist therapy for opioid use disorder, should be provided in correctional facilities; therefore be it

RESOLVED, That our American Medical Association advocate 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 correctional facilities within the United States (New HOD Policy); and be it further

RESOLVED, That our AMA support legislation, standards, policies and funding that encourage correctional facilities within the United States to work in ongoing collaboration with addiction treatment providers, case managers, social workers, and pharmacies in the communities where patients are released to offer post-incarceration treatment plans for opioid use disorder, including education, medication for addiction treatment, and medication for preventing overdose deaths. (New HOD Policy)

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

Received: 10/12/17

Whereas, More than 100,000 people in the United States die annually of alcohol or drug-related causes, making it the fourth leading cause of preventable death\(^1\); and

Whereas, Other mental and physical illnesses commonly co-occur with alcohol and drug use\(^2\); and

Whereas, The federal statutes authorizing the current regulations governing the confidentiality of drug and alcohol treatment and prevention records, 42 CFR Part 2, were written more than 40 years ago; and

Whereas, Major changes in the organization and financing of substance use disorder treatment have occurred since then, including integrated health systems and electronic medical records; and

Whereas, The Health Insurance Portability and Accountability Act (HIPAA), the HIPAA Privacy Rule, the Affordable Care Act (ACA), and the Health Information Technology for Economic and Clinical Health (HITECH) Act have created consistent privacy and security standards for the exchange of health information for treatment, payment, and health care operations, and established protections against disclosure of health information without patient consent; and

Whereas, 42 CFR Part 2 now creates obstacles to safe, quality care for persons with substance use disorder; and

Whereas, Persons with substance use disorder continue to face stigma and discrimination in civil society, and unauthorized disclosure of their medical records may result in adverse employment, housing, public benefit, or child custody actions; therefore be it


RESOLVED, That our American Medical Association seek regulatory and legislative changes that better balance patients’ privacy protections against the need for health professionals to be able to offer appropriate medical services to patients with substance use disorders (Directive to Take Action); and be it further

RESOLVED, That our AMA seek regulatory and legislative changes that enable physicians to fully collaborate with all clinicians involved in providing health care services to patients with substance use disorders (Directive to Take Action); and be it further

RESOLVED, That our AMA support continued protections against the unauthorized disclosure of substance use disorder treatment records outside the healthcare system. (New HOD Policy)

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

Received: 10/12/17
Whereas, The Medicare Quality Payment Program (QPP), authorized under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), was passed in bipartisan fashion; and

Whereas, Most physicians eligible for QPP initially fall under the Merit-Based Incentive Payment System (MIPS), a competitive composite score which would adjust Medicare payments based on calculated quality; and

Whereas, MIPS bonuses or penalties under the statute initially reflected +/- 4% of the Physician Fee Schedule, increasing to +/- 9% in subsequent years; and

Whereas, The CMS 2018 QPP Proposed Rule subjects Medicare Part B drug reimbursement to MIPS adjustments, representing a fundamental departure both from previous CMS programs (such as the Value-Based Payment Modifier) as well as the intent of Congress; and

Whereas, Physicians largely do not control the pass-through costs associated with Part B drugs, with inclusion of drug costs unfairly amplifying the bonus or penalty in specialties which administer high-cost drugs; and

Whereas, The median financial impact for practices in some specialties under the proposal is estimated to range from approximately 16% to 29%, well beyond the Congressionally enacted 4% penalty, cuts which would bankrupt practices receiving negative adjustments; and

Whereas, The inclusion of Part B drugs unjustly punishes or rewards specialties with high utilization of drugs critical to the treatment of their patient and exacerbates the range of payments adjustments established in law; therefore be it

RESOLVED, That our American Medical Association continue work with impacted specialties to actively lobby the federal government to exclude Medicare Part B drug reimbursement from the Merit-Based Incentive Payment System (MIPS) payment adjustment as part of the Quality Payment Program (QPP). (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000.
RELEVANT AMA POLICY

Preserving a Period of Stability in Implementation of the Medicare Access and Children's Health Insurance Program (CHIP) Reauthorization Act (MACRA) D-390.950

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.

Citation: Res. 242, A-16;
Whereas, Nationally, spending on prescription drugs comprise an estimated 17 percent of total health care costs;¹ and

Whereas, After accounting for discounts/rebates, drug spending is an estimated average of 10 to 15 percent higher in the United States than in Canada, France, and Germany;² and

Whereas, Patients are affected by high prescription drug costs particularly when cost-containment strategies shift more costs to patients in the form of higher co-payments/cost sharing, causing higher patient cost exposure, which can reduce patient adherence, and lead to negative health outcomes;³ and

Whereas, The Homeland Security Appropriations Act of 2007 prohibits customs and border security funding to be used to prevent a person from importing a prescription drug from Canada that would otherwise comply with FDA standards--if the medication is “on their person,” for personal-use only, and if the quantity does not exceed a 90-day supply; and

Whereas, The requirement that personally-imported prescription drugs from Canada must otherwise comply with FDA standards can trigger FDA review; and

Whereas, The FDA has issued enforcement guidelines that allow FDA staff who receive referrals of imported drug cases from customs and border personnel to use their discretion and on a case-by-case basis to allow entry of otherwise illegal FDA-regulated products when the quantity and purpose are clearly for personal use, and the product does not present an unreasonable risk to the use;⁴ and

Whereas, Although the 2003 Medicare Modernization Act authorized the development of regulations that would allow waivers for individual drug importation, no Secretary of Health and Human Services has issued such waivers; and

⁴ US Food and Drug Administration. Information on Importation of Drugs. Prepared by the Division of Import Operations and Policy, FDA (available online at https://www.fda.gov/forindustry/importprogram/ucm173751.htm)
Whereas, The current legal climate appears to offer some enforcement discretion, but the personal importation of prescription drugs from Canada remains illegal and there is no guarantee of protection for individuals who do so; and

Whereas, The Safe and Affordable Drugs from Canada Act, bipartisan legislation authored by Sen. Klobuchar (MN) and Sen. McCain (AZ), would allow individuals to import into the US a personal supply of prescription drugs from an approved Canadian pharmacy and dispensed by a licensed pharmacist; and

Whereas, Personal drug importation from Canada will not solve the problem of prescription drugs prices, but incremental efforts deserve support; and

Whereas, Current AMA Policy D-110.983 specifically addresses importation by drug wholesalers and importation via Internet sales, it does not address the issue of importation from a Canadian pharmacy for personal use only; therefore be it

RESOLVED, That our American Medical Association support legislation that would allow for the personal purchase and importation of prescription drugs obtained directly from a licensed Canadian pharmacy, provided such drugs are for personal use and of a limited quantity. (New HOD Policy)

Fiscal Note: Minimal - less than $1,000.

Received: 10/12/17

RELEVANT AMA POLICY

Prescription Drug Importation and Patient Safety D-100.983

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; and
(4) educate its members regarding the risks and benefits associated with drug importation and reimportation efforts.

Citation: BOT Rep. 3, I-04; Reaffirmation A-09; Reaffirmed in lieu of: Res. 817, I-16
Reference Committee F

BOT Report(s)
10 High Cost to Authors for Open Source Peer Reviewed Publications

CLRDPD Report(s)
01* Senior Physicians Section Five-Year Review

Resolution(s)
601 Physician Burnout and Wellness Challenges

* included in the Handbook Addendum
At the 2017 Annual Meeting, the House of Delegates referred Resolution 604, “High Cost to Authors for Open Source Peer Reviewed Publications,” to the Board of Trustees. Resolution 604, introduced by the Pennsylvania Delegation, asked:

That our American Medical Association (AMA) investigate the high dollar costs open source publication rules currently present to the dissemination of research, especially by less well-funded and/or smaller entities; and

That our AMA make recommendations to correct the imbalance of knowledge suppression based solely on financial considerations.

It is important to note that the above resolution indirectly addresses the Open Access Movement (OA) and the fees associated with OA journals. Our AMA publishes some journals that charge these fees. This report aims to explain OA and our AMA’s involvement with this practice.

Additionally, our House of Delegates has adopted relevant policy. Policy G-630.090, AMA Publications, “affirms that JAMA and The JAMA Network journals shall continue to have full editorial independence as set forth in the AMA Editorial Governance Plan.”

BACKGROUND ON THE OPEN ACCESS MOVEMENT

OA refers to research published online that is free of all restrictions on access (e.g., subscriptions and other usage fees) and of some restrictions of use (e.g., certain copyright and license restrictions). Widespread public access to the internet in the late 1990s and early 2000s fueled the OA movement.

Active debate over the economics and reliability of various ways of providing OA continues among researchers, academics, librarians, university administrators, government officials, publishers, and editorial staff. Still, OA is gaining acceptance, and many US and all EU research funders now require that journals offer OA options to the authors supported by their grants.

Conventional non-open access journals cover publishing costs through fees, such as subscriptions, site licenses, and pay-per-view charges. However, OA journals do not sell subscriptions, charge for site licenses, or sell advertising. Their only revenue is from Article Processing Charges (APCs), which help cover costs to review, edit, process, distribute, and host the articles online. These fees
typically range between $3,000 and $5,000 per document. Therefore, OA journals shift the expense of publishing to the investigators and authors.

OPEN ACCESS AND THE JAMA NETWORK®

*JAMA* does not offer OA in exchange for APCs. All original research articles published in *JAMA* are made free to everyone six months after the official date of publication, whether or not the research was publicly funded by the National Institutes of Health (NIH). This release date is well within the NIH Public Access Policy’s mandate of 12 months. All specialty journal original research articles are released for public availability after an embargo period of 12 months in accordance with the NIH Public Access Policy.

With the launch of *JAMA Oncology* in 2015, however, our AMA began to offer an OA option to authors. Through a “hybrid” journal model, authors whose research funders require OA are able to choose the OA option. Our AMA charges APCs around $4,500 to $5,000. However, authors who cannot or do not want to pay for the OA option are not required to pay anything. Approximately 10% of authors to date have chosen the OA option. Generally, funders, not authors, desire OA, and the vast majority of authors select the conventional subscription model.

Because this hybrid model approach appears to balance the demands of funders, changing markets, and business models, it was extended to *JAMA Cardiology*, which was launched in 2016. This model also recognizes the needs and limited resources of independent researchers and authors. Therefore, the hybrid model approach was applied to all 11 of our AMA’s specialty journals across The JAMA Network on April 1, 2017.

DISCUSSION OF THE RESOLVEDS

The reference committee rightfully believed that our AMA is not in a position to direct or recommend that other medical journal publishers reduce or eliminate their OA fees, especially when fees are a necessary component of OA model journals. Likewise, our AMA cannot instruct international research funders to abandon their OA requirements and support only subscription based journals.

Our AMA Publishing division has investigated the range of OA fees charged by commercial and medical society publishers; the fee charged by The JAMA Network specialty journals falls within this spectrum. The JAMA Network journals require adequate revenue to process, peer review, and publish articles of high quality. As such, current OA fees of $4,500 to $5,000 are reasonable, given journal production and hosting expenses. Moreover, our AMA continues to offer a no-fee option for authors, while providing the OA option for research funders that require and will pay for OA.

Further still, according to a recent investigation commissioned by our AMA, several OA journals, whether purely OA or a hybrid, offer discounts or waivers for their APCs. Discounts or waivers are often considered on a case-by-case basis or offered to authors from low-income or developing countries, based on the HINARI Access to Research Initiative or World Bank figures. This finding highlights the idea that many publishers are cognizant of some authors’ financial hardships and are willing to consider each author on an individual basis.

During testimony on the resolution, concern with “predatory publishers” emerged as a central theme. While this concern about predatory publishers is not found in the resolution itself, it became a significant focus of testimony, with findings and materials on predatory publishers entered into testimony. Predatory publishers, as they have come to be known, hold themselves out as OA
journals and purport to offer traditional services, such as peer review, editing, and publication in return for APCs. Unfortunately, authors soon realize that their submissions receive little or no peer review or that the editors listed are not actually on the editorial board. Further still, some predatory publishers fail to adequately inform authors of any charges or fees before their submissions are approved for publication; some of these publishers deny authors the ability to withdraw their submissions, forcing authors to either pay the fees or make their research ineligible for publication in another journal under academic ethics standards.

Understandably, these predatory publishers pose a great cause of concern for the medical profession and our AMA. While estimates as to the number of predatory publishers vary, the problem has become significant enough for the Federal Trade Commission to take action. On August 25, 2016, the Commission filed a complaint against OMICS Group Inc. and two affiliated companies, alleging that OMICS failed to disclose publishing fees until after submissions were approved for publication and then would not allow researchers to withdraw their articles, invented an Impact Factor and falsely informed authors that their journals are indexed by federal research databases (e.g., PubMed and Medline).

Our AMA has advocated for and will continue to lead the movement for widespread dissemination of medical knowledge and research. JAMA’s Key Objective aims “[t]o promote the science and art of medicine and the betterment of the public health.” JAMA and its specialty journals are committed to this mission.

RECOMMENDATION

The Board of Trustees recommends that Resolution 604-A-17 not be adopted and that this report be filed. AMA Publishing, however, plans to implement a process for waiving or reducing OA fees when authors are not supported by funders or cannot afford to pay OA fees.
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.”

The Council analyzed information from the letter of application submitted by the Senior Physicians Section (SPS) for renewal of delineated section status.

APPLICATION OF CRITERIA TO THE SENIOR PHYSICIANS SECTION

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.

When the SPS was established at the 2012 Interim Meeting of the House of Delegates (HOD), the Section identified an array of concerns affecting the landscape of medicine, particularly among physicians age 65 and older. Among the issues identified were decisions on retirement or reducing work capacity; competency evaluation; state licensing and licensure laws, particularly with regard to physician reentry to medicine or volunteering; transitions in payment models, technology, regulations and organizational structures; strategies to engage senior physicians in community leadership for the purposes of advocacy and engagement with the AMA’s strategic focus areas; health and wellness programs; and mentoring roles. Prior to the establishment of the SPS, the interests of senior physicians were represented as a special group, which served an advisory role to the Board of Trustees (BOT) from 2006-2012.

CLRPD assessment: The mission of the SPS is to provide a dedicated forum within the AMA to increase discussion of and advocacy on senior physician issues and strengthen the AMA’s ability to represent this physician constituency. The SPS provides advice and counsel to the Association on policy and program issues of interest to senior physicians, and offers suggestions for activities that best meet the needs of this physician segment. There are currently no other groups or sections within the AMA that specifically address the unique issues of concern of senior physicians. The SPS provides a formal structure for senior physicians to participate directly in the deliberations of the HOD and impact policy.
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 primary objectives of the SPS are to provide a formalized structure for representation in the HOD of active and retired AMA members over the age of 65; to review, discuss and draft policy positions; to develop and promote products and services relevant to senior physicians; and to identify the needs of senior physicians and advocate on their behalves.

The SPS meetings typically include educational sessions and discussions on topics relevant to senior physicians, specifically cognitive and emotional aging; health and wellness among physicians; practice patterns, transitioning out of practice and reentry; and roles for senior physicians in medical education. All surveyed participants at the A-16 SPS Meeting said both that the meeting was a valuable use of their time and that they would recommend the meeting to their peers. A survey conducted by the AMA’s Physician Engagement Unit found that a large percentage of retired physicians rely primarily on medical associations and societies for professional support. The SPS promotes tools that educate physicians as they transition out of full time practice. A July 2016 membership report found the YTD retention rates for senior and retired physicians were 85.1% and 89.6%, respectively.

The SPS collaborates with other sections, AMA units and staff, and councils on issues of shared concern. For the continuing medical education (CME) programs on aging, the SPS partnered with the Council on Science and Public Health, the Organized Medical Staff Section, the Council on Medical Education and the International Medical Graduates Section. In 2016, the SPS collaborated with the Academic Physicians Section on a CME program focused on physician burnout. The SPS develops its strategy with active participation from BOT liaisons, ensuring alignment with AMA priorities. Topics selected for educational programs aim to highlight AMA strategic objectives, such as increasing physician satisfaction, improving safety and quality of medical practice, and continuing education, while collaboration with other groups helps to maximize the efficiency and impact of SPS efforts.

CLRPD Assessment: The SPS serves its constituents by bringing professional issues unique to senior physicians to the forefront of organized medicine, and by providing targeted educational programs and resources for the policymaking process.

Criterion 3: Appropriateness - The structure of the group will be consistent with its objectives and activities.

In 2013, the BOT approved the SPS internal operating procedure (IOP), which designated a seven-member governing council (GC) elected by majority vote of SPS membership to guide the Section’s programs and activities. Modifications to the SPS IOP designated the Immediate Past Chair as an officer position to add continuity to GC leadership, and required candidates for delegate and alternate delegate positions to have previously held local, state, specialty society or national leadership positions, ensuring that those elected possessed the experience required to fulfill those roles. All members of the SPS are eligible for election to any office, aside from the aforementioned requirements for delegate positions. The GC convenes a strategic planning meeting each year, typically facilitated by a BOT liaison, to discuss short- and long-term goals of the SPS, and to outline a specific work agenda and enduring direction for the SPS that meets the needs of senior physicians while supporting the AMA.

The SPS undertakes a collaborative policymaking process leading up to the Section’s meetings that includes involvement/input from individual SPS members. An online member forum affords an
opportunity for SPS members to submit resolution ideas. If AMA policy already exists on a topic, that information is posted to the forum. A virtual SPS meeting allows all SPS members to provide testimony on resolution proposals and reports. A majority vote of those present helps to develop consensus, which guides the actions of the SPS delegate and alternate delegate when submitting items of business to the HOD. At least one liaison from every state participates in the SPS Assembly, a business meeting led by the Section’s delegates and held in conjunction with each HOD meeting, during which liaisons discuss SPS-sponsored resolutions and other HOD business items.

CLRPD Assessment: The SPS convenes a GC from its members and holds strategic planning meetings to plot its annual and long-term goals and ensure alignment with the goals of the AMA. All section members have opportunities throughout the year to contribute to the deliberations of the SPS either in person or by virtual means.

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.

Membership in the SPS is determined by age; all AMA member physicians age 65 and older are members of the SPS, making the segment of the population represented by the SPS easily identifiable. Year-end figures from 2016 indicated that 54,738 members of the AMA were age 65 or older, representing 22.8% of all AMA members. Of all physicians and medical students, 305,181 were age 65 and older, 17.9% of which were AMA members in 2016.

CLRPD Assessment: The SPS is comprised of members from an identifiable segment of AMA membership and the general physician population, and the Section represents a substantial number of members. AMA Physician Masterfile data indicate that the number of physicians age 65 and over has grown steadily for more than a decade, highlighting the alignment of SPS with potential AMA membership growth.

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.

During the 2016 Annual Meeting of the HOD, approximately 60 physicians attended the SPS Assembly, and about 100 attended the subsequent educational session. Typically, SPS educational programs feature nationally recognized speakers, provide actionable insights for senior physicians’ clinical, professional and personal needs, and are highly rated by attendees. Figures from the SPS GC elections indicate increasing engagement. In 2014, the inaugural SPS GC election, 709 votes were cast in the first election and 751 were cast in the runoff; in 2016, 1,259 were cast in the first election and 1,580 were cast in the runoff. Approximately 14,000 physicians have opted in to receive monthly emails on the activities of the SPS.

Governance management of the SPS has for the past three years aligned strategically with the AMA Physician Engagement Unit to leverage the knowledge of SPS members to identify the needs of the senior physician population, and provide products, services and targeted communications to grow engagement with the Section and the AMA, positioning the SPS for further growth. The number of physicians age 65 and over has grown consistently for more than a decade, increasing the potential for future growth of the SPS.
In 2014, the HOD adopted an SPS resolution requesting a study to determine the need for professional regulation in assuring quality and safety of patients cared for by older physicians. SPS leadership collaborated with the Council on Medical Education to explore whether competency tools existed. HOD adoption of the Council on Medical Education’s recommendations (CME Report 5-A-15) resulted in AMA Policy D-275.956, “Assuring Safe and Effective Care for Patients by Senior/Late Career Physicians.” Subsequently, the AMA assembled a workgroup comprised of a large number of national experts from multiple disciplines who study aging to establish principles for determining competence—an effort to avert a call for mandatory retirement age or the imposition of guidelines by others. The Council on Medical Education plans to submit a follow up report in 2018. In 2016, the outcome of this work resulted in the publication of a peer-reviewed paper on the status of senior physician competency authored by Richard Hawkins, MD, the AMA’s VP of Medical Education Programs, and four additional authors, including Paul Wick, MD, an SPS GC member. The report suggests the implementation of a screening process based on evidence-based guidelines and consistent quality standards to determine competency, rather than age-specific retirement mandates and other restrictions.

CLRPD Assessment: SPS meetings, elections and educational sessions are well attended, and demonstrate increasing engagement, while strategies are in place to further grow participation. The population of potential SPS members continues to expand. The AMA has benefited from an increased voice of SPS members within the policymaking body of the Association.

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 SPS delegates have provided testimony to the HOD on items relevant to both senior physicians and the broader AMA, including access to self-administered medications, repeal of anti-kickback safe harbor for group purchasing organizations and guidelines for prescribing opioids. The SPS sends a monthly newsletter to all senior physicians who opt in, which contains a timeline of activities leading up to HOD meetings, and information on how to submit resolutions, post to online forums and attend virtual reference committees. Biannually, the SPS convenes a virtual meeting to maintain open communication among all Section members and allow members to discuss submitted resolutions or testify on items relevant to senior physicians. The SPS uses resolution idea forms and resolution templates to ease the process of introducing resolution topics.

During the Section’s 2016 Interim Meeting, the GC outlined broad areas of focus that adhere to the mission of the SPS, including practice patterns and transitioning out of practice, the roles of senior physicians in supplementing and filling gaps in community health needs, and overcoming barriers to adopting and implementing technology. Meetings of the SPS Assembly are largely spent reviewing items of interest to the SPS, selected in advance by the SPS delegate and alternate delegate, and formulating SPS positions on reports and resolutions submitted to the HOD.

CLRPD Assessment: The SPS provides numerous opportunities for members of the constituency to introduce issues of concern and participate in the HOD policymaking process. The SPS has continually looked for ways to improve member communications and facilitate changes in the resolution process, thereby encouraging member involvement.

As a demographic group, senior physicians are not underrepresented in the HOD. CLRPD Report 2-A-17, Demographic Characteristics of the House of Delegates and AMA Leadership revealed that senior physicians made up 33.8% of all delegates in the HOD—a higher percentage than senior physician AMA members (22.8%) and the proportion of senior physicians that made up the...
nationwide population of physicians and medical students (23.8%). However, when serving on state and specialty delegations, senior physicians are obligated to represent the interests of their respective delegations, limiting their opportunities to address issues of concern specific to their demographic group. AMA Policy G-615.002, “AMA Member Component Groups,” states, “Delineated Sections will allow a voice in the house of medicine for large groups of physicians, who are connected through a unique perspective, but may be underrepresented.” The SPS provides the appropriate structure for a focused voice on issues that uniquely affect senior physicians.

**RECOMMENDATION**

The Council on Long Range Planning and Development recommends that our American Medical Association renew delineated section status for the Senior Physicians Section through 2022 with the next review no later than the 2022 Interim Meeting and that the remainder of this report be filed. (Directive to Take Action)

Fiscal Note: Less than $500
AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 601  
(I-17)

Introduced by: International Medical Graduates Section  
American Association of Physicians of Indian Origin

Subject: Physician Burnout and Wellness Challenges

Referred to: Reference Committee F  
(Julia V. Johnson, MD, Chair)

Whereas, Burnout affects physicians at all levels of training; 28 to 45% of medical students, 27 to 75% of residents and around 37% of attending physicians experience burnout at various stages of their career;¹ ² and

Whereas, The consequences of physician burnout are significant. Apart from the emotional and physical toll it takes on the physician and their families, it threatens our U.S. health care system and affects patient safety, quality of care and health care costs; and

Whereas, Depending on age and gender, 6 to 23% of physicians have used non-prescribed opiates, benzodiazepines, alcohol and other substances;³ and

Whereas, A large majority of health care organizations have no programs to prevent or combat physician burnout and promote wellness. Some hospitals have fragmented programs or committees due to lack of support from leadership, administration and budget; and

Whereas, Stanford Medical School and Hospital is the first hospital in the country to appoint a chief wellness officer;⁴ and

Whereas, Mayo Clinic has also implemented a physician well-being program managed by wellness officers;⁵ and

Whereas, Very few medical societies are developing physician wellness and resilience programs; therefore be it

RESOLVED, That our American Medical Association advocate for health care organizations to develop a wellness plan to prevent and combat physician burnout and improve physician wellness (Directive to Take Action); and be it further

RESOLVED, That our AMA advocate for state and county medical societies to implement wellness programs to prevent and combat physician burnout and improve physician wellness. (Directive to Take Action)

Fiscal Note: Minimal - less than $1,000.

Received: 09/22/17

References:
²Medscape, “Medical Resident Burnout Reaches Epidemic Levels”, May 2015
⁵Mayo Clinic, “Physician Well-Being Program”, http://www.mayo.edu/research/centers-programs/physician-well-being-program/overview
Reference Committee J

CMS Report(s)
01* Affordable Care Act Section 1332 Waivers
02* Hospital Surveys and Health Care Disparities
03 Non-Physician Screening Tests
04* Health Insurance Affordability: Essential Health Benefits and Subsidizing the Coverage of High-Risk Patients
05 Reaffirmation of AMA Policy Opposing Caps on Federal Medicaid Funding

Joint Report(s)
CMS/CSAPH 01* Payment and Coverage for Genetic/Genomic Precision Medicine

Resolution(s)
801 Chronic Care Management Payment for Patients Also on Home Health
802 Opposition to Medicaid Work Requirements
803 Air Ambulance Regulations and Reimbursements
804 Prior Authorization
805 A Dual System for Universal Health Care in the United States
806 Mandate Transparency by Pharmacy Benefit Managers
807 Structural Barriers to Achieving Better Health Care Efficiency and Outcomes: ACOs and Physician Employment by Hospitals
808 Opposition to Reduced Payment for the 25 Modifier
809 Expansion of Network Adequacy Policy
810 Pharmacy Benefit Managers and Prescription Drug Affordability
811 Update OBRA Nursing Facility Preadmission Screening Requirements
812 Medicare Coverage of Services Provided by Proctored Medical Students
813 Sustain Patient-Centered Medical Home Practices
814* Appropriate Reimbursement for Evaluation and Management Services for Patients with Severe Mobility-Related Impairments
815* Pediatric Representation for E/M Documentation Guideline Revision
816* Social Determinants of Health in Payment Models
817* Addressing the Site of Service Deferential
818* On-Call and Emergency Services Pay
819* Consultation Codes and Private Payers
820* Elimination of the Laboratory 14-Day Rules Under Medicare
821* Hormonal Contraception as a Preventive Service

* included in the Handbook Addendum
At the 2016 Interim Meeting, the House of Delegates referred Resolution 206, “Advocacy and Studies on Affordable Care Act Section 1332 (State Innovation Waivers),” which was sponsored by the Medical Student Section. The Board of Trustees assigned this item to the Council on Medical Service for a report back to the House of Delegates at the 2017 Interim Meeting. Resolution 206-I-16 asked:

That our American Medical Association (AMA) advocate that the “deficit-neutrality” component of the current US Department of Health and Human Services (HHS) rule for Section 1332 waiver qualifications be considered only on long-term, aggregate cost savings of states’ innovations as opposed to having costs during any particular year, including in initial “investment” years of a program, reduce the ultimate likelihood of waiver approval; and

That our AMA study reforms that can be introduced under Section 1332 of the Affordable Care Act (ACA) in isolation and/or in combination with other federal waivers to improve healthcare benefits, access and affordability for the benefit of patients, healthcare providers and states, and encourages state societies to do the same.

This report provides background on Section 1332 waivers, outlines regulatory activity on Section 1332 waivers, highlights Section 1332 waiver applications and approvals, summarizes relevant AMA policy, and presents policy recommendations.

BACKGROUND

Section 1332 of the ACA established a new waiver supporting state innovation in order to enable states to experiment with and implement different models to provide health insurance coverage to their residents. Under Section 1332, some of the ACA’s private insurance and coverage provisions can be waived, including those pertaining to premium tax credits and cost-sharing reductions for plans offered through the marketplaces, the individual and employer responsibility requirements and standards for health insurance marketplaces and qualified health plan standards. Other sections of the ACA cannot be waived under Section 1332, including those addressing guaranteed issue and community rating, the law’s prohibition against insurers denying coverage or charging higher premiums to people with pre-existing conditions, the ban on annual and lifetime limits, and the ability of adult dependents up to age 26 to be covered on their parents’ health plans.
Under Section 1332, the Secretaries of HHS and the Treasury are granted the authority to approve a request for a Section 1332 waiver only if the proposal meets the following four criteria:

1. The proposal will provide coverage to at least a comparable number of the state’s residents as would be provided absent the waiver;
2. The proposal will provide coverage and cost-sharing protections against excessive out-of-pocket spending that are at least as affordable for the state’s residents as would be provided absent the waiver;
3. The proposal will provide coverage that is at least as comprehensive for the state’s residents as would be provided absent the waiver; and
4. The proposal will not increase the federal deficit.

If a Section 1332 waiver is approved, a state may receive funding equal to the amount of forgone federal financial assistance that would have been provided to its residents enrolled in marketplace coverage pursuant to the ACA, a process referred to as pass-through funding. Pass-through funding is capped at the amount of forgone marketplace subsidies and does not account for any other changes in federal spending or revenues as a result of the waiver. Accordingly, pass-through funding is especially essential for Section 1332 waivers under which individuals and/or small employers in the state would no longer qualify for premium tax credits, cost-sharing reductions and/or small business credits for which they would otherwise be eligible. For such waivers, the aggregate amount of such credits or reductions that would have been paid on behalf of consumers in the marketplaces had the state not received such waiver would instead be paid to the state to implement its Section 1332 waiver. Section 1332 waivers, which have been available since the beginning of this year, may be approved for periods up to five years and can be renewed.

REGULATORY ACTIVITY ON SECTION 1332 WAIVERS

A final regulation addressing the application, review, and reporting process for Section 1332 waivers was issued in February 2012. Under the final regulation, a state submitting an application for a Section 1332 waiver must provide actuarial analyses and certifications, economic analyses, data and assumptions, targets, an implementation timeline, and other necessary information to show the proposed waiver’s compliance with the ACA criteria for Section 1332 waivers as noted above. Specific to deficit reduction, the economic analyses submitted by the state are required to include a detailed 10-year budget plan that is deficit neutral to the federal government. The final regulation also allows states to submit a single application for a Section 1332 waiver along with existing waivers applicable to Medicare, Medicaid and the Children’s Health Insurance Program (CHIP), which could include Section 1115 (of the Social Security Act) waivers, which currently allow states to implement experimental, pilot, or demonstration projects in the Medicaid and CHIP programs.

In December 2015, the Centers for Medicare & Medicaid Services (CMS) and the Department of the Treasury released guidance that addressed how the agencies will evaluate state applications for Section 1332 waivers. Addressing the ACA’s deficit neutrality requirement, the guidance stated that waivers must not increase the federal deficit over the period of the waiver or in total over the ten-year budget plan submitted by the state. Pertinent to referred Resolution 206-I-16, the agencies stated in the guidance that “a waiver that increases the deficit in any given year is less likely to meet the deficit neutrality requirement.” In addition, the guidance stated that although a state may submit a coordinated waiver application, in such a case each waiver will be evaluated independently according to applicable federal laws. Importantly, the guidance stated that there would be limitations to Section 1332 waiver applications for states that use healthcare.gov for their marketplaces, as the federal platform cannot accommodate different rules for different states.
Therefore, the agencies note that states contemplating waivers that include changes to the
calculation of marketplace financial assistance as well as plan management, for example, may
consider establishing and administering their own platform. 4

In March 2017, HHS Secretary Price sent a letter to governors encouraging states to submit Section
1332 waiver proposals, including proposals for high-risk pool/state-operated reinsurance programs.
In the letter, Secretary Price referenced Alaska’s waiver application, which was approved in July
2017, and sought federal support for a state-managed reinsurance program. The Secretary noted
that if a state’s plan under its waiver proposal is approved, a state may be able to receive pass-
through funding to help offset a portion of the costs for the high-risk pool/state-operated
reinsurance programs.

In May 2017, CMS released a checklist for Section 1332 waiver applications, which also included
specific items pertaining to applications that include high-risk pool/state-operated reinsurance
programs. Pertaining to deficit neutrality, the checklist states as part of waiver applications, states
must include an economic analysis to support the state’s finding that the waiver will not increase
the federal deficit over the five-year waiver period or in total over the ten-year budget period.
Additionally, the checklist stipulates that the deficit analysis submitted by the state should show
yearly changes in the federal deficit due to the waiver. 6

SECTION 1332 WAIVER APPLICATIONS AND APPROVALS

As Section 1332 waivers have only been available starting this year, activity on waivers has been
relatively limited. At the time that this report was prepared, nine states had submitted waiver
applications – Alaska, California, Hawaii, Iowa, Massachusetts, Minnesota, Oklahoma, Oregon and
Vermont. The waiver applications of three states - Hawaii, Alaska and Minnesota - have been
approved. Of note, Minnesota’s waiver was approved with less federal pass-through funding than
was requested by the state. The waiver applications of California and Oklahoma were withdrawn,
while Vermont’s was put on hold. 7 Hawaii’s Section 1332 waiver allowed the state to keep its
longstanding employer coverage provisions resulting from the state’s Prepaid Health Care Act,
which requires employers to provide more generous coverage than is required under the ACA. As
such, Hawaii’s waiver sought to waive the ACA requirement that a Small Business Health Options
Program (SHOP) marketplace operate in Hawaii and other provisions related to SHOP
marketplaces, including the requirement that the small business tax credits could only be available
through the SHOP. 8,9

Alaska’s waiver allows the state to implement the Alaska Reinsurance Program (ARP) for 2018
and subsequent years. The ARP will cover claims in the individual market for individuals with one
or more of 33 identified high-cost conditions to help stabilize premiums. As a result, insurers will
relinquish both premiums received for such individuals as well as claims they would have paid
absent the waiver. As a result of the ARP, it is expected that premiums will be 20 percent lower in
2018 than absent the waiver, and 1,460 additional individuals will have health insurance coverage.
Because the ARP will lower premiums, the second lowest cost silver plan premium is reduced,
which results in the federal government spending less on premium tax credits. 10 The waiver
application of Minnesota would create the Minnesota Premium Security Plan, which was estimated
to yield a 20 percent reduction in average premiums in 2018. 11 While Minnesota’s waiver was
approved, the full amount the state requested in its waiver for federal pass-through funding to
financially support its reinsurance program was not approved. Only federal pass-through funding
reflecting savings from less spending on premium tax credits and cost-sharing reductions was
approved, not the amount also requested by the state that reflects federal savings due to lower
premiums for plans under the state’s Basic Health Program. 12 The waiver application of Oregon,
which was still under review when this report was prepared, anticipates that its waiver to establish
the Oregon Reinsurance Program will reduce premiums, including those for the second-lowest cost
silver plan, by 7.5 percent in 2018 (net of the premium assessment), with an increase in enrollment
in the individual market by approximately 1.7 percent in the same year.13

Likewise, Iowa’s waiver application includes a reinsurance program. However, due to concerns at
the time of its waiver application that there would be no insurers participating in the state’s
marketplace in 2018, Iowa also proposed to make substantive changes to ACA requirements, and
cited the need for “emergency regulatory relief.” Iowa’s Section 1332 waiver proposal calls for the
creation of a single Proposed Stopgap Measure plan that would be the only plan offered by insurers
in the marketplace, and provide coverage similar to that offered by a standard silver plan. In
addition, the initial waiver application proposes replacing the ACA’s premium tax credits with flat
premium subsidies based on age and income, as well as eliminating cost-sharing reductions
(CSRs).14 In response to concerns over the state’s waiver application eliminating cost-sharing
reductions, Iowa submitted a supplement to its waiver application in order to provide additional
cost-sharing support to individuals with incomes between 133 and 150 percent of the federal
poverty level (FPL), to be implemented similarly to how cost-sharing reductions are currently
provided to this population.15 Of note, cost-sharing reductions are currently provided to individuals
with incomes up to 250 percent of the FPL under the ACA. In addition, the state has requested that
HHS waive the requirements that Section 1332 waivers include actuarial analyses, actuarial
certifications, and economic analyses, including those which support the state’s finding that the
waiver will not increase the federal deficit over the period of the waiver or in total over the 10-year
budget period.16 At the time that this report was prepared, Iowa no longer has any counties at risk
of having no insurer participating in the state’s marketplace in 2018.17

In response to the market volatility the uncertainty about continued funding for CSRs has caused,
Massachusetts submitted a waiver request that requested waiver of CSRs and instead create a
Premium Stabilization Fund that would make payments to health plans equivalent to those that
would be made under federal CSR payments. Massachusetts requested expedited review of its
waiver, which if approved would be effective January 1, 2018 for an initial period of at least one
year, and likely blunt premium increases that would otherwise occur in the marketplace due to the
uncertainty as to whether federal CSR funding will continue.18

RELEVANT AMA POLICY

Policy D-165.942 advocates that state governments be given the freedom to develop and test
different models for covering the uninsured, provided that their proposed alternatives 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, ensure and
maximize patient choice of physician and private health plan, and include reforms that eliminate
denials for pre-existing conditions. Policy H-165.845 supports outlined principles to guide in the
evaluation of state health system reform proposals, including:

• Health insurance coverage for state residents should be universal, continuous, and portable.
  Coverage should be mandatory only if health insurance subsidies are available for those
  living below a defined poverty level.
• The health care system should emphasize patient choice of plans and health benefits,
  including mental health, which should be value-based. Existing federal guidelines
  regarding types of health insurance coverage (e.g., Title 26 of the US Tax Code and
  Federal Employees Health Benefits Program [FEHBP] regulations) should be used as
  references when considering if a given plan would provide meaningful coverage.
• The delivery system should ensure choice of health insurance and physician for patients, choice of participation and payment method for physicians, and preserve the patient/physician relationship. The delivery system should focus on providing care that is safe, timely, efficient, effective, patient-centered, and equitable.

• The administration and governance system should be simple, transparent, accountable, efficient, and effective in order to reduce administrative costs and maximize funding for patient care.

• Health insurance coverage should be equitable, affordable, and sustainable. The financing strategy should strive for simplicity, transparency, and efficiency. It should emphasize personal responsibility as well as societal obligations.

Policies D-165.966 and H-165.855 advocate that state governments be given the freedom to develop and test different models for improving coverage for patients with low incomes. Policy D-165.966 also supports changes in federal rules and federal financing to support the ability of states to develop and test such alternatives without incurring new and costly unfunded federal mandates or capping federal funds.

DISCUSSION

The AMA has long advocated that state governments be given the freedom to develop and test different models for improving coverage for patients with low incomes. The Council believes that Section 1332 of the ACA provides states with a unique opportunity to build upon the progress that has been made in expanding health insurance coverage and choice under the ACA. With Section 1332 waivers, states could devise new and innovative approaches to provide quality health insurance coverage to more people, as well as make health insurance coverage more affordable. The Council believes that it is imperative that approved State Innovation Waivers follow the criteria outlined in Section 1332 of the ACA and related regulations: that Section 1332 waiver proposals will provide coverage to at least a comparable number of the state’s residents as would be provided absent the waiver; provide coverage and cost-sharing protections against excessive out-of-pocket spending that are at least as affordable for the state’s residents as would be provided absent the waiver; provide coverage that is at least as comprehensive for the state’s residents as would be provided absent the waiver; and not increase the federal deficit.

However, additional actions should be taken, either administratively or legislatively, to make Section 1332 waivers more workable for states, and be potentially more advantageous for state residents. Under current law, Section 1332 waivers are required to not add to the federal deficit, and current guidance states that waivers must not increase the federal deficit over the period of the waiver or in total over the ten-year budget plan submitted by the state. However, the language in the federal guidance from 2015 also stated that “a waiver that increases the deficit in any given year is less likely to meet the deficit neutrality requirement.” The Council believes that there could be unintended consequences for states seeking to innovate to require deficit neutrality in each individual year of a Section 1332 waiver. The Council recognizes that it would be reasonable for some waivers to project deficits in years one or two of a waiver as a result of start-up and other costs, and savings in subsequent years that offset the earlier deficits. The Council believes it is essential for Section 1332 waivers to remain deficit neutral over the period of the waiver (which may not exceed five years unless renewed), as well as in total over the ten-year budget plan submitted by the state.

The Council also believes that federal pass-through funding provided to states to implement their Section 1332 waivers should capture all federal budgetary savings achieved by the waiver. Under current law, the amount of federal pass-through funding is equal to an annual estimate of forgone
marketplace subsidies and financial assistance that would have otherwise been provided pursuant to the ACA. If a Section 1332 waiver creates additional federal savings outside of the scope of marketplace subsidies, such as reducing the cost of the tax exclusion for employer-sponsored coverage, such savings should also be included in the amount of federal pass-through funding provided to the state to finance its Section 1332 waiver.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted in lieu of Resolution 206-I-16, and that the remainder of the report be filed.

1. That our American Medical Association (AMA) support the criteria outlined in Section 1332 of the Affordable Care Act for the approval of State Innovation Waivers:
   a. The waiver proposal will provide coverage to at least a comparable number of the state’s residents as would be provided absent the waiver;
   b. The waiver proposal will provide coverage and cost-sharing protections against excessive out-of-pocket spending that are at least as affordable for the state's residents as would be provided absent the waiver;
   c. The waiver proposal will provide coverage that is at least as comprehensive for the state’s residents as would be provided absent the waiver; and
   d. The waiver proposal will not increase the federal deficit. (New HOD Policy)

2. That our AMA support the deficit neutrality requirement of Section 1332 waivers being enforced over the period of the waiver and in total over the ten-year budget plan submitted by a state, not in each individual year of the waiver. (New HOD Policy)

3. That our AMA support legislation to allow other federal savings projected to be achieved as a result of a Section 1332 waiver, including any reductions in the cost of the tax exclusion for employer-sponsored coverage, to be included in the amount of federal pass-through funding provided to a state to subsidize state innovations. (New HOD Policy)

Fiscal Note: Less than $500.
REFERENCES


2 Id.


4 Centers for Medicare & Medicaid Services and Department of the Treasury, supra note 1.


11 Tolbert and Pollitz, supra note 8.


16 Iowa Insurance Division, supra note 13.


At the American Medical Association’s (AMA) 2016 Interim Meeting, the House of Delegates adopted Policy D-450.954, “A Study on the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey and Healthcare Disparities,” which asked the AMA to study the impact of the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) on Medicare payments to hospitals serving vulnerable populations and on potential health care disparities.

The Board of Trustees referred this issue to the Council on Medical Service for a report back to the House at the 2017 Interim Meeting. This report provides background on the purpose and use of HCAHPS surveys and the role of safety net hospitals, explains the intersection of HCAHPS scores and safety net hospitals, explores how cultural competency influences patient satisfaction and HCAHPS scores, and outlines relevant legislation. The Council recommends policy to help shield safety net hospitals from the potentially negative financial impact that hospital quality program assessments may have on hospitals that serve a disproportionate share of patients with social risk factors and policy to recognize the importance of cultural competency in patient experience and treatment plan adherence.

BACKGROUND

The HCAHPS survey is the first national, standardized, publicly reported survey of patients’ perspectives of hospital care. HCAHPS has three goals. First, the survey is designed to produce data about patients’ perspectives of care that allow objective and meaningful comparisons of hospitals on topics that are important to patients. Second, public reporting of the survey results creates new incentives for hospitals to improve quality of care. Third, public reporting of survey results serves to enhance accountability in health care by increasing transparency of the quality of hospital care provided in return for the public investment.

HCAHPS survey scores over a three-year period influence a portion of each hospital’s value-based purchasing (VBP) incentive payment. The VBP adjusts payments to hospitals under the Inpatient Prospective Payment System (IPPS) based on the quality of care delivered. The VBP adjusts Medicare’s payment rate to hospitals based on a set of defined process, outcome, and experience of care measures. The measures are represented in four different areas: Clinical Care (Process and Outcomes), Patient Experience of Care (HCAHPS), Efficiency, and Safety. As noted, the patient experience of care measure is based off of HCAHPS.
Safety net hospitals play a critical role in providing health care to vulnerable populations, and it is important to ensure that efforts to improve quality of care do not exacerbate existing health care disparities. Generally, safety net hospitals are financially stressed because they are chronically underfunded and payments are low. Because of these financial constraints, safety net hospitals may have fewer nurses and are more likely to be older buildings, which are factors largely beyond the hospital’s immediate control.²

Safety net hospitals serve many patients without the ability to pay and generally have sicker patients and a more complex patient case mix than traditional hospitals.³ Therefore, many safety net patients have conditions that require additional resources such as social work and behavioral health care; however, the hospitals often do not have the resources to devote to these services or the financial means to provide amenities that positively affect patient satisfaction.⁴

HCAHPS SCORES AND SAFETY NET HOSPITALS

According to one recent study published in the Archives of Internal Medicine, hospitals that serve a disproportionate share of low-income and Medicaid patients generally scored lower than other hospitals on the HCAHPS patient experience care survey and were 60 percent less likely to meet HCAHPS performance benchmarks under the Medicare VBP program.⁵ Researchers compared HCAHPS performance and improvement for safety net hospitals with other hospitals from 2007 to 2010. While scores for both groups of hospitals improved over the four year period, the performance gap between them increased. Overall, 769 hospitals that treat the largest share of low-income patients scored 5.6 percentage points lower than their 2,327 non-safety net counterparts. It is worth noting that the HCAHPS survey is only available in six languages and therefore prohibits some patients from participating.⁶

The authors of the study surmised two explanations for the disparity between the two hospital groups. One explanation was that patients in safety net hospitals have different expectations than patients in other hospitals. The other explanation was that safety net hospitals have not done as good of a job focusing on the patient issues reflected in the survey.

Safety net hospitals have pointed out that they are at a disadvantage and that their scores should be adjusted to take into consideration the diverse case mix, poverty, language barriers, and cultural issues specific to safety net hospitals. They state that the Centers for Medicare & Medicaid Services (CMS) should design incentive programs that reward safety net hospitals prior to implementing financial penalties.

HCAHPS SCORES AND CULTURAL COMPETENCY

Communication measures account for 50 percent of the HCAHPS patient experience index. As previously stated, patient characteristics such as race, ethnicity, and language preference may impact the perception of care provided.⁷ Language and communication barriers may lead to patient dissatisfaction and poor comprehension and treatment adherence.⁸ Patients and families who are non-white, speak a language other than English, and are on Medicaid report lower experience scores than those commercially insured, white, and English-speaking patients and families.⁹ Therefore, demographic and cultural differences seem to be important considerations in improving communication.

The National Quality Forum (NQF) has defined cultural competency as the “ongoing capacity of health care systems, organizations, and professionals to provide for diverse patient populations high-quality care that is safe, patient and family centered, evidence based, and equitable.”¹⁰
Cultural competency has been promoted as a strategy to enhance patient satisfaction and improve organizational performance.\textsuperscript{11}

Patient centered care has been an ongoing focus of the health care community to facilitate quality improvement.\textsuperscript{12} It follows that taking into account demographics and culture is necessary for aligning hospital services and patient preferences. For example, a study of California hospitals found that hospitals with greater cultural competency have better scores for doctor and nurse communication, staff responsiveness, hospital rating, and hospital recommendation.\textsuperscript{13}

**RELEVANT LEGISLATION AND REGULATORY ACTIVITY**

Recent legislation has addressed how to account for social risk factors in Medicare payment. The 21\textsuperscript{st} Century Cures Act requires Medicare to account for a patient’s background when calculating reductions in payments to hospitals under the Hospital Readmissions Reduction Program.\textsuperscript{14} In addition, the Hospital Inpatient Prospective Payment Systems (IPPS) rule requested feedback on how to account for social risk factors in the Inpatient Quality Reporting program. Also, in response to the IMPACT Act, the Assistant Secretary for Planning and Evaluation (ASPE) sponsored a committee of the National Academies of Sciences, Engineering and Medicine to specify criteria that could be used in determining which socioeconomic status factors should be accounted for in Medicare quality and payment systems. The committee released its report in December 2016.\textsuperscript{15} Additionally, at the direction of the Department of Health and Human Services, the National Academy of Medicine (NAM) released a report on how social risk factors may influence health care use, outcomes, and costs in Medicare payment and quality programs.\textsuperscript{16} Importantly, both the ASPE and NAM activities found that existing data sources used to capture social risk factors are insufficient for the purposes of developing better risk adjustment methodologies.

**RELEVANT AMA ACTIVITY AND POLICY**

Policy H-450.946 states that the AMA will advocate for effective quality management programs that incorporate substantial input by actively practicing physicians and physician organizations.

Policy H-450.966 states that the AMA will seek an active role in any efforts to develop national medical quality and performance standards and measures; emphasize the importance of all organizations developing, or planning to develop, quality and performance standards and measures to include actively practicing physicians and physician organizations in the development, implementation, and evaluation of such efforts; and advocate that principles be used to guide the development and evaluation of quality and performance standards and measures under federal and state health system reform efforts, including that standards and measures shall have demonstrated validity and reliability, shall reflect current professional knowledge and available medical technologies, shall be linked to health outcomes and/or access to care, shall be representative of the range of health care services commonly provided by those being measured, shall account for the range of settings and practitioners involved in health care delivery, shall recognize the informational needs of patients and physicians, shall recognize variations in the local and regional health care needs of different patient populations, shall recognize the importance and implications of patient choice and preference, and shall recognize and adjust for factors that are not within the direct control of those being measured.

The AMA has numerous policies on the appropriate use of patient satisfaction surveys. Policy D-450.960 directs the AMA to urge CMS to modify the HCAHPS scoring system so that it assigns a unique value for each rating option available to patients. Policy H-450.982 states that efforts should be continued to improve the measurement of patient satisfaction and to document its
relationship to favorable outcomes and other accepted criteria of high quality care. Additionally, Policy D-385.958 directs the AMA to work with CMS and non-government payers to ensure that subjective criteria, such as patient satisfaction surveys, be used only as an adjunctive and not a determinative measure of physician quality for the purpose of physician payment and to ensure that physician payment determination, when incorporating quality parameters, only consider measures that are under the direct control of the physician. Similarly, Policy H-406.991 states that patient satisfaction surveys should be used to help improve patient care and not be used for the purpose of determining physician payment.

Consistent with the AMA’s continued efforts to refine risk adjustment, Policy H-155.957 encourages further study into the possible causes of geographic variation in health care delivery and spending, with particular attention to risk adjustment methodologies and the effects of demographic factors, differences in access to care, medical liability concerns, and insurance coverage options on demand for and delivery of health care services.

Policy H-295.897 promotes cultural competency training with the goal of emphasizing cultural competence as part of professional practice and encourages training opportunities for students and residents to learn cultural competency from community health workers.

In accordance with these policies, the AMA has advocated extensively for improvements to HCAHPS. The AMA always includes a section on improvements to HCAHPS in comments related to the Medicare physician fee schedule. The AMA successfully lobbied CMS to propose removing the pain questions from HCAHPS and clarifying that HCAHPS is a hospital level survey and that it is not appropriate to tie physician compensation or measure physicians based on HCAHPS scores.

Specifically, in the AMA’s recent comments on the IPPS Proposed Rule, the AMA advocated for continued refinements to HCAHPS and refinements to the risk adjustment methodology used in program measurements. Further, the AMA advocated for CMS’ consideration of measuring and accounting for social risk factors in Hospital Inpatient Quality Reporting and Value-Based Purchasing Programs noting that the AMA continues to believe that in order to ensure the quality of care furnished by physicians and hospitals is assessed as fairly as possible, social risk factors must be taken into account.

DISCUSSION

Safety net hospitals play a critical role in providing needed health care to vulnerable populations. These hospitals provide a necessary function and often have more challenging patient populations and fewer resources to devote to patient care when compared to non-safety net hospitals. While patient satisfaction scores may provide an incentive for hospitals to devote more resources to the measure, safety net hospitals generally do not have the funding to do so. Although the Council believes that the goal of such patient satisfaction surveys should be to identify areas to improve patient outcomes and quality of care, the AMA must guard against efforts aimed at improving the quality of care that have the unintentional effect of stripping safety net hospitals of needed funding and thereby exacerbating health care disparities. Tying financial incentives to HCAHPS patient satisfaction scores may have the effect of financially penalizing such hospitals and unintentionally exacerbating existing inequalities in care.

Further, numerous studies have found that patient satisfaction is not necessarily an objective measure of quality. In a nationally representative sample, higher patient satisfaction was associated with lower emergency department use but with greater use of inpatient care, higher overall health care and prescription drug expenditures, and increased mortality. Therefore, the limitations of
patient experience surveys should be recognized. Additionally, the Council notes that, at times, a statistically minimal number of surveys may have a material effect on overall scores. To that end, the Council recommends reaffirming numerous policies emphasizing that such quality assessments should adjust for factors outside of the physician’s control and recognizing variation in different patient populations, policy stating that patient satisfaction surveys should not be a determinative measure of physician quality for payment purposes, and policy advocating for the continuation of efforts to improve patient satisfaction measurement.

Socioeconomic factors such as age, income, educational level, ethnicity and others have been identified as having a role in not only health care preferences but also health care outcomes. Such factors may present obstacles to successful outcomes and can widen health care disparities. Recognizing socioeconomic factors and focusing on cultural competency in care delivery may reduce racial and ethnic health care disparities and positively contribute to quality improvement. Therefore, the Council believes it is important not only to guard against patient satisfaction surveys unintentionally depriving safety net hospitals of needed funding but also to focus on ways to improve the patient experience. Accordingly, the Council recommends continuing to advocate for improved risk models that account for social risk factors in hospital quality program assessments. The Council notes that excluding a specific mention of HCAHPS from the recommendation and instead mentioning “hospital quality program assessments” makes the policy inclusive of the numerous hospital quality programs, including HCAHPS. Further, the Council recommends reaffirming policy promoting cultural competency training and recommends new policy recognizing the importance of cultural competency to patient experience and encouraging the implementation of such practices across health care settings.

While it may be difficult to determine whether patient satisfaction scores are a result of physician performance or demands and restrictions outside of the physician’s control, the Council believes valuable information can be gleaned from patient surveys. There is evidence supporting the premise that when patients better understand treatment plans, they are more likely to adhere to recommendations and return for follow up care in the future. The Joint Commission, which pools together best practices for HCAHPS scores, notes that positive patient perception of care may improve patient safety and staff retention. Additionally, patient experience of care quality and patient satisfaction are tied to the Triple Aim. Although experience may not necessarily be an indicator of quality, it is important for patient’s perceptions of care to be positive. These perceptions reflect the physician-patient relationship and support patient retention and shared decision-making.

The Council believes improving the patient experience is a shared goal in health care. It also believes that ensuring the financial viability of safety net hospitals is vital to providing care to the most vulnerable and fighting to reduce health care disparities. Therefore, the Council recommends continuing to work with CMS and others, including America’s Essential Hospitals, to address issues related to hospital quality program assessments.

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) reaffirm Policy H-450.966 emphasizing that national medical quality and performance standards and measures should adjust for factors that are not within the direct control of those being measured and should recognize the variations in needs of different patient populations. (Reaffirm HOD Policy)
2. That our AMA reaffirm Policy D-385.958, which calls for the AMA to work with Centers for Medicare & Medicaid Services (CMS) and non-government payers to ensure that subjective criteria, such as patient satisfaction surveys, should not be used as a determinative measure of physician quality for the purpose of physician payment and to ensure that physician payment determination, when incorporating quality parameters, only consider measures that are under the direct control of the physician. (Reaffirm HOD Policy)

3. That our AMA reaffirm Policy H-450.982 stating that efforts should be continued to improve the measurement of patient satisfaction and to document its relationship to favorable outcomes and other accepted criteria of high quality. (Reaffirm HOD Policy)

4. That our AMA reaffirm Policy H-295.897 promoting cultural competency training with the goal of emphasizing cultural competence as part of professional practice. (Reaffirm HOD Policy)

5. That our AMA support that the goal of hospital quality program assessments should be to identify areas to improve patient outcomes and quality of patient care. (New HOD Policy)

6. That our AMA recognize the importance of cultural competency to patient experience and treatment plan adherence and encourage the implementation of cultural competency practices across health care settings. (New HOD Policy)

7. That our AMA support that hospital quality program assessments should account for social risk factors so that they do not have the unintended effect of financially penalizing safety net hospitals and exacerbating health care disparities. (New HOD Policy)

8. That our AMA continue to advocate for better risk models that account for social risk factors in hospital quality program assessments. (New HOD Policy)

9. That our AMA continue to work with CMS and other stakeholders, including representatives of America’s Essential Hospitals, to address issues related to hospital quality program assessments. (New HOD Policy)

10. That our AMA rescind Policy D-450.954. (Rescind HOD Policy)

Fiscal Note: Less than $500.

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8 Cultural Competence in Health Care: Is It Important for People with Chronic Conditions? Georgetown University Health Policy Institute. February 2004. Available at: https://hpi.georgetown.edu/agingssociety/pubhtml/cultural/cultural.html
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13 Weech-Maldonado, supra note 11.
At the American Medical Association’s (AMA) 2016 Interim Meeting, the House of Delegates referred Resolution 901, “Disclosure of Screening Test Risk and Benefits Performed without a Doctor’s Order,” submitted by the American College of Radiology, and the Virginia, Alabama, Georgia, Kentucky, District of Columbia, Mississippi, West Virginia, and South Carolina Delegations. The Board of Trustees referred this issue to the Council on Medical Service for a report back to the House at the 2017 Interim Meeting. Resolution 901-I-16 asked:

That our AMA (1) advocate that if a screening test is being marketed as having a medical benefit and is offered and performed by a wellness program vendor without a specific order by the individual’s physician or other licensed provider, they must provide the patient with the test specific evidence based guidance that supports the utility of the test; (2) advocate that if the procedure is not supported by specific evidence based guidance as a screening test for that patient and the patient still would like the screening test, the Wellness Program Vendor must offer the patient the opportunity to discuss the risks, benefits, and alternatives with a physician licensed to practice medicine in the state in which the test is being performed; (3) engage with federal regulators on whether vendors of health and wellness programs are in compliance with regulations applicable to marketing to patients in view of the impact of such programs on patients; and (4) where possible, continue to work with state medical societies, interested medical specialty societies and state agencies to provide public education regarding appropriate use of vendor wellness programs.

This report provides background on wellness program vendors, particularly focusing on employer-offered wellness programs, discussion on payment for vendor screenings, an overview of the clinical guidelines for screenings, an outline of the relevant legislation, and a series of policy recommendations regarding vendor wellness screenings.

BACKGROUND

Much of today’s health care system was created to provide diagnosis and treatment versus wellness and prevention. However, not only are many diseases preventable but also there are sustained concerns about health care spending. Accordingly, recent years have brought a focus on wellness and prevention. Codified in statutes like the Affordable Care Act (ACA), wellness programs have become a cornerstone in employer and health plan behavior.
More than 5,600 vendors reportedly generate annual revenue of $8 billion in the wellness industry, of which $6 billion is attributable to the workplace wellness industry. Many employers now provide wellness programs to employees in an effort to help employees maintain their health and reduce health care costs. The workplace wellness industry generally consists of vendors that sell companies stand-alone wellness programs or programs that are an optional part of the employee’s health insurance. In addition, some screening services are provided outside of the employer-based wellness program and are often accessed at wellness centers. The Council notes that the scope of this report is limited to basic screenings by a wellness vendor and does not encompass genetic testing. Notably, CMS/CSAPH Joint Report, “Precision Medicine,” also presented at the 2017 Interim Meeting, addresses payment and coverage of genetic testing.

Several companies market wellness screenings, personalized health screenings, and biometric screenings. These services are performed outside of the traditional patient-physician setting and are often marketed to employers as wellness screening programs for their employees. The services provided vary, but they usually include a number of blood tests; ultrasound imaging for conditions, such as abdominal aortic aneurysm, carotid artery disease, and bone density; ankle-brachial index for peripheral artery disease and cardiovascular disease; and sometimes electrocardiogram. Other services include body composition analysis (e.g., body fat percentage, visceral fat, muscle mass and distribution, body water balance, total body weight, body mass index).

The increasing availability of direct-to-consumer screening tests may undermine physician efforts to provide high-quality, cost-conscious screening services to patients through shared decision-making. The wellness vendor screening services at issue are not usually administered by physicians but instead by technicians or other non-physician health professionals outside of traditional health care settings. However, many of these vendor companies have physicians as part of their leadership teams serving as medical directors or members of an advisory board. Some companies are located in retail settings, and others offer services via the internet. Occasionally, the websites of these vendor companies include a disclaimer encouraging those who are interested in testing, or those who have received abnormal test results, to contact their physicians with questions. Some companies offer follow-up with a physician staff member if patients have questions about results.

Employers continue to show interest in wellness and screening programs that help employees identify health issues and manage chronic diseases. Therefore, many firms pay for such screenings and tests and some offer financial incentives to encourage employees to complete the health assessments. Many large employers offering health assessments, biometric screenings, and wellness programs offer participating employees lower premium contributions or reduced cost-sharing.

Outside of the workplace wellness program paradigm, health insurance generally does not cover screenings that have not been recommended by physicians. Further, vendors generally make more money the more screenings they perform and therefore often recommend screenings for otherwise healthy people, a practice that has the effect of increasing overall health care costs.

There is concern that the screening services provided by wellness vendors are not always supported by clinical guidelines. Vendor programs do not need to follow screening guidelines from the US Preventive Services Task Force (USPSTF) or other guideline-making bodies. For example, the USPSTF found insufficient evidence to recommend several wellness tests including high sensitivity...
C-reactive protein testing for coronary heart disease risk and ankle-brachial index to determine risk for peripheral artery disease and cardiovascular disease. Additionally, concerns exist about providing screening tests to large numbers of patients who may not need them. Wellness programs offer blanket screening tests for nearly anyone while most screening guidelines are tailored based on age, gender, and other factors. For example, the USPSTF recommends abdominal aortic aneurysm screening only in men ages 65-75 who are or have been smokers, and when these guidelines are not followed it leads to unnecessary tests for which a given individual may have no indication. Additionally, the larger the screened population, the higher the number of false positive and false negative results. False positive results could set off a cascade of invasive, expensive, and potentially harmful follow-up tests, and false negative results could lead patients to forego necessary care.

EFFECTIVENESS OF WELLNESS PROGRAMS

The return on investment for wellness programs and screenings is mixed. Often the programs fail to pay for themselves and confer no proven health benefit. Commonly, wellness programs focus on two components: a lifestyle management program and a disease management program. The lifestyle management program focuses on individuals with health risks such as obesity and smoking while the disease management program is designed to help those who already have a chronic disease. Programs focusing on disease management provide a greater return on investment than lifestyle management. Overall, it is estimated that wellness programs reduced average health care costs by about $30 per member per month; however, 87 percent of savings were attributable to disease management programs that focus on interventions for individuals with already-diagnosed conditions in order to reduce complications and related health care utilization. Additionally, it is expensive for employers to pay for wellness program screenings and incentives, and interventions such as subsidizing healthy food choices and reimbursing employees for gym memberships may prove more beneficial.

RELEVANT REGULATIONS

Many states have laws allowing patients to order their own laboratory tests. Additionally, the claims of efficacy made by the vendors are subject to Federal Trade Commission rules on truth-in-advertising, and therefore the claims must be truthful, not misleading, and must be substantiated. Many companies providing these services include language on their websites and other publications stating that test results do not constitute medical advice or diagnoses, thereby limiting their liability.

In response to public health concerns over an unregulated industry, Congress passed the Clinical Laboratory Improvement Amendments (CLIA) to establish standards for diagnostic testing including standards related to safety guidelines, standards to ensure the accuracy and reliability of test results, and standards for laboratory staff, including appropriate level of training. In order to operate, wellness vendors are expected to comply with these guidelines with respect to good practices and may then apply for and receive CLIA certification. Three federal agencies are responsible for the CLIA: The Food and Drug Administration, the Centers for Medicare and Medicaid Services, and the Centers for Disease Control and Prevention. Eighteen states have rules and regulations in addition to CLIA, and some states require vendor licensure in their public health codes.

Additionally, wellness programs must comply with a host of federal laws. These laws include the Employee Retirement Income Security Act (ERISA), the Americans with Disabilities Act (ADA), the Genetic Information Nondiscrimination Act (GINA), the ACA, and the Health Insurance Portability and Accountability Act (HIPAA). HIPAA applies to wellness programs offered as part
of an employer’s group health plan. Therefore, information collected from or created about
participants in the wellness program as part of the group health plan is considered personal health
information and is protected by HIPAA.\textsuperscript{16}

RELEVANT AMA POLICY AND ADVOCACY

Policy H-425.996 on multiphasic health screening programs states that entities that operate or
sponsor such multiphasic health screening programs should be urged to include in their
promotional and explanatory materials about the availability of the program, a definitive statement
that reports on the screening test results will be furnished to the individual participants only and
that each participant is responsible for obtaining any needed medical evaluation or follow-up
should the results of the tests deviate from the normal range. Those operating or sponsoring
multiphasic health screening programs also should be urged to utilize report forms that state in bold
type that the report does not constitute a medical diagnosis or evaluation and that the participant
should consult a physician of his or her choice if the screening test results are not within the normal
limits indicated on the report. Policy H-425.997 more generally states that preventive care should
ideally be coordinated by a patient’s physician.

Policy H-425.994 states that the evaluation of a healthy person by a physician can serve as a
convenient reference point for preventive services and for counseling about healthful living and
known risk factors and that the testing of individuals should be pursued only when adequate
treatment and follow-up can be arranged for the abnormal conditions and risk factors identified.

To promote continuity of care, Policy H-160.921 states that retail health clinics must establish
protocols for ensuring continuity of care with practicing physicians within the local community and
that retail health clinics should be encouraged to use electronic health records as a means of
communicating patient information and facilitating continuity of care. Further, Policy H-160.921
states that retail health clinics should encourage patients to establish care with a primary care
physician to ensure continuity of care.

Policy D-35.985 recognizes non-physician providers as valuable components of the physician-led
health care team. With respect to the health care team, Policy H-275.976 states that the health
professional who coordinates an individual’s health care has an ethical responsibility to ensure that
the services rendered are provided by those whose competence and performance are suited to
render those services safely and effectively.

Policy H-330.879 on providers and Medicare’s Annual Wellness Visit (AWV) articulates principles
reinforcing the need to protect against vendors fragmenting care and the need to preserve the
physician-patient relationship. Specifically, Policy H-330.879 recognizes the need for safeguards in
such circumstances and states that the AWV is a benefit most appropriately provided by a
physician or a member of the physician-led health care team that establishes or continues to provide
ongoing continuity of care. Further, this policy supports that, at a minimum, any clinician
performing the AWV must enumerate all findings from the visit and make provisions for all
appropriate follow-up care.

DISCUSSION

Though well intentioned, the wellness industry often has the effect of duplicating care that
physicians are already providing, unnecessarily increasing physician workload, and obstructing the
physician-patient relationship.\textsuperscript{17} The Council believes wellness programs often incentivize
unnecessary testing and practices that are contrary to evidence-based medicine and medical
judgment. Accordingly, the Council offers a number of principles intended to address these issues and advance the goal of reducing cost of care that does not add value and promoting quality care.

If protections are in place, evidence-based wellness programs can have a positive impact on health by encouraging healthy behaviors and proper disease management strategies. To that end and consistent with the intent of Resolution 901-I-16, the Council recommends that wellness program vendors must disclose for whom a screening test is indicated on the basis of accepted evidence-based guidelines. Additionally, the Council believes vendors must inform patients of the potential benefits and risks of performing a test and of positive or negative screening test results before a test is performed. The Council believes these principles will help bring vendor practices in line with evidence-based guidelines and aid patients in informed decision-making.

Further, the Council believes it is important that wellness program vendors disclose the qualifications of any individual performing the test as well as those individuals interpreting the test results. Moreover, wellness program vendors should use local physicians as medical directors or supervisors. These recommendations advance the goals of patient education and recognition that physicians are best suited to lead health care teams pursuant to AMA policy. In addition, the Council believes it is important that any policy on vendor screenings limits a physician’s liability and protects against physician administrative burden. To that end, the Council recommends that results of a screening test should only be sent to the individual and that test results showing a positive or otherwise abnormal test result should require a consultation with the patient’s primary care physician or usual source of care. Additionally, the Council recommends that physicians not be held liable for delayed or missed diagnoses indicated on third party vendor tests. The Council believes that this recommendation expressly reaffirms the rule that physician liability be limited when stemming from tests that have not been shared with the physician. Finally, the Council believes that Policy H-425.996 is outdated and that its recommendations herein regarding non-physician screenings supersede the policy and therefore recommends that Policy H-425.996 be rescinded.

The following recommendations complement the body of AMA policy on non-physician tests and care including that on the Medicare Annual Wellness Visit and retail health clinics. The Council approaches this issue with the belief that, if proper safeguards and guidelines are in place, such wellness program vendors can have an appropriate role in the health care system and help advance the goals of better, more cost effective care.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted in lieu of Resolution 901-I-16 and that the remainder of the report be filed:

1. That our American Medical Association (AMA) reaffirm Policy H-425.994 stating that the evaluation of a healthy person by a physician can serve as a convenient reference point for preventive services and for counseling about healthful living and known risk factors. (Reaffirm HOD Policy)

2. That our AMA reaffirm Policy H-425.997 stating that preventive care should be coordinated by a patient’s physician and encouraging development of policies and mechanisms to assure the continuity, coordination, and continuous availability of patient care, including preventive care and early-detection screening services. (Reaffirm HOD Policy)
3. That it be the policy of our AMA that any wellness program vendor providing non-physician ordered screenings should adhere to the following principles:

   a. Must disclose for whom a screening test is indicated on the basis of accepted evidence-based guidelines;

   b. Must inform patients of the potential benefits and risks of performing a test and of the implications of positive or negative screening test results before a test is performed;

   c. Must disclose the qualifications of any persons in contact with the patient and of any persons interpreting the results of any screening test;

   d. Should use local physicians as medical directors or supervisors in the appropriate specialty with the requisite state licensure;

   e. Should send results of any screening only to the individual patient; and

   f. Should require a consultation with the patient’s primary care physician or usual source of care if a screening test shows a positive or otherwise abnormal test result. (New HOD Policy)

4. That our AMA support that physicians not be held liable for delayed or missed diagnoses indicated on wellness program vendor non-physician ordered screenings. (New HOD Policy)

5. That our AMA rescind Policy H-425.996. (Rescind HOD Policy)

Fiscal Note: Less than $500.
REFERENCES


3 Id.

4 L.V. Anderson. Workplace Wellness Programs are a Sham. Slate. September 2016. Available at: http://www.slate.com/articles/health_and_science/the_ladder/2016/09/workplace_wellness_programs_are_a_sham.html


8 Id.

9 Karen Pollitz and Matthew Rae, supra note 1.

10 Supra note 6.

11 L.V. Anderson, supra note 6.


13 Clinical Laboratory Improvement Amendments (CLIA). U.S. Food and Drug Administration. Available at: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm124105.htm

14 Summit Health, supra note 12.


17 Yul Enjes. Workplace Wellness Program Requirements Should Reflect High-Value Recommendations. ACP Internist. Available at: https://www.acpinternist.org/weekly/archives/2017/02/14/5.htm
EXECUTIVE SUMMARY

As the House of Representatives and the Senate have been discussing and crafting legislation related to health reform, the Council spent the past year reviewing the substantial body of American Medical Association (AMA) policy pertaining to the AMA proposal for reform, as well as assessing whether to potentially revisit policy on certain health reform issues. The Council has concluded that the preponderance of AMA policy regarding coverage, choice and access remain relevant. However, in its review, the Council determined that it was necessary to revisit and modify policy on essential health benefits and the relative merits of high-risk pools versus reinsurance.

The Council believes there is an opportunity to include additional safeguards in AMA policy to ensure that patients have meaningful coverage that protects them against catastrophic expenses. While the AMA has long supported patient choice of health plan, AMA policy has also stressed that any health insurance purchased must provide meaningful coverage for hospital, surgical and medical care; protect patients against catastrophic expenses; and promote preventive services. AMA policy also underscores 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, and that prohibitions on annual and lifetime limits should remain in place under any reform.

The Council notes that most of the health care claims costs associated with essential health benefits (EHB) are attributable to such services as hospital inpatient and outpatient care, physician services, and prescription drugs. These services are arguably viewed as fundamental components of health insurance coverage. Removing any benefits from the EHB requirements, or allowing waivers of such requirements, can cause insurers to cherry pick patients based on the services their plans cover, as well as hinder patient access to necessary services. If insurers are allowed to offer plans with skimpier coverage, plan designs could potentially discriminate against people with pre-existing conditions. In addition, individuals who use services and benefits no longer included in the EHBs could face substantial increases in out-of-pocket costs. As such, the Council is recommending that our AMA oppose the removal of categories from the EHB package. In addition, the Council believes that our AMA should also oppose waivers of EHB requirements that lead to EHB categories and their associated protections against annual and lifetime limits, and out-of-pocket expenses, being eliminated.

In addition, the Council re-evaluated AMA policy with respect to how to best subsidize the costs of high-cost and high-risk patients, who may have pre-existing conditions. Traditional high-risk pools have historically provided individuals with pre-existing conditions with second-class insurance, with waiting periods to get pre-existing conditions covered, higher premiums, potentially high deductibles, and lifetime limits on benefits. Considering the success of the Affordable Care Act’s reinsurance program, as well as state reinsurance programs, and in light of finite resources, the Council believes that resources should be directed to reinsurance programs. Reinsurance provides an equitable, fair and cost-effective mechanism to subsidize the costs of high-risk and high-cost patients, and protects patients with pre-existing conditions.
The American Medical Association (AMA) proposal to cover the uninsured and expand choice, used in AMA advocacy leading up to and following the enactment of the Affordable Care Act (ACA) and highlighted in AMA’s Voice for the Uninsured campaign, is based on numerous policies developed and/or refined by the Council on Medical Service, and adopted by the House of Delegates, during the 1990s and 2000s. The proposal removed the bias toward employment-based insurance and promoted a system of individually selected and owned health insurance coverage, using tax credits, individual responsibility, and other market regulations to maximize coverage gains, make coverage affordable, and ensure patient choice of health plan and physicians.

As the House of Representatives and the Senate have been discussing and crafting legislation related to health reform, the Council spent the past year reviewing the substantial body of AMA policy pertaining to the AMA proposal for reform, as well as assessing whether to potentially revisit policy on certain health reform issues. The Council has concluded that the preponderance of AMA policy regarding coverage, choice and access remain relevant. However, in its review, the Council determined that it was necessary to revisit and modify policy on essential health benefits and the relative merits of high-risk pools versus reinsurance.

This report provides background on the issues of essential health benefits, high-risk pools and reinsurance; assesses their impact on health insurance affordability; summarizes relevant AMA policy; and presents policy recommendations.

ESSENTIAL HEALTH BENEFITS

Background

Under the ACA, all qualified health benefits plans, with the exception of grandfathered individual and employer-sponsored plans, are required to offer at least the essential health benefits (EHB) package, including those offered in health insurance marketplaces and in the individual and small group markets outside of the marketplaces. The ACA specified that the EHB package must cover the following general categories of services:

- Ambulatory patient services;
- Emergency services;
- Hospitalization;
- Maternity and newborn care;
- Mental health and substance use disorder services, including behavioral health treatment;
• Prescription drugs;
• Rehabilitative and habilitative services and devices;
• Laboratory services;
• Preventive and wellness services and chronic disease management; and
• Pediatric services, including oral and vision care.

The Secretary of the US Department of Health and Human Services (HHS) has the responsibility to
determine the scope of the EHB package, which the ACA specified should be equal to the scope of
benefits under a typical employer-sponsored plan. Regulations addressing EHB stated that EHB
shall be defined by state-specific benchmark plans. HHS also stated that “the EHB-benchmark plan
would serve as a reference plan, reflecting both the scope of services and limits offered by a typical
employer plan in that state.” HHS outlined four benchmark plan options for states:

• The largest plan by enrollment in any of the three largest small group insurance products in
  the state’s small group market;
• Any of the largest three state employee health benefit plans by enrollment;
• Any of the largest three national Federal Employees Health Benefits Program (FEHBP)
  plan options by enrollment; and
• The largest insured commercial non-Medicaid health maintenance organization operating
  in the state.¹

Impact on Health Insurance Affordability

Concerns have been raised that certain categories of essential health benefits drive up premium
costs. The Council notes that most of the health care claims costs associated with essential health
benefits are attributable to such services as hospital inpatient and outpatient care, physician
services, and prescription drugs. These services are arguably viewed as fundamental components of
health insurance coverage. For example, Milliman estimated that removing maternity coverage
from insurance coverage may lower premiums by $8 to $14 per month, depending on geographic,
provider and other factors.² In addition, a recent analysis conducted by RAND researchers
projected that, for 2017, maternity care would account for four percent of per capita insurer
spending, and mental health and substance abuse treatment would account for one percent of per
capita insurer spending. Spending on prescription drugs was projected to be more substantial,
accounting for approximately 22 percent of per capita insurer spending.³

The ACA also prohibits annual and lifetime limits, but only for care that is considered to be under
the umbrella of EHBs. In addition, the ACA requires health plans to cap out-of-pocket expenses of
enrollees, but only for care that is considered EHBs. As such, several analyses have concluded that
if EHB categories are removed or allowed to be waived, premiums would decrease, but individuals
who use services and benefits no longer included in the EHBs could face substantial increases in
out-of-pocket costs.⁴,⁵,⁶,⁷ If EHB categories are removed or allowed to be waived, health plans
could react in multiple ways, including no longer covering affected categories; providing a level of
coverage for affected categories (but caps on out-of-pocket spending, as well as annual and lifetime
limits may not apply); or offer coverage “riders” for affected categories. Analyses have found that
categories most likely to be removed from the EHB, if states are allowed flexibility to do so,
include maternity care; mental health and substance abuse benefits; rehabilitative and habilitative
services; certain pediatric services, including oral and vision care; and prescription drugs.⁸,⁹,¹⁰,¹¹

The Council notes, for example, that riders for maternity services were available prior to enactment
of the ACA. In addition, if prescription drugs were removed as an EHB category, plans may
provide a level of coverage for them, but individuals who rely on expensive prescription drugs
could face an exponential increase in out-of-pocket spending due to the loss of the ACA’s financial protections afforded to EHB categories.

In addition, analyses have found that removing EHB categories or allowing EHB waivers could cause market segmentation.\textsuperscript{12,13,14} If categories are removed from EHB, individuals who do not foresee a need for removed services will be attracted to more affordable, less comprehensive plans. However, individuals in need of affected services, which could range from mental health to maternity services to pediatric services, would either not have any plan options or face much higher premiums for plans that offer at least some level of coverage for removed services. As such, health plans would be able to structure their offerings as to attract lower-risk and healthier enrollees, as sicker, higher-risk individuals would tend to gravitate toward richer, more generous coverage.

Finally, concerns have been raised that removing EHB categories or allowing waivers of EHBs could allow for mini-meds and other “sham” health insurance to have greater standing in the marketplace. As ACA’s protections against catastrophic costs are tied to EHBs, if EHBs are eliminated, individuals could increasingly enroll in health insurance coverage that does not protect them against catastrophic expenses. Notably, the health reform debates in the House of Representatives and the Senate have been impacted by the Congressional Budget Office’s definition of private health insurance coverage, which has been outlined as “consisting of a comprehensive major medical policy that, at a minimum, covers high-cost medical events and various services, including those provided by physicians and hospitals… The definition excludes policies with limited insurance benefits (known as mini-med plans); ‘dread disease’ policies that cover only specific diseases; supplemental plans that pay for medical expenses that another policy does not cover; fixed-dollar indemnity plans that pay a certain amount per day for illness or hospitalization; and single-service plans, such as dental-only or vision-only policies. In this estimate, people who have only such policies are described as uninsured because they do not have financial protection from major medical risks.”\textsuperscript{15}

\textbf{AMA Policy Relevant to Essential Health Benefits}

Policy H-165.846 states that existing federal guidelines regarding types of health insurance coverage (e.g., Title 26 of the US Tax Code and Federal Employees Health Benefits Program [FEHBP] regulations) should be used as a reference when considering if a given plan would provide meaningful coverage. The policy also advocates that the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) program be used as the model for any EHB package for children. Policy H-165.865 states that in order to qualify for a tax credit for the purchase of individual health insurance, the health insurance purchased must provide coverage for hospital care, surgical and medical care, and catastrophic coverage of medical expenses as defined by Title 26 Section 9832 of the US Code. Policy H-165.848 states that under an individual mandate, individuals should be required to obtain, at a minimum, coverage for catastrophic health care and evidence-based preventive health care. Policy D-180.986 states that our AMA will encourage local, state, and federal regulatory authorities to aggressively pursue action against “sham” health insurers. Policy H-165.856 cautions that benefit mandates should be minimized to allow markets to determine benefit packages and permit a wide choice of coverage options. Policy H-185.964 opposes new health benefit mandates unrelated to patient protections, which jeopardize coverage to currently insured populations.
HIGH-RISK POOLS AND REINSURANCE

Background

The ACA established risk adjustment, reinsurance, and risk corridor programs to not only stabilize premiums during the early years of ACA implementation, but to blunt the impact of adverse risk selection. ACA’s risk adjustment program, which is permanent in nature, redistributes funds from plans with lower-risk enrollees to plans with higher-risk enrollees, thereby removing insurer incentives to “cherry pick” healthier enrollees. The ACA’s temporary reinsurance program played a role in stabilizing premiums in the individual marketplace during the early years of ACA implementation. The program provided payments to plans that enrolled higher-cost individuals whose costs exceeded a certain threshold, also known as an attachment point, up to the reinsurance cap. The ACA’s temporary risk corridor program aimed to promote accurate premiums while there was uncertainty among insurers in the early years of the marketplaces about who would enroll and the cost of their care. The risk corridor program limited health plan losses and gains beyond an allowable range.16

The ACA established a temporary state-based high-risk pool program, known as the Pre-Existing Condition Insurance Plan (PCIP) program, in 2010, to be phased out when the key coverage provisions of the ACA became operational in 2014. HHS ran the PCIPs in 23 states and the District of Columbia, while 27 states administered their own programs. Individuals had to be uninsured for at least six months before enrolling, but otherwise, the program had no pre-existing condition exclusions. Unlike traditional state high-risk pools that existed before the ACA, PCIP premiums were able to vary by age but were otherwise equal to premiums paid by individuals without pre-existing conditions. In addition, there were no annual or lifetime dollar limits on covered benefits under PCIP, there were caps on out-of-pocket spending, and there was a minimum actuarial value of plans, which impacted deductibles. The ACA appropriated $5 billion to fund net losses of PCIP programs.17

While the CBO estimated in June 2010 that an average of 200,000 individuals would be enrolled in PCIP for the 2011-2013 period,18 PCIP enrollment peaked at about 115,000 in March 2013. Also in March 2013, new PCIP enrollment had to be suspended in order to ensure that there were sufficient resources to pay the claims of individuals already enrolled. Between September 2012 and September 2013, the final 12-month period for which PCIP expense data were reported, PCIP had net losses of more than $2 billion, with $4 billion in total net losses reported as of September 2013.19

Impact on Health Insurance Affordability

Mechanisms to subsidize the costs of high-risk and high-cost enrollees have had various rates of success. Concerning high-risk pools, prior to implementation of the ACA, 35 states offered high-risk pools as a mechanism to cover high-risk and high-cost residents, including those with pre-existing conditions. At their peak, state high-risk pools that existed prior to passage of the ACA covered more than 200,000 people nationally, with combined net losses for the state high-risk pools totaling more than $1.2 billion for 2011, or $5,510 per enrollee, on average. Overall, state high-risk pools featured premiums above standard non-group market rates, with most states capping them at 150 to 200 percent of standard rates. Many also featured high deductibles, including deductibles in the $5,000 range. Nineteen states had some degree of premium subsidy for low-income individuals. In addition, despite the fact that many individuals had to seek coverage in high-risk pools because of a pre-existing condition, most states excluded coverage for these conditions for medically eligible individuals ranging from six to 12 months. Almost all high-risk
pools imposed lifetime limits on covered services, with some also imposing annual limits on
covered benefits. A few states capped or closed enrollment.20

The Council notes that a January 2017 report from the American Academy of Actuaries also raised
concerns regarding high-risk pools, noting that “enrollment has generally been low, coverage has
been limited and expensive, they require external funding, and they have typically operated at a
loss… Removing high-risk individuals from the insured risk pools reduces costs in the private
market only temporarily. Over time, even lower-cost individuals in the individual market can incur
high health care costs, which would put upward pressure on premiums.”

The actuaries also noted that funding could be directed toward a reinsurance program that
reimburses plans the costs of high-risk enrollees. For example, to fund the ACA’s transitional
reinsurance program, insurers and third party administrators paid $63 per enrollee per year in 2014,
$44 in 2015 and $27 in 2016. These investments in reinsurance yielded premium reductions. For
example, in 2014, the $10 billion reinsurance fund, the result of the $63 per enrollee per year
contributions, was estimated to reduce premiums by 10 to 14 percent. The actuaries stated that a
permanent program to reimburse plans for the costs of their high-risk enrollees would reduce
premiums.21 Reinsurance enables high-risk enrollees to remain in the same individual market risk
pool and enjoy the same protections and choices as healthy plan enrollees.

States have also submitted waivers under Section 1332 of the ACA, as outlined in Council on
Medical Service Report 1 being considered at this meeting, to fund state reinsurance programs.
Alaska’s waiver, which has been approved, allows the state to implement the Alaska Reinsurance
Program (ARP) for 2018 and subsequent years. The ARP will cover claims in the individual
market for individuals with one or more of 33 identified high-cost conditions to help stabilize
premiums. As a result, insurers will relinquish both premiums received for such individuals as well
as claims they would have paid absent the waiver. As a result of the ARP, it is expected that
premiums will be 20 percent lower in 2018 than absent the waiver, and 1,460 additional individuals
will have health insurance coverage.22 The waiver application of Minnesota, which has also been
approved, would create the Minnesota Premium Security Plan, which was estimated to yield a 20
percent reduction in average premiums in 2018.23 While Minnesota’s waiver was approved, the full
amount the state requested in its waiver for federal pass-through funding to financially support its
reinsurance program was not approved. Only federal pass-through funding reflecting savings from
less spending on premium tax credits and cost-sharing reductions was approved, not the amount
also requested by the state that reflects federal savings due to lower premiums for plans under the
state’s Basic Health Program.24 The waiver application of Oregon, which was still under review
when this report was prepared, anticipates that its waiver to establish the Oregon Reinsurance
Program will reduce premiums, including those for the second-lowest cost silver plan, by 7.5
percent in 2018 (net of the premium assessment), with an increase in enrollment in the individual
market by approximately 1.7 percent in the same year.25

Maine also had an “invisible high-risk pool” that it implemented in 2011, which in functionality
was more similar to a reinsurance program than a high-risk pool. The main difference between
invisible high-risk pools and the more traditional approach to reinsurance as included in the ACA is
that the pools identify potential high-cost individuals prospectively, versus being reimbursed
retrospectively for patients who actually incur high-cost claims. As a result, some plan enrollees
who end up having unpredictably costly claims may not be included in invisible high-risk pools,
and as such insurers would not be reimbursed for a portion of their claims. For example, under
Maine’s program, all health insurance applicants were required to complete a health statement with
their application for insurance, and insurers used the statement to ascertain which individuals to
place in the invisible high-risk pool, based on what health conditions they had. Selected individuals
were enrolled in the same plan they applied for at the same premium levels, but on the back-end, their health insurers were reimbursed for 90 percent of their claims between $7,500 and $32,500 per year and 100 percent of claims more than $32,500. Premium reductions were achieved as a result, which varied based on applicant age.26

**AMA Policy Relevant to Risk Subsidization**

Policy H-165.842 supports the principle that health insurance coverage of high-risk patients be subsidized through direct risk-based subsidies such as high-risk pools, risk adjustment, and reinsurance, rather than through indirect methods that rely heavily on market regulation; and supports state-based demonstration projects to subsidize coverage of high-risk patients through mechanisms such as high-risk pools, risk adjustment, reinsurance, and other risk-based subsidies.

Policy H-165.995 supports: (1) the establishment in each state of a risk pooling program, in which all health care underwriting entities in the state participate, to provide adequate health insurance coverage at a premium slightly higher than the standard group rate to (a) those who are unable to obtain such coverage because of medical considerations, and (b) those with medically standard risks who could afford, but presently lack, access to such group coverage; (2) the amendment of the federal tax code to require employers to purchase group health insurance coverage from an entity participating in the state risk pool or, if self-insured, to participate in the risk pool if such a pool is available, in order to deduct the cost of their coverage as a business expense; and (3) using state tax revenues as an alternative source for defraying excess pool costs.

**DISCUSSION**

As millions of Americans have gained coverage resulting from the ACA, the Council affirms that progress has been made on a long-time policy priority of the AMA – expanding access to affordable, quality health insurance coverage. However, in light of the health reform discussions and debates that have occurred this year, the Council believes there is an opportunity to include additional safeguards in AMA policy to ensure that patients have meaningful coverage that protects them against catastrophic expenses. While the AMA has long supported patient choice of health plan, AMA policy has also stressed that any health insurance purchased must provide meaningful coverage for hospital, surgical and medical care; protect patients against catastrophic expenses; as well as promote preventive services. AMA policy also underscores 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, and that prohibitions on annual and lifetime limits should remain in place under any reform.

Under current law, the requirement that all qualified health plans, with the exception of grandfathered individual and employer-sponsored plans, offer at least the EHBs in the EHB package, has helped ensure that individuals have had access to meaningful coverage. Importantly, the prohibition on annual and lifetime limits, as well as the cap on out-of-pocket expenses, is only required for care that is considered to be under the umbrella of essential health benefits. Consistent with previously established AMA policy, the Council believes that using the current benchmark approach to EHBs, while requiring ten categories of essential health benefits, strikes a balance between offering meaningful coverage and maintaining patient choice in health plans and their respective benefits packages. The Council believes that the benchmark approach to EHBs recognizes that there is not a “one size fits all” approach to health insurance benefits, and that some variability is needed.
The Council notes that most of the health care claims’ costs associated with EHBs are attributable to such services as hospital inpatient and outpatient care, physician services, and prescription drugs. These services are arguably viewed as fundamental components of health insurance coverage. Removing any benefits from the EHB requirements, or allowing waivers of such requirements, can cause insurers to cherry pick patients based on the services their plans cover, as well as hinder patient access to necessary services. If insurers are allowed to offer plans with skimpier coverage, plan designs could potentially discriminate against people with pre-existing conditions. In addition, individuals who use services and benefits no longer included in the EHBs could face substantial increases in out-of-pocket costs. As such, the Council is recommending that our AMA oppose the removal of categories from the EHB package. In addition, the Council believes that our AMA should also oppose waivers of EHB requirements that lead to EHB categories and their associated protections against annual and lifetime limits, and out-of-pocket expenses, being eliminated.

In addition, after the expiration of the ACA’s reinsurance program, and with policymakers and stakeholders evaluating various options to improve the stability of health insurance premiums and the overall health insurance marketplace, the Council reevaluated AMA policy with respect to how to best subsidize the costs of high-cost and high-risk patients, who may have pre-existing conditions. Critics of high-risk pools as a viable option for covering high-risk individuals have emphasized that the funding allocated to them, in the past and in legislation that was considered this year, has not been sufficient. More importantly, however, is that traditional high-risk pools have provided individuals with pre-existing conditions with second-class insurance, with waiting periods to get pre-existing conditions covered, higher premiums, potentially high deductibles, and lifetime limits on benefits. As such, the Council is recommending that Policy H-165.995 be rescinded, resulting from the evidence that shows the consequences of high-risk pools, and their subjection of individuals with pre-existing conditions to a different level of health insurance. At this juncture, considering the success of the ACA’s reinsurance program, as well as state reinsurance programs, the Council believes that, considering finite resources, that resources should be directed to reinsurance programs. Reinsurance provides an equitable, fair and cost-effective mechanism to subsidize the costs of high-risk and high-cost patients, and protects patients with pre-existing conditions. The Council concludes that data suggest that a permanent reinsurance program may be a desirable policy option, whether administered at the federal or state level.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted and the remainder of the report be filed:

1. That our American Medical Association (AMA) oppose the removal of categories from the essential health benefits (EHB) package and their associated protections against annual and lifetime limits, and out-of-pocket expenses. (New HOD Policy)

2. That our AMA oppose waivers of EHB requirements that lead to the elimination of EHB categories and their associated protections against annual and lifetime limits, and out-of-pocket expenses. (New HOD Policy)

3. That our AMA prefer reinsurance as a cost-effective and equitable mechanism to subsidize the costs of high-cost and high-risk patients. (New HOD Policy)

4. That AMA Policy H-165.995 be rescinded. (Rescind HOD Policy)
Fiscal Note: Less than $500.

REFERENCES

4 Id.
8 Bayram and Dewey, supra note 2.
9 Eibner and Whaley, supra note 3.
10 Jost, supra note 6.
11 CBO, supra note 7.
12 Bayram and Dewey, supra note 2.
13 Fiedler, supra note 5.
14 Jost, supra note 6.
15 CBO, supra note 7.
19 Pollitz, supra note 17.
20 Pollitz, supra note 17.


REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 5-I-17

Subject: Reaffirmation of AMA Policy Opposing Caps on Federal Medicaid Funding
(Council on Medical Service Report 9-A-17)

Presented by: Paul A. Wertsch, MD, Chair

Referred to: Reference Committee J
(Peter C. Amadio, MD, Chair)

At the 2017 Annual Meeting, the House of Delegates referred Council on Medical Service Report 9-A-17, “Capping Federal Medicaid Funding.” The report advocated for a series of safeguards in the event of federal Medicaid funding being capped. Debate on the report focused on an imminent Senate bill to undo the Medicaid expansion of the Affordable Care Act (ACA) and replace it with state per capita caps or block grants.

At the same meeting, the House of Delegates adopted Policy H-290.963, “Federal Medicaid Funding,” which states that our American Medical Association (AMA): (1) opposes caps on federal Medicaid funding; and (2) advocates that Congress and the Department of Health and Human Services seek and take into consideration input from our AMA and interested state medical associations, national medical specialty societies, governors, Medicaid directors, mayors and other stakeholders, during the process of developing federal legislation, regulations, and guidelines on Medicaid funding.

BACKGROUND

Expanding Medicaid eligibility to most individuals with incomes up to 138 percent of the federal poverty level was a key strategy in expanding health insurance coverage under the ACA and accounted for 63 percent of coverage gains in 2014. Medicaid expansion resulted in an estimated 11 million newly enrolled beneficiaries in 2015. The program currently covers approximately 73 million beneficiaries nationwide. The Medicaid cap safeguards proposed in Council on Medical Service Report 9-A-17 included:

a. Individuals, including children and adolescents, who are currently eligible for Medicaid should not lose their coverage, and federal funding for the amount, duration, and scope of currently covered benefits should not be reduced;

b. The amount of federal funding available to states must be sufficient to ensure adequate access to all statutorily required services;

c. Cost savings mechanisms should not decrease patient access to quality care or physician payment;

d. The methodology for calculating the federal funding amount should take into consideration the state’s ability to pay for health care services, rate of unemployment, concentration of low income individuals, population growth, and overall medical costs;

e. The federal funding amount should be based on the actual cost of health care services for each state;

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The federal funding amount should continue to fund the Affordable Care Act (ACA) Medicaid expansion populations in states that have expanded Medicaid and provide non-expansion states with the option to expand Medicaid with additional funding to cover their expansion populations;

The federal funding amount should be indexed to accurately reflect changes in actual health care costs or state-specific trend rates, not on a preset growth index (e.g., consumer price index);

Maximum cost-sharing requirements should not exceed five percent of family income; and

The federal government should monitor the impact of capping federal Medicaid funding to ensure that patient access to care, physician payment and the ability of states to sustain their programs has not been compromised.

The House of Delegates had a robust discussion about the strategic AMA message that would be implied by adopting the proposed safeguards.

In 2017, Congress considered and defeated numerous proposals to repeal and replace the ACA, which included large (up to $880 billion) reductions to Medicaid and recommendations to cap federal Medicaid spending.

- In March 2017, the American Health Care Act was introduced in the US House of Representatives to repeal and replace the ACA, in part by discontinuing funding for the ACA Medicaid expansion and capping federal Medicaid funding to states.
- In June 2017, during the Annual Meeting of the House of Delegates, the Better Care Reconciliation Act was introduced in the Senate and included a large reduction in federal Medicaid spending, a return to categorical Medicaid eligibility, and a state option to receive a federal block grant for the ACA expansion population of nondisabled adults.
- In July 2017, the Senate considered a “skinny repeal” bill that left Medicaid intact.
- In September 2017, the Senate considered the Graham Cassidy measure, which would have terminated the ACA’s Medicaid expansions, premium tax credits, cost-sharing reduction payments, and small business tax credits. It would also have imposed per capita caps on Medicaid funding and offered states the alternative of a broader Medicaid block grant.

DISCUSSION

At the time that this report was written, Congress had not taken up additional legislation to repeal and/or replace the ACA. The AMA opposed all of the noted bills and urged Congress to initiate a bipartisan effort to address shortcomings in the ACA. The Council believes the policy adopted at the 2017 Annual Meeting, which opposes caps on federal Medicaid funding, remains relevant and recommends its reaffirmation.

RECOMMENDATION

The Council on Medical Service recommends that the following be adopted in lieu of Council on Medical Service Report 9-A-17 and the remainder of the report be filed:

That our American Medical Association Policy H-290.963, “Federal Medicaid Funding,” which opposes caps on federal Medicaid funding, be reaffirmed. (Reaffirm HOD Policy)

Fiscal Note: Less than $500.
EXECUTIVE SUMMARY

The discovery of thousands of disease-related genes, aided by the mapping of the human genome, has led to medical innovations capable of dramatically improving patient-centered care and outcomes. Tens of thousands of genetic/genomic tests have been developed to screen for and diagnose diseases, tailor disease treatments, predict susceptibility to certain conditions, and inform prevention strategies. The number of targeted therapeutics capable of responding to particular genetic alterations has also increased exponentially, as have “companion diagnostics” tests that delineate which subpopulations will (or will not) benefit from particular therapeutics.

Precision medicine is a tailored approach to health care that accounts for individual variability in the genes, environment and lifestyle of each person. Physicians already practice precision medicine by managing each patient according to his or her unique symptoms, history, and preferences, but recent technological advances have vastly improved the ability to integrate genetic/genomic aspects of precision medicine into clinical practice. At the same time, new health care payment and delivery models are focused on value and require that health care services demonstrate their value to patients and the health care system as a prerequisite for payment and coverage.

Advanced bioinformatics programs are being used to generate scientific evidence of the validity of genetic/genomic tests and therapeutics and also increase understanding of many health conditions. Notably, there is considerable variability among public and private payers with regard to the evidentiary requirements for coverage of genetic/genomic precision medicine. Moreover, different insurers may review the same evidence yet reach conflicting conclusions about medical necessity and coverage of these services. The Councils initiated this joint report to provide an overview of genetic/genomic precision medicine and the current coverage and payment landscape; describe AMA policy and activity in this arena; and present policy recommendations that address inconsistencies in payment and coverage for genetic/genomic precision medicine services.
Subject: Payment and Coverage for Genetic/Genomic Precision Medicine

Presented by: Paul A. Wertsch, MD, Chair, Council on Medical Service
Robert Gilchick, MD, MPH, Chair, Council on Science and Public Health

Referred to: Reference Committee J
(Peter C. Amadio, MD, Chair)

The discovery of thousands of disease-associated genes, aided by the mapping of the human genome in 2003, has led to medical innovations capable of dramatically improving patient-centered care and outcomes. As of July 2017, the National Institutes of Health’s Genetic Testing Registry (GTR®), which is a central location for voluntary submission of genetic information by providers, included information on more than 52,000 genetic/genomic tests for more than 10,000 conditions. These genetic/genomic tests help screen for and diagnose diseases, tailor disease treatments, predict susceptibility to certain conditions, and inform prevention strategies. The number of targeted therapeutics capable of responding to particular genetic alterations has also increased exponentially, as have “companion diagnostics” tests that delineate which subpopulations will (or will not) benefit from particular therapeutics.

Precision medicine is a tailored approach to health care that accounts for individual variability in the genes, environment and lifestyle of each person. Physicians already practice “precision medicine” by managing each patient according to his or her unique symptoms, medical and family history, and preferences. However, recent technological advances such as the development of large-scale biologic databases (e.g., the human genome sequence), powerful methods for characterizing patients (e.g., proteomics, metabolomics, genomics, cellular assays, and mobile health technologies), and computational tools for analyzing large sets of data have vastly improved the ability to apply precision medicine principles to patient care. Precision medicine tests, technologies and therapeutics are increasingly being adopted into clinical practice as evidence of their effectiveness grows. At the same time, new health care payment and delivery models are focused on value and require that health care services demonstrate their value to patients and the health care system as a prerequisite for payment and coverage.

The Councils initiated this joint report to provide an overview of coverage and payment for genetic/genomic precision medicine; describe AMA policy and activity in this arena; and make policy recommendations. Genetic/genomic testing is used to analyze an individual’s DNA and can confirm or rule out a suspected genetic condition or help determine an individual’s chance of developing or passing on a genetic disorder. Environmental and behavioral data are also essential components of precision medicine, but unlike genetic/genomic data, their clinical use at this time is less common and coverage options are largely undeveloped. The term “genetic/genomic” is used throughout this report to refer to tests that analyze single genes or variants (genetic tests) as well as those that analyze larger portions of the genome, including multiple variants and/or genes, and whole exome and genome sequencing (genomic tests).
BACKGROUND

Precision medicine is routinely used in several specialties, most notably oncology. Using precision oncology, patients with certain cancers undergo testing that enables physicians to molecularly characterize their tumors, and tailor chemotherapy or other targeted therapeutics based on the genetic profile of their tumors. One common example is multi-variant panel tests that determine recurrence risk and potential response to chemotherapy in certain breast cancer patients. Outside of oncology, newborn screening, a state-based program in which every newborn is tested for dozens of genetic diseases that must be treated to avoid serious morbidity, is an example of precision medicine being applied on a large scale. Revolutionary advances in precision medicine have also enabled the diagnosis of rare and difficult-to-diagnose diseases, as well as the treatment of advanced-stage cancers and rare diseases that once were not treatable.

The potential exists for genetic/genomic precision medicine to be adopted more broadly into clinical practice because of advances in the technology used to collect and analyze huge sets of data, which has enabled enhanced research into genomic causes of disease and applications to clinical practice. The amount of data created with just one genome sequence is vast, and advanced bioinformatics programs are required to glean meaningful results from it. These data are being used to generate scientific evidence of the validity of genetic/genomic tests and therapeutics and also increase understanding of many health conditions. Despite these advances and initial evidence of improved health outcomes downstream, most patients do not have access to precision medicine because most public and private health insurers do not offer coverage for genetic/genomic services unless certain clinical criteria and evidentiary standards are met. As a result, access to this next generation of clinical testing services is often limited to individuals who can and choose to pay for it themselves, which has the potential to increase health disparities. While some consumers are paying for genetic tests on their own and without supervision of their physicians, many of these tests (often referred to as direct-to-consumer tests) have little clinical validity and may not be meaningful for physicians and patients. In April 2017, the Food and Drug Administration (FDA) approved marketing of certain direct-to-consumer genetic tests. Assuring the analytical and clinical validity of all clinical tests is critical to delivering optimal care to patients because not all tests are of the same quality and usefulness. Therefore, it is incumbent on physicians as well as payers to pay close attention to evaluations of the evidence supporting their clinical use.

PAYMENT AND COVERAGE

There is considerable variability among private and public payers with regard to the evidentiary requirements for coverage of genetic/genomic tests and services. Criteria used to evaluate tests and therapeutics generally include traditional measures such as analytical validity, clinical validity, and clinical utility. Analytical validity is the accuracy of the test in detecting the specific entity it was designed to detect without implying clinical significance such as diagnosis. Clinical validity is the accuracy with which a test identifies association of a specific entity (e.g., genetic variant) with a clinical purpose such as the presence, absence, predisposition to, or risk of a specific clinical condition. “Clinical utility” is a highly subjective term that does not have a universally accepted definition. Provider organizations, including national medical specialty societies, have defined this term to ensure that physicians are able to utilize testing when it is useful to physicians and patients by informing clinical care. Payers each define the term differently, with many adopting narrow definitions that require evidence of improved health outcomes downstream and that do not encompass the full value that a particular test or therapeutic may provide to patients, their families and society as a whole, such as establishing a diagnosis, reducing spending on continued diagnostic testing, and ending uncertainty for patients and their families. Clinical utility should refer to the
ability of a test to provide information related to the care of patients and to inform treatment decisions.

Currently, there is a well-established clinical evidence base to support coverage of a broad range of genetic/genomic tests; however, newer tests, which may be less expensive but for which the clinical evidence base has not yet matured, are rapidly and continuously becoming available. Because most insurers do not have the capability to assess the evidence for each test themselves they may require third-party health technology assessments (HTAs) which are then used in conjunction with other factors to make coverage determinations. HTA companies often look for evidence based on randomized controlled trials (RCTs)—which have historically been considered the gold standard for evidence generation—or comparable studies; however, the usefulness of many new genetic tests and therapeutics cannot feasibly be demonstrated using an RCT approach and may require novel research approaches. New genetic variants are being identified so rapidly that tests may need to be altered before RCTs can be completed. For example, variants that drive tumor growth and can potentially be targeted by a therapeutic are being identified and continually added to tumor testing panels. And for rare genetic diseases, RCTs may present ethical issues, take many years to complete, or never reach sufficient sample numbers.

HTAs may also require evidence not yet available that correlates genetic/genomic tests and therapies with clinical outcomes. A small study of private-payer challenges to establishing coverage of next-generation tumor sequencing (NGTS), which enables rapid examination of large numbers of genetic tumor alterations, found that most payers understand the potential benefits of NGTS. However, a majority of payers interviewed for the study also reported that NGTS does not fit into their frameworks for medical necessity and does not meet their evidentiary standards requirements. For example, some NGTS tests identify variants for which a specific therapeutic does not yet exist or for which no clinical trials are underway. Despite the potential usefulness of knowing which variants are driving tumor growth for future clinical trials or new therapies, payers do not view such results as immediately actionable. Concerns among payers regarding implementation of NGTS and care delivery, such as the ability to effectively capture results in electronic health records and the preparedness of physicians to use the results in practice, are additional barriers to coverage.

Different types and levels of evidence are currently used to assess genetic/genomic tests, and some organizations—including the Agency for Healthcare Research and Quality, the American College of Medical Genetics and Genomics (ACMG), and the American Society of Clinical Oncology (ASCO)—evaluate available evidence and develop guidelines or recommendations for testing. AdvaMedDx—a trade association for diagnostics manufacturers—has developed a comprehensive framework for assessing the value of diagnostic tests and technologies based on four value drivers: clinical impact, non-clinical patient impact, care delivery revenue and cost impact, and population impact.

Medicare

Certain payers, including Palmetto GBA, a key Medicare contractor in the clinical testing domain, perform both a regulatory function—by requiring and assessing evidence of analytical/clinical validity—and a payer assessment of medical necessity. Medicare local coverage determinations (LCDs) regarding genetic/genomic tests have largely been developed by Palmetto GBA and then routinely adopted by other Medicare contractors in a process that has been lacking in transparency and sufficient stakeholder involvement to ensure that coverage decisions are in the best interests of patients. Several national medical specialty societies representing experts in molecular pathology have expressed serious concerns regarding the credibility of the evidence used by Palmetto GBA in
the drafting of LCDs that have denied coverage for certain genetic/genomic tests. Experts have stated that these LCDs lacked sufficient input, contradicted professional society practice guidelines, and encroached on physician clinical decision-making. As a result of the Palmetto GBA LCD process, the Centers for Medicare & Medicaid Services (CMS) does not cover many of the genetic/genomic tests that might be clinically meaningful to Medicare patients. According to the National Academies of Sciences, Engineering, and Medicine, as of April 2016, well over a thousand genetic tests had been excluded from Medicare coverage.

Federal legislation (S. 794/H.R. 3635, “Local Coverage Determination Clarification Act”) has been introduced to improve the LCD process and enable more patients to benefit from clinically validated medical innovations. This legislation would require Medicare contractors to establish a timely and open process for developing LCDs that includes open public meetings, meetings with stakeholders, an open comment period in the development of draft coverage policies, and a description of all evidence considered when drafting and finalizing coverage determinations. The LCD legislation would also require Medicare contractors seeking to adopt another contractor’s proposal to independently evaluate the evidence needed to make a coverage determination, and would provide physicians and stakeholders a meaningful reconsideration process and options for appealing a Medicare contractor’s decision to CMS. The AMA—along with the ACMG, ASCO, American Society for Radiation Oncology, American Society for Clinical Pathology, the Association for Molecular Pathology and the College of American Pathologists—supports the LCD legislation, which is consistent with AMA policy on LCDs.

Private Insurers

Private insurer coverage determination processes are neither transparent nor standardized across payers, and the evidence used by insurers to make coverage determinations regarding genetic/genomic tests and services can be inconsistent and convoluted. Just as coverage policies differ among insurers, their evidentiary standards requirements, interpretations of those standards, and evidence review processes vary as well. As a result, different insurers may review the same evidence of the validity and utility of a particular test or service yet reach conflicting conclusions about its medical necessity and coverage.

In addition to evidence-based evaluations of a genetic/genomic test’s validity and utility, private payers often seek evidence of the service’s cost-effectiveness, recommendations in professional society consensus statements or clinical practice guidelines, and peer-reviewed studies supporting its use. One study examined private insurer coverage policies for cell-free DNA prenatal screening tests, which are routinely covered for high-risk pregnant women, to gain insights into payer decision-making for next-generation sequencing-based tests in general. Most payers in this study used analytical and clinical validity and clinical utility to evaluate the evidence, and there was some variation in how they interpreted the evidence. This study also found that payers kept abreast of new peer-reviewed studies and professional society recommendations, and updated their coverage policies accordingly.

Research into payer coverage of BRCA1/2 tests and gene panels has found that while nearly all payers covered BRCA1/2-only tests, gene panels that include BRCA1/2 were not likely to be covered because payers sought more evidence demonstrating the panels’ clinical validity and clinical utility. Gene panels identify more mutations than BRCA1/2-only tests but may also uncover incidental (or secondary) findings and variants of uncertain significance. A study of payer-perceived challenges to covering hereditary cancer panels (HCPs) found that these panels may not be covered because they include variants or genes that have not been sufficiently studied and, as a consequence, the entire panel is considered investigational or experimental. The study
highlights the complexity and uncertainty of the payment landscape by noting that while insurers
generally do not cover HCPs, they may pay for them if, for example, they are billed for elements of
the panel they considered medically necessary, or if payment denials are successfully appealed.\textsuperscript{10}
Payer policies may allow coverage of certain genetic/genomic tests and therapeutics under special
circumstances or after successful appeal by physicians advocating on a patient’s behalf. Physicians
routinely advocate for patient access to testing that will inform diagnosis or management of
disease, as well as patient access to therapeutics needed to treat disease; however, these efforts can
be unduly burdensome.

On the front end, private insurers employ prior authorization, step therapy, and other forms of
utilization management to control their members’ access to certain services, including
genetic/genomic testing and the treatments indicated by this testing. Utilization management
requirements also involve very time-consuming processes that divert physician resources away
from patient care. Prior authorization often interferes with patient care by either delaying that care
or denying access to certain tests and therapeutics. Several large private insurers have established
national prior authorization programs for genetic/genomic testing and will deny payment for
services that have not been properly authorized or, in some cases, ordered by a geneticist or genetic
counselor or carried out by insurer-approved laboratories. Some of these insurers have launched
online, automated prior authorization programs for genetic/genomic testing. Certain insurers have
instituted a stepwise approach to genetic/genomic testing, in which a less comprehensive test
(assessing only one or a few variants or genes) must be ordered first and have inconclusive results
before more comprehensive testing (sequencing of one or more entire genes or multiple variants)
can be ordered. Insurers may also enforce limitations on the frequency of genetic testing, including
sequencing, which is not appropriate in situations where test results may significantly change over
time.

At least one large insurer requires physicians to use the insurer’s own clinical decision support tool,
which may not be compatible with physicians’ EHRs and which may be viewed as potentially
infringing on the clinical judgment of physicians. Certain national insurers have also instituted
precertification requirements that require patients to receive pre-test genetic counseling from a
board-certified genetic counselor or clinical geneticist before genetic tests can be ordered. These
policies effectively reduce access to genetic testing for patients who do not have access to those
professionals or are being treated by non-geneticist physicians who are fully capable of providing
pre-test counseling. While AMA Policy H-480.944 supports genetic counseling, Policy H-460.902
opposes genetic testing restrictions based on specialty. A study of BRCA1/2 test cancellation rates
during the periods before and after one national insurer began mandating pre-test counseling by
 genetic counselors or clinical geneticists found that the mandate significantly reduced patient
access to testing.\textsuperscript{11}

Cost-effectiveness

Health care costs continue to rise despite widespread efforts to insert value into models of care
delivery and benefit design. Accordingly, cost-effectiveness, affordability, and value are critical to
the Councils’ discussion of precision medicine and the growing market of genetic/genomic tests
and therapeutics. Although whole genome sequencing has become much more affordable than it
once was, most multi-variant tests are expensive, ranging from $500 to $5000. Single gene tests
may cost as low as about $100 for targeted mutation analysis (testing for one or a few variants in
the gene) and approximately $500 for sequencing the entire gene.

For many genetic/genomic tests, there is widespread variability in the test’s price as well as
payment and coverage for that test, which must be sorted out by ordering physicians who must also
take into account patient cost-sharing expenses. In some cases, patients may request genetic/genomic testing that is not covered by insurance and is instead purchased directly from a test company at an entirely different price. Cost comparison tools (e.g., Fair Health) can be used by patients and physicians to estimate the costs of some genetic tests and services.

More research is needed to demonstrate the cost-effectiveness and economic value of precision medicine. A 2014 study concluded that many genetic tests are cost-effective but fewer are cost saving. Notably, a large number of available tests have not yet been evaluated. A systematic review of economic evaluations of genetic and pharmacogenetics tests found that only 21 percent of pharmacogenetics tests and 12 percent of predictive genetic tests are cost saving. Reporting of incidental/secondary findings using sequencing technologies has been found to be cost-effective in certain circumstances but not necessarily cost saving in healthy populations unless the cost of the sequencing is below a certain threshold.

Genetic Discrimination and Privacy

In 2008, after 13 years of effort on the part of many advocacy organizations including the AMA, Congress passed the Genetic Information Nondiscrimination Act (GINA) nearly unanimously. Title I of GINA prohibits group and individual health insurers from using a person’s genetic information in determining eligibility or premiums and prohibits health insurers from requesting or requiring that a person undergo a genetic test in order to collect genetic information on that person for underwriting decisions. Importantly, GINA does not prohibit health insurance underwriting based on current health status, including manifest disease of a genetic nature. Rather, it is intended to protect individuals with a genetic predisposition to disease that has not manifested, whether or not an individual has knowledge about that predisposition based on his or her own genetic test results or the genetic test results or manifestation of disease in a family member. Since the enactment of GINA, only a modest number of genetic discrimination complaints have been filed under its provisions; in 2016, 238 cases of genetic discrimination were filed out of nearly 100,000 total discrimination cases filed. It is possible that the small number of cases reflects the effectiveness of GINA at discouraging the practice of discrimination on the basis of genetics by health insurers, or alternatively, that discrimination is occurring but is unrecognized or unreported.

Fears about genetic discrimination have led to refusal by some to undergo genetic testing. This can have serious health implications for individuals for whom genetic testing would be beneficial. Even among those who do undergo genetic testing, many withhold test results from their physicians, and some request that their results be placed in a “shadow chart” or withheld entirely from their medical record. Information that is not available to physicians can have detrimental effects on patient care because treating physicians unfamiliar with the patient will have no knowledge of genetic test results unless that information is volunteered by the patient. With more frequent use of technologies that involve analysis of patients’ genomic information, the potential for misuse and discrimination grows. A very important additional consideration is how difficult it has become to maintain the privacy and security of genomic information. In October 2012, the Presidential Commission for the Study of Bioethical Issues concluded that efforts to de-identify genetic information are exceptionally challenging and will gradually become impossible. In January 2013, a group of scientists demonstrated that the genetic information provided by individuals who had been assured anonymity could in fact be re-identified. Therefore, given the rapid uptake of genomic-based technologies in both the clinical setting and outside the clinic, there is a pressing need to remain vigilant on policies that protect the privacy of individuals’ genetic information.
Physician Education

Educating physicians about precision medicine, including genetic/genomic testing and therapeutics, presents its own unique challenges, given the rapid pace of discoveries as well as extensively documented physician time constraints. Physicians must have the knowledge and skills to integrate precision medicine into their clinical practice for obvious reasons related to professionalism and patient care, and also to effectively advocate for insurer coverage of valid and meaningful genetic/genomic tests and targeted therapeutics. From a payment perspective, physicians will likely need more time for counseling patients and to analyze and explain genetic test results, and they should be adequately paid for these services. Patients who have paid for direct-to-consumer testing may also present genetic risk factor findings to their physicians, who are then challenged to consider how to explain the test results and also justify payment for clinical follow-up. Additionally, laboratories providing the tests are increasingly requesting large quantities of documentation from physicians that are needed for retrospective reviews.

The technical complexity of precision medicine adds to the hurdles faced by physicians interested in integrating this type of care into their practices. Training and implementation costs associated with adopting new care practices must be taken into consideration. As in many areas of medicine, there is also the need for significant health information technology (health IT) improvements that will enable interoperability, access, and clinical decision support while not creating additional burdens and usability challenges for physicians.

AMA ACTIVITY

In recent years, the AMA House of Delegates has established relevant policies recommended by the councils. The Council on Science and Public Health (CSAPH) has addressed several topics related to precision medicine including genome editing (CSAPH Report 3-I-16), genomics in hypertension (CSAPH Report 1-I-14), genomics in type 2 diabetes (CSAPH Report 2-A-14), genetic discrimination (CSAPH Report 7-A-13), and next-generation genomic sequencing (CSAPH Report 4-I-12). CSAPH Report 3-A-16 discusses the Precision Medicine Initiative (PMI), now called the All of Us initiative, which is creating a research cohort of over one million volunteers who will share their genetic, environmental and lifestyle data.

The Council on Medical Service developed Report 2-A-13 on value-based insurance design; Report 7-A-14 on coverage and payment for telemedicine; Report 5-I-16 on incorporating value into pharmaceutical pricing; and Report 6-I-16 on integrating mobile health applications and devices into clinical practice.

Regulatory Activity

Uncertainties in the oversight and regulation of genetic/genomic testing services have the potential to stifle innovation and impede patient access to what could be transformative, life-altering care. The AMA, in collaboration with several national medical specialty societies, has developed legislative principles (https://www.ama-assn.org/sites/default/files/public/genetics/personalized-medicine-guiding-principles.pdf) to guide its advocacy efforts in this arena. The principles make clear that payment and coverage policies should not dictate which diagnostic or treatment options are available to physicians and patients, and should take into account the role of physicians in driving and applying genetic/genomic innovations. Furthermore, the principles reinforce that testing alone will not dictate treatment. Rather, physicians’ diagnostic impressions and their interpretation of test results in the context of the patient’s clinical situation and preferences should guide treatment options. Since regulation of
genetic tests is integral to physician practice and patient care, the AMA is engaged in ongoing advocacy with policymakers and other stakeholders to preserve the physician’s role in all aspects of patient care, including the oversight of laboratory-developed tests and other components of precision medicine.

The AMA actively supports a Clinical Laboratory Improvement Amendments (CLIA)-based laboratory oversight system along with appropriate third-party accreditation, and is opposed to FDA oversight of laboratory-developed testing services in all but the most narrow of circumstances. Accordingly, the AMA has made public comments and statements opposing FDA oversight activities that infringe on the practice of medicine, and is engaged with a broad group of stakeholders to support regulatory reform for genetic tests that promotes innovation and preserves patient access. The AMA has also urged Congress to pursue modernization of the CLIA oversight framework for high complexity laboratory testing services that would establish standards for clinical validity and strengthen established standards related to quality control and quality assurance, and to personnel standards including regular proficiency testing. Strengthening the existing CLIA oversight framework will assure patient safety and provide a stronger structure to prevent laboratory errors while preserving patient access to care.

**Protecting Access to Medicare Act (PAMA)**

Section 216 of the Protecting Access to Medicare Act (PAMA), which was enacted in 2014, significantly revised the Medicare payment system for clinical tests by requiring that Medicare payment for laboratories be based on the weighted median of private payer rates. Regulations issued by CMS in June 2016 required laboratories that provide clinical testing, including certain physician office-based laboratories, to collect and report private payer payment and test volume data to CMS. CMS is using this private payer data to set new payment rates that will become effective on January 1, 2018.

The AMA has urged CMS to implement a number of measures to ensure the accuracy of the new payment rates, which will be based on a retrospective reporting period for data collection from 2016. The AMA has expressed serious concerns to CMS regarding the integrity of the data that will be used to calculate the new payment rates, and whether the rates will accurately reflect the weighted median of private payer payments, as Congress intended. Based on the lack of data integrity, the AMA and other stakeholders anticipate that the new payment rates could effectively reduce patient access to clinical lab testing. The AMA also continues to urge CMS to ensure that implementation of the new payment rates results in as little administrative burden for physicians as possible.

PAMA regulations also required CMS to issue Healthcare Common Procedure Coding System (HCPCS) codes to identify new advanced diagnostic laboratory tests (ADLTs), and clinical tests that are cleared or approved by the FDA (referred to as Clinical Diagnostic Laboratory Tests, or CDLTs), if an applicable Current Procedural Terminology (CPT) code (HCPCS level I) does not exist; and to provide, upon request, either a HCPCS code or unique identifier for test tracking and monitoring. In order to address these coding provisions, the CPT Editorial Panel approved in November 2015, and finalized at its February 2016 panel meeting, the new Proprietary Laboratory Analyses (PLA) section of the CPT code set. PLA codes include a descriptor for laboratories or manufacturers that want to more specifically identify their tests. An important part of the development of this new set of codes is that industry and other stakeholders, including subject matter experts, actively participate in the PLA process. To that end, the Panel created the Proprietary Laboratory Analyses Technical Advisory Group (PLA-TAG) to advise the Panel on applications received for codes to be added to the PLA section of CPT. Along with representation...
by the Panel and certain Panel workgroups, the PLA-TAG is composed of individuals with expertise relating to the services covered under the CPT PLA section. These include, but are not limited to, members from various industry segments such as independent laboratories, private payers, professional/industry organizations, commercial laboratories, academic medical institutions and private practitioners. Members of the PLA-TAG will play a crucial role in the PLA code creation process by reviewing CPT PLA code change applications and making recommendations regarding these requests for CPT codes that describe ADLTs or CDLTs.

Prior Authorization

Due to its widespread usage and the significant administrative and clinical concerns it can present, the AMA addresses prior authorization through a multifaceted approach that includes a number of high-profile activities, including the release of Prior Authorization and Utilization Management Reform Principles to address priority concerns. The principles were developed by a workgroup of state and national medical specialty societies, national provider associations and patient representatives convened by the AMA. The 21 principles (https://www.ama-assn.org/sites/default/files/media-browser/principles-with-signatory-page-for-slsc.pdf) seek to improve prior authorization and utilization management programs by addressing broad categories of concern including: clinical validity; continuity of care; transparency and fairness; timely access and administrative efficiency; and alternatives and exemptions. Health plans, benefit managers and any other parties conducting utilization management, as well as accreditation organizations, have been urged to apply the principles to both medical and pharmacy benefits. The principles, which have gained widespread support since their release, with over 100 stakeholder organizations signing on in support of their objectives, include the following:

- Any utilization management program applied to a service, device or drug should be based on accurate and up-to-date clinical criteria and never cost alone. The referenced clinical information should be readily available to the prescribing/ordering provider and the public.
- Utilization management programs should allow for flexibility, including the timely overriding of step therapy requirements and appeal of prior authorization denials.
- Utilization review entities should offer an appeals system for their utilization management programs that allows a prescribing/ordering provider direct access to a provider of the same training and specialty/subspecialty for discussion of medical necessity.

The AMA has also engaged in two research projects to gather data on the impact of prior authorization on patients and physician practices. A web-based survey of 1000 practicing physicians conducted with a market research partner in December 2016 found that practices complete an average of 37 prior authorizations per physician per week, which take the physician and his/her staff an average of 16 hours—the equivalent of two business days—to process. Ninety percent of physicians reported that prior authorization delays patients’ access to necessary care. The survey results (https://www.ama-assn.org/sites/default/files/media-browser/public/government/advocacy/2016-pa-survey-results.pdf) serve as a valuable framework for the aforementioned principles and have provided a strong evidence base for AMA advocacy efforts related to prior authorization. The AMA is also partnering on an academic research project seeking to measure the overall impact of prior authorization on health care costs and outcomes.

The AMA also works closely with state medical associations and national medical specialty societies to address prior authorization and other utilization management issues through state legislation. Several bills passed by state legislatures have been based on the AMA’s model legislation, the “Ensuring Transparency in Prior Authorization Act” (https://www.ama-assn.org/sites/default/files/media-browser/specialty%20group/arc/model-bill-ensuring-
transparency-in-prior-authorization.pdf). The AMA’s Prior Authorization Toolkit provides a useful overview of the current prior authorization landscape and tips for reducing practice burdens related to prior authorization, including implementation of standard electronic processes. In sum, prior authorization and other utilization management programs are high-priority targets for the AMA.

Educating Physicians

The AMA recognizes the importance of educating physicians and physicians-in-training about the clinical uses and ethical considerations of genetic/genomic services. To assist physicians who are encountering new precision medicine technologies, the AMA has partnered with Scripps Translational Science Institute and The Jackson Laboratory to develop “Precision Medicine for Your Practice” (http://education.ama-assn.org/precision-medicine.html), a series of short, online continuing medical educational modules covering specific topics in genomics and precision medicine, including expanded carrier screening in prenatal care, prenatal cell-free DNA screening, somatic cancer panel testing, large scale sequencing in the healthy individual, large scale sequencing as a diagnostic tool, and pharmacogenomics. In the near future, the AMA will be adding modules on sequencing the healthy individual, pharmacogenomics and neurogenomics.

Additionally, the AMA is carrying out research to identify physicians’ educational and resource needs for appropriate implementation of precision medicine into practice. The AMA will continue to develop tools to assist physicians with precision medicine needs.

AMA and All of Us Initiative

As part of its pledge to assist with the PMI, which includes the All of Us Research Program, the AMA is committed to actively working to improve patient access to personal medical information and helping physicians leverage electronic tools to make health information more readily available; developing and disseminating resources including toolkits, podcasts and fact sheets; and improving awareness of the PMI/All of Us Initiative, and how to enroll in its cohort, among physicians.

Health IT and Digital Health

Significant improvements in EHR and other health IT capabilities are critically needed for precision medicine to reach its potential. Robust and interoperable health IT systems must be able to access and display longitudinal health data from each patient regardless of where the data is stored. EHRs are rich with biological, behavioral and environmental data; however, impediments to accessing and enabling the secure exchange of data across health care systems must be overcome. Clinical decision support that will enable application of the data to care management is also an essential component; however, many EHR systems in use today do not have such capabilities, and physicians are frustrated with the usability of EHR systems and report that they sometimes hamper safe and effective care. The AMA actively promotes EHRs that can provide clinical decision support and use genetic/genomic data to provide clinically meaningful information to physicians.

Beyond EHRs, the AMA is committed to understanding and influencing the evolution of health IT and digital health, both of which are integral to the implementation of precision medicine. The AMA provides leadership on digital solutions involving telemedicine and telehealth, mobile health, wearables, and remote monitoring. Using the expertise of physicians and input from partners on the leading edge of health technology, the AMA has developed resources, toolkits and training to help physicians navigate and maximize technology for improved patient care.
AMA POLICY

Policy H-460.908 acknowledges the increasingly important role of genomic-based personalized medicine applications in the delivery of care; calls for the development of educational resources and tools to assist in the clinical implementation of genomic-based personalized medicine; and directs the AMA to continue to represent physicians’ voices and interests in national policy discussions of issues pertaining to the clinical implementation of genomic-based personalized medicine, such as genetic test regulation, clinical validity and utility evidence development, insurance coverage of genetic services, direct-to-consumer genetic testing, and privacy of genetic information. Policy D-460.968 supports the AMA’s work with the PMI and also advocates for improvements to electronic health record systems that will enable interoperability and access without creating additional burdens and usability challenges for physicians.

Policy D-460.976 directs the AMA to maintain a visible presence in genetics and molecular medicine. Policy H-460.905 addresses the clinical application of next generation genomic sequencing, while genome analysis and variant identification is the subject of Policy D-460.971. Policy D-480.987 focuses on direct-to-consumer marketing and availability of genetic tests, and recommends that genetic testing be carried out under the supervision of a qualified health professional. Policy H-65.969 strongly opposes discrimination based on genetic information.

Policy H-185.939 supports flexibility in the design and implementation of value-based insurance design (VBID), which explicitly considers the clinical value of a given service or treatment when determining cost-sharing structures or other benefit design elements. Policy H-185.939 calls for active involvement of practicing physicians; the use of high-quality, evidence-based data; and transparency of the methodology and criteria used to determine high- or low-value services or treatments and coverage and cost-sharing policies. The policy states that VBID should not restrict access to patient care and must include an appeals process to enable patients to secure care recommended by their physicians. The policy also calls for plan sponsors to engage in ongoing evaluation of the plan designs to ensure VBID coverage rules are updated in accordance with evolving clinical evidence.

AMA policy promotes price transparency and education regarding cost-sharing by health plans (Policies D-155.987 and H-165.828). Policy H-320.949 states that utilization management criteria should be based on sound clinical evidence, permit variation to account for individual patient differences, and allow physicians to appeal decisions. Policy D-330.908 advocates for improvements in the LCD process, including increased transparency and a prohibition on Medicare contractors adopting another contractor’s LCD without a full and independent review. Policy D-330.918 directs the AMA to work with national medical specialty societies and CMS to identify outdated coverage decisions that create obstacles to clinically appropriate patient care. Policy H-460.909 outlines principles for comparative effectiveness research, and Policy D-390.961 advocates for adequate investment in this type of research and also better methods of data collection, development, reporting and dissemination of practical clinical decision-making tools. Policy H-155.960 promotes value-based decision-making, collection of clinical and cost data, and cost-effectiveness research, while principles to guide value-based decision-making are delineated in Policy H-450.938.
DISCUSSION

The Councils’ work on precision medicine is timely given passage of the 21st Century Cures Act and continued funding of the PMI, including the All of Us Research Program, and the Cancer Moonshot. The speed and volume of advances in genetics and genomics are impacting an array of regulatory, coding and payment processes that remain very fluid and will continue to be closely monitored by the AMA so that the physician perspective is clearly articulated. As with past health care innovations, the initial period of implementation of genetic/genomic precision medicine is complex and costly. Payers, policymakers and other stakeholders are challenged to keep up with the rapid development of new tests and technologies and the generation of evidence supporting their use, which are essential to ensuring patient safety while also preventing delays in payment and coverage for valid and meaningful services. In the long run, the Councils anticipate that genetic/genomic precision medicine services will become more affordable and in the mainstream across a variety of medical specialties.

The Councils’ recommendations build upon existing AMA policy to establish new, foundational policy addressing the inconsistencies in payment and coverage of genetic/genomic precision medicine services. The Councils recommend reaffirmation of seven integral policies: Policy H-460.968, which directs the AMA’s work on the PMI; Policy H-460.908, which directs the AMA to continue engaging in policy discussions related to the clinical implementation of genetics/genomics; Policy D-480.987, which focuses on direct-to-consumer marketing and availability of genetic testing; Policy H-185.939, which supports implementation of value-based insurance design, consistent with a series of principles regarding the clinical value of treatments and services; Policy H-329.949, which focuses on utilization management-related barriers to care; Policy H-65.969, which opposes discrimination based on genetic information; and Policy H-460.902, which opposes limitations by payers on the ordering of genetic testing based solely on physician specialty.

The Councils discussed the importance of sharing genomic variant data and ensuring that patients and physicians are notified of clinical significance changes. The Councils recommend adding a third clause to Policy D-460.971, which would encourage laboratories to establish a process by which patients and their physicians could be notified when interpretation and clinical significance changes for previously reported variants.

The Councils are concerned by the lack of transparency and standardization across payer coverage determination processes, which may hinder access to valid and meaningful tests and therapeutics as well as future innovations. Accordingly, the Councils recommend that the AMA encourage public and private payers to adopt processes and methodologies for determining coverage and payment for genetic/genomic precision medicine that promote transparency and clarity; involve stakeholders across disciplines, including genetic/genomic medicine experts; describe the evidence being considered and methods for updating the evidence; provide opportunities for comment and meaningful reconsiderations; and incorporate value assessments that consider the value of genetic/genomic tests and therapeutics to patients, families and society as a whole.

The Councils further recognize that the usefulness of many new genetic tests and therapeutics cannot feasibly be demonstrated using an RCT approach and will require novel research approaches. Accordingly, the Councils recommend that the AMA encourage coverage and payment policies for genetic/genomic precision medicine that are evidence-based and take into account the unique challenges of traditional evidence development through RCTs, and work with test developers to establish clear thresholds for acceptable evidence for coverage.
Because patient access to genetic/genomic precision medicine services is largely dependent on
public and private insurer decisions to pay for them, the Councils recommend that the AMA work
with national medical specialty societies and other stakeholders to encourage the development of a
comprehensive payment strategy that facilitates more consistent coverage of genetic/genomic tests
and therapeutics.

As additional steps toward timely and appropriate application of precision medicine into practice,
the Councils recommend that the AMA encourage national medical specialty societies to develop
clinical practice guidelines incorporating precision medicine approaches that support adoption of
appropriate, evidence-based services; and support continued research and evidence generation
demonstrating the validity, meaningfulness, cost-effectiveness and value of precision medicine.

Finally, the Councils recognize that the payment and coverage landscape for precision medicine is
evolving, and emphasize that the Councils’ work is ongoing. Future studies may be warranted by
further innovation and as new technologies—such as artificial intelligence—are adopted into
clinical practice.

RECOMMENDATIONS

The Council on Medical Service and the Council on Science and Public Health recommend that the
following be adopted and that the remainder of the report be filed:

1. That our American Medical Association (AMA) reaffirm Policy H-460.968, which directs the
   AMA to work with the Precision Medicine Initiative, develop resources for physicians on this
   initiative, and continue to advocate for improvements to electronic health record systems that
   will enable interoperability and access while not creating additional burdens and usability
   challenges for physicians. (Reaffirm HOD Policy)

2. That our AMA reaffirm Policy H-460.908, which directs our AMA to continue representing
   physicians in policy discussions of issues related to the clinical implementation of genomic-
   based medicine, such as genetic test regulation, clinical validity and utility evidence
   development, insurance coverage of genetic services, direct-to-consumer genetic testing, and
   privacy of genetic information. (Reaffirm HOD Policy)

3. That our AMA reaffirm Policy D-480.987, which recommends that genetic testing be carried
   out under the supervision of a qualified health professional; encourages individuals interested
   in obtaining genetic testing to contact a qualified health professional; and directs the AMA to
   educate and inform physicians on the types of genetic tests available directly to consumers.
   (Reaffirm HOD Policy)

4. That our AMA reaffirm Policy H-185.939, which supports flexibility in the design and
   implementation of value-based insurance design programs consistent with a series of principles
   regarding the clinical value of treatments and services. (Reaffirm HOD Policy)

5. That our AMA reaffirm Policy H-329.949, which states that utilization management criteria
   should be based on sound clinical evidence, permit variation to account for individual patient
   differences, and allow physicians to appeal decisions. (Reaffirm HOD Policy)

6. That our AMA reaffirm Policy H-65.969, which strongly opposes discrimination based on an
   individual’s genetic information; support legislation that protects against genetic discrimination
   and misuse of genetic information; and supports education for health care providers and
patients on the protections against genetic discrimination currently afforded by federal and
state laws. (Reaffirm HOD Policy)

7. That our AMA reaffirm Policy H-460.902, which opposes limitations by public and private
payers on the ordering of genetic testing that are based solely on physician specialty. (Reaffirm
HOD Policy)

8. That our AMA modify Policy D-460.971 by addition and deletion to read as follows:

Our AMA: (1) encourages payers, regulators and providers to make clinical variant data and
their interpretation publicly available through a system that assures patient and provider
privacy protection; and (2) encourages laboratories to place all clinical variants and the clinical
data that was used to assess the clinical significance of these results, into the public domain
which would allow appropriate interpretation and surveillance for these variations that can
impact the public's health; and (3) encourages laboratories to establish a process by which
patients and their physicians could be notified when interpretation and clinical significance
changes for previously reported variants. (Modify Current HOD Policy)

9. That our AMA encourage public and private payers to adopt processes and methodologies for
determining coverage and payment for genetic/genomic precision medicine that:

a. Promote transparency and clarity;
b. Involve multidisciplinary stakeholders, including genetic/genomic medicine experts and
relevant national medical specialty societies;
c. Describe the evidence being considered and methods for updating the evidence;
d. Provide opportunities for comment and review as well as meaningful reconsiderations; and
e. Incorporate value assessments that consider the value of genetic/genomic tests and
therapeutics to patients, families and society as a whole, including the impact on quality of
life and survival. (New HOD Policy)

10. That our AMA encourage coverage and payment policies for genetic/genomic precision
medicine that are evidence-based and take into account the unique challenges of traditional
evidence development through randomized controlled trials, and work with test developers and
appropriate clinical experts to establish clear thresholds for acceptable evidence for coverage.
(New HOD Policy)

11. That our AMA work with interested national medical specialty societies and other stakeholders
to encourage the development of a comprehensive payment strategy that facilitates more
consistent coverage of genetic/genomic tests and therapeutics. (New HOD Policy)

12. That our AMA encourage national medical specialty societies to develop clinical practice
guidelines incorporating precision medicine approaches that support adoption of appropriate,
evidence-based services. (New HOD Policy)

13. That our AMA support continued research and evidence generation demonstrating the validity,
meaningfulness, short-term and long-term cost-effectiveness and value of precision medicine.
(New HOD Policy)

Fiscal Note: Less than $500
REFERENCES

4 Id.
6 Id.
8 Id.
10 Id.
Whereas, The Centers for Medicare and Medicaid Services (CMS) may reimburse physicians for Chronic Care Management (CCM) services to manage patients with two or more chronic conditions, meeting requirements outlined in Medicare regulations; and

Whereas, When patients are enrolled in home health episodes, physicians in Rural Health Clinics (RHCs) or Federally Qualified Health Centers (FQHCs) are unable to receive CCM reimbursement for treatment or supervision of a patient with chronic conditions under the CCM or home health supervision codes; and

Whereas, Most physicians can receive reimbursement for another service when providing home health supervision, except physicians in RHCs or FQHCs that are unable to receive reimbursement for home healthcare supervision code G0181 (Physician supervision of a patient receiving Medicare covered services provided by a participating home health agency requiring complex and multidisciplinary care modalities involving regular physician development and/or revision of care plans); and

Whereas, For RHCs or FQHCs to provide integrated healthcare as Patient-Centered Medical Homes (PCMH) and provide patients with better health and lower healthcare costs, allowing CCM reimbursement to patients in a current home health episode would align with CMS regulations for CCM; therefore be it

RESOLVED, That our American Medical Association advocate for the authorization of Chronic Care Management (CCM) reimbursement for Rural Health Clinics, Federally Qualified Health Centers, and all other physician clinics providing CCM for patients enrolled in a home health episode, to the Centers for Medicare and Medicaid Services and to Congress if federal law must be amended. (New HOD Policy)

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

Received: 09/19/17
Whereas, An estimated 1.75 million full-time students are currently enrolled in the Medicaid program and are not working;¹ and

Whereas, Several states are in the process of or have formally submitted Section 1115 state waiver requests to include work requirements for Medicaid eligibility;² and

Whereas, The Centers for Medicare and Medicaid Services indicated support for Section 1115 state waiver initiatives involving “training, employment and independence”;³ and

Whereas, Studies have found that Medicaid expansion has had a positive or neutral effect on employment and the labor market;⁴,⁵ and

Whereas, Implementation of work requirements would expand the administrative cost of the Medicaid program per enrollee for states while only having a modest benefit to employment that decreases over time when implemented in other programs;²,⁶,⁷,⁸ and

Whereas, An estimated 3.43 million non-Supplemental Security Income Medicaid recipients report being too sick to work in addition to 2.74 million non-SSI Medicaid recipients report they couldn’t work because of taking care of their home or family;¹ and

Whereas, A work requirement as a criterion for Medicaid eligibility could bar access to healthcare from vulnerable people too sick to work, acting as caregivers, or unable to find employment;¹ therefore be it

RESOLVED, That our American Medical Association oppose work requirements as a criterion for Medicaid eligibility. (New HOD Policy)

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

Received: 09/20/17

**RELEVANT AMA POLICY**

Proposed Revisions to AMA Policy on Medical Student Debt H-305.928  
Medicaid Expansion Options and Alternatives H-290.966  
Medicaid - Towards Reforming the Program H-290.997  
Giving States New Options to Improve Coverage for the Poor D-165.966  
Medicaid Expansion D-290.979  
Affordable Care Act Medicaid Expansion H-290.965
Whereas, Air ambulances requested by third-party medical professionals or first responders improve access to level 1 trauma centers for 87 million Americans who would not be able to receive emergent care in a timely manner otherwise, with 86.4% of the U.S. population living within a 15-to-20-minute response area of an air ambulance; and

Whereas, Fifty-nine percent of patients transported by air ambulance had minor injuries, as defined by an Injury Severity Score of less than 15; and

Whereas, The Airline Deregulation Act of 1978 prohibits states from regulating the price, route, or service of an air carrier, including air ambulances, for the purposes of increasing competition, reducing rates, and improving airline passenger service; however, since Medicare’s creation of a national fee schedule for air ambulances in 2002, more than half of the air ambulance industry is controlled by 4 for-profit operators, with an increase in the number of air ambulances from 545 in 2002 to 1,045 in 2015; and

Whereas, Air Methods, the nation’s largest air ambulance operator, has seen an increase in their average bill of $17,262 in 2009 to $50,199 in 2016, far more than the actual cost for a flight of only $10,199; and

Whereas, Lawsuits to collect payment from patients for use of medical helicopters are on the rise; and

Whereas, Medicare only reimburses 59% of air ambulance costs, adding an average of $15,984 to the cost of self-pay or privately insured patients as air ambulance operators recoup what they lose on below-cost transports funded by the government; and

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Whereas, Private insurance companies that offer ambulance coverage only cover an average of
36.5% of the air ambulance’s bill and, unlike Medicare and Medicaid, there are no regulations
preventing them from balance billing patients for charges after coverage has been applied;7,8

and

Whereas, Between 2013 and 2016, insurance departments from nine states reviewed 55
incidences in which consumers complained of $3.8 million in combined charges, an average
charge of $70,000 per trip;9 and

Whereas, Laws from Wyoming seeking to cap air ambulance fees and North Dakota forcing air
ambulance companies to become participating providers by joining major insurance company
networks have been struck down in federal courts;10 and

Whereas, The AMA supports the education of physicians and the public about the costs
associated with inappropriate use of emergency patient transportation systems (AMA Policy
H-130.954); therefore be it

RESOLVED, That our American Medical Association and appropriate stakeholders study the
role, clinical efficacy, and cost-effectiveness of air ambulance services, including barriers to
adequate competition, reimbursement, and quality improvement. (Directive to Take Action)

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

Received: 09/20/17

RELEVANT AMA POLICY

Non-Emergency Patient Transportation Systems H-130.954
The AMA: (1) supports the education of physicians and the public about the costs associated
with inappropriate use of emergency patient transportation systems; and (2) 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.

See also:
H-45.986 Protection of Insurance Coverage for Medical Attendants Aboard Non-Scheduled
Aircraft
H-240.978 Medicare’s Ambulance Service Regulations
H-215.973 Emergent Care Adjacent to Hospitals

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10 Neary, B. Wyoming seeks to block judge’s order on air ambulance fees. Associated Press. August 2016
Whereas, The cost of health care is ever-increasing; and

Whereas, Employers and other payers are incessantly looking for ways to evaluate the use of certain high-cost medications and services; and

Whereas, One way to do that is to require prior authorization for more and more services; and

Whereas, The additional work required by physician offices has exponentially increased, as witnessed by the need for clinical practices to hire additional employees who spend their total day requesting and arguing for care and services deemed appropriate by the attending physician; and

Whereas, On May 22, 2014, the Centers for Medicare & Medicaid Services released a proposed rule to establish a prior authorization process, endorsing that this would ensure Medicare beneficiaries receive medically necessary care while minimizing the risk of improper payments and therefore protecting the Medicare Trust Fund; and

Whereas, This prior authorization process has been difficult to manage, and has been a significant drain on provider resources—especially at the beginning of each calendar year; and

Whereas, Long-term, effective clinical treatments are frequently required to be re-authorized at the beginning of each calendar year or with any third-party payer change, and often denied with suggestions to take steps backward to previously tried and failed treatments; and

Whereas, This prior authorization process may have worked with some limited cases, but overall, it increases provider burden, complicates patient care and has the potential to cause clinical relapses and worsening medical conditions, which are well-understood by the attending doctor; and

Whereas, Websites with lists of approvable, preferred or otherwise acceptable care and services are neither consistent nor transparent; therefore be it

RESOLVED, That our American Medical Association promote the appropriate use of prior authorization primarily for initial requests and services that fall outside the standard of care (Directive to Take Action); and be it further
RESOLVED, That our AMA implement and promote policy that minimizes the need for prior authorization annually or on any other schedule when the request is for continuity of care and the prior authorization is for regimens that are working well to control a patient’s condition (Directive to Take Action); and be it further

RESOLVED, That our AMA create a policy that prior authorizations need to be completed within three working days by the health plan or pharmacy if approved, or if the prior authorization is denied, the denial must include an explanation, unique and specific to the individual patient, and, if no answer is obtained within three days, the prior authorization is deemed approved and patient care may proceed (New HOD Policy); and be it further

RESOLVED, That our AMA create a policy for the prior authorization process that, unless a health plan, pharmacy vendor or other payer source can document that medical care or a specific service or pharmaceutical is NOT appropriate or medically-indicated based on nationally recognized evidence-based guidelines, the health plan, pharmacy vendor or other payer source shall approve the request of the attending physician (New HOD Policy); and be it further

RESOLVED, That our AMA schedule quarterly meetings with insurance companies to discuss any prior authorization issues, as well as any other matters pertinent to physicians and patients (Directive to Take Action); and be it further

RESOLVED, That our AMA support any effort to allow the physician to bill the insurance company directly for prior authorization time, and that the cost not be a pass-through charge to the patient (New HOD Policy); and be it further

RESOLVED, That our AMA work, both by administrative and/or legislative means, to address the problem of excessive burden from prior authorizations and meaningful use regulations by regulatory and/or legislative means (Directive to Take Action); and be it further

RESOLVED, That our AMA work with Medicare Advantage plans to follow Medicare guidelines if the plan chooses to follow their own guidelines. The plan must be transparent on the criteria for approval or denial. (Directive to Take Action)

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

Received: 09/26/17
Whereas, The delivery and finance of healthcare in the United States is at imminent risk of
collapse; and

Whereas, The Affordable Care Act has not stabilized the delivery and finance of healthcare in
the United States; and

Whereas, The steadily rising US healthcare expenditures threaten the financial viability of the
people, corporations, municipal, state and federal governments of the United States; and

Whereas, The people of the United States have deep philosophical and political divisions
regarding the proper reform of our healthcare system; and

Whereas, The achievement of a fully socialized or fully privatized healthcare system is politically
impossible and ill-advised given our current status quo; and

Whereas, People of the United States have the freedom to choose the terms under which we
receive our healthcare; and

Whereas, We believe it is our right as physicians to choose the terms under which we provide
our professional services; and

Whereas, It is our duty as physicians to advocate for quality healthcare services on behalf of all
patients who need our services; and

Whereas, The ongoing ideological battle is leading to the failure of both private and government
healthcare in the United States; and

Whereas, The ongoing dysfunction in our system is having a severely corrosive effect on the
profession of medicine and the patient doctor relationship; and

Whereas, The public and private healthcare systems successfully co-exist in other developed
nations; and

Whereas, The public and private services successfully co-exist in other parts of the economy
such as transportation, utilities, housing, legal services and education; and

Whereas, It should be politically possible at this moment to craft legislation which forward the
agenda and objectives of those who favor a public system and those who favor a private
system; therefore be it
RESOLVED, That our American Medical Association vigorously advocate for compromise health care reform legislation which restructures all existing government health care programs into a single universal government system which provides health care to all United States citizens and legal residents at a level which is sustainable and affordable (Directive to Take Action); and be it further

RESOLVED, That our AMA simultaneously, with equal vigor, advocate for a far reaching deregulation of privately purchased health care, while maintaining the emphasis on improving quality and safety (Directive to Take Action); and be it further

RESOLVED, That our AMA resist all legislation which attempts to coerce or infringe upon the freedom of the people of the United States to choose the terms of their health care (Directive to Take Action); and be it further

RESOLVED, That our AMA advocate for both public and private health care reforms as an inseparable package. (Directive to Take Action)

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

Received: 09/27/17

**RELEVANT AMA POLICY**

- Health System Reform Legislation H-165.838
- Individual Health Insurance H-165.920
- Preservation of Physician-Patient Relationships and Promotion of Continuity of Patient Care H-160.901
- Access to Affordable Health Care Insurance through Deregulation of State Mandated Benefits H-180.978
Whereas, There have been numerous documented cases of pharmacy benefit managers (PBM) and local pharmacies charging much higher prices for prescription generic medications if insured, than if these medications were being paid by cash without insurance, thereby raising patient co-pays needlessly;\(^1\),\(^2\),\(^3\) and

Whereas, Pharmacy benefit manager’s contracts are cloaked in secrecy, not allowing patients to see the true cost of medications;\(^3\),\(^4\),\(^5\) and

Whereas, Such PBM practices drive up the cost prescription medications and insurance cost enriching PBM’s and pharmacies;\(^2\),\(^3\),\(^4\),\(^5\) and

Whereas, There is now evidence of widespread price gouging by PBM;\(^4\),\(^5\) and

Whereas, PBM’s are thinly regulated allowing these abuses to occur;\(^5\),\(^6\) therefore be it

RESOLVED, That our American Medical Association ask Congress and other appropriate entities to require that there be transparency of drug pricing by pharmacy benefit managers (PBM) to help prevent PBM price manipulation of patient prescription costs (Directive to Take Action); and be it further

RESOLVED, That our AMA advocate for policy that retail pharmacies and health plans be required to disclose to patients the lowest possible cost of any prescription medication—specifically, any price differential between the price of a drug when using an insurance benefit vs the price of the drug without using that benefit. (Directive to Take Action)

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

Received: 09/28/17
Whereas, Accountable Care Organizations (ACOs) have been promoted for their putative ability to “bend the cost curve” and reduce total medical expenditures; and

Whereas, Physician employment by hospitals has been increasing; and

Whereas, Increasing physician employment has been reported to be a contributor to physician burnout; and

Whereas, "Site of service" payment differentials are causing an unfair advantage favoring hospital employment over independent practice; and

Whereas, Despite early hopes that physicians would lead ACOs, most ACOs are in fact controlled by hospitals and hospital systems; and

Whereas, Hospital-controlled ACOs have sometimes created restrictive referral policies that serve to promote hospital services rather than to seek the lower cost, higher quality, or more accessible location for given service; therefore be it

RESOLVED, That our American Medical Association study and report back on health system-led Accountable Care Organization related barriers to utilizing the site of service determined by the physician to be in the best interest of the patient. (Directive to Take Action)

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

Received: 09/28/17
Introduced by: American Academy of Dermatology, American Society for Dermatologic Surgery Association, American College of Mohs Surgery, American Society of Dermatopathology, Society for Investigative Dermatology, American College of Allergy, Asthma and Immunology, Florida

Subject: Opposition to Reduced Payment for the 25 Modifier

Referred to: Reference Committee J
(Peter C. Amadio, MD, Chair)

Whereas, Several insurers—including Independence Blue Cross, Blue Cross Blue Shield Rhode Island, Harvard Pilgrim Health Care, and Tufts Health Plan—have implemented policies that inappropriately reduce reimbursement for modifier 25; and

Whereas, Anthem announced it will implement the same policy in Kentucky, Ohio and Wisconsin in January of 2018; and

Whereas, When an Evaluation & Management (E/M) code with modifier 25 and a procedure code are billed by the same provider for the same date of service, these plans will only compensate the E/M service at 50 percent of the otherwise allowed amount; and

Whereas, The intent of modifier 25, according to Current Procedural Terminology (CPT) guidelines, is to describe a significant, separately identifiable, and medically necessary E/M service performed on the same day as a procedure, outside of the global fee concept; and

Whereas, Providing medically necessary, distinct services on the same date allows physicians to provide effective and efficient, high quality care, in many cases saving patients a return visit; and

Whereas, The AMA Relative Value Scale (RVS) Update Committee (RUC) already reduces the reimbursement for surgical codes that are typically reported with an E/M to account for any overlapping pre-and post-operative work; and

Whereas, By having an insurer impose a reduction on the E/M service, the insurer is in effect reimbursing both codes at a reduced rate; and

Whereas, If there is not a strong response from the House of Medicine the policy will likely spread to other insurers; and

Whereas, Increased uptake in this policy would lead to reimbursement below the cost of physician expense, patients incurring higher out of pocket costs due to follow up visit, and longer waits to see a specialist; therefore be it
RESOLVED, That our American Medical Association amend Policy D-70.971 by addition and deletion to read as follows:

**Uses and Abuses of CPT Modifier -25 D-70.971**

(1) Our AMA Private Sector Advocacy Group will continue to collect information on the use and acceptance of CPT modifiers, particularly modifier -25, and that it continue to advocate for the acceptance of modifiers and the appropriate alteration of payment based on CPT modifiers.

(2) The CPT Editorial Panel in coordination with the CPT/HCPAC Advisory Committee will continue to monitor the use and acceptance of CPT Modifiers by all payers and work to improve coding methods as appropriate.

(3) Our AMA will collect information on the use and acceptance of modifier -25 among state Medicaid plans and use this information to advocate for consistent acceptance and appropriate payment adjustment for modifier -25 across all Medicaid plans.

(4) Our AMA will encourage physicians to pursue, in their negotiations with third party payers, contract provisions that will require such payers to adhere to CPT rules concerning modifiers.

(5) Our AMA will include in its model managed care contract, provisions that will require managed care plans to adhere to CPT rules concerning modifiers, and, in the case where a procedure is appropriately modified by a modifier – 25, require that both the procedure and evaluation and management are paid at 100% of the non-reduced, allowable payment rate.

(6) Our AMA will continue to educate physicians on the appropriate use of CPT rules concerning modifiers.

(7) Our AMA will actively work with third party payers to encourage their disclosure to physician providers any exceptions by those payers to CPT guidelines, rules and conventions.

(8) Our AMA will include in CPT educational publications (i.e. CPT Assistant) examples of commonly encountered situations where the -25 modifier would and would not apply.

(Modify Current HOD Policy)

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

Received: 09/29/17

**RELEVANT AMA POLICY**

**Uses and Abuses of CPT Modifier -25 D-70.971**

(1) Our AMA Private Sector Advocacy Group will continue to collect information on the use and acceptance of CPT modifiers, particularly modifier -25, and that it continue to advocate for the acceptance of modifiers and the appropriate alteration of payment based on CPT modifiers.

(2) The CPT Editorial Panel in coordination with the CPT/HCPAC Advisory Committee will continue to monitor the use and acceptance of CPT Modifiers by all payers and work to improve coding methods as appropriate.

(3) Our AMA will collect information on the use and acceptance of modifier -25 among state Medicaid plans and use this information to advocate for consistent acceptance and appropriate payment adjustment for modifier -25 across all Medicaid plans.

(4) Our AMA will encourage physicians to pursue, in their negotiations with third party payers, contract provisions that will require such payers to adhere to CPT rules concerning modifiers.

(5) Our AMA will include in its model managed care contract, provisions that will require managed care plans to adhere to CPT rules concerning modifiers.

(6) Our AMA will continue to educate physicians on the appropriate use of CPT rules concerning modifiers.

(7) Our AMA will actively work with third party payers to encourage their disclosure to physician providers any exceptions by those payers to CPT guidelines, rules and conventions.

(8) Our AMA will include in CPT educational publications (i.e. CPT Assistant) examples of commonly encountered situations where the -25 modifier would and would not apply.

BOT Rep. 10, I-03 Reaffirmation A-10
Whereas, The Centers for Medicare & Medicaid Services piloted a network adequacy test in 2016 and found several plans with outdated directories; and

Whereas, Exchange plans are required to provide publicly available directories and update them on a monthly basis; and

Whereas, Plans continually update networks, but often mistakenly terminate physicians; and

Whereas, As a result of the false termination patients receive notice that the physician chooses to no longer remain in the patient’s network; and

Whereas, In cases where a patient has been informed about the pending termination status of a physician they have seen in the last year that is overturned the patient should receive a corrected notice from the insurer informing them the physician remains available in their selected plan; therefore be it

RESOLVED, That our American Medical Association amend Policy H-285.908 by addition to read as follows:

Network Adequacy H-285.908

12. Our AMA supports requiring that health insurers that terminate in-network providers:
   a) Notify providers of pending termination at least 30 days prior to removal from network.
   b) Give to providers, at least 14 days prior to distribution, a copy of the health insurer’s letter notifying patients of the provider’s change in network status. (Modify Current HOD Policy)

Fiscal Note: Minimal - less than $1,000.

Received: 09/29/17
RELEVANT AMA POLICY

Network Adequacy H-285.908
1. Our AMA supports state regulators as the primary enforcer of network adequacy requirements.
2. Our AMA supports requiring that provider terminations without cause be done prior to the enrollment period, thereby allowing enrollees to have continued access throughout the coverage year to the network they reasonably relied upon when purchasing the product. Physicians may be added to the network at any time.
3. Our AMA supports requiring health insurers to submit and make publicly available, at least quarterly, reports to state regulators that provide data on several measures of network adequacy, including the number and type of providers that have joined or left the network; the number and type of specialists and subspecialists that have left or joined the network; the number and types of providers who have filed an in network claim within the calendar year; total number of claims by provider type made on an out-of-network basis; data that indicate the provision of Essential Health Benefits; and consumer complaints received.
4. Our AMA supports requiring health insurers to indemnify patients for any covered medical expenses provided by out-of-network providers incurred over the co-payments and deductibles that would apply to in-network providers, in the case that a provider network is deemed inadequate by the health plan or appropriate regulatory authorities.
5. Our AMA advocates for regulation and legislation to require that out-of-network expenses count toward a participant's annual deductibles and out-of-pocket maximums when a patient is enrolled in a plan with out-of-network benefits, or forced to go out-of-network due to network inadequacies.
6. Our AMA supports fair and equitable compensation to out-of-network providers in the event that a provider network is deemed inadequate by the health plan or appropriate regulatory authorities.
7. Our AMA supports health insurers paying out-of-network physicians fairly and equitably for emergency and out-of-network bills in a hospital. AMA policy is that any legislation which addresses this issue should assure that insurer payment for such care be based upon a number of factors, including the physicians' usual charge, the usual and customary charge for such service, the circumstances of the care and the expertise of the particular physician.
8. Our AMA provides assistance upon request to state medical associations in support of state legislative and regulatory efforts, and disseminate relevant model state legislation, to ensure physicians and patients have access to adequate and fair appeals processes in the event that they are harmed by inadequate networks.
9. Our AMA supports the development of a mechanism by which health insurance enrollees are able to file formal complaints about network adequacy with appropriate regulatory authorities.
10. Our AMA advocates for legislation that prohibits health insurers from falsely advertising that enrollees in their plans have access to physicians of their choosing if the health insurer's network is limited.
11. Our AMA advocates that health plans should be required to document to regulators that they have met requisite standards of network adequacy including hospital-based physician specialties (i.e. radiology, pathology, emergency medicine, anesthesiologists and hospitalists) at in-network facilities, and ensure in-network adequacy is both timely and geographically accessible.

Citation: CMS Rep. 4, I-14; Reaffirmation I-15; Reaffirmed in lieu of Res. 808, I-15; Modified: Sub. Res. 811, I-15; Reaffirmed: CMS Rep. 03, A-17; Reaffirmed: Res. 108, A-17
WHEREAS, Pharmacy benefit managers (PBMs) play a key part in the US prescription drug industry and have significant influence over drug costs and patient access to effective and affordable treatment; and

WHEREAS, According to a recent poll conducted by the Kaiser Family Foundation, 77% of Americans believe the cost of prescription drugs is unreasonable; and

WHEREAS, The AMA’s Truth in Rx advocacy campaign is designed to bring attention to rising drug costs and help develop solutions to make prescription drugs more affordable; and

WHEREAS, Manufacturers pay retroactive rebates to PBMs in exchange for favorable placement on their formularies, which creates perverse financial incentives that motivate PBMs to develop their formularies based on the size of the rebate they can obtain, influence list prices (higher the list price, higher the potential rebate amount), and cause many patients to be denied coverage for their prescribed medication due to an unnecessary formulary restriction; and

WHEREAS, Patient cost-sharing obligations such as deductibles and coinsurance are calculated based off of the list price and not the actual net price that takes into manufacturer rebates, which greatly increases out-of-pocket costs for the many patients; and

WHEREAS, Physicians are now held to account for spending per patient episode, and risk being removed from networks based on that spend; and

WHEREAS, Step therapy, prior authorization, and other utilization management techniques used by insurers and largely stem from the formulary restrictions caused by the rebate system and not only impede patient access to effective and appropriate treatment, but also place a cumbersome and even crippling administrative burden on physicians; and

WHEREAS, PBM practices have greatly impacted the ability of providers to appropriately treat and effectively care for their patients; therefore be it

RESOLVED, That our American Medical Association expand the Truth in Rx advocacy campaign to include and explicitly address through educational outreach the effects of pharmacy benefit manager (PBM) practices on drug prices and access to affordable treatment (Directive to Take Action); and be it further
RESOLVED, That our AMA engage in efforts to educate federal lawmakers about the role of PBM practices in drug pricing and urge Congressional action to increase transparency of PBM practices (Directive to Take Action); and be it further

RESOLVED, That our AMA work at the federal and state level to increase transparency for PBMs by: eliminating increases in patient cost-sharing obligations for prescription drugs if such drugs are chosen for profit to the PBM; restricting PBM use of non-medical switching and other utilization management techniques related to PBM formulary development that disrupt the patient treatment plan; and further regulating PBM practices in order to ensure patients have access to effective and affordable medication therapies (Directive to Take Action); and be it further

RESOLVED, That our AMA develop model guidelines for effective and meaningful transparency in the rebate system, to include PBM and health plan disclosure to physicians of the contracted cost of medications including discounts and rebates from manufacturers paid back to health plans and PBMs, and urge PBMs to take active steps to implement those guidelines. (Directive to Take Action)

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

Received: 09/29/17

RELEVANT AMA POLICY

Pharmaceutical Cost H-110.987
1. Our AMA encourages Federal Trade Commission (FTC) actions to limit anticompetitive behavior by pharmaceutical companies attempting to reduce competition from generic manufacturers through manipulation of patent protections and abuse of regulatory exclusivity incentives.
2. Our AMA encourages Congress, the FTC and the Department of Health and Human Services to monitor and evaluate the utilization and impact of controlled distribution channels for prescription pharmaceuticals on patient access and market competition.
3. Our AMA will monitor the impact of mergers and acquisitions in the pharmaceutical industry.
4. Our AMA will continue to monitor and support an appropriate balance between incentives based on appropriate safeguards for innovation on the one hand and efforts to reduce regulatory and statutory barriers to competition as part of the patent system.
5. Our AMA encourages prescription drug price and cost transparency among pharmaceutical companies, pharmacy benefit managers and health insurance companies.
6. Our AMA supports legislation to require generic drug manufacturers to pay an additional rebate to state Medicaid programs if the price of a generic drug rises faster than inflation.
7. Our AMA supports legislation to shorten the exclusivity period for biologics.
8. Our AMA will convene a task force of appropriate AMA Councils, state medical societies and national medical specialty societies to develop principles to guide advocacy and grassroots efforts aimed at addressing pharmaceutical costs and improving patient access and adherence to medically necessary prescription drug regimens.
9. Our AMA will generate an advocacy campaign to engage physicians and patients in local and national advocacy initiatives that bring attention to the rising price of prescription drugs and help to put forward solutions to make prescription drugs more affordable for all patients.
10. Our AMA supports: (a) drug price transparency legislation that requires pharmaceutical manufacturers to provide public notice before increasing the price of any drug (generic, brand, or specialty) by 10% or more each year or per course of treatment and provide justification for the price increase; (b) legislation that authorizes the Attorney General and/or the Federal Trade Commission to take legal action to address price gouging by pharmaceutical manufacturers and increase access to affordable drugs for patients; and (c) the expedited review of generic drug applications and prioritizing review of such applications when there is a drug shortage, no available comparable generic drug, or a price increase of 10% or more each year or per course of treatment.

Citation: CMS Rep. 2, I-15; Reaffirmed in lieu of: Res. 817, I-16; Appended: Res. 201, A-17; Reaffirmed in lieu of: Res. 207, A-17; Modified: Speakers Rep. 01, A-17;

See also: Pharmaceutical Benefits Management Companies H-125.986, Inappropriate Actions by Pharmacies and Pharmacy Benefit Managers D-120.988; Interference in the Practice of Medicine D-125.997; Private Health Insurance Formulary Transparency H-125.979; Expanded Use of the AMA’s Principles of a Sound Drug Formulary H-125.985; Health Plan Coverage of Prescription Drugs D-125.995; Health Plan Coverage of Prescription Drugs D-185.995; Access to Self-Administered Medications H-120.931
Whereas, Preadmission Screening and Resident Review (PASRR) is a federal requirement, which was originally enacted as part of the Nursing Home Reform Act under the Omnibus Reconciliation Act of 1987 (OBRA), designed to protect patients with serious mental illness or intellectual disabilities from lack of access to proper mental health care services and from possible inappropriate admission and retention in nursing facilities; and

Whereas, Although states are required to have a PASRR program whereby applicants to Medicaid-certified nursing facilities receive a comprehensive mental health assessment if they are identified as having a serious mental illness or intellectual disability, there is much variation in how PASRR is implemented across states; and

Whereas, This screening process is comprised of two steps--a Level I screening to identify individuals with a PASRR disability and a Level II screening if the Level I screening indicates an individual may have a serious mental illness or intellectual disability; and

Whereas, The results of the Level II evaluation provide recommendations pertaining to need, appropriate care setting, and necessary specialized services; and

Whereas, The completion time for Level II screening can take up to four to five business days; and

Whereas, Coverage under Medicare Part A funding for a skilled nursing facility (SNF) stay has necessitated a three-day hospital stay in the past, often leading to unnecessarily prolonged lengths of stay for acute inpatient hospitalizations with resultant increases in the total cost of care for many patients; and

Whereas, The development of several payment models such as the Bundled Payment Care Improvement Initiative, Medicare Shared Savings Program Accountable Care Organizations, and other Alternative Payment Models under the Medicare Access and CHIP Reauthorization Act of 2015 has led to a potential waiver of the three-day stay to allow more timely transfer of patients requiring SNF services (sub-acute rehabilitation or long-term care) with a possible reduction in the total cost of care for many patients; and

Whereas, The need for the completion of the PASRR screening prior to admission to a SNF essentially invalidates the potential for more immediate transfers to SNFs from emergency rooms, physicians’ offices, or even other levels of care within the continuum of a nursing facility; therefore be it
RESOLVED, That our American Medical Association work with the US Department of Health and Human Services and Congress to amend applicable statutes and regulations to revise the Preadmission Screening and Resident Review requirement for nursing facility placement to provide more consistent enactment among states and to allow more reasonable and cost-effective approaches to this mandatory screening process. (Directive to Take Action)

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

Received: 09/29/17

RELEVANT AMA POLICY

Direct Admission of Medicare Patients to Skilled Nursing Facilities H-280.977
Our AMA supports regulatory change and any necessary legislation which would delete the 3-day prior hospitalization requirement for provision of skilled nursing facility benefits under Medicare, so as to allow coverage for direct admission of Medicare patients to a skilled nursing facility whether or not they have been discharged from an acute care hospital within the last 30 days.
Citation: (Res. 33, A-91; Res. 48, I-81; Reaffirmed: CLRPD Rep. F, I-91; CMS Rep. 11, I-95; Reaffirmation A-97; Reaffirmation I-00; Reaffirmed: Res. 730, A-06; Reaffirmed: Res. 234, A-09; Reaffirmed: BOT Rep. 32, A-09; Reaffirmation A-11; Reaffirmation A-15)

Three Day Stay Rule H-280.947
1. Our American Medical Association will continue to advocate that Congress eliminate the three-day hospital inpatient requirement for Medicare coverage of post-hospital skilled nursing facility services, and educate Congress on the impact of this requirement on patients.
2. Our AMA will continue to advocate, as long as the three-day stay requirement remains in effect, that patient time spent in the hospital, observation care or in the emergency department count toward the three-day hospital inpatient requirement for Medicare coverage of post-hospital skilled nursing facility services.
3. Our AMA will actively work with the Centers for Medicare and Medicaid Services (CMS) to eliminate any regulations requiring inpatient hospitalization as a prerequisite before a Medicare beneficiary is eligible for skilled (SNF) or long-term care (LTC) placement.
Citation: (Sub. Res. 103, A-15; Res. 110, A-15)

Inclusion of Observation Status in Mandatory Three Day Inpatient Stay D-280.989
1. Our AMA will continue to monitor problems with patient readmissions to hospitals and skilled nursing facilities and recoding of inpatient admissions as observation care and advocate for appropriate regulatory and legislative action to address these problems.
2. Our AMA will continue to advocate that the Centers for Medicare & Medicaid Services explore payment solutions to reduce the inappropriate use of hospital observation status.
Citation: (BOT Rep. 32, A-09; Appended: CMS Rep. 4, A-14)

Observation Status and Medicare Part A Qualification D-280.988
Our AMA will advocate for Medicare Part A coverage for a patient's direct admission to a skilled facility if directed by their physician and if the patient's condition meets skilled nursing criteria.
Citation: (Res. 117, A-13; Reaffirmed: CMS Rep. 4, A-14; Reaffirmation A-15)

Three Day Prior Hospital Stay Requirement H-330.948
Our AMA will recommend that the Secretary of the U.S. Department of Health and Human Services, in consultation with health care professionals and skilled care providers, define a subset of patients (or DRGs) for whom the elimination of the three day prior hospital stay requirement for eligibility of the Medicare Skilled Nursing Facility benefit would avert hospitalization and generate overall cost savings.
Citation: (Res. 805, I-93; Reaffirmation A-97; Reaffirmation I-00; Reaffirmation A-04; Reaffirmed: Res. 234, A-09; Reaffirmation A-11)
Whereas, Current trends in medical education in the US often lead to medical students providing medical services under the practiced eyes of proctoring medical professionals (both teaching physicians and other health care providers such as medical assistants and respiratory therapists); and

Whereas, Services provided by intern or resident physicians are billable under Centers for Medicare and Medicaid Services (CMS) through the Medicare Physician Fee Schedule if a teaching physician is physically present during the critical or key portions of the service; and

Whereas, Services provided by medical students (such as obtaining a Pap smear or setting up a nebulizer treatment) are not currently billable under CMS even if proctoring medical professionals are directly assisting or overseeing the service as part of medical education; and

Whereas, The inability to bill for these services may result in unnecessary duplication of services for patients, including the potential risk of repetitive minor procedures; and

Whereas, The inability to bill for these services may also result in restrictions in medical student education access since the educational facility may not be able to sustain the educational process without the procedural revenue; therefore be it

RESOLVED, That our American Medical Association amend Policy, H-390.999, “Payments to Physicians in Teaching Setting by Medicare Fiscal Intermediaries,” by addition as follows:

When a physician assumes responsibility for the services rendered to a patient by a medical student, a resident, or an intern, the physician may ethically bill the patient for services which were performed under the physician's personal observation, direction, and supervision (Modify Current HOD Policy); and be it further

RESOLVED, That our AMA work with the Centers for Medicare and Medicaid Services to require coverage of medical services performed by medical students while under the physician's personal observation, direction, and supervision. (Directive to Take Action)

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

Received: 09/29/17
RELEVANT AMA POLICY

Payments to Physicians in Teaching Setting by Medicare Fiscal Intermediaries H-390.999
When a physician assumes responsibility for the services rendered to a patient by a resident or an intern, the physician may ethically bill the patient for services which were performed under the physician's personal observation, direction, and supervision.

Clinical Proctoring H-375.974
AMA policy states that clinical proctoring is an important tool for education and the evaluation of clinical competence of new physicians seeking privileges or existing medical staff members requesting new privileges. Therefore, the AMA:
(1) encourages hospital medical staffs to develop proctoring programs, with appropriate medical staff bylaws provisions, to evaluate the clinical competency of new physicians seeking privileges and existing medical staff members requesting new privileges; and
(2) encourages hospital medical staffs to consider including the following provisions in their medical staff bylaws for use in their proctoring program:
(a) Except as otherwise determined by the medical executive committee, all initial appointees to the medical staff and all members granted new clinical privileges shall be subject to a period of proctoring.
(b) Each appointee or recipient of new clinical privileges shall be assigned to a department where performance of an appropriate number of cases as established by the medical executive committee, or the department as designee of the medical executive committee, shall be observed by the chair of the department, or the chair's designee, during the period of proctoring specified in the department's rules and regulations, to determine the suitability to continue to exercise the clinical privileges granted in that department. The exercise of clinical privileges in any other department shall also be subject to direct observation by that department's chair or the chair's designee.
(c) The members shall remain subject to such proctoring until the medical executive committee has been furnished with: a report signed by the chair of the department(s) to which the member is assigned as well as other department(s) in which the appointee may exercise clinical privileges, describing the types and numbers of cases observed and the evaluation of the applicant's performance, a statement that the applicant appears to meet all of the qualifications for unsupervised practice in that department, has discharged all of the responsibilities of staff membership, and has not exceeded or abused the prerogative of the category to which the appointment was made, and that the member has satisfactorily demonstrated the ability to exercise the clinical privileges initially granted in those departments.
Citation: (BOT Rep. 30-A-94; Amended: CMS Rep. 3, A-99; Reaffirmed: CLRPD Rep. 1, A-09)

Supervision and Proctoring by Facility Medical Staff H-375.967
Our AMA advocates that the conduct of medical staff supervision be included in medical staff bylaws and be guided by the following principles:
(1) Physicians serving as medical staff supervisors should be indemnified at the facility's expense from malpractice claims and other litigation arising out of the supervision function.
(2) Physicians being supervised should be indemnified at the facility's expense for any damages that might occur as a result of implementing interventions recommended by medical staff supervisors.
(3) AMA principles of peer review as found in Policies H-320.968 [2,d], H-285.998 [5], and H-320.982 [2c,d] should be adhered to in the conduct of medical staff supervision.
(4) The medical staff member serving as supervisor should be determined through a formal process by the department chair or medical staff executive committee.
(5) The scope of the medical staff supervision should be limited to the provision of services that have been restricted, are clearly questionable, or are under question, as determined by the department chair or medical staff executive committee.
(6) The duration of the medical staff supervision should be limited to the amount of time necessary to adequately assess the degree of clinical competence in the area of skill being assessed.
(7) Medical staff supervision should include a sufficient volume of procedures or admissions for meaningful assessment.
(8) Medical staff supervisors should provide periodic performance reports on each patient to the appropriate designated medical staff committee. The reports should be transcribed or transcripted by the medical staff office to assure confidentiality. The confidentiality of medical staff supervision reports must be strictly maintained.
(9) Physicians whose performance is supervised should have access to the performance reports submitted by medical staff supervisors and should be given the opportunity to comment on the contents of the reports.
Citation: (CMS Rep. 3, A-99; Reaffirmed: CLRPD Rep. 1, A-09)
AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 813
(I-17)

Introduced by: Michigan

Subject: Sustain Patient-Centered Medical Home Practices

Referred to: Reference Committee J
(Peter C. Amadio, MD, Chair)

Whereas, The Patient-Centered Medical Home (PCMH) practice model has been implemented throughout the health care delivery system for several years; and

Whereas, Third-party payers are benefiting from the hard work of physicians; and

Whereas, The ongoing costs to physicians to sustain PCMH are significant; therefore be it

RESOLVED, That our American Medical Association amend Policy, H-160.918, “The Patient-Centered Medical Home,” by addition as follows:

Our AMA:
1. will urge the Centers for Medicare and Medicaid Services (CMS) to work with our AMA and national medical specialty societies to design incentives to enhance care coordination among providers who provide medical care for patients outside the medical home;
2. will urge CMS to assist physician practices seeking to qualify for and sustain medical home status with financial and other resources;
3. will advocate that Medicare incentive payments associated with the medical home model be paid for through system-wide savings—such as reductions in hospital admissions and readmissions (Part A), more effective use of pharmacologic therapies (Part D), and elimination of government subsidies for Medicare Advantage plans (Part C)—and not be subject to a budget neutrality offset in the Medicare physician payment schedule; and
4. will advocate that all health plans and CMS use a single standard to determine whether a physician practice qualifies to be a patient-centered medical home. (Modify Current HOD Policy); and be it further

RESOLVED, That our AMA work with and encourage the Centers for Medicare and Medicaid Services to subsidize the cost of sustaining Patient-Centered Medical Home designated practices for practicing physicians. (Directive to Take Action)

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

Received: 09/29/17
RELEVANT AMA POLICY

The Patient-Centered Medical Home H-160.918

Our AMA:
1. will urge the Centers for Medicare and Medicaid Services (CMS) to work with our AMA and national medical specialty societies to design incentives to enhance care coordination among providers who provide medical care for patients outside the medical home;
2. will urge CMS to assist physician practices seeking to qualify for medical home status with financial and other resources;
3. will advocate that Medicare incentive payments associated with the medical home model be paid for through system-wide savings--such as reductions in hospital admissions and readmissions (Part A), more effective use of pharmacologic therapies (Part D), and elimination of government subsidies for Medicare Advantage plans (Part C)--and not be subject to a budget neutrality offset in the Medicare physician payment schedule; and
4. will advocate that all health plans and CMS use a single standard to determine whether a physician practice qualifies to be a patient-centered medical home.

Citation: (CMS Rep. 8, A-09)

See also: Principles of the Patient-Centered Medical Home H-160.919
Whereas, People with severe mobility impairments often face significant challenges to access of medical care due to problems with cognition, communication, mobility, community access, insurance, and providers' lack of familiarity with the needs and preferences of people with disabilities; and

Whereas, Care provided for patients with severely impaired mobility requires greater investment of time, staff, and office equipment such as adjustable height chairs or tables, patient lift teams or electric lifts, and adjustable leg supports; and

Whereas, Current reimbursement structures for evaluation and management services (E/M) do not account for the increased time and investment needed to provide comprehensive patient centered care for patients with severely impaired mobility, and thus have the potential to decrease access to appropriate and timely medical care for these patients; therefore be it

RESOLVED, That our American Medical Association support additional reimbursement for evaluation and management services for patients who require additional time and specialized equipment during medical visits due to severe mobility-related impairments (New HOD Policy); and be it further

RESOLVED, That our AMA support that no additional cost-sharing for the additional reimbursement will be passed on to patients with mobility disabilities, consistent with Federal Law (New HOD Policy); and be if further

RESOLVED, That our AMA support that primary and specialty medical providers be educated regarding the care of patients with severely impaired mobility to improve access to care. (New HOD Policy)

Fiscal Note: Minimal - less than $1,000.

Received: 10/05/17

References:
RELEVANT AMA POLICY

Federal Legislation on Access to Community-Based Services for People with Disabilities H-290.970 - Our AMA strongly supports reform of the Medicaid program established under title XIX of the Social Security Act (42 U.S.C. 1396) to provide services in the most appropriate settings based upon the individual’s needs, and to provide equal access to community-based attendant services and supports. Citation: Res. 917, I-07; Reaffirmed: BOT Rep. 22, A-17

Medical Care of Persons with Developmental Disabilities H-90.968
1. Our AMA encourages: (a) clinicians to learn and appreciate variable presentations of complex functioning profiles in all persons with developmental disabilities; (b) medical schools and graduate medical education programs to acknowledge the benefits of education on how aspects in the social model of disability (e.g. ableism) can impact the physical and mental health of persons with Developmental Disabilities; (c) medical schools and graduate medical education programs to acknowledge the benefits of teaching about the nuances of uneven skill sets, often found in the functioning profiles of persons with developmental disabilities, to improve quality in clinical care; (d) the education of physicians on how to provide and/or advocate for quality, developmentally appropriate medical, social and living supports for patients with developmental disabilities so as to improve health outcomes; (e) medical schools and residency programs to encourage faculty and trainees to appreciate the opportunities for exploring diagnostic and therapeutic challenges while also accruing significant personal rewards when delivering care with professionalism to persons with profound developmental disabilities and multiple co-morbid medical conditions in any setting; (f) medical schools and graduate medical education programs to establish and encourage enrollment in elective rotations for medical students and residents at health care facilities specializing in care for the developmentally disabled; and (g) cooperation among physicians, health & human services professionals, and a wide variety of adults with developmental disabilities to implement priorities and quality improvements for the care of persons with developmental disabilities.
2. Our AMA seeks: (a) legislation to increase the funds available for training physicians in the care of individuals with intellectual disabilities/developmentally disabled individuals, and to increase the reimbursement for the health care of these individuals; and (b) insurance industry and government reimbursement that reflects the true cost of health care of individuals with intellectual disabilities/developmentally disabled individuals.
3. Our AMA entreats health care professionals, parents and others participating in decision-making to be guided by the following principles: (a) All people with developmental disabilities, regardless of the degree of their disability, should have access to appropriate and affordable medical and dental care throughout their lives; and (b) An individual's medical condition and welfare must be the basis of any medical decision. Our AMA advocates for the highest quality medical care for persons with profound developmental disabilities; encourages support for health care facilities whose primary mission is to meet the health care needs of persons with profound developmental disabilities; and informs physicians that when they are presented with an opportunity to care for patients with profound developmental disabilities, that there are resources available to them.
4. Our AMA will continue to work with medical schools and their accrediting/licensing bodies to encourage disability related competencies/objectives in medical school curricula so that medical professionals are able to effectively communicate with patients and colleagues with disabilities, and are able to provide the most clinically competent and compassionate care for patients with disabilities.
5. Our AMA recognizes the importance of managing the health of children and adults with developmental disabilities as a part of overall patient care for the entire community.
6. Our AMA supports efforts to educate physicians on health management of children and adults with developmental disabilities, as well as the consequences of poor health management on mental and physical health for people with developmental disabilities.
7. Our AMA encourages the Liaison Committee on Medical Education, Commission on Osteopathic College Accreditation, and allopathic and osteopathic medical schools to develop and implement curriculum on the care and treatment of people with developmental disabilities.
8. Our AMA encourages the Accreditation Council for Graduate Medical Education and graduate medical education programs to develop and implement curriculum on providing appropriate and comprehensive health care to people with developmental disabilities.
9. Our AMA encourages the Accreditation Council for Continuing Medical Education, specialty boards, and other continuing medical education providers to develop and implement continuing education programs that focus on the care and treatment of people with developmental disabilities. Citation: CCB/CLRPD Rep. 3, A-14; Appended: Res. 306, A-14; Appended: Res. 315, A-17

Equal Access for Physically Challenged Physicians H-90.987 - Our AMA supports equal access to all hospital facilities for physically challenged physicians as part of the Americans with Disabilities Act. Citation: (Res. 816, I-91; Reaffirmed: Sunset Report, I-01; Modified: CSAPH Rep. 1, A-11

See also: Community Mobility Devices H-90.978; Access to Public Buildings for Handicapped Persons H-90.999; Enhancing Accommodations for People with Disabilities H-90.971
Whereas, The Centers for Medicare and Medicaid Services (CMS) expressed desire to revise current Evaluation and Management (E/M) documentation guidelines; and

Whereas, AMA also publishes E/M documentation guidelines in its annual CPT book; and

Whereas, The medical provider community benefits from the regulatory clarity achieved when both CMS and CPT documentation guidelines are aligned and consistent (as well as when other payer documentation requirements, such as those of Medicaid programs, are aligned) with CMS/Medicare and CPT; and

Whereas, Pediatric caregivers confront unique history, physical exam, and medical decision making challenges in documenting their patients’ care both from the perspective of progressively advancing age as well as evolving developmental stage; and

Whereas, The American Academy of Pediatrics is a fully committed participant in the CPT process and has extensive experience in representing the clinical and coding needs of the pediatric community; therefore be it

RESOLVED, That, in the process of collaborating with the Centers for Medicare and Medicaid Services for the future revision of Evaluation and Management Documentation Guidelines, our American Medical Association rely on the American Academy of Pediatrics in addressing the needs of pediatricians and their patients. (New HOD Policy)

Fiscal Note: None

Received: 10/11/17

References:
Proposed Rule, Department of Health and Human Services, Centers for Medicare and Medicaid Services, 42 CFR Parts 405, 410, 414, 424, 425, Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program (Page 374 of PDF).
Whereas, Healthy People 2020 defines “social determinants of health” as “conditions in the environments 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 risks”\(^1\); and

Whereas, The estimated number of deaths attributable to social factors in the United States is comparable to the number attributed to pathophysiological and behavioral causes\(^2\); and

Whereas, There is strong evidence that increased investment in selected social services and models of partnership between healthcare and social services (including housing support, nutrition assistance, case management, and integrated healthcare and housing services) can confer substantial health benefits and reduce healthcare costs for targeted populations\(^3\); and

Whereas, Programs such as the Medicaid-funded Community Support Program for People Experiencing Chronic Homelessness (CSPECH), started in 2006 by the Massachusetts Behavioral Health Partnership and the Massachusetts Housing and Shelter Alliance, are associated with up to an $11,914 reduction in annual per-person healthcare costs and an annual per-person net savings of up to $7,013\(^4\); and

Whereas, A National Quality Forum panel of experts suggests that not adjusting for patients’ sociodemographic factors might actually harm patients, exacerbate disparities in care, and produce misleading performance scores for a variety of providers\(^5\); and

Whereas, Even though a shift has begun from paying for volume (fee-for-service) to paying for quality, known as value-based payment (VBP), there is concern that VBP designs that don’t account for social risk factors could harm socially at-risk populations\(^6\); and

Whereas, An ad hoc committee, requested by the Department of Health and Human Services and convened by the National Academies of Sciences, Engineering, and Medicine, found that changes to the current VBP system to account for social risk factors would especially influence the lives of patients who have historically experienced barriers to accessing high-quality

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\(^1\) US Department of Health and Human Services, Office of Disease Prevention and Health Promotion. www.healthypeople.gov.


healthcare, and that accounting for social risk factors in quality measurement and payment in combination with complementary approaches may achieve the policy goals of reducing disparities in access, quality, and outcomes and promote health equity; therefore be it

RESOLVED, That our American Medical Association support payment reform policy proposals that incentivize screening for social determinants of health, as defined by Healthy People 2020, and referral to community support systems. (New HOD Policy)

Fiscal Note: Minimal - less than $1,000.

Received: 10/12/17

RELEVANT AMA POLICY

Educating Medical Students in the Social Determinants of Health and Cultural Competence H-295.874
Our AMA: (1) Supports efforts designed to integrate training in social determinants of health and cultural competence across the undergraduate medical school curriculum to assure that graduating medical students are well prepared to provide their patients safe, high quality and patient-centered care. (2) Supports faculty development, particularly clinical faculty development, by medical schools to assure that faculty provide medical students’ appropriate learning experiences to assure their cultural competence and knowledge of social determinants of health. (3) Supports medical schools in their efforts to evaluate the effectiveness of their social determinants of health and cultural competence teaching of medical students, for example by the AMA serving as a convener of a consortium of interested medical schools to develop Objective Standardized Clinical Exams for use in evaluating medical students' cultural competence. (4) Will conduct ongoing data gathering, including interviews with medical students, to gain their perspective on the integration of social determinants of health and cultural competence in the undergraduate medical school curriculum. (5) Recommends studying the integration of social determinants of health and cultural competence training in graduate and continuing medical education and publicizing successful models.
Citation: CME Rep. 11, A-06; Reaffirmation A-11; Modified in lieu of Res. 908, I-14; Reaffirmed in lieu of Res. 306, A-15
Whereas, Health care costs continue to rise faster than the rate of inflation, and are now approaching 20% of GDP, and the country cannot afford to continue diverting resources into health care from other sectors of the economy such as education and infrastructure; and

Whereas, Hospitals and hospital owned outpatient clinics are paid under the Hospital Outpatient Prospective Payment System (HOPPS), and are given an annual increase of approximately 3% based on the government’s Market Basket estimate of the cost of providing health care, goods and services by hospitals; and

Whereas, Practice expense has increased by inflation, but also by increased regulatory requirements, including EHRs, data submission to attempt to measure quality, Medicare Advantage plans imposing all the prior authorization requirements of commercial plans but paying at Medicare rates; and

Whereas, Many practices now offer sophisticated outpatient services such as imaging, infusion, extensive laboratory support, etc., and must purchase the same equipment and hire the same personnel as hospitals, but are unable to charge facility fees to cover the infrastructure costs the way hospitals can, further widening the difference in infrastructure expenses between practices and hospitals; and

Whereas, Physician fees paid under the Physician Fee Schedule (PFS) did not increase under the 15 years of the Sustainable Growth Rate (SGR) law, and are only increasing a fraction of a percent under MACRA, thus creating a large and increasing Site of Service Differential between the payment to hospitals and the payment to practices not owned by hospitals, for exactly the same services; and

Whereas, The ongoing widening of the Site of Service Differential has made it increasingly difficult for independent practices to compete with hospital owned practices, resulting in the accelerated acquisition of practices by hospitals and therefore a shift from the less expensive PFS to the much more expensive HOPPS, increasing health care costs and decreasing patient and physician choice, without any proven increase in quality of care; and

Whereas, MedPAC in its June 2017 report¹ and in previous reports to Congress, expressed concerns "that consolidation among and between hospitals and physicians has increased prices without any increase in quality... [and] by creating true 'site-neutral' payments, the Medicare program could be further insulated from the cost of physician–hospital consolidation"; and

Whereas, Hospitals attempt to justify the higher HOPPS payment by claiming that they provide more charity care than independent practices, but there is no good data on the amount of charity care given by hospitals or independent practices, nor any clarity regarding the methods by which uncompensated care is estimated or compared, nor consideration of the fact that under Medicare, hospital owned practices can collect a significant percentage of billed charges for uncompensated care but independent practices cannot; and

Whereas, Practice expense has not been studied since the Practice Expense Advisory Committee completed its work over a decade ago; and

Whereas, Existing AMA Policies (H-330.925 and D-330.997) address payment disparities between hospitals and ambulatory surgery centers, but there is no existing policy concerning the global Site of Service Differential issue and no policy addressing providing equivalent facility fees and equivalent uncompensated care reimbursement to independent practices and hospital owned practices; therefore be it

RESOLVED, That our American Medical Association study the Site of Service Differential with a report back no later than the 2018 Interim Meeting, including:

a) The rising gap between independent practice expenses and Medicare reimbursement, taking into account the costs of the regulatory requirements;

b) The increased cost of medical personnel and equipment, including electronic health record (EHR/EMR) purchase, software requirements, and ongoing support and maintenance;

c) The expense of maintaining hospital based facilities not common to independent practices, such as burn units and emergency departments, and determine what payment should be provided to cover those explicit costs;

d) The methodology by which hospitals report their uncompensated care, and the extent to which this is based on actual costs, not charges (Directive to Take Action); and be it further

RESOLVED, That our AMA advocate for a combined Health Care Payment System for patients who receive care that is paid for by the Centers for Medicare and Medicaid Services (CMS), that:

a) Follows the recommendation of MedPAC1 to pay "Site-Neutral" reimbursement that sufficiently covers practice expenses without regard to whether services are performed under the Hospital Outpatient Prospective Payment System (HOPPS) or the Physician Fee Schedule (PFS);

b) Pays appropriate facility fees for both hospital owned facilities and independently owned non-hospital facilities, computed using the real costs of a facility based on its fair market value; and

c) Provides independent practices with the same opportunity to receive reimbursement for uncompensated care as is provided to hospital owned practices. (New HOD Policy)

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

Received: 10/12/17

RELEVANT AMA POLICY

Appropriate Payment Level Differences by Place and Type of Service H-330.925
Our AMA (1) encourages CMS to adopt policy and establish mechanisms to fairly reimburse physicians for office-based procedures; (2) encourages CMS to adopt a site neutral payment
policy for hospital outpatient departments and ambulatory surgical centers; (3) advocates for the use of valid and reliable data in the development of any payment methodology for the provision of ambulatory services; (4) advocates that in place of the Consumer Price Index for all Urban Consumers (CPI-U), CMS use the hospital market basket index to annually update ambulatory surgical center payment rates; (5) encourages the use of CPT codes across all sites-of-service as the only acceptable approach to payment methodology; and (6) will join other interested organizations and lobby for any needed changes in existing and proposed regulations affecting payment for ambulatory surgical centers to assure a fair rate of reimbursement for ambulatory surgery.


Appropriate Payment Level Differences by Place and Type of Service D-330.997
1. Our AMA encourages CMS to: (A) define Medicare services consistently across settings and, in particular, to avoid the use of diagnosis codes in determining Medicare payments to hospital outpatient departments and other ambulatory settings; and (B) adopt payment methodology for hospital outpatient departments and ambulatory surgical centers that will assist in leveling the playing field across all sites-of-service. If necessary, the AMA should consider seeking a legislative remedy to the payment disparities between hospital outpatient departments and ambulatory surgical centers.

2. Our AMA will continue to encourage the CMS to collect data on the frequency, type and cost of services furnished in off-campus, provider-based departments.


Offsetting the Costs of Providing Uncompensated Care H-160.923
Our AMA: (1) supports the transitional redistribution of disproportionate share hospital (DSH) payments for use in subsidizing private health insurance coverage for the uninsured; (2) supports the use of innovative federal- or state-based projects that are not budget neutral for the purpose of supporting physicians that treat large numbers of uninsured patients, as well as EMTALA-directed care; and (3) encourages public and private sector researchers to utilize data collection methodologies that accurately reflect the amount of uncompensated care (including both bad debt and charity care) provided by physicians.

Citation: CMS Rep. 8, A-05; Reaffirmation A-07; Modified: CMS Rep. 01, A-17
Whereas, The number of patients seen on-call and in Emergency Departments who do not have insurance is large and likely to increase; and

Whereas, It is essential for physicians working on-call and in EDs to have access to medical and surgical specialists to deal appropriately with patients and their medical and surgical problems; and

Whereas, To be able to respond to the on-call and ED requests, a physician who is on-call is prohibited from participating in any activity that might make him/her unable to meet on-call or ED requests for service; and

Whereas, Some, but not all specialties, that need to be available on-call or to the ED currently receive compensation which reimburses them to some degree for their availability or service; and

Whereas, Some medical and surgical specialists are also felt to be essential and available, but are not reimbursed for the time that they are required to be available; therefore be it

RESOLVED, That our American Medical Association amend Policy H-130.948, “On-Call Physicians,” by addition to read as follows:

H-130.948 On-Call Physicians
Our AMA:
(1) strongly encourages physicians and hospitals to work collaboratively to develop solutions based on adequate compensation or other appropriate incentives as the preferred method of ensuring on-call coverage and will monitor and oppose any state legislative or regulatory efforts mandating emergency room on-call coverage as a requirement for medical staff privileges and state licensure that are not supported by the state medical association;
(2) advocates that physician on-call coverage for emergency departments be guided by the following principles:
(a) The hospital and physicians should jointly share the responsibility for the provision of care of emergency department patients.
(b) Every hospital that provides emergency services should maintain policies to ensure appropriate on-call coverage of the emergency department by medical staff specialists that are available for consultation and treatment of patients.
(c) The organization and function of on-call services should be determined through hospital policy and medical staff by-laws, and include methods for monitoring and assuring appropriate on-call performance.
(d) Physicians should be provided adequate compensation for being available and providing on-call and emergency services.

(d-e) Hospital medical staff by-laws and emergency department policies regarding on-call physicians' responsibilities must be consistent with Emergency Medical Treatment and Active Labor Act (EMTALA) requirements.

(e-f) Medical staffs should determine and adopt protocols for appropriate, fair, and responsible medical staff on-call coverage.

(f-g) Hospitals with specialized emergency care capabilities need to have a means to ensure medical staff responsibility for patient transfer acceptance and care.

(g-h) Hospitals that lack the staff to provide on-call coverage for a particular specialty should have a plan that specifies how such care will be obtained.

(h-i) The decision to operate or close an emergency department should be made jointly by the hospital and medical staff;

(3) supports the enforcement of existing laws and regulations that require physicians under contract with health plans to be adequately compensated for emergency services provided to the health plans' enrollees; and

(4) supports the enactment of legislation that would require health plans to adequately compensate out-of-plan physicians for emergency services provided to the health plans' enrollees or be subject to significant fines similar to the civil monetary penalties that can be imposed on hospitals and physicians for violation of EMTALA (Modify Current HOD Policy); and be it further

RESOLVED, That our AMA develop and make available policy guidance for physicians to negotiate with hospital medical staffs to support physician compensation for on call and emergency services. (Directive to Take Action)

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

Received: 10/12/17

RELEVANT AMA POLICY

On-Call Physicians H-130.948
Our AMA:

(1) strongly encourages physicians and hospitals to work collaboratively to develop solutions based on adequate compensation or other appropriate incentives as the preferred method of ensuring on-call coverage and will monitor and oppose any state legislative or regulatory efforts mandating emergency room on-call coverage as a requirement for medical staff privileges and state licensure that are not supported by the state medical association;

(2) advocates that physician on-call coverage for emergency departments be guided by the following principles: (a) The hospital and physicians should jointly share the responsibility for the provision of care of emergency department patients. (b) Every hospital that provides emergency services should maintain policies to ensure appropriate on-call coverage of the emergency department by medical staff specialists that are available for consultation and treatment of patients. (c) The organization and function of on-call services should be determined through hospital policy and medical staff by-laws, and include methods for monitoring and assuring appropriate on-call performance.

(d) Hospital medical staff by-laws and emergency department policies regarding on-call physicians responsibilities must be consistent with Emergency Medical Treatment and Active Labor Act (EMTALA) requirements. (e) Medical staffs should determine and adopt protocols for appropriate, fair, and responsible medical staff on-call coverage. (f) Hospitals with specialized emergency care capabilities need to have a means to ensure medical staff responsibility for patient transfer acceptance and care. (g) Hospitals that lack the staff to provide on-call coverage for a particular specialty should have a plan that specifies how such care will be obtained. (h) The decision to operate or close an emergency department should be made jointly by the hospital and medical staff;

(3) supports the enforcement of existing laws and regulations that require physicians under contract with health plans to be adequately compensated for emergency services provided to the health plans' enrollees; and

(4) supports the enactment of legislation that would require health plans to adequately compensate out-of-plan physicians for emergency services provided to the health plans' enrollees or be subject to significant fines similar to the civil monetary penalties that can be imposed on hospitals and physicians for violation of EMTALA.

Citation: CMS Rep. 3, I-99; Reaffirmation A-00; Modified: Sub. Res. 217, I-00; Reaffirmation I-01; Reaffirmation A-07; Appended and Reaffirmed: CMS Rep. 1, I-09
Whereas, Some commercial insurance companies may be considering or proposing discontinuation of payment for consultation codes; and

Whereas, When providing a consultation a physician must often review substantial prior documentation; refine the differential diagnosis; recommend diagnostic and/or therapeutic options; educate the patient regarding diagnostic and other considerations, prognosis and treatment options; and coordinate next steps with the patient’s often myriad other providers; and

Whereas, Failing to acknowledge the difference in work between a consultation and the relative simplicity of assuming the care of a patient with a known diagnosis is misguided and will predictably limit the ability of providers to consult on complex cases; and

Whereas, Discontinuation of payment for consultation codes could result in another barrier to patient care by dissuading usual coordination of care, as the additional work that goes into providing a consultation and coordinating care amongst other treating physicians would not be properly recognized; and

Whereas, When the Centers for Medicare and Medicaid Services discontinued payment for consultation codes in 2010, the medical community raised significant concerns because in its decision the agency failed to recognize the expertise and additional collaboration that is reflected in the use of consultation codes; and

Whereas, Commercial insurance entities should provide alternative provider outreach and education on coding errors rather than eliminate important codes such as consultation codes; therefore be it

RESOLVED, That our American Medical Association 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 (Directive to Take Action); and be it further
RESOLVED, Where a reason given by an insurance company for policy change to discontinue payment of consultation codes includes purported coding errors or abuses, that our AMA 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. (Directive to Take Action)

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

Received: 10/12/17

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/CLRDP Rep. 2, A-14; Reaffirmation: A-17
Whereas, The Medicare Date of Service (DOS) policy for Clinical and Laboratory Pathology Specimens was adopted by the Centers for Medicare & Medicaid Services (CMS) in 2007, creating the Laboratory 14-Day Rule; and

Whereas, The 14-Day Rule specifies that billing for “complex diagnostic laboratory services” performed on pathologic specimens collected in the hospital setting be bundled into the inpatient diagnosis-related group (DRG) or outpatient (OPPS) payments made to the hospital if ordered within 14 days of discharge; and

Whereas, Payment bundling of pathologic tests, including molecular and genomic testing of cancer specimens, creates a strong disincentive to hospitals to perform or send out specialized pathologic tests during the 14-day window after discharge, leading to delays in diagnosis and therapy; and

Whereas, Since the adoption of the 14-day rule in 2007 there have been a growing number of therapies that are targeted to specific somatic (tumoral) mutations and delays in molecular testing can result in delays in initiation of these effective treatments; and

Whereas, Amidst complaints from stakeholders, CMS is currently considering changes to the Medicare Outpatient Prospective Payment System (OPPS) including whether to limit or eliminate the 14-Day Rule, therefore be it

1 42 CFR § 414.510
3 “Affordable Care Act (Pub. L. 111-148), Section 3113(a)(2) defines the term “complex diagnostic laboratory test” to mean a diagnostic laboratory test—(A) that is an analysis of gene protein expression, topographic genotyping, or a cancer chemotherapy sensitivity assay; (B) that is determined by the Secretary to be a laboratory test for which there is not an alternative test having equivalent performance characteristics; (C) which is billed using a Healthcare Common Procedure Coding System (HCPCS) code other than a not otherwise classified (NOC) code under such Coding System; (D) which is approved or cleared by the Food and Drug Administration or is covered under title XVIII of the Social Security Act; and (E) is described in section 1861(s)(3) of the Social Security Act (42 U.S.C. 1395x(s)(3)).”
6 Centers for Medicare & Medicaid Services. Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs. 82 Federal Register 138, 33558-33724. 20 Jul 2017. 33650-33653.
RESOLVED, That our American Medical Association actively lobby the federal government to change laboratory Date of Service rules under Medicare such that complex diagnostic laboratory services performed on pathologic specimens collected from a hospital procedure be paid separately from inpatient and outpatient bundled payments. (Directive to Take Action)

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

Received: 10/12/17

RELEVANT AMA POLICY

Laboratory Services Contracted by a Physician H-260.998
Our AMA believes that: (1) laboratories should bill and collect from patients or third party payers for laboratory services; (2) attending physicians are entitled to fair compensation for professional services rendered; and (3) bills for laboratory services performed by attending physicians should show the location where services were rendered and a description of such services.
Whereas, The majority of women of reproductive age in the United States currently use at least one contraceptive method, with more than 99 percent having used contraception during their lifetime; and

Whereas, Health care practitioners frequently prescribe hormonal contraception to treat a variety of conditions; and

Whereas, Fifty-eight percent of pill users cite non-contraceptive health benefits such as treatment for excessive menstrual bleeding, menstrual pain, and acne as reasons for using the method. Hormonal contraceptives are also used to treat conditions such as Polycystic Ovary Syndrome (PCOS) and endometriosis; and

Whereas, Hormonal contraception can also reduce a woman’s risk of developing ovarian and endometrial cancer; and

Whereas, Hormonal contraception provides a myriad of benefits beyond the expected reproductive planning by decreasing the number of unintended pregnancies and pregnancy-related health risks such as preeclampsia, gestational diabetes, and complications of childbirth; and

Whereas, Unintended pregnancies cost American taxpayers at least $21 billion each year. Nationally, 68 percent of these unintended pregnancies were paid for by public insurance programs including Medicaid, Children’s Health Insurance Program, and the Indian Health Service; and

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2 Ibid.
Whereas, For every public dollar invested in contraception, short-term Medicaid expenditures are reduced by $7.09 for the pregnancy, delivery, and early childhood care related to births from unintended pregnancies; and

Whereas, Expanding access to free contraception has a positive impact on insurance costs. Estimates show that the cost to provide contraception per year ranges from $100-$600 while the cost for prenatal care, delivery, and newborn care averages $18,000-$28,000 under private insurance; and

Whereas, 77 percent of women and 64 percent of men support increased access to no-cost hormonal contraception; and

Whereas, The category of employers who can claim a moral objection to providing contraception to their employees at no-cost was broadened through the October 6, 2017 Rule, thereby taking away this preventive health benefit from a significant number of women; therefore be it

RESOLVED, That our American Medical Association advocate to rescind the 2017 Rule “Moral Exemptions and Accommodations for Coverage of Certain Preventive Services under the Affordable Care Act,” to ensure that all women have access to no-cost hormonal contraception. (New HOD Policy)

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

Received: 10/12/17

RELEVANT AMA POLICY

Support for Access to Preventive and Reproductive Health Services H-425.969

Our AMA supports access to preventive and reproductive health services for all patients and opposes legislative and regulatory actions that utilize federal or state health care funding mechanisms to deny established and accepted medical care to any segment of the population. Citation: Sub. Res. 224, I-15

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Reference Committee K

CME Report(s)
01* Promoting and Reaffirming Domestic Medical School Clerkship Education

CSAPH Report(s)
01 Universal Color Scheme for Respiratory Inhalers
02 Targeted Education to Increase Organ Donation
03 Neuropathic Pain as a Disease
04 National Drug Shortages Update
05* Clinical Implications and Policy Considerations of Cannabis Use

Resolution(s)
901 Harmful Effects of Screen Time in Children
902 Expanding Expedited Partner Therapy to Treat Trichomoniasis
903 Improving Screening and Treatment Guidelines for Domestic Violence Against Lesbian, Gay, Bisexual, Transgender, Queer/Questioning, and Other Individuals
904 Educating Physicians About the Importance of Cervical Cancer Screening for Female-to-Male Transgender Patients
905 Addressing Social Media Usage and its Negative Impacts on Mental Health
906 Opioid Abuse in Breastfeeding Mothers
907 Addressing Healthcare Needs of Foster Children
908 Updating Energy Policy and Extraction Regulations to Promote Public Health and Sustainability
909 Expanding Naloxone Programs
910 Improving Treatment and Diagnosis of Maternal Depression Through Screening and State-Based Care Coordination
911* State Maternal Mortality Review Committees
912* Corrective Statements Ordered to be Published by Tobacco Companies for the Violation of the Racketeer Influenced and Corrupt Organizations Act
913* Increased Death Rate and Decreased Life Expectancy in the United States
914* Support of Training, Ongoing Education, and Consultation in Order to Reduce the Health Impact of Pediatric Environmental Chemical Exposures
915 Implicit Bias, Diversity and Inclusion in Medical Education and Residency Training
916 Fees for Taking Maintenance of Certification Examination
917 Developing Physician Led Public Health / Population Health Capacity in Rural Communities
918 Minimization of Bias in the Electronic Residency Application Service Residency Application
919 House Physicians Category
920 Standardization of Family Planning Training Opportunities in OB-BYN Residencies
921 Sex and Gender Based Medicine in Clinical Education
922* Lifestyle Medicine Education in Medical School Training and Practice

* included in the Handbook Addendum
REPORT 1 OF THE COUNCIL ON MEDICAL EDUCATION (I-17)
Promoting and Reaffirming Domestic Medical School Clerkship Education (Resolution 308-I-16)
(Reference Committee K)

EXECUTIVE SUMMARY

The catalyst for this report was Resolution 308-I-16, “Promoting and Reaffirming Domestic Medical School Clerkship Education,” from the Medical Student Section, which asked that our American Medical Association (AMA): 1) pursue legislative and/or regulatory avenues that promote the regulation of the financial compensation which medical schools can provide for clerkship positions in order to facilitate fair competition amongst medical schools and prevent unnecessary increases in domestically-trained medical student debt; 2) support the expansion of partnerships of foreign medical schools with hospitals in regions which lack local medical schools in order to maximize the cumulative clerkship experience for all students; and 3) reaffirm policies D-295.320, D-295.931, and D-295.937. Due to the complexity of the issues surrounding this topic, the resolution was referred.

This report considers concerns that have been raised about the availability of clinical clerkship training sites due to continuing increases in the enrollment of U.S. allopathic and osteopathic medical schools and in the absolute numbers of U.S. medical schools—as well as the growing number of foreign medical schools that seek to place their students in clerkships in U.S. institutions. These schools, which cater primarily to U.S. citizen international medical graduates (USIMGs), are generally located in the Caribbean, and are sometimes referred to as “offshore medical schools.” The educational experience of U.S. medical students could be compromised through competition with other learners for faculty attention and access to patients.

This report comprises:
• A review of state efforts to address this issue, in New York and Texas
• A summary of relevant medical school accreditation standards
• An analysis of potential implications for the physician workforce
• Consideration of legal and antitrust issues around this issue
• A review of past Council on Medical Education reports and AMA policy on this topic
• Proposed emendations to current AMA policy to strengthen and streamline the AMA’s position on this important topic

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Subject: Promoting and Reaffirming Domestic Medical School Clerkship Education
(Resolution 308-I-16)

Presented by: Lynne Kirk, MD, Chair

Referred to: Reference Committee K
(L. Samuel Wann, MD, Chair)

GENESIS AND OUTLINE

Resolution 308-I-16, “Promoting and Reaffirming Domestic Medical School Clerkship Education,” introduced by the Medical Student Section, asked that the American Medical Association (AMA): 1) pursue legislative and/or regulatory avenues that promote the regulation of the financial compensation which medical schools can provide for clerkship positions in order to facilitate fair competition among medical schools and prevent unnecessary increases in domestically-trained medical student debt; 2) support the expansion of partnerships of foreign medical schools with hospitals in regions which lack local medical schools in order to maximize the cumulative clerkship experience for all students; and 3) reaffirm policies D-295.320, D-295.931, and D-295.937.

Testimony at Reference Committee C during the 2016 Interim Meeting was unanimous in support of referral of Resolution 308. This is a complex issue, with numerous factors, ranging from state law to physician workforce implications. It was felt that a thorough analysis by the Council on Medical Education was required to ensure an in-depth, nuanced solution to this issue—one that involves all key stakeholders and places patient care and education needs at the forefront. Accordingly, Resolution 308-I-16 was referred.

This report comprises:

- A review of state efforts to address this issue, in New York and Texas.
- A summary of relevant medical school accreditation standards.
- An analysis of potential implications for the physician workforce.
- Consideration of legal and antitrust issues around this issue.
- A review of past Council on Medical Education reports and AMA policy on this topic.

BACKGROUND

Clinical clerkships are required of medical school programs accredited by the Liaison Committee on Medical Education (LCME). These clerkships are conducted, at least in part, within teaching hospitals with which the medical school has an affiliation or formal agreement for instruction of its students. The clinical phase of education traditionally takes place in years three and four in LCME-accredited medical schools.
Concerns have been raised about the availability of clinical clerkship training sites due to continuing increases in the enrollment of U.S. allopathic and osteopathic medical schools and in the absolute numbers of U.S. medical schools, as well as competition for placement sites from other health professions programs, such as nurse practitioner and physician assistant programs. Further, the extensive and ongoing consolidation in the health care industry has led to closure of multiple hospital facilities, with concomitant reduction in the number of sites available for clinical education. The educational experience of U.S. medical students could be compromised through competition with other learners for faculty attention and access to patients.

A final factor (which is most pertinent to this report) is the growing number of foreign medical schools that seek to place their students in clerkships in U.S. institutions—in particular, those schools that cater primarily to U.S. citizen international medical graduates (USIMGs). Many of these institutions are located in the Caribbean, and are sometimes referred to as “offshore medical schools.” The eight largest of these institutions (by number of students certified by the Educational Commission for Foreign Medical Graduates [ECFMG] in 2013) include:

- St George’s University School of Medicine (Grenada) 891
- Ross University School of Medicine (Dominica) 815
- American University of Antigua College of Medicine (Antigua and Barbuda) 347
- American University of the Caribbean (Sint Maarten) 281
- Saba University School of Medicine (Saba) 156
- Windsor University School of Medicine (Saint Kitts and Nevis) 139
- Medical University of the Americas (Saint Kitts and Nevis) 135
- Saint Matthew’s University (Cayman Islands) 129

(Note: A full list is available in Appendix A, as adapted from Eckhert NL, van Zanten M. Overview of For-Profit Schools in the Caribbean. 2014. Foundation for Advancement of International Medical Education and Research.)

Accreditation/approval of these institutions is the purview of a variety of bodies, each with varying standards and requirements for quality of education. These include seeking recognition through the Ministry of Education or Ministry of Health of the institution’s home country, or accreditation or approval from regional agencies, such as the Caribbean Accreditation Authority for Education in Medicine and other Health Professions (CAAM-HP) and the Accreditation Commission on Colleges of Medicine, (a nonprofit organization in Ireland that inspects and accredits medical schools in countries that do not have a national medical accreditation body). As of 2023, the ECFMG will require that physicians applying for ECFMG Certification graduate from a medical school that has been “appropriately accredited”—that is, “accredited through a formal process that uses criteria comparable to those established for U.S. medical schools by the Liaison Committee on Medical Education (LCME) or that uses other globally accepted criteria, such as those put forth by the World Federation for Medical Education (WFME).”

Offshore medical schools typically do not own teaching hospitals. It is common for these students to complete their required clinical clerkships in another country, and the level of supervision and instruction provided to the medical student can vary widely. Medical students attending these schools tend to complete their required clinical clerkships in the U.S. Offshore medical schools are often willing to provide significant financial remuneration to secure slots for their students’ clerkship experiences. These funds are often an attractive source of revenue, particularly for urban hospitals/institutions in underserved areas.
In theory, U.S. medical schools could provide similar financial incentives to gain access to clinical sites or faculty. However, the cost would most likely be passed on to students in the same way such costs are covered for students who are attending offshore medical schools. This could result in raised tuition, and ultimately increase U.S. medical student debt (as noted in Resolve 1 of Resolution 308-I-16).

The buying (and selling) of clerkship slots benefits the offshore medical student seeking a clerkship as well as the offshore medical school and the stateside institution providing the clerkship. Medical schools (and medical students) in the United States, however, may be negatively affected. Data compiled from the 2012-2013 LCME Annual Medical Questionnaire (Part II) showed that, of the 136 medical school programs accredited at that time, 52.2 percent (71) saw increased difficulty in finding inpatient clinical placements for students in core clerkships. Of these schools, 25 attributed this increased difficulty in part to “competition for placement sites from offshore international medical schools” (along with other factors, including increase in class size and other U.S. schools in the region). Of the 15 states with the highest number of schools reporting such issues, 12 are in the northeast and mid-Atlantic regions and the upper Midwest.

STATE REGULATIONS

Nine states evaluate the physician’s clinical clerkships in connection with an application for licensure. In most states, clerkships for U.S. medical students must take place in hospitals affiliated with medical schools accredited by the LCME or with residency programs accredited by the Accreditation Council for Graduate Medical Education (ACGME). A number of states have special rules that apply to students of non-LCME-accredited medical schools in the Caribbean.

New York

Since 1981, the New York State Board of Regents has had in place regulations on the eligibility of students enrolled in offshore medical schools for clinical clerkships in New York hospitals. In summary, only students from offshore medical schools that have been approved by the New York State Education Department are eligible to complete clinical clerkships totaling more than 12 weeks in New York teaching hospitals. In addition, students wishing to participate in such clerkships must pass the United States Medical Licensing Examination (USMLE) Step 1 examination, and the clerkship may only occur in a teaching hospital with which the offshore medical school has an approved affiliation agreement. In addition, the teaching hospital must have a residency program accredited by the ACGME in the clerkship discipline.

The approval process for offshore medical schools, handled by the New York State Education Department, is based on an assessment of educational quality similar to a medical school accreditation review. Students from medical schools that are unapproved by the department are limited to no more than 12 weeks’ clerkship experience in New York teaching hospitals.

In 2008, New York City Health and Hospitals Corporation signed a 10-year, $10 million exclusive contract with a state-approved offshore medical school, through which the school pays $400 per student per week for training slots. Several other such schools soon entered into similar agreements with other New York institutions, and a 2009 report subsequently found that “about half of the 4,000 medical students doing third- and fourth-year rotations in New York State were from offshore medical schools.” These agreements began to raise concern among U.S.-based educators as to the availability of clerkships for their own students, as well as concerns that accreditation standing might be jeopardized if the quality of clerkship experiences was negatively affected due to the sheer number of students in a given rotation.
One challenge in evaluating these concerns is that the literature is silent with respect to the appropriate number of medical students in a clerkship or the resources needed to assure that a rotation is “adequate,” and indeed, the “adequate” number of students may change based on patient population and geographic location. To attempt to better ascertain these data, the Association of Medical Schools of New York (AMSNY) fielded a survey of clerkship directors in 2009. A second iteration of that survey is scheduled soon. The survey, which included questions on the availability of an adequate number of faculty/residents/staff and patients, as well as physical and IT resources, concluded that:

- LCME and COCA standards control the educational behaviors of accredited schools, but have no influence on hospitals seeking to enhance revenue streams through the sale of clerkship “slots” to unaccredited bidders.
- The establishment of quantitative benchmarks may help schools in negotiations with their traditional academic affiliates.
- Legislative action may be needed to assure quality training and patient safety in state- or federal-regulated care delivery-sites.

Texas

In April 2013, the Texas legislature passed legislation to address growing concerns that affiliation agreements between offshore medical schools and Texas hospitals and other health care facilities would limit Texas medical students’ options for clinical training. Through the enacted legislation, the following subsection was added to the state’s Education Code:

(c) The board may not issue a certificate of authority for a private postsecondary institution to grant a professional degree or to represent that credits earned in this state are applicable toward a degree if the institution is chartered in a foreign country or has its principal office or primary educational program in a foreign country. In this subsection, “professional degree” includes a Doctor of Medicine (M.D.), Doctor of Osteopathy (D.O.), Doctor of Dental Surgery (D.D.S.), Doctor of Veterinary Medicine (D.V.M.), Juris Doctor (J.D.), and Bachelor of Laws (LL.B.)

The legislation was supported by the Texas Medical Association (TMA) and the state’s medical schools, which feared a diminution in the number of clinical clerkships for its medical students, due in part to the willingness of offshore medical schools to pay for clerkships for their students. With only one exception, Texas medical schools do not pay for clerkships and are in no position financially to do so. Had the state legislation not been passed, it would have been expected that Texas medical schools would not have been able to afford to compete in paying for clerkships, thereby displacing Texas medical students from long-standing clerkships at Texas teaching hospitals. As a result, medical schools would likely have been forced to participate in bidding wars for clerkship space, and, consequently, pass on this added cost to medical students, resulting in increased tuition and likely, increased student debt. Noted one of the co-authors of the Texas legislation, “Our Texas medical students should be prioritized, and we must ensure they have access to those clinical rotations without doing anything to jeopardize that. They are our investment. [The state] invests in medical education, and we have to protect that investment.”

The TMA’s advocacy on this issue was buttressed by policy adopted in 2013, which resulted from a report of the association’s Council on Medical Education (see Appendix B). The policy stated, in part, that the TMA “strongly objects to the practice of substituting clinical experiences provided by U.S. institutions for core clinical curriculum of foreign medical schools. Moreover, our association strongly disapproves of the placement of any medical school undergraduate students in hospitals and other medical care delivery facilities that lack sufficient educational resources for the
supervised teaching of clinical medicine.“ In addition, the policy states, “2. Institutions that accept
students for clinical placements should ensure that all such students are trained in programs that
meet requirements for curriculum, clinical experiences, and attending supervision as expected for
[LCME- and COCA-accredited] programs… 3. TMA opposes extraordinary payments by any
medical school for access to clinical rotations. 4. Foreign medical students should not displace
Texas medical students in clinical training positions at Texas health care facilities. Priority should
be given to Texas medical students and other health care professionals for clinical training." 8

RELEVANT LCME STANDARDS

A number of LCME standards9 are relevant to the topic of this report, including:

4.1 Sufficiency of Faculty
A medical school has in place a sufficient cohort of faculty members with the qualifications
and time required to deliver the medical curriculum and to meet the other needs and fulfill the
other missions of the institution.

5.5 Resources for Clinical Instruction
A medical school has, or is assured the use of, appropriate resources for the clinical
instruction of its medical students in ambulatory and inpatient settings and has adequate
numbers and types of patients (e.g., acuity, case mix, age, gender).

5.10 Resources Used by Transfer/Visiting Students
The resources used by a medical school to accommodate any visiting and transfer medical
students in its medical education program do not significantly diminish the resources available
to already enrolled medical students.

10.8 Visiting Students
A medical school does all of the following:
• Verifies the credentials of each visiting medical student
• Ensures that each visiting medical student demonstrates qualifications comparable to
  those of the medical students he or she would join in educational experiences
• Maintains a complete roster of visiting medical students
• Approves each visiting medical student’s assignments
• Provides a performance assessment for each visiting medical student
• Establishes health-related protocols for such visiting medical students
• Identifies the administrative office that fulfills these responsibilities

LCME requirements also provide guidance as to faculty serving as supervisors for medical students
from more than one institution. For example, a 2014 LCME white paper10 notes the following, in
part:

4. A given medical school must evaluate the quality of its education across sites, including at
the site(s) that serve(s) students from multiple schools, and must ensure and document that
comparability exists in the curricular core, including in required clinical encounters.

5. There must be sufficient patient resources and faculty numbers so that medical students from
each medical education program are able to meet their defined objectives and required clinical
encounters and have appropriate levels of supervision and assessment.
The presence of students from another school must not diminish the access to resources needed by students from a given medical school to meet the objectives of the specific course/clerkship, including appropriate patients/procedures and faculty.

6. If two or more LCME-accredited medical schools share faculty at a given instructional site, there should be coordination between the schools, for example, an agreement that each medical school will have appropriate access to needed resources to support its medical education program.

Resources include: 1) faculty with sufficient time to teach each cohort of students and to participate in relevant faculty development, 2) patients sufficient to meet the required clinical conditions specified by each medical school, and 3) appropriate facilities for the total numbers of students at the site at any given time.

LIMITATIONS ON AMA ACTIONS

The types of actions that the AMA can take are limited by antitrust considerations. That is, the AMA as a private entity cannot act in concert with others to limit competition by attempting to deny or restrict access of medical students from offshore medical schools to U.S. teaching hospitals. The AMA can, however, advocate to governmental entities for such limitations as a means to assure the ongoing quality of the U.S. medical education system. The AMA can also develop model state legislation that would reflect best practices for financial remuneration of clerkships.

PAST COUNCIL ON MEDICAL EDUCATION REPORTS AND RELEVANT AMA POLICY

The availability of clerkships for medical students has been the topic of three recent Council on Medical Education reports:

2. Report 4-I-09, “Factors Affecting the Availability of Clinical Training Sites for Medical Student Education” (http://bit.ly/2tmi4ds)

As a result of these and other reports and resolutions, the AMA has a number of policies on this topic:

3. H-295.995 (30, 31), “Recommendations for Future Directions for Medical Education”
4. D-295.320, “Factors Affecting the Availability of Clinical Training Sites for Medical Student Education”
5. D-295.931, “Update on the Availability of Clinical Training Sites for Medical Student Education”

This report includes recommendations for revisions to consolidate and streamline these policies, as shown in Appendix C.
DISCUSSION

The issue of adequate availability of clerkships for U.S. medical students can be seen in the context of larger issues—in particular, the quality and quantity of the future physician workforce. That workforce comprises both U.S. medical school graduates as well as a significant number of IMGs (both U.S. citizens and noncitizens). To clarify thinking in this regard, several questions may be posed. For example, is the quality of education/training for U.S. medical students imperiled by competition for clerkships by students from offshore medical schools? Also, are USIMGs receiving an adequate education to prepare them for residency and practice in the U.S.?

Recent literature on this topic urges increased scrutiny of offshore medical schools and their graduates. Eckhart\textsuperscript{11} writes, “Just as the Flexner Report strengthened medical education by raising standards, recommending quality improvements, and suggesting closure of weaker schools, a present-day review of the schools \textcolor{red}{[in other countries]} whose purpose is to train physicians for the United States could lead to recommendations for improvement and/or accreditation, educational innovations, or sanctions against poorly performing medical schools.” She argues that the U.S. must “look beyond our borders to ensure that physicians around the world obtain the best possible education. To begin this effort close to home—in the Caribbean Basin—makes good sense, because the growing number of graduates from the \textcolor{red}{[offshore medical schools]} there will be part of the next generation of physicians caring for the U.S. public and practicing alongside U.S.-trained physicians.”

Likewise, note Halperin and Goldberg,\textsuperscript{12} “U.S. medical education today faces a threat similar to that leading up to the Flexner Report, although this time the schools that do not meet the training standards necessary to ensure public health are outside U.S. borders. A dire emergency is approaching that could compromise American medical education.” They call for a number of potential solutions; most pertinent to this report, these include that state higher education boards “deny students of proprietary offshore schools access to clinical education in U.S. teaching hospitals unless these schools meet accreditation standards equivalent to those expected of U.S. medical schools.” In addition, they urge additional legislation at the state level, similar to that passed in Texas in 2013, described above.

Related to the second question posed above, the educational standards of offshore medical schools are a topic of some concern—particularly as students at these institutions are able to obtain federal funding. Attrition (and tuition) rates are high, and educational resources often lack in comparison to those at LCME-accredited medical school programs. Norcini et al. raised concerns about “striking” gaps in clinical performance among practicing USIMGs versus their non-citizen IMG and U.S. medical school graduate counterparts, and proposed further research “to clarify whether [USIMG] performance is a result of their medical education experiences or their ability. To the degree that it is the former, U.S. citizens will need information about international medical schools on which to base their application decisions. To the degree that it is the latter, and as additional training opportunities become available for U.S. citizens, medical schools and residency programs will need to be more vigilant in their selection procedures and not accept students who lack the ability to perform as physicians.”\textsuperscript{13}

As to the resolve clauses of Resolution 308-I-16, the AMA can pursue or support legislative and regulatory advocacy to promote fair competition amongst medical schools vying for clerkship positions. Additionally, the AMA can focus on educational quality, to include the appropriate number of students on a given clerkship at any one time, and address such educational aspects as curriculum, supervision, and procedural experience (logbooks). The AMA can work with interested
state and specialty medical associations to pursue legislation that addresses this issue and helps
ensure a quality experience for all medical students.

Related to Resolve 2 of Resolution 308-I-16, fostering partnerships with hospitals that are not
currently used for clinical teaching may benefit both students from offshore schools as well as U.S.
students; this possibility also aligns with AMA policy on addressing geographic disparities in
access to care. In fact, it may be appropriate that clerkship training slots be treated as public
resources to help expand the physician workforce—particularly in underserved areas—versus
being seen as the “property” of academic medical centers and teaching hospitals.

Finally, Resolve 3, which asks for reaffirmation of AMA policy, is obviated through the
recommendations below, which incorporate changes to consolidate and streamline existing policy.

RECOMMENDATIONS

The Council on Medical Education recommends that the following recommendations be adopted in
lieu of Resolution 308-I-16, and the remainder of the report be filed.

1. That our American Medical Association (AMA):

   1) Work with the Association of American Medical Colleges, American Association of
      Colleges of Osteopathic Medicine, and other interested stakeholders to encourage local and
      state governments and the federal government, as well as private sector philanthropies, to
      provide additional funding to support: a) infrastructure and faculty development and
      capacity for medical school expansion; and b) delivery of clinical clerkships and other
      educational experiences. (Directive to Take Action)

   2) Encourage clinical clerkship sites for medical education (to include medical schools and
      teaching hospitals) to collaborate with local, state, and regional partners to create additional
      clinical education sites and resources for students. (Directive to Take Action)

   3) Advocate for federal and state legislation/regulations to:

      a. Oppose any extraordinary compensation granted to clinical clerkship sites that would
         displace or otherwise limit the education/training opportunities for medical students in
         clinical rotations enrolled in medical school programs accredited by the Liaison
         Committee on Medical Education (LCME) or Commission on Osteopathic College
         Accreditation (COCA);

      b. Ensure that priority for clinical clerkship slots be given first to students of LCME- or
         COCA-accredited medical school programs; and

      c. Require that any institution that accepts students for clinical placements ensure that all
         such students are trained in programs that meet requirements for educational quality,
         curriculum, clinical experiences and attending supervision that are equivalent to those
         of programs accredited by the LCME and COCA. (Directive to Take Action)

   4) Encourage relevant stakeholders to study whether the “public service community benefit”
      commitment and corporate purposes of not for profit, tax exempt hospitals impose any
      legal and/or ethical obligations for granting priority access for teaching purposes to
      medical students from medical schools in their service area communities and, if so,
advocate for the development of appropriate regulations at the state level. (Directive to Take Action)

5) Work with interested state and specialty medical associations to pursue legislation that ensures the quality and availability of medical student clerkship positions for U.S. medical students. (Directive to Take Action)

2. Our AMA supports the practice of U.S. teaching hospitals and foreign medical schools entering into appropriate relationships directed toward providing clinical educational experiences for advanced medical students who have completed the equivalent of U.S. core clinical clerkships. Policies governing the accreditation of U.S. medical education programs specify that core clinical training be provided by the parent medical school; consequently, the AMA strongly objects to the practice of substituting clinical experiences provided by U.S. institutions for core clinical curriculum of foreign medical schools. Moreover, it strongly disapproves of the placement of medical students in teaching hospitals and other clinical sites that lack appropriate educational resources and experience for supervised teaching of clinical medicine, especially when the presence of visiting students would disadvantage the institution’s own students educationally and/or financially and negatively affect the quality of the educational program and/or safety of patients receiving care at these sites. (New HOD Policy)

3. Our AMA supports agreements for clerkship rotations, where permissible, for U.S. citizen international medical students between foreign medical schools and teaching hospitals in regions that are medically underserved and/or that lack medical schools and clinical sites for training medical students, to maximize the cumulative clerkship experience for all students and to expose these students to the possibility of medical practice in these areas. (New HOD Policy)

4. U.S. citizens should have access to factual information on the requirements for licensure and for reciprocity in the various U.S. medical licensing jurisdictions, prerequisites for entry into graduate medical education programs, and other relevant factors that should be considered before deciding to undertake the study of medicine in schools not accredited by the LCME or COCA. (New HOD Policy)

5. Existing requirements for foreign medical schools seeking Title IV Funding should be applied to those schools that are currently exempt from these requirements, thus creating equal standards for all foreign medical schools seeking Title IV Funding. (New HOD Policy)

6. That Policies H-255.988 (6, 23, 25), H-255.998, H-295.995 (30, 31), D-295.320, D-295.931, and D-295.937 be rescinded, as described in Appendix C to this report. (Rescind HOD Policy)

Fiscal Note: $1,000 for staff time
APPENDIX A: OFFSHORE MEDICAL SCHOOLS IN 2013, BY NUMBER OF ECFMG-CERTIFIED STUDENTS/GRADUATES

<table>
<thead>
<tr>
<th>School</th>
<th>Location</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>St George’s University School of Medicine</td>
<td>Grenada</td>
<td>891</td>
</tr>
<tr>
<td>Ross University School of Medicine</td>
<td>Dominica</td>
<td>815</td>
</tr>
<tr>
<td>American University of Antigua College of Medicine</td>
<td>Antigua and Barbuda</td>
<td>347</td>
</tr>
<tr>
<td>American University of the Caribbean</td>
<td>Sint Maarten</td>
<td>281</td>
</tr>
<tr>
<td>Saba University School of Medicine</td>
<td>Saba (Special Municipality of the Netherlands)</td>
<td>156</td>
</tr>
<tr>
<td>Windsor University School of Medicine</td>
<td>Saint Kitts and Nevis</td>
<td>139</td>
</tr>
<tr>
<td>Medical University of the Americas</td>
<td>Saint Kitts and Nevis</td>
<td>135</td>
</tr>
<tr>
<td>Saint Matthew’s University</td>
<td>Cayman Islands</td>
<td>129</td>
</tr>
<tr>
<td>American University of Integrative Sciences</td>
<td>Sint Maarten</td>
<td>86</td>
</tr>
<tr>
<td>University of Medicine and Health Sciences</td>
<td>Saint Kitts and Nevis</td>
<td>56</td>
</tr>
<tr>
<td>Saint James School of Medicine</td>
<td>Saint Vincent and the Grenadines</td>
<td>49</td>
</tr>
<tr>
<td>Xavier University School of Medicine</td>
<td>Aruba</td>
<td>38</td>
</tr>
<tr>
<td>Avalon University School of Medicine</td>
<td>Curacao</td>
<td>24</td>
</tr>
<tr>
<td>Spartan Health Sciences University</td>
<td>Saint Lucia</td>
<td>23</td>
</tr>
<tr>
<td>Trinity School of Medicine</td>
<td>Saint Vincent and the Grenadines</td>
<td>16</td>
</tr>
<tr>
<td>Aureus University School of Medicine</td>
<td>Aruba</td>
<td>12</td>
</tr>
<tr>
<td>23 additional institutions</td>
<td>varies</td>
<td>Fewer than 10</td>
</tr>
</tbody>
</table>

APPENDIX B: REPORT 3-A-12 OF THE TEXAS MEDICAL ASSOCIATION COUNCIL ON MEDICAL EDUCATION

Subject: Clinical Training Resources for Texas Medical Students
Presented by: Cynthia A. Jumper, MD, Chair
Referred to: Reference Committee on Public Health, Science, and Education

A medical school in the Caribbean is seeking to establish affiliation agreements with Texas hospitals and other health care facilities to provide clinical training for its third- and fourth-year medical students to complete their core clinical clerkships in Texas. Our council has grave concerns about the potential damaging effects of a proposal that has the risk of displacing Texas medical students from the already limited clinical training capacity in our state. Our educational institutions already have commitments to Texas students to provide reasonable access to training opportunities. Diminishing our own students’ access to clinical training in the state would negatively affect the quality and affordability of education for Texas medical students, resident physicians, and other health professionals — all who need and deserve priority access to clinical training in the state.

Economic Impact

State support for educating medical students, resident physicians, and other health professionals was severely reduced in the 2012-13 state budget. At the same time, in response to increasing physician demand, Texas medical schools plan an increase of 30 percent in enrollments by 2015. This will result in an estimated total of 3,300 third- and fourth-year medical students each year — the highest numbers ever for our state. There is also a strong potential for a new four-year medical school in South Texas. This vigorous growth in enrollments clearly dictates a need for more hospital clinical training space for our own students in the very near future.

Adding foreign medical students simultaneously with the large Texas enrollment growth will only exacerbate the shortage of clinical training space. The limited supply could result in a considerable increase in the cost of clerkships for medical schools, as is occurring in northeastern states, that could force increases in medical school tuition and related student debt as well as the displacement of our own medical students, and threaten the accreditation status of our own schools.

Benefit to the State

Recognizing that the state has only limited training capacity and the potential financial impact on Texas medical schools and students, thoughtful consideration must be given to the potential benefit to the state. Texas ranks second in the nation, behind California, in the retention of our medical school graduates in the state, at 59 percent.¹

In contrast, it is not known how many students enrolled in foreign medical schools would even have an interest in practicing in Texas. Substituting foreign students for Texas medical students would not benefit the state’s escalating physician workforce needs. It makes little sense for the state to invest at least $170,000 per year for each Texas medical student yet not provide for their reasonable access to core clinical clerkships in the state.

Further, as reported by the American Medical Association Medical Student Section in November 2011,
U.S. medical school accreditation standards require both a broad and significant portfolio of undergraduate experiences as well as a rigorous and specifically defined standard of preclinical education in the first two years of medical school before admitted, visiting, or transfer American medical students are allowed to participate in third year clerkships, yet for-profit offshore medical schools do not provide any standardized or equivalent system of evaluation before they participate in third year clerkships in American hospitals.

**Availability of Clinical Faculty and Student Supervision Rules**

Given the increases in our own medical school enrollment, it is unclear whether there are sufficient numbers of qualified clinical faculty to oversee the training of our own medical students in addition to foreign medical students. The Texas Medical Board has regulations that delineate specific requirements for physicians eligible to supervise medical students. The board’s rules also must be considered to ensure that medical students who complete clerkships in Texas would ultimately be eligible for medical licensure in the state.

**Policy Proposals**

Our council believes it is in the best interest of the state … for quality, education, workforce, as well as economic considerations … to ensure that Texas medical school students are provided first access to core clinical clerkships in the state. The council proposes adoption of the following principles as Texas Medical Association policy, including relevant policies of AMA, with their adaptation for Texas.

1. Policies governing the accreditation of U.S. medical education programs specify that core clinical training be provided by the parent medical school; consequently, the Texas Medical Association strongly objects to the practice of substituting clinical experiences provided by U.S. institutions for core clinical curriculum of foreign medical schools. Moreover, our association strongly disapproves of the placement of any medical school undergraduate students in hospitals and other medical care delivery facilities that lack sufficient educational resources for the supervised teaching of clinical medicine.

2. Institutions that accept students for clinical placements should ensure that all such students are trained in programs that meet requirements for curriculum, clinical experiences, and attending supervision as expected for programs accredited by the Liaison Committee on Medical Education or the Commission on Osteopathic College Accreditation.

3. The Texas Medical Association opposes extraordinary payments by any medical school for access to clinical rotations.

4. Foreign medical students should not displace Texas medical students in clinical training positions at Texas health care facilities. Priority should be given to Texas medical students and other health care professionals for clinical training.

**Recommendation: Approval as TMA policy.**


ii. Texas Medical Board Program Rule, §162.1. Supervision of Medical Students.

(a) In order to supervise a medical student who is enrolled at a Texas medical school as a full-time student or visiting student the physician must have an active and unrestricted Texas license.
(b) In order to supervise a medical student who does not meet the criteria in subsection (a) of this section the physician must:

(1) have an active and unrestricted Texas license;
(2) hold a faculty position in the graduate medical education program in the same specialty in which the student will receive undergraduate medical education;
(3) supervise the student during the educational period; and
(4) supervise the student’s medical education in either a Texas hospital or teaching institution, which sponsors or participates in a program of graduate medical education accredited by the Accrediting Council for Graduate Medical Education, the American Osteopathic Association, or the Texas Medical Board in the same subject as the medical or osteopathic medical education in which the hospital or teaching institution has an agreement with the applicant’s school.

(c) If the physician is not licensed in Texas as required in subsection (a) or (b) of this section, the physician must be employed by the federal government and maintain an active and unrestricted license.

(d) Physician applicants who receive medical education in the United States in settings that do not comply with statutory requirements set forth in Texas Occupations Code §155.003(b) - (c) may be ineligible for licensure.
APPENDIX C: RECOMMENDED ACTIONS ON HOUSE OF DELEGATES’ POLICIES RELATED TO CLERKSHIPS

H-255.988, “AMA Principles on International Medical Graduates”

Delete 6, 23, and 25, for incorporation into the proposed new policy. These three items are more relevant to the topic of availability of clinical clerkships than to principles on international medical graduates.

Our AMA supports:
1. Current U.S. visa and immigration requirements applicable to foreign national physicians who are graduates of medical schools other than those in the United States and Canada.
2. Current regulations governing the issuance of exchange visitor visas to foreign national IMGs, including the requirements for successful completion of the USMLE.
3. The AMA reaffirms its policy that the U.S. and Canada medical schools be accredited by a nongovernmental accrediting body.
4. Cooperation in the collection and analysis of information on medical schools in nations other than the U.S. and Canada.
5. Continued cooperation with the ECFMG and other appropriate organizations to disseminate information to prospective and current students in foreign medical schools. An AMA member, who is an IMG, should be appointed regularly as one of the AMA's representatives to the ECFMG Board of Trustees.
6. The core clinical curriculum of a foreign medical school should be provided by that school; U.S. hospitals should not provide substitute core clinical experience for students attending a foreign medical school.
7. Working with the Accreditation Council for Graduate Medical Education (ACGME) and the Federation of State Medical Boards (FSMB) to assure that institutions offering accredited residencies, residency program directors, and U.S. licensing authorities do not deviate from established standards when evaluating graduates of foreign medical schools.
8. In cooperation with the ACGME and the FSMB, supports only those modifications in established graduate medical education or licensing standards designed to enhance the quality of medical education and patient care.
9. The AMA continues to support the activities of the ECFMG related to verification of education credentials and testing of IMGs.
10. That special consideration be given to the limited number of IMGs who are refugees from foreign governments that refuse to provide pertinent information usually required to establish eligibility for residency training or licensure.
11. That accreditation standards enhance the quality of patient care and medical education and not be used for purposes of regulating physician manpower.
12. That AMA representatives to the ACGME, residency review committees and to the ECFMG should support AMA policy opposing discrimination. Medical school admissions officers and directors of residency programs should select applicants on the basis of merit, without considering status as an IMG or an ethnic name as a negative factor.
13. The requirement that all medical school graduates complete at least one year of graduate medical education in an accredited U.S. program in order to qualify for full and unrestricted licensure.
14. Publicizing existing policy concerning the granting of staff and clinical privileges in hospitals and other health facilities.
15. The participation of all physicians, including graduates of foreign as well as U.S. and Canadian medical schools, in organized medicine. The AMA offers encouragement and assistance to state,
county, and specialty medical societies in fostering greater membership among IMGs and their participation in leadership positions at all levels of organized medicine, including AMA committees and councils and state boards of medicine, by providing guidelines and non-financial incentives, such as recognition for outstanding achievements by either individuals or organizations in promoting leadership among IMGs.

16. Support studying the feasibility of conducting peer-to-peer membership recruitment efforts aimed at IMGs who are not AMA members.

17. AMA membership outreach to IMGs, to include a) using its existing publications to highlight policies and activities of interest to IMGs, stressing the common concerns of all physicians; b) publicizing its many relevant resources to all physicians, especially to nonmember IMGs; c) identifying and publicizing AMA resources to respond to inquiries from IMGs; and d) expansion of its efforts to prepare and disseminate information about requirements for admission to accredited residency programs, the availability of positions, and the problems of becoming licensed and entering full and unrestricted medical practice in the U.S. that face IMGs. This information should be addressed to college students, high school and college advisors, and students in foreign medical schools.

18. Recognition of the common aims and goals of all physicians, particularly those practicing in the U.S., and support for including all physicians who are permanent residents of the U.S. in the mainstream of American medicine.

19. Its leadership role to promote the international exchange of medical knowledge as well as cultural understanding between the U.S. and other nations.

20. Institutions that sponsor exchange visitor programs in medical education, clinical medicine and public health to tailor programs for the individual visiting scholar that will meet the needs of the scholar, the institution, and the nation to which he will return.

21. Informing foreign national IMGs that the availability of training and practice opportunities in the U.S. is limited by the availability of fiscal and human resources to maintain the quality of medical education and patient care in the U.S., and that those IMGs who plan to return to their country of origin have the opportunity to obtain GME in the United States.

22. U.S. medical schools offering admission with advanced standing, within the capabilities determined by each institution, to international medical students who satisfy the requirements of the institution for matriculation.

23. Providing U.S. students who are considering attendance at an international medical school with information enabling them to assess the difficulties and consequences associated with matriculation in a foreign medical school.

24. The Federation of State Medical Boards, its member boards, and the ECFMG in their willingness to adjust their administrative procedures in processing IMG applications so that original documents do not have to be recertified in home countries when physicians apply for licenses in a second state.

25. Our AMA supports the application of the existing requirements for foreign medical schools seeking Title IV Funding to those schools which are currently exempt from these requirements, thus creating equal standards for all foreign medical schools seeking Title IV Funding.

H-255.998, “Foreign Medical Graduates”

Rescind and incorporate into the proposed new policy.

Our AMA supports the following principles, based on recommendations of the Ad Hoc Committee on Foreign Medical Graduates (FMGs): Our AMA supports the practice of U.S. teaching hospitals and foreign medical educational institutions entering into appropriate relationships directed toward providing clinical educational experiences for advanced medical students who have completed the equivalent of U.S. core clinical clerkships. Policies governing the accreditation of U.S. medical education programs specify that core clinical training be provided by the parent medical school; consequently, the AMA strongly objects to the practice of substituting clinical experiences provided by U.S. institutions for core clinical curriculum of foreign medical schools. Moreover, it strongly disapproves of the placement of any medical school undergraduate students in hospitals and other medical care delivery facilities which lack educational resources and experience for supervised teaching of clinical medicine.


H-295.995, “Recommendations for Future Directions for Medical Education”

Delete 30 and 31, for insertion into the proposed new policy.

Our AMA supports the following recommendations relating to the future directions for medical education:

(1) The medical profession and those responsible for medical education should strengthen the general or broad components of both undergraduate and graduate medical education. All medical students and resident physicians should have general knowledge of the whole field of medicine regardless of their projected choice of specialty.

(2) Schools of medicine should accept the principle and should state in their requirements for admission that a broad cultural education in the arts, humanities, and social sciences, as well as in the biological and physical sciences, is desirable.

(3) Medical schools should make their goals and objectives known to prospective students and premedical counselors in order that applicants may apply to medical schools whose programs are most in accord with their career goals.

(4) Medical schools should state explicitly in publications their admission requirements and the methods they employ in the selection of students.

(5) Medical schools should require their admissions committees to make every effort to determine that the students admitted possess integrity as well as the ability to acquire the knowledge and skills required of a physician.

(6) Although the results of standardized admission testing may be an important predictor of the ability of students to complete courses in the preclinical sciences successfully, medical schools should utilize such tests as only one of several criteria for the selection of students. Continuing review of admission tests is encouraged because the subject content of such examinations has an influence on premedical education and counseling.

(7) Medical schools should improve their liaison with college counselors so that potential medical students can be given early and effective advice. The resources of regional and national organizations can be useful in developing this communication.

(8) Medical schools are chartered for the unique purpose of educating students to become physicians and should not assume obligations that would significantly compromise this purpose.

(9) Medical schools should inform the public that, although they have a unique capability to identify the changing medical needs of society and to propose responses to them, they are only one
of the elements of society that may be involved in responding. Medical schools should continue to identify social problems related to health and should continue to recommend solutions.

(10) Medical school faculties should continue to exercise prudent judgment in adjusting educational programs in response to social change and societal needs.

(11) Faculties should continue to evaluate curricula periodically as a means of insuring that graduates will have the capability to recognize the diverse nature of disease, and the potential to provide preventive and comprehensive medical care. Medical schools, within the framework of their respective institutional goals and regardless of the organizational structure of the faculty, should provide a broad general education in both basic sciences and the art and science of clinical medicine.

(12) The curriculum of a medical school should be designed to provide students with experience in clinical medicine ranging from primary to tertiary care in a variety of inpatient and outpatient settings, such as university hospitals, community hospitals, and other health care facilities. Medical schools should establish standards and apply them to all components of the clinical educational program regardless of where they are conducted. Regular evaluation of the quality of each experience and its contribution to the total program should be conducted.

(13) Faculties of medical schools have the responsibility to evaluate the cognitive abilities of their students. Extramural examinations may be used for this purpose, but never as the sole criterion for promotion or graduation of a student.

(14) As part of the responsibility for granting the MD degree, faculties of medical schools have the obligation to evaluate as thoroughly as possible the non-cognitive abilities of their medical students.

(15) Medical schools and residency programs should continue to recognize that the instruction provided by volunteer and part-time members of the faculty and the use of facilities in which they practice make important contributions to the education of medical students and resident physicians. Development of means by which the volunteer and part-time faculty can express their professional viewpoints regarding the educational environment and curriculum should be encouraged.

(16) Each medical school should establish, or review already established, criteria for the initial appointment, continuation of appointment, and promotion of all categories of faculty. Regular evaluation of the contribution of all faculty members should be conducted in accordance with institutional policy and practice.

(17a) Faculties of medical schools should reevaluate the current elements of their fourth or final year with the intent of increasing the breadth of clinical experience through a more formal structure and improved faculty counseling. An appropriate number of electives or selected options should be included. (17b) Counseling of medical students by faculty and others should be directed toward increasing the breadth of clinical experience. Students should be encouraged to choose experience in disciplines that will not be an integral part of their projected graduate medical education.

(18) Directors of residency programs should not permit medical students to make commitments to a residency program prior to the final year of medical school.

(19) The first year of postdoctoral medical education for all graduates should consist of a broad year of general training. (a) For physicians entering residencies in internal medicine, pediatrics, and general surgery, postdoctoral medical education should include at least four months of training in a specialty or specialties other than the one in which the resident has been appointed. (A residency in family practice provides a broad education in medicine because it includes training in several fields.) (b) For physicians entering residencies in specialties other than internal medicine, pediatrics, general surgery, and family practice, the first postdoctoral year of medical education should be devoted to one of the four above-named specialties or to a program following the general requirements of a transitional year stipulated in the "General Requirements" section of the "Essentials of Accredited Residencies." (c) A program for the transitional year should be planned, designed, administered, conducted, and evaluated as an entity by the sponsoring institution rather than one or more departments. Responsibility for the executive direction of the program should be
assigned to one physician whose responsibility is the administration of the program. Educational programs for a transitional year should be subjected to thorough surveillance by the appropriate accrediting body as a means of assuring that the content, conduct, and internal evaluation of the educational program conform to national standards. The impact of the transitional year should not be deleterious to the educational programs of the specialty disciplines.

(20) The ACGME, individual specialty boards, and respective residency review committees should improve communication with directors of residency programs because of their shared responsibility for programs in graduate medical education.

(21) Specialty boards should be aware of and concerned with the impact that the requirements for certification and the content of the examination have upon the content and structure of graduate medical education. Requirements for certification should not be so specific that they inhibit program directors from exercising judgment and flexibility in the design and operation of their programs.

(22) An essential goal of a specialty board should be to determine that the standards that it has set for certification continue to assure that successful candidates possess the knowledge, skills, and the commitment to upgrade continually the quality of medical care.

(23) Specialty boards should endeavor to develop a consensus concerning the significance of certification by specialty and publicize it so that the purposes and limitations of certification can be clearly understood by the profession and the public.

(24) The importance of certification by specialty boards requires that communication be improved between the specialty boards and the medical profession as a whole, particularly between the boards and their sponsoring, nominating, or constituent organizations and also between the boards and their diplomates.

(25) Specialty boards should consider having members of the public participate in appropriate board activities.

(26) Specialty boards should consider having physicians and other professionals from related disciplines participate in board activities.

(27) The AMA recommends to state licensing authorities that they require individual applicants, to be eligible to be licensed to practice medicine, to possess the degree of Doctor of Medicine or its equivalent from a school or program that meets the standards of the LCME or accredited by the American Osteopathic Association, or to demonstrate as individuals, comparable academic and personal achievements. All applicants for full and unrestricted licensure should provide evidence of the satisfactory completion of at least one year of an accredited program of graduate medical education in the US. Satisfactory completion should be based upon an assessment of the applicant's knowledge, problem-solving ability, and clinical skills in the general field of medicine. The AMA recommends to legislatures and governmental regulatory authorities that they not impose requirements for licensure that are so specific that they restrict the responsibility of medical educators to determine the content of undergraduate and graduate medical education.

(28) The medical profession should continue to encourage participation in continuing medical education related to the physician's professional needs and activities. Efforts to evaluate the effectiveness of such education should be continued.

(29) The medical profession and the public should recognize the difficulties related to an objective and valid assessment of clinical performance. Research efforts to improve existing methods of evaluation and to develop new methods having an acceptable degree of reliability and validity should be supported.

(30) U.S. citizens should have access to factual information on the requirements for licensure and for reciprocity in the various jurisdictions, prerequisites for entry into graduate medical education programs, and other factors that should be considered before deciding to undertake the study of medicine in schools not accredited by the LCME.

(31) Policies governing the accreditation of U.S. medical education programs specify that core clinical training be provided by the parent medical school; consequently, the AMA strongly objects
to the practice of substituting clinical experiences provided by U.S. institutions for core clinical curriculum of foreign medical schools. Moreover, it strongly disapproves of the placement of any medical school undergraduate students in hospitals and other medical care delivery facilities which lack educational resources and experience for supervised teaching of clinical medicine.

(32) Methods currently being used to evaluate the readiness of graduates of foreign medical schools to enter accredited programs in graduate medical education in this country should be critically reviewed and modified as necessary. No graduate of any medical school should be admitted to or continued in a residency program if his or her participation can reasonably be expected to affect adversely the quality of patient care or to jeopardize the quality of the educational experiences of other residents or of students in educational programs within the hospital.

(33) The Educational Commission for Foreign Medical Graduates should be encouraged to study the feasibility of including in its procedures for certification of graduates of foreign medical schools a period of observation adequate for the evaluation of clinical skills and the application of knowledge to clinical problems.

(34) The AMA, in cooperation with others, supports continued efforts to review and define standards for medical education at all levels. The AMA supports continued participation in the evaluation and accreditation of medical education at all levels.

(35) The AMA, when appropriate, supports the use of selected consultants from the public and from the professions for consideration of special issues related to medical education.

(36) The AMA encourages entities that profile physicians to provide them with feedback on their performance and with access to education to assist them in meeting norms of practice; and supports the creation of experiences across the continuum of medical education designed to teach about the process of physician profiling and about the principles of utilization review/quality assurance.

(37) Our AMA encourages the accrediting bodies for MD- and DO-granting medical schools to review, on an ongoing basis, their accreditation standards to assure that they protect the quality and integrity of medical education in the context of the emergence of new models of medical school organization and governance.


D-295.320, “Factors Affecting the Availability of Clinical Training Sites for Medical Student Education”

Rescind and incorporate into the proposed new policy.

1. Our AMA will work with the Association of American Medical Colleges and the American Association of Colleges of Osteopathic Medical Education to encourage local and state governments and the federal government, as well as private sector philanthropies, to provide additional funding to support infrastructure and faculty development for medical school expansion.

2. Our AMA will encourage medical schools and the rest of the medical community within states or geographic regions to engage in collaborative planning to create additional clinical education resources for their students.

3. Our AMA will support the expansion of medical education programs only when educational program quality, including access to appropriate clinical teaching resources, can be assured.

4. Our AMA will advocate for regulations that would ensure clinical clerkship slots be given first to students of US medical schools that are Liaison Committee on Medical Education- or Commission on Osteopathic College Accreditation-approved, or schools currently given preliminary accreditation status, provisional accreditation status, or equivalent, from either of the above bodies.
5. Our AMA will advocate for federal and state legislation or regulations to oppose any extraordinary compensation for clinical clerkship sites by medical schools or other clinical programs that would result in displacement or otherwise limit the training opportunities of United States LCME/COCA students in clinical rotations.

D-295.931, “Update on the Availability of Clinical Training Sites for Medical Student Education”

Rescind and incorporate into new proposed policy.

1. Our AMA will work with appropriate collaborators to study how to build additional institutional and faculty capacity in the US for delivering clinical education.
2. Our AMA, in collaboration with interested stakeholders, will:
   (a) study options to require that students from international medical schools who desire to take clerkships in US hospitals come from medical schools that are approved by an independent public or private organization, such as the Liaison Committee on Medical Education, using principles consistent with those used to accredit US medical schools;
   (b) advocate for regulations that will assure that international students taking clinical clerkships in US medical schools come from approved medical schools that assure educational quality that promotes patient safety; and
   (c) advocate that any institution that accepts students for clinical placements be required to assure that all such students are trained in programs that meet requirements for curriculum, clinical experiences and attending supervision as expected for Liaison Committee on Medical Education and American Osteopathic Association accredited programs.
3. Our AMA will study whether the “public service community benefit” commitment and corporate purposes of not for profit, tax exempt hospitals impose any legal and/or ethical obligations for granting priority access for teaching purposes to medical students from medical schools in their service area communities and, if so, advocate for the development of appropriate regulations at the state level.
4. Our AMA opposes any arrangements of US medical schools or their affiliated hospitals that allow the presence of visiting students to disadvantage their own students educationally or financially.

D-295.937, “Competition for Clinical Training Sites”

Rescind; this analysis was completed through Council on Medical Education Report 2-I-08, “Update on Availability of Clinical Training Sites for Medical Student Education.”

Our AMA will, through the Council of Medical Education, conduct an analysis of the adequacy of clinical training sites to accommodate the increasing number of medical students in the US accredited medical schools and study the impact of growing pressure, including political and financial, to accommodate clinical training in US hospitals for US citizen international medical students.
(Res. 324, A-08)
### APPENDIX D: SUMMARY OF PROPOSED POLICY CHANGES

<table>
<thead>
<tr>
<th>Our AMA will work with the Association of American Medical Colleges and the American Association of Colleges of Osteopathic Medical Education to encourage local and state governments and the federal government, as well as private sector philanthropies, to provide additional funding to support infrastructure and faculty development for medical school expansion. D-295.320 (1)</th>
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<td>3. Advocate for federal and state legislation/regulations to a) Oppose any extraordinary compensation granted to clinical clerkship sites that would displace or otherwise limit the education/training opportunities for medical students in clinical rotations enrolled in medical school programs accredited by the Liaison Committee on Medical Education (LCME) or Commission on Osteopathic College Accreditation (COCA); b) Ensure that priority for clinical clerkship slots be given first to students of LCME- or COCA-accredited medical school programs; and</td>
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Our AMA supports the practice of U.S. teaching hospitals and foreign medical educational institutions entering into appropriate relationships directed toward providing clinical educational experiences for advanced medical students who have completed the equivalent of U.S. core clinical clerkships. Policies governing the accreditation of U.S. medical education programs specify that core clinical training be provided by the parent medical school; consequently, the AMA strongly objects to the practice of substituting clinical experiences provided by U.S. institutions for core clinical curriculum of foreign medical schools. Moreover, it strongly disapproves of the placement of any medical school undergraduate students in hospitals and other medical care delivery facilities which lack educational resources and experience for supervised teaching of clinical medicine. H-255.998

Our AMA supports the practice of U.S. teaching hospitals and foreign medical schools entering into appropriate relationships directed toward providing clinical educational experiences for advanced medical students who have completed the equivalent of U.S. core clinical clerkships. Policies governing the accreditation of U.S. medical education programs specify that core clinical training be provided by the parent medical school; consequently, the AMA strongly objects to the practice of substituting clinical experiences provided by U.S. institutions for core clinical curriculum of foreign medical schools. Moreover, it strongly disapproves of the placement of medical students in teaching hospitals and other clinical sites that lack appropriate educational resources and experience for supervised teaching of clinical medicine, especially when the presence of visiting students would disadvantage the institution’s own students educationally and/or
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<td>Our AMA will support the expansion of medical education programs only when educational program quality, including access to appropriate clinical teaching resources, can be assured. D-295.320 (3)</td>
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<td>Providing U.S. students who are considering attendance at an international medical school with information enabling them to assess the difficulties and consequences associated with matriculation in a foreign medical school. H-255.988 (23)</td>
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<td>(new)</td>
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<td>3. Our AMA supports agreements for clerkship rotations, where permissible, for U.S. citizen international medical students between foreign medical schools and teaching hospitals in regions that are medically underserved and/or that lack medical schools and clinical sites for training medical students, to maximize the cumulative clerkship experience for all students and to expose these students to the possibility of medical practice in these areas. (New HOD Policy)</td>
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<td>U.S. citizens should have access to factual information on the requirements for licensure and for reciprocity in the various U.S. medical licensing jurisdictions, prerequisites for entry into graduate medical education programs, and other relevant factors that should be considered before deciding to undertake the study of</td>
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<th><strong>Our AMA supports the application of the existing requirements for foreign medical schools seeking Title IV Funding to those schools which are currently exempt from these requirements, thus creating equal standards for all foreign medical schools seeking Title IV Funding.</strong></th>
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| **Existing requirements for foreign medical schools seeking Title IV Funding should be applied to those schools that are currently exempt from these requirements, thus creating equal standards for all foreign medical schools seeking Title IV Funding. (New HOD Policy)** |

| **Note: This is not needed in the new policy; as of 2023, the Educational Commission for Foreign Medical Graduates has announced that physicians applying for ECFMG certification will be required to graduate from a medical school that has been appropriately accredited. To satisfy this requirement, the physician’s medical school must be accredited through a formal process that uses criteria comparable to those established for U.S. medical schools by the Liaison Committee on Medical Education (LCME) or that uses other globally accepted criteria. The World Federation of Medical Education Recognition Programme will allow medical schools accredited by recognized agencies, and their graduates, to meet ECFMG’s accreditation requirement.** |

| **medicine in schools not accredited by the LCME or COCA. (New HOD Policy)** |


3 Standards and process for the approval of international medical schools to place students in long-term clinical clerkships in New York State. New York Codes, Rules and Regulations. 8 CRR-NY 60.10; NY-CRR. Available at: http://bit.ly/2sy9y8x. Accessed July 7, 2017


REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 1-I-17

Subject: Universal Color Scheme for Respiratory Inhalers
(Resolution 906-I-16)

Presented by: Robert Gilchick, MD, MPH, Chair

Referred to: Reference Committee K
(L. Samuel Wann, MD, Chair)

INTRODUCTION

Resolution 906-I-16, “Universal Color Scheme for Respiratory Inhalers,” introduced by the Resident and Fellow Section and referred by the House of Delegates asked:

That our American Medical Association work with leading respiratory inhaler manufacturing companies and health agencies such as the Federal Drug Administration and the American Pharmacists Association to develop consensus of a universal color scheme for short-acting beta-2 agonist respiratory inhalers that are used as “rescue inhalers” in the United States;

That our AMA work with leading respiratory inhaler manufacturing companies to ensure the universal color scheme for respiratory inhalers would allow for the least disruption possible to current inhaler colors, taking into account distribution of each brand and impact on current users if color were to change;

That our AMA work with leading respiratory inhaler manufacturing companies to ensure that universal color scheme for respiratory inhalers be designed for adherence and sustainability, including governance for future companies entering the respiratory inhaler market, and reserving colors for possible new drug classes in the future.

Traditionally, in the United Kingdom, Canada, and parts of Europe short-acting β2-adrenergic agonist (SABA) respiratory inhalers are colored blue and referred to as “relievers” or “rescuers,” while inhaled corticosteroids (ICS) are colored brown, orange, or red and are referred to as “preventers” or “controllers.” No convention exists in the United States for the coloration of respiratory inhalers.

CURRENT AMA POLICY

Policy H-115.980, “Distinctive Labeling of Vials and Ampules, Prefilled Syringes, Ophthalmic Solutions and Related Liquid Medications,” is somewhat related to this resolution, calling for the development of appropriate guidelines aimed at developing easily identifiable labeling to optimize the safe use of liquid medication. No current AMA policy related to color coding of respiratory inhalers exists.
METHODS

English-language articles were selected from a search of the PubMed database through July, 2017 using the search term “inhaler” coupled with “color” and “colour.” 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 relevant clinical guidelines, position statements, and reports.

COLOR CODING

Color coding is the systematic, standard application of a color system to aid in the classification and identification of drug products. Conceptually, a color coding system allows users to associate a color with a function. Color coding as an aid to patient safety requires the use of consistent coloring schemes by all manufacturers.

Color Coding and Medication Errors

In a 2004 report, titled “The Role of Color Coding in Medication Error Reduction,” the Council on Scientific Affairs (CSA) (predecessor to the Council on Science and Public Health) noted controversy among experts and a variety of potential problems with color coding of pharmaceutical products, which suggest that a universal color scheme should not be universally adopted. Several organizations involved in medication error prevention, including the American Society of Health-System Pharmacists (ASHP), Institute for Safe Medication Practices (ISMP), U.S. Food and Drug Administration (FDA), and the pharmaceutical industry either oppose color coding or recommend caution in its application. The report also noted a lack of evidence proving that color coding reduces medication errors; this lack of evidence still exists.

The result of the CSA report was a directive that was sunsetted in 2014 after AMA provided testimony to the FDA regarding the report’s findings, which identified potential problems associated with the color coding of pharmaceutical products. The FDA released a draft guidance in 2013, entitled “Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors.” The draft guidance recommends avoiding color coding in most instances and goes on to note that “[c]olor coding schemes developed to decrease error may actually increase error when the color is relied upon as a shortcut to proper identification (i.e., not reading the label).” FDA intends to finalize this guidance.

Additional Disadvantages of Color Coding of Pharmaceutical Products

In addition to the lack of scientific evidence that proves color coding reduces medication errors, experts in the field of medication errors also cite other reasons why the widespread adoption of...
color coding systems for pharmaceutical products should be done with great caution.\textsuperscript{1,3,5,6,9-12} Potential problems include:

- There is a limit to the number of discernable colors available for commercial use.
- Subtle distinctions in color are poorly discernable unless products are adjacent to one another.
- Color coding of drug classes can increase the chance of “intraclass” medication errors.
- Colors may fade when exposed to light.
- It is not always possible to exactly reproduce Pantone colors from batch to batch.
- Approximately 8\% of men and fewer than 1\% of women have some difficulty with color vision (colorblindness).
- Color coding can be error-prone if it is not applied consistently across the industry, or within a single manufacturer’s product line.
- Physicians and other health professionals may be unable to remember large or multiple-color coding systems.
- Color coding may offer a false sense of security and, in some instances, result in failure of the physician or other health professional to “read the label.”

COLOR CODING OF RESPIRATORY INHALERS

The coloring of outpatient SABA inhalers as blue and ICS as brown/red/orange in the United Kingdom and Canada is an informal convention that has been an accepted practice for several decades. No regulations have been issued by the United Kingdom Medicines and Healthcare Products Regulatory Agency, the European Medicines Agency, or Health Canada, and no formal agreement exists for manufacturers, regarding a color convention for respiratory inhalers. As a general principle, the three health agencies recommend against color coding.\textsuperscript{9,15,14} The European Medicines Agency has stated that "there can be no substitute for carefully reading the label before any medicine is taken."\textsuperscript{15} Color of inhalers is not addressed in guidelines for the management of asthma.\textsuperscript{16,17}

With the increasing diversity of inhaler devices, including combination products, entering the market in the United Kingdom and Canada, color coding is becoming more complex and inconsistent. The recent Health Canada approval of a long-acting β\textsubscript{2}-adrenergic agonist (LABA) and ICS combination inhaler in the color blue\textsuperscript{18} has raised concerns.\textsuperscript{19} The existence of a generic salbutamol (a SABA) inhaler in brown in the United Kingdom adds confusion to the color coding convention.\textsuperscript{15} Manufacturers have been called on to consider universal concepts such as color coded dots or bands that correspond to different types of medications.\textsuperscript{20} However, the aforementioned disadvantages of color coding pharmaceutical products such as colorblindness and limited color availability persist and no formal action has been taken to ensure universal concepts.\textsuperscript{21}

Color Coding Respiratory Inhalers and Patient Adherence

A small survey of health care professionals in the United Kingdom found that the existing color convention for inhalers appears to be helpful in aiding communication between health care professionals and patients and can be helpful for reinforcing the different roles of inhalers and aiding in medication adherence.\textsuperscript{13} However, it should be noted that this communication between patients and physicians regarding inhaler color in the United Kingdom is likely aided by the color convention that has existed and been known for decades. A parallel situation of familiarity with a color convention does not exist for patients in the United States. The authors of the survey also noted a lack of studies regarding color-standardization in general and specific issues surrounding color coding such as color blindness.
Poor adherence to maintenance therapy is common among asthma patients and a complex challenge to overcome. Individualized action plans developed in a collaborative fashion between asthma patients and their physicians that focus on self-management are typically employed to promote adherence and appropriate clinical use of different inhalers. Inhaler color was of little importance in action plan discussions; emphasis was placed on when to use medications, skills training for use of inhalers, and education for asthma symptom management.

CONCLUSION

Although looked to for simplicity, limited evidence exists that color coding systems reduce medication errors in outpatients. Disadvantages of using color coding systems have been cited and experts either oppose color coding or recommend caution in its application. The FDA, Health Canada, and health agencies in the United Kingdom emphasize the best course of action before administration of any medication is to read the label. Even though the health agencies of United Kingdom and Canada recommend against color coding, an informal respiratory inhaler color coding convention exists in these countries. However, because of continued development of new products, including combinations, this color coding convention is becoming inconsistent and more complex. Experts evaluating the adherence of patients using inhalers have suggested that individualized counseling with personalized action plans and inhaler skills training are the best approach for improving adherence. With the lack of evidence to support a color coding scheme for outpatient respiratory inhalers, there is no justification for urging manufacturers to change inhaler colors, the potential cost associated with such a change which may be passed along to patients, and disruption to the current market of familiar inhaler products.

RECOMMENDATION

The Council on Science and Public Health recommends that the following statement be adopted in lieu of Resolution 906-I-16, “Universal Color Scheme for Respiratory Inhalers,” and the remainder of the report be filed:

Our American Medical Association supports research into mechanisms to improve patient understanding of their respiratory inhaler medications with the aim of improving safety and reducing unintentional medication errors, such as inhaler skills training and individualized action plans. (New HOD Policy)

Fiscal Note: Less than $500
REFERENCES


EXECUTIVE SUMMARY

Background. This report responds to Policy D-370.984 by reviewing current organ donation statistics, attitudes about donation, the disproportion between those needing a transplant and the organs available, factors influencing the decision to designate oneself as a donor, and educational interventions targeted to segments of the population with historically low rates of organ donation.

Methods. Literature searches were conducted in the PubMed database for English-language articles published between 2007 and 2017 using the search term “organ donation,” with the terms “minority,” “religion,” “education,” and “barriers.” A Google search was conducted using the same search terms. Additional articles were identified by manual review of the references cited in identified publications. The Health Resources and Services Administration (HRSA) Organ Donation and Transplantation and Organ Procurement and Transplantation Network websites, and the United Network for Organ Sharing website also were consulted.

Results. More than 33,000 transplants were performed in 2016, with kidney and liver transplants making up the majority. Most adults in the United States report supporting organ donation, yet only about half are registered as organ donors. Small but significant differences in support for organ donation and registration as an organ donor exist among certain racial and ethnic groups. Factors influencing support for organ donation are relational ties, religious and cultural beliefs, family influence, beliefs about body integrity after death, prior experience with the health care system, and knowledge about organ donation. Several educational programs addressing these factors and targeted to populations with low organ donation rates have been conducted in community and church settings, and have been variably successful in improving knowledge and positive perceptions about organ donation and intent to donate.

Conclusion. Although the number of organ donors and transplants has grown over the last two decades, the need for donated organs still far exceeds the number available for transplantation. This disparity is especially true for certain racial and ethnic minorities that make up a larger proportion of the transplant waiting list compared to their relative proportion among organ donors. Educational programs that address identified factors influencing attitudes toward organ donation and targeted to populations with historically low organ donation rates have been developed to improve donation. Those that have been successful should be continued and expanded to improve organ donation rates among populations most in need. In addition to targeted educational programs, successful non-targeted educational programs and other approaches should be continued as well.
REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 2-I-17

Subject: Targeted Education to Increase Organ Donation

Presented by: Robert Gilchick, MD, MPH, Chair

Referred to: Reference Committee K
             (L. Samuel Wann, MD, Chair)

INTRODUCTION

Policy D-370.984, “Targeted Education to Increase Organ Donation,” asked:

That our American Medical Association study potential educational efforts on the issue of
organ donation tailored to demographic groups with low organ donation rates.

This report responds to Policy D-370.984 by reviewing current organ donation statistics, attitudes
about donation, disproportion between those needing a transplant and the organs available, factors
influencing the decision to designate oneself as a donor, and educational interventions targeted to
segments of the population with historically low rates of organ donation. Other factors affecting
organ donation rates, including mandated choice and presumed consent for donation of cadaver
organs, as well as novel models for living donation, have been discussed in Board of Trustees

METHODS

Literature searches were conducted in the PubMed database for English-language articles published
between 2007 and 2017 using the search term “organ donation,” with the terms “minority,”
“religion,” “education,” and “barriers.” A Google search was conducted using the same search
terms. Additional articles were identified by manual review of the references cited in identified
publications. The Health Resources and Services Administration Organ Donation and
Transplantation and Organ Procurement and Transplantation Network websites and the United
Network for Organ Sharing website also were consulted.

ORGAN DONATION STATISTICS AND ATTITUDES

Donated organs and tissues for transplantation are most often obtained from deceased donors,
referred to as deceased organ donation. Deceased organ donors can donate kidneys, liver, lungs,
heart, pancreas, and intestines.3 In addition to these organs, tissues such as heart valves, skin, bone,
and tendons; corneas; and face and hands can be donated after death.3 Approximately 90% of organ
donations are from deceased donors; the remaining donations are from living donors.4 Organs
donated by living donors include one of two kidneys, one of two lobes of the liver, a lung or part of
the lung, part of the pancreas, and part of the intestines. Tissues donated by living donors include
skin, bone, bone marrow cells and umbilical cord blood cells, amnion (donated after childbirth),
and blood.5 More than 33,000 transplants were performed in 2016.6 Kidney and liver transplants
made up the vast majority of organs transplanted (approximately 58 and 23 percent, respectively).

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Less common transplants were heart (9 percent), lung (7 percent), kidney and pancreas (2 percent), pancreas (0.7 percent), intestine (0.5 percent), and heart and lung (0.05 percent).4

Organ and tissue donation in the United States is voluntary. Individuals wishing to donate their organs after death “opt in” by documenting their desire. Deceased organ donation registration is a state process; individuals can sign up online with the state registry or through a state’s Department of Motor Vehicles. When the person’s preferences are not documented or known, the next of kin may decide to allow organs to be harvested for transplantation after death.5 More than 130 million adults in the United States (approximately 54% of the population) are registered as organ and tissue donors.4

Living organ donation is not administered through state or other government programs. Rather, it most often occurs in the form of directed donation, in which the donor names a specific person to receive the organ or tissue, usually a biological relative or a biologically unrelated person with a personal or social connection (spouse, significant other, friend, or acquaintance).7 In non-directed donation, the living organ donor does not name a recipient. Those wishing to be non-directed donors can do so by contacting a designated Organ Procurement and Transplant Network (OPTN) transplant center, or by contacting the United Network for Organ Sharing (UNOS).7

A 2012 survey of a nationally representative sample of US adults, administered by the Health Resources and Services Administration (HRSA), examined organ donation attitudes and behaviors. More than 95 percent of respondents supported or strongly supported the donation of organs for transplantation.8 Small but significant differences in support exist among racial and ethnic groups. Approximately 95 percent of those categorizing themselves as White, Asian/Pacific Islander, or Hispanic support or strongly support donation, while approximately 92 percent of Native Americans and 87 percent of African Americans support or strongly support donation.8 Despite strong support for organ donation, the survey indicated that fewer people took steps to register as organ donors; only 60 percent of respondents with a driver’s license reported that they had granted permission for organ donation on their driver’s license.8 Racial and ethnic differences were apparent on this measure as well; 65 percent of White, 56 percent of Asian/Pacific Islander, 47 percent of Native American, 44 percent of Hispanic, and 39 percent of African-American respondents with a driver’s license reported that they had granted permission for organ donation on their license.8

ORGAN DONATION NEEDS

Although the number of both donors and transplants has been growing slowly over the last two decades, the need for donated organs far exceeds the number available for transplantation. Nearly 120,000 people are on the national transplant waiting list, with the vast majority (81 percent) waiting for a kidney.4 Only about three in 1,000 registered donors actually become donors after death. This is due to a number of criteria that must be met for a donor organ to be appropriate for an intended recipient (the “matching” process). These include blood and human leukocyte antigen (HLA) type, body size, severity of the recipient’s medical condition, severity of donor’s pre-death medical condition, length of time on the waiting list, distance between the donor’s and recipient’s hospitals, and the availability of the recipient.9

The proportion of racial and ethnic minority patients on the waiting list is higher than the corresponding proportion of racial and ethnic minorities who are donors.4 For example, African Americans make up nearly 30 percent of patients on the waiting list, but only approximately 16 percent of donors are African American.4 Hispanics and Asians make up nearly 20 and 8 percent, respectively, of patients on the waiting list, but only approximately 14 and 3 percent of donors are
Hispanics and Asians, respectively. This disparate representation on the transplant waiting list exists partially because minority groups, specifically African Americans, are disproportionately impacted by chronic conditions such as diabetes, heart disease, and hypertension, which often are managed with transplants. Additionally, African Americans have more HLA polymorphisms and enhanced alloreactivity, making the chance of finding a matching donor, especially among a pool of donors that includes proportionally fewer African Americans, particularly difficult.

FACTORS INFLUENCING ORGAN DONATION

Irving et al. conducted a systematic review of studies that characterized factors influencing attitudes toward deceased and living organ donation, and categorized the factors into several broad themes:

- Relational ties: The needs of family members or friends appear to be more influential in the decision to become a donor than those of strangers. Many study participants were willing to donate an organ to a family member or friend even if they were not willing to donate to someone they did not know.

- Religious beliefs: While some believe that organ donation aligns with the altruistic tenets of their religion, others believe that donation is not consistent with their religion. For example, some Islamic study participants interpret the Qur’an and traditional Islamic literature as forbidding organ donation. Others believe that transplantation, and therefore the facilitation of transplantation through organ donation, is “playing God.” The most common religious objection to organ donation was the need to maintain body wholeness to enter the next life.

- Cultural beliefs: Cultural beliefs concerning health care and death and dying, often based on superstition, are associated with lack of support for organ donation. For example, study participants cited the belief among some cultures that discussing death could lead to one’s own death. Others believe that death is a private matter, that ancestral approval is needed before organ donation, and that grieving rituals are disrupted by organ donation.

- Family influence: Family members’ beliefs about organ donation often influence individual beliefs. Study participants with one or both parents who object to organ donation expressed reluctance to be donors themselves, and some participants believed that they should seek permission from family members if they wanted to be donors. Other participants believed that by designating themselves as organ donors, they were sparing their family members difficult decisions after their death.

- Body integrity: Apart from religion, body integrity after death appears to influence support for donation. Participants worried that family members would be traumatized about the thought of their bodies being “cut up,” and that organ donation would preclude an open coffin at their funeral.

- Interaction with the health care system: A distrust of the organ donation system and process, often based on negative experiences with the health care system, reduce support for organ donation. Participants questioned the concept of “brain death,” and were suspicious of health care providers making such a designation. Some believed that organ donors would not receive proper care since health care personnel would only be interested in harvesting their organs, or that donor bodies would not be treated with dignity and
respect. Opinions based on previous experience or interactions with the health care system were more prevalent among study participants belonging to minority groups that have historically experienced a sense of marginalization from the health care system.

- Knowledge about the organ donation process: A lack of knowledge about the organ donation process is a barrier to donation. Study participants expressed the need for more information before they could commit to donation, and a lack of awareness about where such information could be obtained.

Across a number of studies assessing characteristics of those willing to donate, individuals who are younger, are female, have higher educational levels and/or socioeconomic status, and have higher knowledge about organ donation are generally more likely to have positive attitudes toward donation and are more willing to donate. The HRSA organ donation attitudes and behaviors survey found that the following attitudes were predictors of designating oneself as an organ donor: placing low importance on body wholeness after death, family support for organ donation, being receptive to receiving a transplant as a life-saving measure, an understanding that many people die while on the transplant waiting list, and not believing the notion that physicians would be less likely to save the life of a person who is a donor.

Some factors influencing support for organ donation are more pronounced in certain racial or ethnic groups than in others. For example, interviews with African Americans found the following as predominant barriers: religious beliefs and misperceptions, distrust of the medical establishment, fear of premature declaration of death if a donor card has been signed, and a preference among African American donors for assurance that the organs will be given preferentially to African American recipients. In Native Americans, the importance of traditional religious beliefs, including the need to be buried with an intact body, is a barrier to deceased organ donation. Among Hispanics, greater concern over body disfigurement and greater doubt that physicians do all they can to preserve life before pursuing organ donation exist compared to non-Hispanic whites.

It is unclear that religion itself is a consistent barrier to organ donation. The role of religion in support for organ donation is often confounded by community and cultural norms. In international studies, Buddhists have reported objection to deceased organ donation based on the religious belief that a person’s spirit remains in the body as long as the heart is still beating, even though brain death has occurred. This is despite a central Buddhist tenet that honors persons who donate their organs to save a life. Studies of Muslims have indicated that religious beliefs are a barrier to organ donation, and in the United States, Muslims who demonstrate negative aspects of religious coping (a psychological state in which individuals express an insecure relationship with God and an ominous view of the world) are more likely to hold negative attitudes toward organ donation. However, other measures of Muslim religiosity are not correlated with organ donation attitude, and many Muslims in the United States believe that donation is justified. Among Christians, non-Catholic Christians are more likely to report willingness to be organ donors than are Catholic Christians.

TARGETED EDUCATIONAL INTERVENTIONS TO INCREASE DONATION

Given the significant need to increase the number of organs available for donation, educational interventions are needed to improve willingness to donate. Ideal interventions include those that address perceptions that influence the decision to donate and target populations most likely to hold such perceptions. A systematic review of interventions to improve organ donor registration among minorities found that educational interventions alone or combined with mass media
approaches (as opposed to mass media alone) were most effective. Those that included strong interpersonal components, were delivered by members of the local community in familiar environments, and included immediate opportunities to register were important for improving outcomes. Others have emphasized culturally appropriate strategies to engage minority groups, and comprehensive information about organ donation that can be easily obtained. A recent study examining factors that may facilitate the willingness of African Americans to become organ donors determined that improving knowledge about organ donation, particularly with regard to donor involvement and donation-related risks, may be successful in increasing organ donation.

Examples of national, church-based, and community-based targeted educational interventions are summarized below. It is important to note that although some interventions appear to have been successful in improving knowledge and attitudes about organ donation, discussion of organ donation with family members, and changing organ donor status, it is generally difficult to measure intervention success because of concurrent programs that directly or indirectly affect organ donation. For example, policies aimed at motorcycle helmet use, health system transformation, public health spending, smoking rates, and chronic disease affect the health of the donor pool, which in turn could affect the number of organs available for donation.

**Nationally Targeted Interventions**

The National Minority Organ Tissue Transplant Education Program (MOTTEP) was created in 1991 with a mission to decrease the number of ethnic minority Americans on transplant waiting lists. Fifteen national sites were funded to carry out community-based programs that centered on approaches including community participation and direction to target specific community differences; face-to-face presentations, especially to smaller audiences to foster discussion; collaboration and partnerships with religious, social, and civic organizations; media promotion of MOTTEP's message; dissemination of culturally sensitive and informative brochures, videos, public service announcements, and other information; and comprehensive evaluation to gauge effectiveness of the program. The number of organs recovered for transplantation from African Americans increased more than 3-fold between 1991 and 2016, with some suggesting the success is partially due to MOTTEP efforts.

**Church-Based Targeted Interventions**

Another educational program targeting African Americans, Project ACTS (About Choices in Transplantation and Sharing), was a self-administered donation education intervention developed with a focus on addressing religious barriers to donation and encouraging family discussion. The program consisted of materials distributed at churches that are taken home and reviewed individually. The materials included a video hosted by a gospel choir with excerpts from individual and family conversations about beliefs, attitudes, myths, misconceptions, and fears about organ donation/transplantation; an educational pamphlet; a donor card; a National Donor Sabbath pendant; and several additional items embossed with the project name and logo. Participants in the program were 1.6 times more likely to have discussed, or be in discussion, with family members about their organ donation wishes than those who had not participated in the program. A revised program, Project ACTS II, was designed to improve uptake by testing the intervention in individual and group settings. Participants in the revised program who viewed the video in a group setting had a significantly greater increase in positive attitudes toward donation and beliefs than those who were given the video to view at home. It is thought that the group dynamic provided an opportunity for active contemplation of donation-related beliefs, attitudes, and the act of registration, and engaged people in a way that could not be attained by reviewing materials individually.
A church-based intervention targeted to Hispanics entailed a 45-60 minute educational program, created specifically for religious organizations, administered to participants in four Catholic churches whose membership was predominantly Hispanic. The program, led by a local organ procurement organization and conducted in both English and Spanish, included factual information about the need for organ and tissue transplantation, how the organ donation and allocation process serves such a need, and discussion of religious misconceptions regarding organ donation. After the intervention, significant increases in organ donation knowledge and positive perceptions regarding organ donation were observed. However, no change in intent to donate was observed. Interestingly, both before and after the intervention, those whose families supported organ donation were more likely to indicate intent to donate than those whose families did not support donation. The study authors therefore suggest that education focused on family support is important in improving intent to donate.

Other church-based education programs have not been successful. A peer-led program at predominantly African American churches, in which a church member was trained to provide educational sessions within the church, included the viewing of a video and discussions about organ donation and the provision of brochures and flyers containing the web address of the donor registry. No statistically significant differences in organ donation attitudes or intent to donate were observed following the intervention. The study concluded that lack of pastoral support may have influenced outcomes, and that participants misinterpreted the consent form to be involved in the study as an affirmative indication that they wished to be organ donors.

Community-Based Targeted Interventions

A 2007-2012 community-based intervention targeting Hispanics resulted in an increase in consent for organ donation. Media messages were conveyed on television and radio, and culturally sensitive educational programs were held at high schools, churches, and medical clinics in four Southern California neighborhoods with a high percentage of Hispanic residents. Among those targeted by the intervention, the consent rate for organ donation increased significantly from 56 percent before the intervention to 83 percent after the intervention.

A different approach has been to use peer-to-peer techniques to deliver health education messages. This technique was employed in several Michigan hair salons, with hair stylists acting as lay health advisors to improve organ donation among their African-American clients. Stylists delivering the intervention were asked to discuss organ donation at least twice with their clients. Following the intervention, clients in the intervention group were 1.7 times more likely than those in the control group (in which general health topics, but not organ donation specifically, were discussed) to report positive donation status.

CURRENT AMA POLICY

The AMA has a number of policies related to improving organ donation. Regarding education, AMA policy supports “state of the art” educational materials for the medical community and the public that address the importance of organ donation and the need for organ donors, development of effective methods for meaningful exchange of information to educate the public about donating organs, implementation of UNOS recommendations for organ donation, and the provision of educational materials by states and local organ procurement organizations to attendees of driver education and safety classes. AMA policy also encourages research on methods for increasing the number of organ donors in the United States, including studies that evaluate the effectiveness of mandated choice and presumed consent models for increasing organ donation; studies evaluating the use of incentives,
including valuable considerations, to increase living and deceased organ donation rates (H-370.958); and pilot studies on promotional efforts that stimulate each adult to respond "yes" or "no" to the option of signing a donor card. Ethical Opinion 6.1.4, “Presumed Consent and Mandated Choice for Organs from Deceased Donors,” describes the ethical challenges of presumed consent and mandated choice models and emphasizes the need for education about organ donation.

CONCLUSIONS

Although the numbers of organ donors and transplants have grown over the last two decades, the need for donated organs still far exceeds the number available for transplantation. This disparity is especially true for certain racial and ethnic minorities that make up a larger proportion of the transplant waiting list compared to their relative proportion among organ donors. Educational programs that address identified factors influencing attitudes toward organ donation and targeted to populations with historically low organ donation rates have been developed to improve donation. Some have been successful at improving knowledge about organ donation, comfort in discussing organ donation wishes with family members, and intent to donate; however, it is difficult to determine the impact of the programs on donation because they do not occur in isolation from other factors that may influence organ donation rates.

Non-targeted educational approaches have had success as well. For example, an organ donation registration campaign in California consisting of intense public awareness using public service announcements; news conferences; and community outreach in federal buildings, universities, and libraries; combined with an online organ donor registration process at the Department of Motor Vehicles, improved consent for donation from 47.5 percent before the campaign to 51 percent after the campaign. And direct mail campaigns, in which information about organ donation and a request to join the state organ donor registry are mailed to residents, have been successful in prompting both young adults and older adults to join organ donation registries.

Additionally, other approaches to improving organ donation rates should be explored. A 2015 analysis examined a number of state policies on organ donation, including first-person consent laws, donor registries, dedicated revenue streams for donor recruitment activities, population education programs, paid leave for donation, and tax incentives, and found that only revenue policies to promote organ donation had any effect on organ donation and transplantation. These revenues can be used on funding for outreach campaigns and educational programs that incorporate elements that appear to be most successful in increasing intent to donate. Others have proposed that financial incentives in the form of a contribution to a donor’s retirement fund, an income tax credit, a tuition voucher, or a posthumous funeral benefit would be far more effective at increasing the donor pool than educational approaches.

The Council on Science and Public Health supports continued implementation of targeted educational programs that have shown promise in increasing intent to donate, and encourages further study of other approaches that may be successful.
RECOMMENDATIONS

The Council on Science and Public Health recommends that the following statements be adopted and remainder of report filed.

1. That Policy H-370.959, "Methods to Increase the US Organ Donor Pool," be amended by addition to read as follows:

   In order to encourage increased levels of organ donation in the United States, our American Medical Association: (1) supports studies that evaluate the effectiveness of mandated choice and presumed consent models for increasing organ donation; (2) urges development of effective methods for meaningful exchange of information to educate the public and support well-informed consent about donating organs, including educational programs that address identified factors influencing attitudes toward organ donation and targeted to populations with historically low organ donation rates; and (3) encourages continued study of ways to enhance the allocation of donated organs and tissues. (Modify Current HOD Policy)

2. That Policy D-370.984 be rescinded, having been accomplished through this report. (Rescind HOD Policy)

Fiscal note: Less than $1000
REFERENCES

25. Deedat S, Kenten C, Morgan M. What are effective approaches to increasing rates of organ donor
EXECUTIVE SUMMARY

Objective. This report considers whether neuropathic pain should be recognized as a distinct disease state.

Methods. English-language reports on studies using human subjects were selected from a MEDLINE search of the literature from 2005 to August 2017 using the search terms “neuropath*,” in combination with “pain,” and “pathophysiology,” “chronic,” and “pain as a disease.” A total of 103 articles were retrieved for analysis based on their ability to supply new information about the pathogenesis of chronic and neuropathic pain, as well as viewpoints on whether chronic (including neuropathic) pain can or should be considered as a disease in its own right. Medical dictionaries were consulted for definitions of disease and related terms.

Results. Understanding 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. Many “diseases” are accompanied by persistent pain, and chronic pain itself has been described by some as a disease. With respect to neuropathic pain, many different types of neural lesions and systemic diseases trigger neuropathic pain symptoms, which include various positive, negative, and evoked symptoms. Much of the thinking about chronic pain as a disease has been driven by the results of neuroimaging studies. Neuropathic pain also is characterized by adaptive cellular and functional changes which appear to persist after healing of the original injury. Based on neuroimaging, 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. 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.

Conclusion. Evaluating neuropathic pain as a distinct disease state would be best deliberated by a group of multi-specialty experts involved in the evaluation and treatment of pain who could more deeply focus on the topic and consider all of its ramifications. At the 2016 Interim Meeting the House adopted a resolution directing the American Medical Association (AMA) to convene a Federation-based pain care task force (Policy D-160.922). This task force is in the process of being formed, and the Council believes that it is a more appropriate body to address this issue in a comprehensive manner.
Resolution 912-I-16, “Neuropathic Pain as a Disease,” introduced by the American Academy of Pain Medicine at the 2016 Interim Meeting and referred to the Board of Trustees, asked:

That our American Medical Association recognize neuropathic pain as a disease state with multiple pathophysiological aspects requiring a range of interventions to advance neuropathic pain treatment and prevention.

METHODS

English-language reports on studies using human subjects were selected from a MEDLINE search of the literature from 2005 to August 2017 using the search terms “neuropath*,” in combination with “pain,” and “pathophysiology,” “chronic,” and “pain as a disease.” A total of 103 articles were retrieved for analysis based on their ability to supply new information about the pathogenesis of chronic and neuropathic pain, as well as viewpoints on whether chronic (including neuropathic) pain can or should be considered as a disease in its own right. Medical dictionaries were consulted for definitions of disease and related terms.

BACKGROUND

The Council previously examined the issue of neuropathic pain on two occasions. In 2005, the Council reviewed the neurobiology of nociceptive and neuropathic pain, and the definition, classification, common causes, diagnostic approach, and pharmacologic management of neuropathic pain.1 In 2010, the Council reviewed more recent findings about how neural damage, which is the signature precipitating event for the development of neuropathic pain, provokes multiple responses in nociceptive pathways that generate and amplify pain.2 Such responses include peripheral and central sensitization, ectopic activity in pain carrying fibers, neuronal cell death, disinhibition, altered gene expression, neuron sprouting, neuronal plasticity and modified neural connectivity.2 Some discussion was devoted to whether such changes, which can eventually persist in the absence of ongoing noxious stimuli, should be considered maladaptive and warrant consideration as a disease. The Council did not specifically endorse that viewpoint, concluding in part, that the clinical value of viewing chronic or neuropathic pain as a disease was not established.

This report responds to the specific request that our AMA, through Council evaluation and deliberation by the House of Delegates, recognize neuropathic pain as a disease state. It is already established that neuropathic pain is characterized by “multiple pathophysiologic aspects” and requires a treatment approach that differs from that applied to chronic nociceptive and inflammatory pain.
RELEVANT DEFINITIONS

Pain
Pain is “an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.” This definition acknowledges that pain is a conscious experience involving interpretation of (painful) sensory input that is influenced by emotional, pathological, and cognitive factors, as well as previous pain experiences.

Nociceptive Pain
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.

Chronic Pain
Chronic pain has been variously defined. The definition used by the Centers for Disease Control and Prevention in developing its guideline on the use of opioids in chronic noncancer pain is based on the International Association for the Study of Pain (IASP) definition: “Ongoing or recurrent pain, lasting beyond the usual course of acute illness or injury healing, more than 3 to 6 months, and which adversely affects the individual’s well-being.”

Neuropathic Pain
Neuropathic pain was re-defined by the IASP in 2012 as “pain initiated or caused by a lesion or disease of the somatosensory system.” 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.”

Disease
- An interruption, cessation, or disorder of body function, system, or organ OR a morbid entity characterized usually by at least two of these criteria: recognized etiologic agent(s), identifiable group of signs and symptoms, or consistent anatomic alterations.
- Any deviation from or interruption of the normal structure or function of any body part, organ, or system that is manifested by a characteristic set of symptoms and signs whose etiology, pathology, and prognosis may be known or unknown.

Syndrome
The aggregate of symptoms and signs associated with any morbid process, and constituting together the picture of the disease.

Disorder
An illness that disrupts normal physical or mental functions.

EVOLUTION OF PAIN THEORY
Initial investigation and understanding of pain focused on describing the specific somatosensory pathways involved in pain processing. Nociception is the perception of noxious stimuli and represents an alarm signal mediated by specialized primary afferent (sensory) neurons that respond to sufficiently intense thermal, mechanical, or chemical stimuli, transduce these stimuli into electrical activity, and transmit signals via well-defined pathways in the central nervous system. Cell bodies of the primary afferent neurons are located in dorsal root ganglia and the spinal sensory
nucleus of cranial nerve V; bifurcated axonal processes are distributed to the periphery for
detection, and to the spinal cord to transmit information centrally. Aδ fibers ( thinly myelinated)
carry a well-localized “first” pain of sharp, pricking quality. C fibers ( unmyelinated) carry a poorly
localized “second” pain of dull and persistent or burning quality. Muscle and deep tissue nociceptor
stimulation produce aching or cramping type pain. There are several sub-populations of primary
afferents that differ in their axon diameter, response to stimuli, neurophysiologic and
neurochemical characteristics and targets in the dorsal horn of the spinal cord.9 When local
inflammation ensues, certain features of the nociceptive response are modified and magnified to
aid healing and repair.

In the spinal cord, peripheral pain-carrying primary afferent terminals synapse on (second order)
neurons within the superficial lamina of the dorsal horn, which ascends to form the spinothalamic
tract and spinoreticular system. The former transmits information about acute pain (location,
intensity, quality) through the thalamus to the somatosensory cortex and the latter is involved with
autonomic and affective reactions to pain. The dorsal horn is not a simple relay station but is
subject to “gating” by local interneurons with inhibitory and excitatory influences, as well as
descending influences from the midbrain and higher centers.10

Secondary spinal projection neurons transmit nociceptive information to brainstem regions,
including the rostral ventral medulla and periaqueductal gray (PAG); this information is further
modulated in the brainstem, relayed to the thalamus, and then transmitted to the cortex where it is
interpreted as pain. Several cortical regions are involved in pain processing, including the primary
somatosensory cortex, secondary somatosensory cortex, insular cortex, prefrontal cortex, and
motor cortex.11

The Pain Matrix

Although a detailed understanding of the neuroanatomy of nociception exists, neuroimaging
studies have identified several brain regions that are activated during the “pain experience.” This
pattern of neural activation has been posited to represent an array of interrelated brain regions
integral to human pain perception and response or colloquially representing the “neurosignature of
pain.” An extensive neural network (dubbed the “pain matrix”) is accessed during the
processing of nociceptive input including the primary and secondary somatosensory, insular,
anterior cingulate, and prefrontal cortices and the thalamus; subcortical areas (e.g., brain stem,
PAG, hypothalamus, amygdala, hippocampus, and even the cerebellum) also are involved in the
pain experience.15-19 Thus, modulation of the primary nociceptive stimulus occurs within the spinal
cord where noxious stimuli are just part of the overall sensory input, in response to descending
neuronal influences, and at numerous supraspinal levels affecting the discriminative, emotional,
and cognitive aspects of pain.4,10,20

Neuroimaging studies have shown that many brain regions activated by nociceptive stimuli also are
activated during various emotional and behavioral responses, and that non-nociceptive events or
inputs (e.g., loss of a loved one, social exclusion) can produce pain-like experiences.21-23 These
types of findings have informed a conceptual three-tiered hierarchical model of the human pain
experience based on nociception (1st tier), conscious perception subject to cognitive and attentional
modulation and the triggering of somatic reactions (perceptive-attentional, 2nd tier), and
consideration of how individual factors and characteristics (including psychological factors and
emotional context) influence pain and the memory of that experience (reappraisal-emotional, 3rd
tier).24 Brains regions involved in the second and thirds tiers can either inhibit or facilitate
nociception in a descending fashion.
The Biopsychosocial Model of Chronic Pain

Pain is an individual and subjective experience, recognized as an integrative sum of nociceptive input and factors related to cognition, mood, and context, as well as individual variables such as genetics and sex. Chronic pain and patient outcomes are influenced by individual biologic, psychologic and social factors and various common comorbidities (Figure 1). Brain regions involved in the pain matrix are involved in many other sensory, motor, cognitive, and emotional functions and a reciprocal relationship exists between chronic pain and mental health disorders. Neural pathways that involve pain, depression and anxiety overlap and likely have important biological interactions that are not well understood. Chronic pain induces disturbances in mood (reactive depression or anxiety), impaired coping (often with catastrophization), and other processes which can worsen pain and pain-related distress and lead to fear-avoidance behaviors. Pain patients also have much higher premorbid or comorbid psychosocial concerns, mental health disorders and cognitive distortions that influence the pain experience and drive pain-related distress. Individuals who observe other people’s suffering often experience a subjective enhancement of their own pain suffering. Thus, the pain experience is influenced by various cognitive, emotional, and environmental factors affecting brain function. Chronic pain is a multidimensional experience that, like other chronic conditions has multiple contributors, including psycho-behavioral ones. Effective management often demands a multidisciplinary assessment and treatment plan that identifies and addresses all the components of the individual’s pain experience.

IS CHRONIC (OR NEUROPATHIC) PAIN A DISEASE?

Many “diseases” are accompanied by persistent pain including cancer, human immunodeficiency virus infection, osteoarthritis/rheumatoid arthritis, lower back injury, headache, degenerative spine disease, fibromyalgia, diabetes, post herpetic neuralgia, etc. However, when considering whether neuropathic pain is a disease, it is important to note that the question of whether chronic pain should be considered a disease is not a new concept.

In 2001, the IASP and the European Federation of IASP Chapters adopted the following declaration:

“Pain is a major healthcare problem worldwide. Although acute pain may reasonably be considered a symptom of disease or injury, chronic and recurrent pain is a specific healthcare problem, a disease in its own right.”

The landmark 2011 report by the Institute of Medicine on Relieving Pain in America concluded that:

Chronic pain can be a disease in itself. Chronic pain has a distinct pathology, causing changes throughout the nervous system that often worsen over time. It has significant psychological and cognitive correlates and can constitute a serious, separate disease entity.

In 2016 Vardeh et al noted:

The past few decades have witnessed a huge leap forward in our understanding of the mechanistic underpinnings of pain, in normal states where it helps protect from injury, and also in pathological states where pain evolves from a symptom reflecting tissue injury to become the disease itself.

Neuropathic Pain

With respect to neuropathic pain, 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). Signs and symptoms characteristic of neuropathic pain include spontaneous “positive” (gain of function) signs (e.g., paresthesias, burning, shooting or shock-like pains), “negative” (loss of function) signs (e.g., numbness, weakness, hypoalgesia, decreased tendon reflexes) and certain stimulus-dependent or evoked signs (e.g., allodynia, hyperalgesia) (Figure 2). Diseases causing neuropathic pain vary substantially in terms of anatomical location and cause; depending on the cause, individual patients exhibit similar clinical characteristics, but not all symptoms that are commonly associated with neuropathic pain. Two prominent neuropathic pain symptoms across causes are allodynia (pain induced by normally innocuous stimuli) and hyperalgesia (increased pain in response to noxious stimuli) (see below).

Debate on Chronic Pain as a Disease

The field of pain medicine, the Institute of Medicine and some clinicians and researchers have proposed that chronic pain should be considered a disease; others continue to see pain primarily as a symptom of disease. Much of the thinking about chronic pain as a disease has been driven by neuroimaging studies, and structural/functional changes observed in animal models of chronic pain and/or neural injury. It has been proposed that because some unique changes accompany neural injury, chronic pain with a neuropathic component should be considered in a distinct fashion.

Neuroimaging. An extensive literature base exists on using various brain imaging techniques in patients with chronic pain, including neuropathic pain; most studies have been cross-sectional. A comprehensive review is beyond the scope of this report. A critical review of more than 100 brain neuroimaging reports identified neural correlates of chronic pain associated with various diseases (i.e., osteoarthritis, irritable bowel syndrome, back pain, fibromyalgia) and demonstrated distinctions from images associated with acute nociceptive pain. Patients suffering from chronic pain also exhibit dysfunction in descending inhibition of pain, less gray matter in the thalamus and prefrontal cortex with more gray matter loss in patients with neuropathic components; differences in various measures of brain neurochemistry also have been demonstrated. Subsequent studies extended these findings to other chronic pain conditions (pelvic pain, complex regional pain syndrome, diabetic peripheral neuropathy, phantom limb pain) demonstrating changes in gray matter density in multiple cortical regions, as well as the amygdala and hippocampus. What remains unresolved is to what extent altered structure, function and neurochemistry represents a “disease” or are simply neuroplastic adaptive processes in response to ongoing nociceptive input, or reflect the consequences of pain, common co-morbid conditions, medications, or altered lifestyles in patients with chronic pain.

Cellular and Functional Changes. Adaptive and persistent cellular and functional modifications also have been used to support the concept that neuropathic pain, in particular, is a chronic disease. As described in the previous Council report, neural injury provokes a host of neuroplastic and neuroimmune responses which become drivers of neuropathic pain, some of which also are common to persistent nociceptive/inflammatory pain. These include:

- peripheral sensitization of nociceptors related to altered trafficking of ion channels. Peripheral sensitization decreases the threshold for activation and augments normally painful stimuli (primary hyperalgesia) and triggers the development of spontaneous (ectopic) activity in primary afferent neurons;
- central sensitization, characterized by increased spontaneous activity, expansion of receptive fields, and a decreased threshold to primary afferent inputs into the dorsal horn. This ultimately enhances the function of neurons and circuits in nociceptive pathways via
increased membrane excitability, increased synaptic efficacy, and reduced inhibition. It manifests as mechanical allodynia and secondary hyperalgesia;

- changes in the phenotype of low threshold sensory fibers (Aβ) that are normally activated by touch, pressure, and vibration, to one whereby they can generate sensations of pain or tenderness;
- a pathological triad of reciprocal interactions among neurons, immune cells, and glial cells with glia activation and release of proinflammatory mediators that contributes to both peripheral and central sensitization; and
- 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.

DISCUSSION AND COMMENT

Recognition of chronic pain as a disease may lead to increases in resources, education, and priority, but considerable attention has already been devoted to the burden of chronic pain in the United States, and a National Pain Strategy has been developed.47

A disease, by definition, requires a set of “characteristic signs and symptoms.” Chronic pain is:

- complex, affecting individuals physically, mentally, socially and spiritually. This results in a common symptomatic and functional spectrum of physical, cognitive, psychological and behavioral effects. Decreased physical functioning coupled with little hope for effective treatment often results in a downward spiral of depression, distress, anxiety, and sleep problems, which lead to impaired social functioning and family relationship that all increase perceived pain.48

Some of these consequences may be explained by common neural substrates or reciprocal interactions and may not be considered unique to chronic pain because they can accompany any chronic condition that causes substantial distress.

With 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. Do these phenomena fulfill the requirement for the presence of “characteristic signs and symptoms?” Does it make sense to consider an altered pain response as a symptom that can logically define pain as a disease?

With respect to pain management and relieving the burden of suffering among patients with chronic pain, it would seem that wider adoption of the biopsychosocial model of pain management should be the most important goal, with attention to reducing pain, restoring function, cultivating well-being and improving quality of life. This requires identifying and addressing psychosocial contributors and emphasizing active over passive modalities. For neuropathic pain, diagnostic and management approaches are different; preferred initial pharmacological interventions are antiepileptic and antidepressant drugs. Several interventional approaches are available but psychobehavioral approaches can be more challenging in patients with neural injury.2
CONCLUSION

The topic of neuropathic pain as disease would be best deliberated by a multi-specialty group of experts involved in the evaluation and treatment of pain that could more deeply focus on the topic and consider all of its ramifications. At the 2016 Interim Meeting the House of Delegates adopted a resolution directing the AMA to convene a Federation-based pain care task force (Policy D-160.922). This task force is in the process of being formed and the Council believes that it is a more appropriate body to address this issue in a comprehensive manner.

RECOMMENDATION

The Council on Science and Public Health recommends that the following statement be adopted in lieu of Resolution 912-I-16 and the remainder of this report be filed:

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. (Directive to Take Action)

Fiscal Note: Less than $500
REFERENCES


Figure 1. Biopsychosocial Context of Pain

Physiologic Stimulus
Neuropathic/Nociceptive

Individual
Biopsychosocial
Context

Experience of Pain

Life Experiences
Environmental Stressors
Work History
Family/Friends
   Dynamics & Support
Culture
Self-Efficacy
Coping
Acceptance
Suffering

Quality of Life
Health Status
Conditioning
Functioning
Cognition
Mood
Substance Use
Sleep
Biogenetics
Figure 2. Signs and Symptoms Characteristic of Neuropathic Pain

- **Positive Signs**
  - Paresthesias ("Tingling", "Pins and Needles")
  - "Burning" or "Hot"

- **Stimulus-dependent Evoked**
  - Allodynia
  -Hyperalgesia
  - Hyperpathia

- **Negative Signs**
  - Numbness
  - Weakness
  - Hypoesthesia
  - Hypoalgesia
  - ↓Tendon reflexes
REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 4-I-17

Subject: National Drug Shortages: Update

Presented by: Robert A. Gilchick, MD, MPH, Chair

Referred to: Reference Committee K
(L. Samuel Wann, MD, Chair)

INTRODUCTION

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 informational 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 2016 to August 2017, using the text term “drug shortages” combined with “impact,” “crisis,” “oncology,” “chemotherapy,” “antibacterial,” “pediatric(s),” “nutrition,” and “parenteral.” 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), American Society of Health-System Pharmacists (ASHP), Pew Charitable Trusts, the Association for Accessible Medicines, the Pharmaceutical and Research Manufacturers of America (PhRMA) and by direct contact with key FDA, ASHP, and Utah Drug Information Service staff who monitor drug shortages and related issues on a daily basis.

BACKGROUND

The Council has issued seven reports on drug shortages.\(^1\textsuperscript{-7}\) The findings and conclusions of the first five reports are summarized in CSAPH Report 2-I-15.\(^6\) The remainder of this report will update information on drug shortages since the 2016 report was developed.

CURRENT TRENDS IN DRUG SHORTAGES

The two primary data sources for information on drug shortages in the United States continue to be the Drug Shortage Resource Center maintained by ASHP in cooperation with the University of Utah Drug Information Service and the Drug Shortage Program at the FDA.\(^5\textsuperscript{-9}\) Table 1 summarizes how the ASHP’s and FDA’s information and statistics on drug shortages are developed. The ASHP defines a drug shortage as “a supply issue that affects how the pharmacy prepares or dispenses a drug product or influences patient care when prescribers must use an alternative agent.”

The FDA defines shortages as “a period of time when the demand or projected demand for a medically necessary drug in the United States exceeds its supply.” Medically necessary drugs are

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defined by FDA as “any drug product used to diagnose, treat, or prevent a serious disease or medical condition for which there is no other drug that is judged to be an appropriate substitute or there is an inadequate supply of an acceptable alternative.”

Because their criteria differ (the main distinction being the FDA’s definition of a “medically necessary drug”), the ASHP site lists more drug shortages than the FDA site.

American Society of Health-System Pharmacists

As of August 7, 2017, ASHP’s Drug Shortage Resource Center identified 133 drugs in shortage, approximately the same number as at the corresponding time in 2016 (135). In addition, 14 products are not commercially available at all. Seventy-one manufactured drugs have been discontinued since 2010, an increase of two from a year ago. Nearly 85% of drug shortages are generic sterile injectable formulations. The top active shortages by drug class remain antimicrobials, electrolytes and nutritional components, central nervous system agents, chemotherapeutic agents and cardiovascular/autonomic drugs. For a longitudinal view of new drug shortages on an annual basis, and the number of active drug shortages quarterly, see the Appendix. Active shortages include both new and unresolved drug shortages. According to ASHP, the number of new shortages is currently on a par with 2016, and the number of active shortages has stabilized.

US Food and Drug Administration

As of August 7, 2017, the FDA reported that 46 drugs were currently in shortage (compared with 61 one year ago), and 13 other shortages had been resolved. The latter are closely monitored because they may be at risk for falling back into shortage. Based on passage of the Food and Drug Administration Safety and Innovation Act (FDASIA) in 2012, companies are required to notify the FDA of a permanent discontinuance or an interruption in manufacturing of certain drug products six months in advance, or if that is not possible, as soon as practicable. The shortage notification requirement has apparently reduced the number of new shortages by allowing FDA additional time to work with manufacturers to prevent shortages. The FDA’s drug shortages website lists drugs that meet these criteria, reflecting shortage information supplied by manufacturers. A Final Rule published on July 27, 2015, provides further guidance on the notification process and adds biologic products to the requirements for notification about potential supply disruptions.

Drug Shortages Metrics Reported by FDA. The FDA’s fourth annual report on drug shortages (required by FDASIA) noted the following metrics during the first three quarters of calendar year 2016.

- FDA was notified of 186 potential shortage situations by 67 different manufacturers, a 35% increase over the number of potential shortages reported in 2015.
- 64 new drug shortages were prevented in the first three quarters of 2016, a 50% decrease over the comparable time period for 2015.
- The review of 102 generic abbreviated new drug or supplemental applications was expedited, exactly the same as the number reported in 2015.
- 10 inspections were prioritized to address a drug shortage, comparable to the number reported in 2015.
- Three fewer new drug shortages occurred in 2016 (23) compared with 2015 (26); currently, FDA is working to resolve 24 ongoing shortages that began prior to 2016, which is a decrease from the 64 ongoing shortages tracked at the end of 2015 (Personal Communication, Valerie Jensen, RPh, FDA).
FDA exercised regulatory flexibility and discretion in 25 instances affecting 15 medically necessary products. Most of these involved measures to mitigate risks such as the use of filters to remove particulate matter, extra testing for quality, third-party oversight of production, provision of special instructions to prescribers and/or patients, approval of foreign sources, and expanded access to investigational drugs for treatment use. With respect to approval of new foreign sources, the FDA now conducts regular virtual meetings with their international regulatory counterparts to share information on drug shortages and mitigation strategies impacting patients in other countries.

The FDA continues its work to improve its system for data tracking and drug shortage analysis. The FDA released a new technology platform in 2017 for drug manufacturers/applicants to send drug shortage and supply notifications. The “Direct NextGen” platform allows users to login, enter their shortage information, and submit to the FDA. This approach is intended to “streamline day-to-day work to identify and mitigate shortages, including research, data entry, and data management.”

The FDA also has developed apps for both the iPhone and Android operating systems that provide access to drug shortage information as well as notifications about new and resolved drug shortages. Physicians can directly report a drug shortage via the app, the ASHP drug shortage website, or to the Center for Drug Evaluation and Research via email (drugshortages@fda.hhs.gov) or by phone at 240-402-7770.

In late June 2017, the FDA took additional steps to increase competition in the market for prescription drugs and facilitate entry of lower-cost alternatives. The agency published a list of off-patent, off-exclusivity branded drugs without approved generics, and also implemented, for the first time, a new policy to expedite the review of generic drug applications where competition is limited.

STATE OF THE INDUSTRY

Report from Pew Charitable Trusts

Potential economic drivers of drug shortages were previously evaluated by the Council. A new report from Pew Charitable Trusts and the International Society for Pharmaceutical Engineering took a closer look at shortages of sterile injectable pharmaceutical products based on interviews with company executives; the main focus areas were market forces, business continuity planning, and supply chain management.

The report confirmed that quality issues continue to be a driving force behind shortages. Examples included FDA-inspection-related delays, delays in active pharmaceutical ingredient acquisition, failure of final product quality to meet good manufacturing practices, and problems arising from transferring the product from development (or in transferring new technology for a legacy product) to commercial manufacturing site. Factors cited by companies that contributed to drug shortages other than quality included market withdrawals, supply chain design, lack of business continuity elements needed to protect against shortages, limited purchaser-manufacturer incentives, limited insight into future market demands, and regulatory challenges impacting facility expansion or upgrading equipment; the latter is especially pertinent for legacy products.
CURRENT PERSPECTIVE

Based on analysis by the Utah Drug Information Service, during the past 2 years, the number of new drug shortages affecting clinicians and patients has been declining, and the number of active and ongoing drug shortages has remained similar (Appendix, Personal Communication, Erin Fox, PharmD). Shortages have stabilized, but even though the number remains elevated, it is significantly lower than 3 to 4 years ago. The fact that a high number of shortages continues to exist has obscured to a certain degree the progress that has been made, largely attributable to manufacturer notification requirements and proactive steps taken by the FDA. These changes have substantially decreased the actual number of shortages by preventing a large number of new ones. Significant progress has been made overall, but this progress has remained largely unnoticed by hospital pharmacists and practicing physicians who continue to experience the effects of ongoing shortages on a daily basis.

Additionally, it is apparent that some difficult challenges to continued progress exist. As previously noted, most drug shortages involve generic sterile injectable formulations and the cause of these shortages is typically manufacturing and quality problems. The 2016 report from the Government Accountability Office (discussed in the 2016 Council report) identified a decline in the number of suppliers, failure of a supplier to comply with manufacturing standards resulting in a warning letter, and manufacturers operating at low profit margins for generic drugs as primary contributing factors. A major contributing factor to this trend was the failure of Boehringer Ingelheim’s Ben Venue manufacturing facility in Bedford, Ohio, in 2013, which at the time was one of the largest suppliers of sterile injectable drugs, including many cancer chemotherapy products. The failure occurred despite the investment of $350 million to upgrade the facility; facing projected deficits of at least $750 million, the facility was not profitable and was closed.

Currently, the majority of sterile injectables for the US market are produced by Pfizer (Hospira), Fresenius Kabi (Akorn), Teva and Baxter; other contributors are American Regent (Luitpold), Sandoz, and Mylan. Pfizer completed its acquisition of Hospira, at the time the largest manufacturer of sterile injectable in the United States, in September 2015. Recent events have created a climate of worsening drug shortages for critical care and emergency medications as well as some of what would be considered “basic products” emanating from the Hospira portfolio. In April 2017, Pfizer notified clinicians about a shortage of pre-packaged emergency drug syringes including atropine, dextrose, epinephrine, and sodium bicarbonate. In June, Pfizer recalled 42 lots of sodium bicarbonate vials (approximately half of supplies) due to concerns that the product may not be sterile; succinylcholine was also impacted by this recall. Most recently, Pfizer had to halt production of 30 different Carpuject™ products (morphine, hydromorphone, etc.) due to problems at a specific manufacturing facility. Vial substitutes exist for most of the Carpuject™ products, but there may be shortages later this year. In response, the FDA extended expiration dating for emergency syringes, approved another supplier of sodium bicarbonate, and also allowed imported sodium bicarbonate.

Although attention remains focused on injectable products, shortages of some solid dosage forms, including atenolol, furosemide, and methylphenidate tablets also have created problems for clinical management this year.

CONCLUSION

The generic sterile injectable drug industry is fragile and some drug supplies for acutely and critically ill patients in the United States remain vulnerable despite industry and federal efforts. Until new and reliable production capacity for sterile injectables is developed, the situation will not
appreciably improve. Some progress is being made, but permanent solutions remain elusive and
beyond the control of individual practitioners and the health care system. As long as a free market
economy exists and no one entity, including the FDA can mandate that a company produce a
specific product, drug shortages will exist into the foreseeable future as the industry continues to
merge and contract (except for high cost specialty drugs), the number of drugs emerging off patent
increases each year, and the profit margin for legacy products disappears. This dynamic is
occurring at the same time that pharmaceutical companies are under increasing pressure to reduce
drug costs. The recent acquisition of Hospira by Pfizer and the resulting shortages raises the issue
of how such acquisitions or mergers might impact the likelihood of such shortages.

RECOMMENDATION

The Council recommends that Policy H-100.956 be amended by addition to read as follows:
National Drug Shortages
1. 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 experience drug shortages, and will work in a
collaborative fashion with these and other stakeholders to implement these recommendations in
an urgent fashion.
2. Our AMA supports authorizing the Secretary of Health and Human Services to expedite
facility inspections and the review of manufacturing changes, drug applications and
supplements that would help mitigate or prevent a drug shortage.
3. 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.
4. The Council on Science and Public Health shall continue to evaluate the drug shortage issue
and report back at least annually to the House of Delegates on progress made in addressing
drug shortages.
5. Our AMA urges the development of a comprehensive independent report on the root causes of
drug shortages. Such an analysis should consider federal actions, the number of manufacturers,
economic factors including federal reimbursement practices, as well as contracting practices by
market participants on competition, access to drugs, and pricing. In particular, further
transparent analysis of economic drivers is warranted. The Centers for Medicare & Medicaid
Services 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.
6. 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.
7. 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.
8. Our AMA will collaborate with medical specialty partners in identifying and supporting
legislative remedies to allow for more reasonable and sustainable payment rates for
prescription drugs.
9. 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. (Modify Current HOD Policy)

Fiscal Note: Less than $500
REFERENCES

Table 1. Contrasting the FDA (CDER) and ASHP Drug Shortage Websites

<table>
<thead>
<tr>
<th></th>
<th>FDA</th>
<th>ASHP</th>
</tr>
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<tbody>
<tr>
<td><strong>Purpose</strong></td>
<td>Provides information obtained from manufacturers about current shortages, estimated duration, and discontinuations and provides information about FDA’s and other stakeholders’ roles in addressing and preventing shortages.</td>
<td>Notification of new shortages and status of ongoing shortages; drug shortage management resources.</td>
</tr>
<tr>
<td><strong>Audience</strong></td>
<td>Public</td>
<td>Healthcare practitioners</td>
</tr>
<tr>
<td><strong>Scope of shortage list</strong></td>
<td>All drugs are listed that are confirmed to be a national shortage by FDA. A shortage is considered to be the period of time when the demand for the drug within the United States exceeds the supply of the drug.²</td>
<td>All drug and biologic shortages reported and confirmed with manufacturer that are national in impact.</td>
</tr>
<tr>
<td><strong>Source of shortage report</strong></td>
<td>Manufacturers notify FDA of production disruption and voluntarily provide updates. Reports are also received from ASHP and from public via <a href="mailto:drugshortages@cder.fda.gov">drugshortages@cder.fda.gov</a>. Note: Manufacturer-provided information represents shortage status at drug firm level.</td>
<td>Voluntary reports from practitioners, patients, pharmaceutical industry representatives and others. Note 1: Information is updated based on release dates from manufacturers. Note 2: Reports reflect status at healthcare provider level.</td>
</tr>
<tr>
<td><strong>Criteria for inclusion on list</strong></td>
<td>Manufacturers cannot meet current market demand for the drug based on information provided by manufacturers and market sales research. Drug listed are defined as “medically necessary.”</td>
<td>(1) Shortage is verified with manufacturers and (2) affects how pharmacy prepares or dispenses a product, or (3) requires use of alternative drugs, which may affect patient care.</td>
</tr>
<tr>
<td><strong>Criteria for resolving shortage</strong></td>
<td>One or more manufacturers are in production and able to meet full market demand.</td>
<td>All manufacturers of the drug restore all formulations and dosage sizes to full availability. Note: Products are listed despite partial or restricted availability as supply chain disruptions can result in intermittent shortages at the provider or patient level.</td>
</tr>
<tr>
<td><strong>Reason for shortage</strong></td>
<td>Provided by manufacturers using reasons required by legislation.³ FDA encourages firms to provide additional information about reasons and other information which, if proprietary, is nondisclosable without the firm’s permission.</td>
<td>Provided by manufacturer, if willing to disclose. Note: May differ from FDA’s due to different sources of information and legislation requiring FDA to use specified reasons.</td>
</tr>
<tr>
<td><strong>Other information</strong></td>
<td>Estimated duration, links to regulatory information such as recalls and Dear Healthcare Provider Letters</td>
<td>Estimated duration, list of available products, implications for patient care and safety, shortage management strategies, therapeutic alternatives</td>
</tr>
</tbody>
</table>

² Note: A separate shortage webpage for vaccines and some biologics is maintained by the Center for Biologics Evaluation and Research.
³ Categories include (a) requirement related to complying with good manufacturing practices; (b) regulatory delay; (c) shortage of an active ingredient
APPENDIX

National Drug Shortages
New Shortages by Year
January 2001 to June 30, 2017

Note: Each column represents the number of new shortages identified during that year.
University of Utah Drug Information Service
Errin.Fox@hsc.utah.edu, @foxerinr

National Drug Shortages –
Active Shortages by Quarter

Note: Each column represents the number of active shortages at the end of each quarter.
University of Utah Drug Information Service
Errin.Fox@hsc.utah.edu, @foxerinr
EXECUTIVE SUMMARY

**Background.** This report responds to Resolution 907-I-16, “Clinical Implications and Policy Considerations of Cannabis Use” introduced by the Resident and Fellow Section and referred by the House of Delegates. Resolution 907 asked that our AMA amend existing policies.

**Methods.** English language reports were selected from searches of the PubMed, Google Scholar, and Cochrane Library databases from March 2013 to July 2017 using the search terms as outlined in the body of the report. The 2017 report of the National Academies of Sciences, Engineering, and Medicine (National Academies) on the health effects of cannabis and cannabinoids as well as reports developed by state agencies regarding the impact of legalizing recreational cannabis were also utilized in developing this report.

**Results.** The National Academies published a comprehensive report on the health effects of cannabis in January 2017. The report found conclusive or substantial evidence that cannabis or cannabinoids have some therapeutic benefits; the report also found substantial or conclusive evidence of a statistical association between cannabis smoking and health harms. The findings of a systematic review on the analgesic effects of cannabis released subsequent to the National Academies report were inconsistent with the National Academies report, which highlights the lack of agreement on this issue, and serves as a source of confusion among physicians, patients, and the public and demonstrates the need for additional research.

Legalizing the recreational use of cannabis may result in increased use over time due to changes in perceptions of safety and health risks. Existing data, although limited, have yet to confirm this pattern of use for children and adolescents. However, cannabis use has increased in adults and pregnant women. Data from jurisdictions that have legalized cannabis demonstrate concerns around unintentional pediatric exposures as well as an increase in traffic deaths due to cannabis-related impaired driving. Limited data also show a decrease in cannabis-related treatment admissions as well as a possible decrease in the use of opioids for chronic pain. Limited data suggest convictions for possession of cannabis may decline in states that legalize cannabis. States have also experienced an increase in governmental revenue through sales and excise taxes on retail cannabis.

**Conclusion.** The evidence available at this time does not support a substantial change in the AMA’s policy on cannabis. Ongoing surveillance to determine the impact of cannabis legalization and commercialization on public health and safety will be critical. Surveillance should include, but not be limited to the impact on patterns of use, traffic fatalities and injuries, emergency department visits and hospitalizations, unintentional exposures, exposure to second-hand smoke, and cannabis-related treatment admissions. At-risk populations, including pregnant women and children, should be a focus of attention. Continued evaluation of the effectiveness of regulations developed to ensure public health and safety in states that have legalized the medical and/or recreational use of cannabis is necessary. Jurisdictions that have legalized cannabis should 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.
REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 5-I-17

Subject: Clinical Implications and Policy Considerations of Cannabis Use
(Resolution 907-I-16)

Presented by: Robert A. Gilchick, MD, MPH, Chair

Referred to: Reference Committee K
(L. Samuel Wann, MD, Chair)

INTRODUCTION

Resolution 907-I-16, “Clinical Implications and Policy Considerations of Cannabis Use,” introduced by the Resident and Fellow Section and referred by the House of Delegates, asked that our AMA amend Policy H-95.998 by addition and deletion to read as follows:

H-95.998 AMA Policy Statement on Cannabis
Our AMA believes that (1) cannabis is a dangerous drug and as such is a public health concern; (2) sale of cannabis should not be legalized; (3) public health based strategies, rather than incarceration, should be utilized in the handling of individuals possessing cannabis for personal use; and (4) additional research should be encouraged (Modify Current HOD Policy),

and amend Policy D-95.976 by deletion to read as follows:

D-95.976 Cannabis - Expanded AMA Advocacy
1. Our AMA will educate the media and legislators as to the health effects of cannabis use as elucidated in CSAPH Report 2, I-13, A Contemporary View of National Drug Control Policy, and CSAPH Report 3, I-09, Use of Cannabis for Medicinal Purposes, and as additional scientific evidence becomes available. 2. Our AMA urges legislatures to delay initiating full legalization of any cannabis product until further research is completed on the public health, medical, economic and social consequences of use of cannabis and, instead, support the expansion of such research. 3. Our AMA will also increase its efforts to educate the press, legislators and the public regarding its policy position that stresses a "public health", as contrasted with a "criminal," approach to cannabis. 4. Our AMA shall encourage model legislation that would require placing the following warning on all cannabis products not approved by the U.S. Food and Drug Administration: "Marijuana has a high potential for abuse. It has no scientifically proven, currently accepted medical use for preventing or treating any disease process in the United States." (Modify Current HOD Policy)

The Council on Science and Public Health (Council) has issued four previous reports on cannabis (1997, 2001, 2009, and 2013) establishing a broad policy base.1-4 This report focuses on the health effects (both therapeutic and harmful) of cannabis and reviews available data on the impact of legalization. While the AMA prefers to use the scientific term “cannabis,” the colloquial term...
“marijuana” is used interchangeably in this report, for example, when quoting a source or identifying the official name of a committee.

METHODS

English language reports were selected from searches of the PubMed, Google Scholar, and Cochrane Library databases from March 2013 to July 2017 using the search terms “marijuana or cannabis” in combination with “health,” “mental health,” “health effects,” “therapeutic use,” “therapeutic benefits,” “legalization,” “youth or adolescents,” “edibles,” “driving,” “taxes,” and “treatment.” Additional articles were identified by manual review of the reference lists of pertinent publications. Websites managed by federal and state agencies and applicable regulatory and advocacy organizations were reviewed for relevant information.

CURRENT AMA AND FEDERATION POLICY

Existing AMA policy on cannabis states that it is a dangerous drug and as such is a public health concern (H-95.998). The 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 (D-95.952). The AMA also 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 (D-95.952). The AMA also believes that public health based strategies, rather than incarceration, should be utilized in the handling of individuals possessing cannabis for personal use (H-95.998).

The AMA believes that the sale of cannabis should not be legalized (H-95.998) and urges legislatures to delay initiating full legalization of any cannabis product until further research is completed on the public health, medical, economic, and social consequences of recreational use (D-95.976). The AMA supports 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. It has no scientifically proven, currently accepted medical use for preventing or treating any disease process in the United States” (D-95.976). The AMA also advocates for regulations requiring point-of-sale warnings and product labeling for cannabis and cannabis-based products regarding the potential dangers of use during pregnancy and breastfeeding (H-95.936). The AMA supports increased educational programs relating to use and abuse of alcohol, marijuana, and controlled substances (H-170.992). (see Appendix A)

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. 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.

STATE LAWS ON CANNABIS

At the state level, trends in law have moved from decriminalization, to the legalization of medical use of cannabis, to cannabis regulated for adult recreational use. California was the first jurisdiction in the United States (U.S.) to legalize the medical use of cannabis. Today, 29 states, the District of Columbia (D.C.), Guam, and Puerto Rico have legalized the medical use of cannabis through either the legislative process or ballot measures. 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, and consumption
method (some states prohibit smoking the product). 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 it is illegal
under federal law. In recent years, an additional 17 states have enacted laws allowing access to low
delta-9-tetrahydrocannabinol (THC)/high cannabidiol (CBD) products for children with epilepsy.7

In 2012, Colorado (CO) and Washington (WA) were the first U.S. jurisdictions to legalize the adult
use of cannabis for recreational purposes.3,9 Today, a total of 8 states and D.C. have legalized
cannabis for recreational purposes, all through the ballot measure process.7 (Figure 1) Most of these
jurisdictions have created for-profit, commercial cannabis production and distribution markets
where the product is sold and taxed. D.C. is the exception; they have adopted a “grow and give”
model whereby residents are permitted to possess, use, grow, and give away cannabis, but they
cannot sell it.10 In 2017, legislatures in 20 states introduced legislation to legalize cannabis for
recreational use. Vermont’s legislature was the first in the country to vote in favor of legalizing
cannabis for recreational use.11 The bill was ultimately vetoed by the governor due to the lack of
provisions to protect public health and safety. Specifically, he called on policymakers to hold off
on moving forward with commercialization until the state could:

…detect and measure impairment on our roadways, fund and implement additional substance
abuse prevention education, keep our children safe and penalize those who do not, [and]
measure how legalization impacts mental health and substance abuse issues our communities
are already facing.12

RELEVANT FEDERAL LAW AND POLICY

Under the U.S. Controlled Substances Act (CSA) of 1970, cannabis is classified as a Schedule I
controlled substance, 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.13
In 2011, the governors of Washington and Rhode Island petitioned the Drug Enforcement
Administration (DEA) asking it to change cannabis from a Schedule I to a Schedule II drug under
the CSA. In August of 2016, the DEA announced that cannabis would remain a Schedule I
controlled substance.14 The notice stated that:

The DEA and FDA continue to believe that scientifically valid and well-controlled clinical
trials conducted under investigational new drug applications are the proper way to research all
potential new medicines, including marijuana. Furthermore, we believe that the drug approval
process is the proper way to assess whether a product derived from marijuana or its constituent
parts is safe and effective for medical use.14

Cannabis is not FDA-approved as a safe and effective drug for any indication. However, the
agency has approved three drug products containing synthetic versions of the main psychoactive
ingredient of cannabis, THC. Marinol® and Syndros™, which include the active ingredient
dronabinol, are indicated for nausea and vomiting associated with cancer chemotherapy and
anorexia associated with weight loss in patients with AIDS.15 Cesamet®, which contains the active
ingredient nabilone, also is indicated for the treatment of the nausea and vomiting associated with
cancer chemotherapy.15 Clinical investigations are underway for one CBD-based product,
Epidiolex® for Lennox-Gastaut syndrome and Dravet syndrome and the THC/CBD combination
product Sativex® for cancer pain.15,16
In 2016, the DEA announced a change in policy designed to increase the number of DEA-registered cannabis manufacturers. Currently the University of Mississippi is the only entity authorized to produce cannabis for research purposes in the United States. The new policy will allow additional entities to submit applications and become registered with the DEA to grow and distribute cannabis for FDA-authorized research purposes.17

Under the Obama Administration, a memorandum to all U.S. Attorneys outlined cannabis enforcement priorities for the federal government. The memo explained that jurisdictions enacting laws legalizing cannabis that also have strong regulatory enforcement systems would be less likely to be threatened with federal enforcement.18 Federal priorities include preventing: (1) the distribution of cannabis to minors; (2) revenue from the sale of cannabis from going to criminal enterprises, gangs, and cartels; (3) the diversion of cannabis from states where it is legal under state law in some form to other states; (4) state-authorized cannabis activity from being used as a cover or pretext for the trafficking of other illegal drugs or other illegal activity; (5) violence and the use of firearms in the cultivation and distribution of cannabis; (6) drugged driving and the exacerbation of other adverse public health consequences associated with cannabis use; (7) the growing of cannabis on public lands and the attendant public safety and environmental dangers posed by cannabis production on public lands; and, (8) cannabis possession or use on federal property.18 Accordingly, if particular conduct threatens federal priorities, that person or entity would be subject to federal enforcement actions.

While the Obama Administration tolerated state laws legalizing cannabis, it is still unclear how the Trump Administration will handle the issue.19 In July of 2017, the Attorney General sent letters to four governors warning them that he had “serious concerns” about the effects of cannabis legalization, raising questions as to whether the current compromise on enforcement with the Justice Department may be under reconsideration.20

THE HEALTH EFFECTS OF CANNABIS

The National Academies of Sciences, Engineering, and Medicine (National Academies) 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.”6 The report’s recommendations outline priorities for a research agenda and highlight the potential for improvements in data collection efforts and enhanced surveillance capacity.5 The report also contained 98 conclusions based on the accumulated evidence related to cannabis or cannabinoid use and health.6 (see Appendix B)

The report 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; perinatal, neonatal, and neonatal exposure; psychosocial and mental health; problem cannabis use; and cannabis use and the misuse of other substances. The findings are organized into 5 evidence categories: conclusive, substantial, moderate, limited, and no/insufficient evidence. The report found conclusive or substantial evidence that cannabis or cannabinoids are effective: (1) for the treatment of chronic pain in adults (cannabis); (2) as antiemetics in the treatment of chemotherapy-induced nausea and vomiting (oral cannabinoids); and (3) for improving patient-reported multiple sclerosis spasticity symptoms (oral cannabinoids).6 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); and
(4) the development of schizophrenia or other psychoses, with the highest risk among the most frequent users.6

A systematic review published subsequent to the National Academies report examined 27 clinical trials involving patients with chronic pain and found limited evidence that cannabis may alleviate neuropathic pain in some patients, but that insufficient evidence exists to demonstrate analgesic effects in patients with other types of chronic pain.21 This conclusion contradicts the finding of the National Academies report and is an example of how research findings on the therapeutic effects of cannabis remain inconsistent, leading to confusion among physicians, patients, the media, policy makers, and others.

IMPACT OF STATE LEGALIZATION OF CANNABIS

In 2012, CO and WA were the first states to legalize cannabis for recreational use. As jurisdictions continue to follow in their footsteps, many are looking at data from these states to determine the impact of legalization on public health and safety. Issues being examined include the impact of legalization on patterns of use by adults, children and adolescents, and pregnant women; cannabis-related exposures; cannabis-related hospital or emergency department visits; cannabis-related treatment admissions; impaired driving; crime; opioid use; and governmental costs and revenue. Since regulatory structures governing cannabis vary by jurisdiction and continue to evolve, the impact on health and safety is difficult to discern. It is also worth noting that although recreational use of cannabis was first legalized in 2012, cannabis products for recreational use were not commercially available for sale in CO or WA until 2014. Alaska (AK), D.C., and Oregon (OR) voted to legalize recreational use in 2014. While OR allowed limited sales of cannabis through medical dispensaries in 2015, cannabis dispensaries for recreational users did not open in AK or OR until 2016 (Figure 2). As a result, limited data are currently available to determine the overall impact of legalizing recreational cannabis use on specific outcome measures.

The Colorado Department of Public Health and Environment (CDPHE) appointed a Retail Marijuana Public Health Advisory Committee (RMPHAC), to review scientific literature on the health effects of cannabis and state-specific health outcomes and patterns of use.22 The RMPHAC report was informed by state-based data and 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) and Pregnancy Risk Assessment Monitoring System (PRAMS). The Washington State Institute for Public Policy (WSIPP) has conducted a benefit-cost analysis of the implementation of WA Initiative 502 as required by law.23 The Northwest High Intensity Drug Trafficking Area (NWHIDTA) and the Rocky Mountain High Intensity Drug Trafficking Area (RMHIDTA) have also issued reports on the impacts of the legalization of cannabis in WA and CO, respectively.24,25 The results from these reports were utilized in examining the impact of cannabis legalization on public health and safety.

Use among Adults

In the United States, cannabis is the most commonly used illicit drug.26 Overall, from 2002-2014, the prevalence of cannabis use during the past month, past year, and daily or almost daily increased among persons aged 18 years and older.27 In 2016, the percentage of young adults (18-25 years) who were current marijuana users (past month) was similar to the percentages in 2014 and 2015, while the percentage of older adults (≥ 26 years) who were current users continued to increase.28
The percentage of young Coloradan adults aged 18 to 25 years reporting cannabis use within the past year increased significantly after “medical” cannabis legalization (35 percent in 2007 to 2008 to 43 percent in 2010 to 2011).29 The latest data available suggest cannabis use has remained fairly constant in CO (45 percent in 2013-2014). In 2015, based on the BRFSS data, 13 percent of CO adults ages 18 and up had used cannabis in the past-month.22 The NSDUH estimate for past-month use is higher, at 17 percent.22 However, neither survey showed a statistical change from 2014 to 2015.22 According to NSDUH data, adult use of cannabis in CO has continued to be higher than the national average, which was 8 percent.22 In WA, young adults’ (18-25 years) past-year cannabis use was 6 percent higher than the nation’s in 2012-2013, and adults’ use (≥ 26 years) was 5 percent higher.24 Past month use of cannabis was 5 percent higher than the nation’s average for young adults and adults in 2012-2013.24 Statewide BRFSS data indicate that since the legalization of recreational cannabis in WA, use has increased among adults.23

Use among Pregnant Women

Cannabis is the most commonly used illicit drug during pregnancy.30 The movement toward the legalization of cannabis may result in more women using cannabis during pregnancy.31 Cannabis crosses the placenta and is found in breast milk.30 It may have adverse effects on both perinatal outcomes and fetal neurodevelopment, though evidence is limited.31 In 2015, the American College of Obstetricians and Gynecologists issued a committee opinion discouraging physicians from suggesting the use of marijuana during preconception, pregnancy, and lactation.30

Overall, cannabis use during pregnancy is increasing with 3.85 percent of pregnant women between the ages of 18 and 44 years reporting past-month cannabis use in 2014, compared with 2.37 percent in 2002.32 PRAMS data for CO showed that among new mothers, 11.2 percent used cannabis prior to pregnancy, 5.7 percent used cannabis during pregnancy, and 4.5 percent of breastfeeding mothers used cannabis after delivery.22 Cannabis use during pregnancy was statistically higher among women with an unintended pregnancy (9.1 percent) than among women who intended to become pregnant (4.0 percent).22 When cannabis use during pregnancy was compared among different demographics, both education and age showed statistical differences, whereas race and ethnicity did not.22

Use among Adolescents

Adolescents are of particular interest in cannabis-policy discussions because the negative health effects of the drug are heightened when use begins in adolescence.33 In addition to the health effects, including the increased risk of addiction, 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.33-35 Changes in the legal status of cannabis may affect use among adolescents by decreasing the perceived risk of harm or through the marketing of legal cannabis. Studies examining the impact of “medical” cannabis laws found no measurable effect on the patterns of adolescent cannabis use.36-38 States with recreational or adult use cannabis laws also have not experienced an increase in adolescent use in the short term.22,23 However, further surveillance is necessary to determine long-term results.

NSDUH data for 2016 suggest that 6.5 percent or 1.6 million adolescents (12-17 years) were current (past month) users of cannabis.28 The percentage of adolescents who were current cannabis users in 2016 was lower than the percentages in most years from 2009 to 2014, but was similar to the percentage in 2015.28 In CO, estimates of current cannabis use (2002-2015) among high school students have fluctuated between approximately 20 percent and 25 percent.22 Survey results from 2015 indicate that approximately 38 percent of CO high school students reported having ever used
cannabis and 21 percent reported use in the past 30 days.\textsuperscript{22} These estimates are similar to national estimates of ever and current cannabis use among high school students. Among CO middle school students in 2015, an estimated 7.6 percent had ever used cannabis and an estimated 4.4 percent reported currently using cannabis.\textsuperscript{22} In WA, the Healthy Youth Survey, found that cannabis use indicators across grades 6, 8, 10, and 12, have been stable or fallen slightly since the legalization of recreational cannabis.\textsuperscript{23}

\textbf{Cannabis-Related Exposures}

Cannabis-related exposures generally refer to the number of human exposures related to accidental or excessive consumption or inhalation of cannabis and cannabis edibles. Early data from states that have legalized cannabis have shown an increase in calls to poison control centers related to cannabis exposures. According to the WA State Poison Control Center (WAPC), calls related to cannabis exposure nearly doubled from 2011 (n=146) to 2016 (n=286).\textsuperscript{39} In 2016, over 42 percent (n=120) of the total cannabis-related calls involved individuals 13-29 years of age who had been exposed to some form of cannabis.\textsuperscript{39} Over 70 percent (n=226) of patients were exposed to cannabis through ingestion.\textsuperscript{39}

In CO, 7.9 percent of adults with children 1-14 years old in the home reported having cannabis or cannabis products in or around the home (2015).\textsuperscript{22} It was estimated that approximately 14,000 homes in CO with children 1-14 years old had cannabis in the home with potentially unsafe storage.\textsuperscript{22} Cannabis-related exposures in CO increased 100 percent in the three-year average (2013-2015) since CO legalized recreational use of cannabis compared to the three-year average (2010-2012) prior to legalization.\textsuperscript{25} In children (≤ 5 years old), cannabis-related exposures increased 169 percent after legalization of recreational cannabis in CO.\textsuperscript{25} However, overall human exposures reported to Rocky Mountain Poison Center involving cannabis were marginally lower in 2016 (n=224) compared with 2015 (n=231).\textsuperscript{22}

A retrospective cohort study of CO children’s hospital admissions and regional poison control (RPC) cases for cannabis exposures between January 1, 2009, and December 31, 2015, found that hospital visits and RPC case rates for cannabis exposures in patients under 10 years of age increased between the 2 years prior to and the 2 years after legalization.\textsuperscript{40} During this time period, RPC calls increased at a significantly higher rate in CO than in the rest of the U.S. (34 percent vs. 19 percent per year).\textsuperscript{40} In CO, edible products were responsible for more than half of the exposures.\textsuperscript{40}

\textbf{Cannabis Secondhand Smoke Exposure}

For 2014 and 2015 together, 3.2 percent of adults with children 1-14 years old reported cannabis being used inside the home in CO.\textsuperscript{22} Of these, 83.2 percent reported the cannabis was smoked, vaporized, or dabbed (dabs are a highly concentrated extract of THC).\textsuperscript{22} It is estimated that approximately 16,000 homes in CO had children 1-14 years old with possible exposure to secondhand cannabis smoke or vapor in the home.\textsuperscript{22}

\textbf{Cannabis-Related Emergency Department Visits and Hospital Admissions}

In addition to hospitalizations for unexpected pediatric exposure to cannabis, increased cannabis use after legalization has resulted in an increase in the number of ED visits and hospitalizations related to acute marijuana intoxication.\textsuperscript{29} Retrospective data from the CO Hospital Association has shown that the prevalence of hospitalizations for cannabis exposure in patients aged 9 years and older essentially doubled after the legalization of medical cannabis (15 per 100,000 hospitalizations
in 2001 to 2009 versus 28 per 100,000 hospitalizations from 2010 to 2013) and that cannabis-related ED visits nearly doubled after the legalization of recreational cannabis (22 per 100,000 ED visits in 2010 to 2013 versus 38 per 100,000 ED visits from January to June of 2014).\textsuperscript{29} 

Cannabis legalization may also eventually contribute to increased ED visits for the sequelae of chronic cannabis use, including cannabinoid hyperemesis syndrome.\textsuperscript{29} Patients with cannabinoid hyperemesis present to the ED with periodic bouts of intractable vomiting that are unresponsive to traditional antiemetics. CO saw a doubling of ED visits for cyclic vomiting after the legalization of medical cannabis in CO in 2009, although the total number of visits remained small.\textsuperscript{29}

\textit{Cannabis-Related Treatment Admissions}

Limited data is available regarding the impact of laws legalizing the recreational use of cannabis on cannabis-related treatment admissions,\textsuperscript{*} though the early data suggests a decline in treatment admissions. A study of cannabis-related treatment admissions in Denver from 2001-2013 found that such admissions increased from 2005 (2,694) to 2008 (3,295) and then declined by 10.6 percent to 2,887 in 2011.\textsuperscript{41} Significant decreases in treatment entries after 2009, a time when access to cannabis through CO’s medical cannabis program was increasing, have been hypothesized to be a reflection of an accepting public opinion of cannabis use resulting in fewer individuals seeking treatment.\textsuperscript{41} In WA, cannabis-related treatment admissions fell in the three years following legalization of recreational use dropping from 7,843 in 2012, to 7,374 in 2013, 6,885 in 2014, and 6,142 in 2015.\textsuperscript{23} Youth treatment admissions for cannabis have remained between 66 percent and 70 percent of overall admissions in WA state since 2010.\textsuperscript{24}

\textit{Impaired Driving}

A potential unintended consequence of legalizing cannabis use for medical or recreational purposes is increased cannabis-related driving impairment. While the effects of alcohol on driving performance and crash risk are well understood, less is known regarding the effects of cannabis on driving. Research, including direct observations made in a driving simulator, has demonstrated the potential of cannabis to impair driving related skills.\textsuperscript{42-44} Individuals driving under the influence of cannabis seem to exhibit a general reckless driving style and cannabis smoking increases the risk of involvement in a motor vehicle accident approximately 2-fold.\textsuperscript{44} Cannabis use is associated with slower driving, an increased tendency to drive below the speed limit, increased following distance, increased lane weaving, and increased mean distance headway to the preceding vehicle.\textsuperscript{45} These behaviors suggest that those driving under the influence of cannabis are aware of their impairment and decrease their speed to compensate.\textsuperscript{44}

Unlike alcohol, THC is not water soluble, but is stored in fatty tissues and released over time. A clear relationship between THC levels and impairment has been difficult to establish, in part, because a urine or even serum level of THC could reflect cannabis used quite remotely from the date of the specimen collection.\textsuperscript{45} Peak THC level can occur when low impairment is measured, and high impairment can be measured when THC level is low.\textsuperscript{45} Additionally, some individuals may demonstrate little or no impairment at a THC level that impairs someone else.\textsuperscript{45}

The most recent data from CO show that cannabis-related traffic deaths increased 48 percent in the three-year average (2013-2015) after recreational use of cannabis was legalized compared with the three-year average (2010-2012) prior to legalization.\textsuperscript{25} Similarly, the WA State Traffic Safety

\textsuperscript{*} Treatment admissions data as reported by substance abuse treatment facilities for inclusion in the national Treatment Episode Data Set.
Commission found that the number of drivers with THC in their blood involved in fatal driving accidents increased more than 120 percent from 2010 to 2014. Despite data from these individual states, another study found that three years after recreational cannabis legalization, motor vehicle crash fatality rates overall for WA and CO were not statistically different from those in similar states without recreational cannabis legalization.

Criminal Justice

Legalizing cannabis for recreational use could have variable impacts on crime. Some have argued that legalization could result in a decrease in drug-trafficking and possession charges; others contend that the increased use of cannabis could result in increases in violent crime.

Data from WA’s Administrative Office of the Courts demonstrated that among adult offenders, misdemeanor cannabis possession convictions declined from 297 convictions in January 2012 to 0 by January 2013. Among youth offenders, misdemeanor cannabis convictions dropped from 1,015 in the first three months of 2012 to 722 in the first quarter of 2013. WA reports that from 2012 through 2014, cannabis seizure offenses reported to the National Incident-Based Reporting System decreased by nearly 62 percent. Despite the overall decline in seizures in the state, youth cannabis seizure offenses have not followed this trend. In 2010, youth twelve to seventeen years old represented 28.9 percent (n=855) of all seizures. In 2012 (legalization), they represented 37.5 percent (n=2,378) of seizures, and in 2013 they represented 68.6 percent (n=1,840) of total seizures. By the end of 2014 (commercialization), 74 percent (n=1,791) of seizures involved youth aged twelve to seventeen years.

Crime in Denver and Colorado has increased from 2013 to 2015. Since 2014, there has been an increase in organized, large-scale home grows for trafficking to states where cannabis is not legalized. Seizures of Colorado marijuana in the U.S. mail increased 471 percent from an average of 129 pounds (2010-2012) to 736 pounds (2013-2015) over the three-year period after recreational use was legalized. In addition, in Colorado, property crime increased 6.2 percent, violent crime increased 6.7 percent, and all crime increased 6.2 percent from 2014 to 2015.

Opioid Use

According to the Centers for Disease Control and Prevention, increases in unintentional overdoses and deaths due to prescription opioids and heroin are the biggest driver of the drug overdose epidemic. Studies have found a decrease in the use of opioids among pain patients provided with medical cannabis. Furthermore, medical cannabis laws are associated with significantly lower state-level opioid overdose mortality rates. Additional research is necessary to determine how cannabis laws may impact opioid use, morbidity, and mortality.

Governmental Costs and Revenue

Cannabis tax collections in CO and WA have continued to increase, and, on a national basis, legalization and associated taxation of cannabis could result in billions of dollars per year of tax revenue for states. In WA, I-502 required the WA State Liquor and Cannabis Board to oversee the recreational cannabis market and imposed a 25% excise tax on producers, processors, and retailers, which was later replaced with a 37% excise tax on retail sales. The Dedicated Marijuana Account was created for cannabis revenues and expenditures. Voters were told legalization could bring in as much as $1.9 billion over five years, with 40 percent going to the state general fund and local budgets and the remaining 60 percent intended for substance abuse prevention, research,
education, and health care. As of April 2016, state sales average over $2 million a day, which translates into mean excise tax revenue approaching $270 million per year.48

In CO, voters were initially told cannabis excise taxes would boost state revenues by $70 million per year, with the first $40 million each year to be allocated to school construction, leaving $30 million for enforcement and general state funds.48 Revenues in calendar year 2016 reached nearly $200 million. The CO legislature established a Marijuana Tax Cash Fund (MTCF) in 2014, which collects tax revenue from both medical and recreational cannabis sales. Funds in the MTCF have been appropriated to government agencies to address the possible health and safety consequences of legalization such as monitoring the health effects of cannabis, conducting health education campaigns, and providing substance abuse prevention and treatment programs.

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. For example, in Colorado, the Marijuana Enforcement Division (MED) is responsible for regulating both medical and recreational cannabis businesses in the state. The MED’s four offices and 55 employees are responsible for rulemaking, licensing and inspecting cannabis-related businesses, and taking enforcement actions. The annual budget for the MED is approximately $10.5 million.

MINIMIZING HEALTH RISKS OF LEGALIZATION

As jurisdictions continue to understand the impact of legalization on health and other outcomes, the regulatory structure governing cannabis will continue to evolve. In CO, CDPHE continues to assess the knowledge gaps related to cannabis and develop policies to protect vulnerable populations.49 For example, the issue of child cannabis exposure from edibles has been concerning. In CO, confusion surrounding the serving size for edible products and the delayed onset of the effects of THC are thought to have contributed to overconsumption.49 Regulations were changed to ensure easier identification of average serving size in a single edible product.49 CO, OR and WA now require a universal symbol to be affixed to edibles. Four states (Alaska, CO, OR, and WA) prohibit the manufacture or packaging of edibles that appeal to youth.50 Concerns remain regarding the regulatory gaps that exist in each of these states and whether these regulations are actually informing consumers and keeping the public safe.50

To address motor vehicle crashes due to driving under the influence of cannabis, some states have established per se limits for driving under the influence of cannabis. For example, CO and WA have established 5 ng/ml of THC as the legal limit for cannabis-impaired driving.49 However, little evidence exists to support the enactment of specific per se limits for cannabis.24 As a first step, states are being encouraged to conduct prevalence studies on the number and proportion of drivers testing positive for THC.24

The Vermont Department of Health has conducted a health impact assessment to determine the potential impact of legislation to regulate and tax cannabis for recreational use on the health of Vermonters and to recommend ways to mitigate the adverse health impacts of such legislation. The recommendations include expanding all current tobacco laws to include cannabis, prohibiting the use of cannabis in public places, standardizing and testing packaging and potency, funding prevention and education, restricting advertising, prohibiting infused products on the regulated market, setting a blood level operating limit for THC, expanding screening for substance use disorders in primary care, training health care providers on the health impacts of cannabis, and funding surveillance and research.51
CONCLUSION

Although the National Academies found conclusive or substantial evidence that cannabis or cannabinoids have some therapeutic benefits, they also found substantial or conclusive evidence of a statistical association between cannabis smoking and health harms. Furthermore, the findings of a systematic review on the analgesic effects of cannabis released subsequent to the National Academies report were inconsistent with the National Academies report, which highlights the lack of agreement on this issue, and serves as a source of confusion among physicians, patients, and the public and demonstrates the need for additional research.

Legalizing the recreational use of cannabis may result in its increased use over time due to changes in perceptions of safety and health risks. Existing data, although limited, have yet to confirm this expectation for children and adolescents. However, cannabis use has increased in adults and pregnant women. Data from jurisdictions that have legalized cannabis demonstrate concerns particularly around unintentional pediatric exposures resulting in increased calls to poison control centers and ED visits as well as an increase in traffic deaths due to cannabis-related impaired driving. Limited data also show a decrease in cannabis-related treatment admissions as well as a possible decrease in the use of opioids for chronic pain. In terms of crime, convictions for the possession of cannabis may decline in states that legalize cannabis. While states have seen an increase in revenue through sales and excise taxes on retail cannabis, the administrative and enforcement costs as well as the costs to society in terms of public health and safety should not be minimized.

Ongoing surveillance to determine the impact of cannabis legalization and commercialization on public health and safety will be critical. Surveillance should include, but not be limited to, the issues covered in this report – impact on patterns of use, traffic fatalities and injuries, emergency department visits and hospitalizations, unintentional exposures, exposure to second-hand smoke, and cannabis-related treatment admissions. There should also be a focus on at-risk populations including pregnant women and children. Continued evaluation of the effectiveness of regulations developed to ensure public health and safety in states that have legalized the medical and/or recreational use of cannabis is necessary. Jurisdictions that have legalized cannabis should 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.

For physicians, legalization may require practice modifications, particularly regarding patient-provider conversations about use and risk. Additional education on counseling patients about the danger of second-hand smoke exposure, underage use, safe storage, impaired driving, and the over-consumption of edibles may be warranted.

RECOMMENDATIONS

The Council on Science and Public Health recommends that the following statements be adopted in lieu of Resolution 907-I-16 and the remainder of this report be filed:

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; (3) 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 use; (6) supports public health based strategies, rather than incarceration, in the handling of individuals possessing cannabis for personal use. (New HOD Policy)

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) opposes the legalization of cannabis for medicinal use 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; and (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. (New HOD Policy)

2. That the following new policy be adopted:

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. (New HOD Policy)

3. That Policy H-95.952, “Cannabis for Medicinal Use,” be amended by addition and deletion to read as follows:

H-95.952. “Cannabis Research for Medicinal Use”

(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 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. 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. (Modify Current HOD Policy)

4. That Policy H-95.936, “Cannabis Warnings for Pregnant and Breastfeeding Women,” be 
reaffirmed. (Reaffirm HOD Policy)

95.938, “Immunity from Federal Prosecution for Physicians Recommending Cannabis,” and D-
95.976, “Cannabis – Expanded AMA Advocacy,” be rescinded since they have been 
implemented, were duplicative of another policy, or portions were incorporated into new 
policies proposed in this report. (Rescind HOD Policy)

Fiscal Note: Less than $1,000
FIGURE 1
Status of State Laws on Cannabis Legalization (Source: ASTHO)

![Status of State Laws on Cannabis Legalization](image)

FIGURE 2
Timeline of State Recreational Cannabis Laws

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>CO, WA legalize recreational cannabis</td>
</tr>
<tr>
<td>2013</td>
<td></td>
</tr>
</tbody>
</table>
| 2014 | CO, WA recreational cannabis sales begin  
|      | AK, DC, OR legalize recreational cannabis |
| 2015 | OR recreational cannabis sales begin |
| 2016 | AK recreational cannabis sales begin  
|      | CA, MA, ME vote to legalize recreational cannabis |
| 2017 | NV recreational cannabis sales begin |
| 2018 | CA, MA, ME recreational cannabis sales expected to begin |
REFERENCES


8 CO Amendment 64. (2012).


13 21 USC 812.

14 81 FR 53687.


17 81 FR 53846.


APPENDIX A
Existing AMA Policies Related to Cannabis

D-95.976, “Cannabis - Expanded AMA Advocacy”
1. Our AMA will educate the media and legislators as to the health effects of cannabis use as elucidated in CSAPH Report 2, I-13, A Contemporary View of National Drug Control Policy, and CSAPH Report 3, I-09, Use of Cannabis for Medicinal Purposes, and as additional scientific evidence becomes available. 2. Our AMA urges legislatures to delay initiating full legalization of any cannabis product until further research is completed on the public health, medical, economic and social consequences of use of cannabis and, instead, support the expansion of such research. 3. Our AMA will also increase its efforts to educate the press, legislators and the public regarding its policy position that stresses a "public health", as contrasted with a "criminal," approach to cannabis. 4. Our AMA shall encourage model legislation that would require placing the following warning on all cannabis products not approved by the U.S. Food and Drug Administration: "Marijuana has a high potential for abuse. It has no scientifically proven, currently accepted medical use for preventing or treating any disease process in the United States.” Res 213, I-14.

H-95.952, “Cannabis for Medicinal Use”
(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 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. 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.

H-95.998, “AMA Policy Statement on Cannabis”
Our AMA believes that (1) cannabis is a dangerous drug and as such is a public health concern; (2) sale of cannabis should not be legalized; (3) public health based strategies, rather than incarceration, should be utilized in the handling of individuals possessing cannabis for personal use; and (4) additional research should be encouraged. BOT Rep. K, I-69, Reaffirmed: CLRPD

H-95.936, “Cannabis Warnings for Pregnant and Breastfeeding Women”
Our AMA advocates for regulations requiring point-of-sale warnings and product labeling for cannabis and cannabis-based products regarding the potential dangers of use during pregnancy and breastfeeding wherever these products are sold or distributed. Res. 922, I-15.

H-95.938, “Immunity from Federal Prosecution for Physicians Recommending Cannabis”
Our American Medical Association 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. Res. 233, A-15.

H-95.997, “Cannabis Intoxication as a Criminal Defense”

H-170.992, “Alcohol and Drug Abuse Education”
Our AMA: (1) supports continued encouragement for increased educational programs relating to use and abuse of alcohol, marijuana and controlled substances; (2) supports the implementation of alcohol and marijuana education in comprehensive health education curricula, kindergarten through grade twelve; and (3) encourages state medical societies to work with the appropriate agencies to develop a state-funded educational campaign to counteract pressures on young people to use alcohol. Sub. Res. 63, I-80 Reaffirmed: CLRPD Rep. B, I-90 Reaffirmation and Reaffirmed: Sunset Report, I-00 Appended: Res. 415, I-01 Reaffirmed: CSAPH Rep. 1, A-11.
### CONCLUSIONS FOR THERAPEUTIC EFFECTS

<table>
<thead>
<tr>
<th>Evidence</th>
<th>Conclusions for Therapeutic Effects</th>
</tr>
</thead>
</table>
| Conclusive or substantial evidence | - For the treatment for chronic pain in adults (cannabis)  
- Antiemetics in the treatment of chemotherapy-induced nausea and vomiting (oral cannabinoids)  
- For improving patient-reported multiple sclerosis spasticity symptoms (oral cannabinoids) |
| Moderate evidence | - 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) |
| Limited evidence | - Increasing appetite and decreasing weight loss associated with HIV/AIDS (cannabis and oral cannabinoids)  
- Improving clinician-measured multiple sclerosis spasticity symptoms (oral cannabinoids)  
- Improving symptoms of Tourette syndrome (THC capsules)  
- Improving anxiety symptoms, as assessed by a public speaking test, in individuals with social anxiety disorders (cannabidiol)  
- Improving symptoms of posttraumatic stress disorder (nabilone) |
| Limited evidence of a statistical association between cannabinoids and | - Better outcomes (i.e., mortality, disability) after a traumatic brain injury or intracranial hemorrhage. |
| Limited evidence | - Improving symptoms associated with dementia (cannabinoids)  
- Improving intraocular pressure associated with glaucoma (cannabinoids)  
- Reducing depressive symptoms in individuals with chronic pain or multiple sclerosis (nabiximols, dronabinol, and nabilone) |
| No or insufficient evidence | - Cancers, including glioma (cannabinoids)  
- Cancer-associated anorexia cachexia syndrome and anorexia nervosa (cannabinoids)  
- Symptoms of irritable bowel syndrome (dronabinol)  
- Epilepsy (cannabinoids)  
- Spasticity in patients with paralysis due to spinal cord injury (cannabinoids)  
- Symptoms associated with amyotrophic lateral sclerosis (cannabinoids)  
- Chorea and certain neuropsychiatric symptoms associated with Huntington’s disease (oral cannabinoids)  
- Motor system symptoms associated with Parkinson’s disease or the levodopa-induced dyskinesia (cannabinoids)  
- Dystonia (nabilone and dronabinol)  
- Achieving abstinence in the use of addictive substances (cannabinoids)  
- Mental health outcomes in individuals with schizophrenia or schizophreniform psychosis (cannabidiol) |

### CONCLUSIONS FOR CANCER

<table>
<thead>
<tr>
<th>Evidence</th>
<th>Conclusions for Cancer</th>
</tr>
</thead>
</table>
| Moderate evidence of no statistical association between cannabis use and | - Incidence of lung cancer (cannabis smoking)  
- Incidence of head and neck cancers |
<p>| Limited evidence of a statistical association between cannabis smoking and | - Non-seminoma-type testicular germ cell tumors (current, frequent, or chronic cannabis smoking) |
| No or insufficient evidence | - Incidence of esophageal cancer (cannabis smoking) |</p>
<table>
<thead>
<tr>
<th><strong>EVIDENCE</strong></th>
<th><strong>CONCLUSIONS FOR CARDIOMETABOLIC RISK</strong></th>
</tr>
</thead>
</table>
| There is **limited evidence** of a statistical association between cannabis use and: | • Incidence of prostate cancer, cervical cancer, malignant gliomas, non-Hodgkin lymphoma, penile cancer, anal cancer, Kaposi’s sarcoma, or bladder cancer  
• Subsequent risk of developing acute myeloid leukemia/acute non-lymphoblastic leukemia, acute lymphoblastic leukemia, rhabdomyosarcoma, astrocytoma, or neuroblastoma in offspring (parental cannabis use) |
| There is no evidence to support or refute a statistical association between **chronic effects** of cannabis use and: | • The increased risk of acute myocardial infarction |

<table>
<thead>
<tr>
<th><strong>EVIDENCE</strong></th>
<th><strong>CONCLUSIONS FOR RESPIRATORY DISEASE</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>There is <strong>substantial evidence</strong> of a statistical association between cannabis smoking and:</td>
<td>• Worse respiratory symptoms and more frequent chronic bronchitis episodes (long-term cannabis smoking)</td>
</tr>
</tbody>
</table>
| There is **moderate evidence** of a statistical association between cannabis smoking and: | • Improved airway dynamics with acute use, but not with chronic use  
• Higher forced vital capacity (FVC) |
| There is **moderate evidence** of a statistical association between the **cessation** of cannabis smoking and: | • Improvements in respiratory symptoms. |
| There is **limited evidence** of a statistical association between cannabis smoking and: | • An increased risk of developing chronic obstructive pulmonary disease (COPD) when controlled for tobacco use (occasional cannabis smoking) |
| There is no or insufficient evidence to support or refute a statistical association between cannabis smoking and: | • Hospital admissions for COPD  
• Asthma development or asthma exacerbation |

<table>
<thead>
<tr>
<th><strong>EVIDENCE</strong></th>
<th><strong>CONCLUSIONS FOR IMMUNITY</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>There is <strong>limited evidence</strong> of a statistical association between cannabis smoking and:</td>
<td>• A decrease in the production of several inflammatory cytokines in healthy individuals</td>
</tr>
<tr>
<td>There is <strong>limited evidence</strong> of <strong>no statistical association</strong> between cannabis use and:</td>
<td>• The progression of liver fibrosis or hepatic disease in individuals with viral hepatitis C (HCV) (daily cannabis use)</td>
</tr>
</tbody>
</table>
| There is no or insufficient evidence to support or refute a statistical association between cannabis use and: | • Other adverse immune cell responses in healthy individuals (cannabis smoking)  
• Adverse effects on immune status in individuals with HIV(cannabis or dronabinol use)  
• Increased incidence of oral human papilloma virus (HPV) (regular cannabis use) |

<table>
<thead>
<tr>
<th><strong>EVIDENCE</strong></th>
<th><strong>CONCLUSIONS FOR INJURY AND DEATH</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>There is <strong>substantial evidence</strong> of a statistical association between cannabis use and:</td>
<td>• Increased risk of motor vehicle crashes</td>
</tr>
<tr>
<td>There is <strong>moderate evidence</strong> of a statistical association between cannabis use and:</td>
<td>• Increased risk of overdose injuries, including respiratory distress, among pediatric populations in U.S. states where cannabis is legal</td>
</tr>
</tbody>
</table>
| There is no or insufficient evidence to support or refute a statistical association between cannabis use and: | • All-cause mortality (self-reported cannabis use)  
• Occupational accidents or injuries (general, nonmedical cannabis use)  
• Death due to cannabis overdose |
<table>
<thead>
<tr>
<th>EVIDENCE</th>
<th>CONCLUSIONS FOR PRENATAL, PERINATAL, AND NEONATAL EXPOSURE</th>
</tr>
</thead>
<tbody>
<tr>
<td>There is <strong>substantial evidence</strong> of a statistical association between maternal cannabis smoking and:</td>
<td>• Lower birth weight of the offspring</td>
</tr>
</tbody>
</table>
| There is **limited evidence** of a statistical association between maternal cannabis smoking and: | • Pregnancy complications for the mother  
• Admission of the infant to the neonatal intensive care unit (NICU) |
| There is **insufficient evidence** to support or refute a statistical association between maternal cannabis smoking and: | • Later outcomes in the offspring (e.g., sudden infant death syndrome, cognition/academic achievement, and later substance use) |

<table>
<thead>
<tr>
<th>EVIDENCE</th>
<th>CONCLUSIONS FOR PSYCHOSOCIAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>There is <strong>moderate evidence</strong> of a statistical association between cannabis use and:</td>
<td>• The impairment in the cognitive domains of learning, memory, and attention (acute cannabis use)</td>
</tr>
</tbody>
</table>
| There is **limited evidence** of a statistical association between cannabis use and: | • Impaired academic achievement and education outcomes  
• Increased rates of unemployment and/or low income  
• Impaired social functioning or engagement in developmentally appropriate social roles |
| There is **limited evidence** of a statistical association between **sustained abstinence from** cannabis use and: | • Impairments in the cognitive domains of learning, memory, and attention |

<table>
<thead>
<tr>
<th>EVIDENCE</th>
<th>CONCLUSIONS FOR MENTAL HEALTH</th>
</tr>
</thead>
<tbody>
<tr>
<td>There is <strong>substantial evidence</strong> of a statistical association between cannabis use and:</td>
<td>• The development of schizophrenia or other psychoses, with the highest risk among the most frequent users</td>
</tr>
</tbody>
</table>
| There is **moderate evidence** of a statistical association between cannabis use and: | • Better cognitive performance among individuals with psychotic disorders and a history of cannabis use  
• Increased symptoms of mania and hypomania in individuals diagnosed with bipolar disorders (regular cannabis use)  
• A 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  
• Increased incidence of social anxiety disorder (regular cannabis use) |
| There is **moderate evidence** of no statistical association between cannabis use and: | • Worsening of negative symptoms of schizophrenia (e.g., blunted affect) among individuals with psychotic disorders |
| There is **limited evidence** of a statistical association between cannabis use and: | • An increase in positive symptoms of schizophrenia (e.g., hallucinations) among individuals with psychotic disorders  
• The likelihood of developing bipolar disorder, particularly among regular or daily users  
• The development of any type of anxiety disorder, except social anxiety disorder  
• Increased symptoms of anxiety (near daily cannabis use)  
• Increased severity of posttraumatic stress disorder symptoms among individuals with posttraumatic stress disorder |
| There is **no evidence** to support or refute a statistical association between cannabis use and: | • Changes in the course or symptoms of depressive disorders  
• The development of posttraumatic stress disorder |

<table>
<thead>
<tr>
<th>EVIDENCE</th>
<th>CONCLUSIONS FOR PROBLEM CANNABIS USE</th>
</tr>
</thead>
<tbody>
<tr>
<td>There is <strong>substantial evidence</strong> that:</td>
<td>• Stimulant treatment of attention deficit hyperactivity disorder (ADHD) during adolescence is <em>not</em> a risk factor for the development of problem cannabis use</td>
</tr>
</tbody>
</table>
• Being male and smoking cigarettes are risk factors for the progression of cannabis use to problem cannabis use
• Initiating cannabis use at an earlier age is a risk factor for the development of problem cannabis use

There is **substantial evidence** of a statistical association between:

• Increases in cannabis use frequency and the progression to developing problem cannabis use
• Being male and the severity of problem cannabis use, but the recurrence of problem cannabis use does not differ between males and females

There is **moderate evidence** that:

• Anxiety, personality disorders, and bipolar disorders are *not* risk factors for the development of problem cannabis use
• Major depressive disorder is a risk factor for the development of problem cannabis use
• Adolescent ADHD is *not* a risk factor for the development of problem cannabis use
• Being male is a risk factor for the development of problem cannabis use
• Exposure to the combined use of abused drugs is a risk factor for the development of problem cannabis use
• Neither alcohol nor nicotine dependence alone are risk factors for the progression from cannabis use to problem cannabis use
• During adolescence the frequency of cannabis use, oppositional behaviors, a younger age of first alcohol use, nicotine use, parental substance use, poor school performance, antisocial behaviors, and childhood sexual abuse are risk factors for the development of problem cannabis use

There is **moderate evidence** of a statistical association between:

• A persistence of problem cannabis use and a history of psychiatric treatment
• Problem cannabis use and increased severity of posttraumatic stress disorder symptoms

There is **limited evidence** that:

• Childhood anxiety and childhood depression are risk factors for the development of problem cannabis use

**EVIDENCE**

**CONCLUSIONS FOR CANNABIS USE AND THE ABUSE OF OTHER SUBSTANCES**

There is **moderate evidence** of a statistical association between cannabis use and:

• The development of substance dependence and/or a substance abuse disorder for substances, including alcohol, tobacco, and other illicit drugs

There is **limited evidence** of a statistical association between cannabis use and:

• The initiation of tobacco use
• Changes in the rates and use patterns of other licit and illicit substances

**EVIDENCE**

**CONCLUSIONS FOR CHALLENGES AND BARRIERS IN CONDUCTING CANNABIS RESEARCH**

There are several challenges and barriers in conducting cannabis and cannabinoid research, including:

• There are specific regulatory barriers, including the classification of cannabis as a Schedule I substance, that impede the advancement of cannabis and cannabinoid research
• It is often difficult for researchers to gain access to the quantity, quality, and type of cannabis product necessary to address specific research questions on the health effects of cannabis use
• A diverse network of funders is needed to support cannabis and cannabinoid research that explores the beneficial and harmful health effects of cannabis use
• To develop conclusive evidence for the effects of cannabis use on short- and long-term health outcomes, improvements and standardization in research methodology (including those used in controlled trials and observational studies) are needed
Whereas, Increased screen time amongst youth has been associated with an increase in
morbidities such as obesity, sleep problems, depression and anxiety¹; and

Whereas, Screen time can be utilized for both educational and recreational purposes; and

Whereas, Screens with artificial light, as found in smart phones and tablets, can emit a
substantial amount of short-wavelength (blue-enriched) light emissions²; and

Whereas, The blue light emitted from screens can lead to disruption of circadian rhythm, as it
suppresses melatonin secretion, and enhances alertness which can ultimately impact duration
and quality of sleep²³; therefore be it

RESOLVED, That our American Medical Association encourage all schools to incorporate into
health class curriculum the topic of balancing screen time with physical activity and sleep (New
HOD Policy); and be it further

RESOLVED, That the AMA encourage research into the utility of blue light filtering glasses and
a blue light filter option on devices such as smart phones and tablets (New HOD Policy); and be
it further

RESOLVED, That our AMA encourage physicians to assess all patients and educate all parents
about amount of screen time, physical activity and sleep habits. (New HOD Policy)

Fiscal Note: Minimal - less than $1,000.

Received: 09/06/17

References:
¹ https://www.ncbi.nlm.nih.gov/pubmed/28168778
² http://www.health.harvard.edu/staying-healthy/blue-light-has-a-dark-side

RELEVANT AMA POLICY
Human and Environmental Effects of Light Emitting Diode (LED) Community Lighting H-135.927
1. Our AMA supports the proper conversion to community-based Light Emitting Diode (LED) lighting, which
reduces energy consumption and decreases the use of fossil fuels.
2. Our AMA encourages minimizing and controlling blue-rich environmental lighting by using the lowest
emission of blue light possible to reduce glare.
3. Our AMA encourages the use of 3000K or lower lighting for outdoor installations such as roadways. All LED
lighting should be properly shielded to minimize glare and detrimental human and environmental effects, and
consideration should be given to utilize the ability of LED lighting to be dimmed for off-peak time periods.
(CSAPH Rep. 02, A-16)
Whereas, Trichomoniasis is the most common curable sexually transmitted infection (STI) in the United States according to the Centers for Disease Control and Prevention (CDC) and the most common non-viral sexually transmitted infection (STI) in the world according to the World Health Organization,¹,² with a rate of reinfection increasing to 31% among women treated for Trichomonas vaginalis;³,⁴ and

Whereas, Trichomoniasis is not a reportable STI and “partner notification programmes are not available in most clinic settings”;⁵,⁶ and

Whereas, The most recent CDC 2015 STD treatment guidelines state, “concurrent treatment of all sex partners is critical for symptomatic relief, microbiologic cure, and prevention of transmission and reinfections, […] EPT might have a role in partner management for Trichomoniasis and can be used in states where permissible by law”;⁷ and

Whereas, Metronidazole is an effective, curative, easy, and safe treatment for Trichomonas vaginalis with recommended regimens yielding cure rates of approximately 84%–98%, and expedited partner therapy has been shown to decrease rates of reinfection;⁸ and

Whereas, Current AMA policy already supports state legislation that permits physicians to provide partner therapy for gonorrhea and/or chlamydia infections, both of which are less common than Trichomoniasis (AMA Policy H-440.868); and

Whereas, Expedited partner therapy potentially abrogates the standard informed consent process (Ethical Opinion E-8.9, “Expedited Partner Therapy”), and appropriate use of this therapy ultimately improves public health through management of sexually transmitted diseases; therefore be it

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⁷ CDC. Sexually Transmitted Diseases Treatment Guidelines, 2015. MMWR, 64(RR-03):1-137. https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6403a1.htm
RESOLVED, That our American Medical Association amend policy H-440.868 by addition and deletion to read as follows:

H-440.868 Expedited Partner Therapy
Our AMA supports state legislation that permits physicians to provide expedited partner therapy to patients diagnosed with gonorrhea, and/or chlamydia, and/or Trichomoniasis infection. (Modify Current HOD Policy)

Fiscal Note: Minimal - less than $1,000.

Received: 09/12/17

RELEVANT AMA POLICY

H-440.868 Expedited Partner Therapy
Our AMA supports state legislation that permits physicians to provide expedited partner therapy to patients diagnosed with gonorrhea and/or chlamydia infection. Citation: Sub. Res. 928, I-07 Reaffirmed: CSAPH Rep. 01, A-17

H-440.979 Control of Sexually Transmitted Infections
The AMA urges increased efforts at all levels of organized medicine to bring sexually transmitted infections under control, through professional and public education, and support of the efforts of state Departments of Health, the Centers for Disease Control and Prevention, the National Institutes of Health, and other appropriate organizations. Citation: Res. 84, A-84 Reaffirmed by CLRPD Rep. 3 - I-94 Reaffirmation A-99 Modified and Reaffirmed: CSAPH Rep. 1, A-09 Reaffirmation A-10

See also: H-440.983 Update on Sexually Transmitted Infections; H-440.996 Sexually Transmitted Disease Control; E-8.9 Expedited Partner Therapy
Whereas, Nearly 3 in 10 women and 1 in 10 men in America have experienced some form of intimate partner violence, including rape, physical violence, and/or stalking;¹ and

Whereas, Victims of violence by an intimate partner report issues such as fearing injury, the perpetrator limiting the victim’s access to money or social support, or needing resources such as medical care, legal services, housing services, victim’s advocate services, and/or crisis hotlines;¹ and

Whereas, Our AMA has not updated its Diagnostic and Treatment Guidelines on Domestic Violence since 1992, and since, research has shown that relationship violence in couples involving a transgender or otherwise identifying individual present unique circumstances²; and

Whereas, Violence against LGBT individuals, including domestic violence, is underreported and at times falsely attributed to other kinds of violence like hate crimes;³,⁴ and

Whereas, Lesbian, Gay, Bisexual, Transgender, Queer/Questioning, and Others (LGBTQ+) individuals who are victims of domestic violence may have an added pressure of staying in the relationship and/or seeking treatment out of fear of being outed to family members, friends, or employers;⁵,⁶,⁷ and

Whereas, Some transgender individuals may be pressured to stay in an abusive relationship due to their partner’s threats of limiting access to sex replacement hormones or otherwise exploiting their vulnerabilities with gender transitioning;⁸,⁹ and

Whereas, Some transgender victims of domestic violence avoid reporting their abuse or seeking treatment because they do not want to add to stigma against the transgender community;\(^9\) and

Whereas, Our AMA has committed to address health disparities in LGBT populations and has committed to address family and intimate partner violence (AMA PoliciesH-65.976, H-515.965); and

Whereas, The term Lesbian, Gay, Bisexual, Transgender, Queer/Questioning, and Others (LGBTQ+) is an umbrella term for individuals whose gender identities and sexual orientations differ from those who are cisgender and heterosexual, and should be considered as an effort to be more inclusive than other acronyms like LGB, LGBT, etc. which may be present in some research throughout this resolution;\(^10\) therefore be it

RESOLVED, That our American Medical Association publish an update to its 1992 Diagnostic and Treatment Guidelines on Domestic Violence to reflect recent data and to address unique issues faced by the LGBTQ+ population (Directive to Take Action); and be it further

RESOLVED, That our AMA promote crisis resources for LGBTQ+ patients that cater to the specific needs of LGBTQ+ victims of domestic violence (New HOD Policy); and be it further

RESOLVED, That our AMA amend AMA Policy H-65.976 by addition to read as follows:

Nondiscriminatory Policy for the Health Care Needs of LGBTQ+ Populations H-65.976

Our AMA encourages physician practices, medical schools, hospitals, and clinics to broaden any nondiscriminatory statement made to patients, healthcare workers, or employees to include "sexual orientation, sex, or gender identity" in any nondiscrimination statement (Modify Current HOD Policy); and be it further

RESOLVED, That our AMA amend AMA policy H-160.991 by addition and deletion to read as follows:

Health Care Needs of Lesbian Gay Bisexual and Transgender Populations H-160.991

1. Our AMA: (a) believes that the physician's nonjudgmental recognition of patients' sexual orientations, sexual behaviors, and gender identities enhances the ability to render optimal patient care in health as well as in illness. In the case of lesbian, gay, bisexual, \(\text{and}\) transgender, queer/questioning, and other (LGBTQ+) patients, this recognition is especially important to address the specific health care needs of people who are or may be LGBTQ+; (b) is committed to taking a leadership role in: (i) educating physicians on the current state of research in and knowledge of LGBTQ+ Health and the need to elicit relevant gender and sexuality information from our patients; these efforts should start in medical school, but must also be a part of continuing medical education; (ii) educating physicians to recognize the physical and psychological needs of LGBTQ+ patients; (iii) encouraging the development of educational programs in LGBTQ+ Health; (iv) encouraging physicians to seek out local or national experts in the health care needs of LGBTQ+ people so that all physicians will achieve a better understanding of the medical needs of these populations; and (v) working with LGBTQ+ communities to offer physicians the opportunity to better understand the medical needs of LGBTQ+ patients; and (c) opposes, the use of "reparative" or "conversion" therapy for sexual orientation or gender identity.


2. Our AMA will collaborate with our partner organizations to educate physicians regarding:
(i) the need for women who have sex with women to undergo regular cancer and sexually transmitted infection screenings due to their comparable or elevated risk for these conditions; and (ii) the need for comprehensive screening for sexually transmitted diseases in men who have sex with men; and (iii) appropriate safe sex techniques to avoid the risk for sexually transmitted diseases; and (iv) that individuals who identify as a sexual and/or gender minority (lesbian, gay, bisexual, transgender, queer/questioning individuals) experience intimate partner violence, and how sexual and gender minorities present with intimate partner violence differs from their cisgender, heterosexual peers and may have unique complicating factors.

3. Our AMA will continue to work alongside our partner organizations, including GLMA, to increase physician competency on LGBTQ+ health issues.

4. Our AMA will continue to explore opportunities to collaborate with other organizations, focusing on issues of mutual concern in order to provide the most comprehensive and up-to-date education and information to enable the provision of high quality and culturally competent care to LGBTQ+ people. (Modify Current HOD Policy)

Fiscal Note: Estimated cost of $85,500 to implement resolution.

Received: 09/12/17

RELEVANT AMA POLICY

Education of Medical Students and Residents about Domestic Violence Screening H-295.912
Family and Intimate Partner Violence H-515.965
Nondiscriminatory Policy for the Health Care Needs of LGBT Populations H-65.976
WHEREAS, Cervical cancer screening is indicated for female-to-male transgender patients who have a cervix and are sexually active, according to general cervical screening guidelines;¹ and

WHEREAS, Routine cervical screening has been shown to greatly reduce both the incidence of new cervical cancers diagnosed each year and deaths from the disease;² ³ ⁴ and

WHEREAS, Some health care providers employ a misconception that female-to-male transgender patients have a lower risk of cervical cancer;⁵ and

WHEREAS, A recent survey of obstetricians and gynecologists found that only 29% were comfortable caring for female-to-male transgender patients;⁶ and

WHEREAS, Female-to-male transgender patients are significantly less likely to be up to date on Pap smears than cisgender women;⁷ and

WHEREAS, Female-to-male transgender patients face barriers to adequate cervical cancer screening, including lack of access to safe and inclusive health care providers and lack of education on the importance of continuing to receive Pap smears as compared to cisgender patients facing cervical cancer screenings;⁸ ⁹ ¹⁰ ¹¹ and

Whereas, Even when receiving Pap smears, female-to-male transgender patients are significantly more likely to have longer periods to test follow up from ambiguous lab results than non-transgender patients; therefore be it

RESOLVED, That our American Medical Association amend Policy H-160.991[2] by addition to read as follows:

Health Care Needs of Lesbian Gay Bisexual and Transgender Populations H-160.991

2. Our AMA will collaborate with our partner organizations to educate physicians regarding: (i) the need for women who have sex with women and female-to-male transgender patients when medically indicated to undergo regular cancer and sexually transmitted infection screenings due to their comparable or elevated risk for these conditions; and (ii) the need for comprehensive screening for sexually transmitted diseases in men who have sex with men; and (iii) appropriate safe sex techniques to avoid the risk for sexually transmitted diseases.

(Modify Current HOD Policy)

Fiscal Note: Minimal - less than $1,000.

Received: 09/12/17

RELEVANT AMA POLICY

Health Care Needs of Lesbian Gay Bisexual and Transgender Populations H-160.991

1. Our AMA: (a) believes that the physician’s nonjudgmental recognition of patients’ sexual orientations, sexual behaviors, and gender identities enhances the ability to render optimal patient care in health as well as in illness. In the case of lesbian gay bisexual and transgender (LGBT) patients, this recognition is especially important to address the specific health care needs of people who are or may be LGBT; (b) is committed to taking a leadership role in: (i) educating physicians on the current state of research in and knowledge of LGBT Health and the need to elicit relevant gender and sexuality information from our patients; these efforts should start in medical school, but must also be a part of continuing medical education; (ii) educating physicians to recognize the physical and psychological needs of LGBT patients; (iii) encouraging the development of educational programs in LGBT Health; (iv) encouraging physicians to seek out local or national experts in the health care needs of LGBT people so that all physicians will achieve a better understanding of the medical needs of these populations; and (v) working with LGBT communities to offer physicians the opportunity to better understand the medical needs of LGBT patients; and (c) opposes, the use of “reparative” or “conversion” therapy for sexual orientation or gender identity.

2. Our AMA will collaborate with our partner organizations to educate physicians regarding: (i) the need for women who have sex with women to undergo regular cancer and sexually transmitted infection screenings due to their comparable or elevated risk for these conditions; and (ii) the need for comprehensive screening for sexually transmitted diseases in men who have sex with men; and (iii) appropriate safe sex techniques to avoid the risk for sexually transmitted diseases.

3. Our AMA will continue to work alongside our partner organizations, including GLMA, to increase physician competency on LGBT health issues.

4. Our AMA will continue to explore opportunities to collaborate with other organizations, focusing on issues of mutual concern in order to provide the most comprehensive and up-to-date education and information to enable the provision of high quality and culturally competent care to LGBT people.


See also: HPV Vaccine and Cervical Cancer Prevention Worldwide H-440.872
WHEREAS, 71% of American teenagers use Facebook, 52% use Instagram, 41% use Snapchat, 24% of teens “go online almost constantly”, and 92% go online every day; 1

WHEREAS, 68% of all US adults use Facebook, with 76% of them saying they check it daily; 2

WHEREAS, Several recent studies indicate a link between increased use of social media and higher levels of anxiety and depression; 3,4,5,6

WHEREAS, The American Academy of Pediatrics recognizes depression that develops when preteens and teens spend a great deal of time on social media sites, and advises parents to talk to their children and adolescents about their online use; 7

WHEREAS, There are school-based mental health programs that have evidence of positive impact across a range of emotional and behavioral problems; however, there are few programs that address the association between social media usage and negative mental health sequelae; 8,9

Therefore be it

RESOLVED, That our American Medical Association collaborate with relevant professional organizations to (a) develop continuing education programs to enhance physicians’ knowledge of the health impacts of social media usage, and (b) develop effective clinical tools and protocols for the identification, treatment, and referral of children, adolescents, and adults at risk for and experiencing mental health sequelae of social media usage (Directive to Take Action); and be it further

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RESOLVED, That our AMA advocate for schools to provide safe and effective educational programs by which students can learn to identify and mitigate the onset of mental health sequelae of social media usage. (New HOD Policy)

Fiscal Note: Estimated cost to implement resolution is $375,000.

Received: 09/12/17

RELEVANT AMA POLICY

Reduction of Online Bullying H-515.959

Internet Pornography: Protecting Children and Youth Who Use the Internet and Social Media H-60.934

Bullying Behaviors Among Children and Adolescents H-60.943

Providing Medical Services through School-Based Health Programs H-60.991

Awareness, Diagnosis and Treatment of Depression and other Mental Illnesses H-345.984

Increasing Detection of Mental Illness and Encouraging Education D-345.994
Whereas, Neonatal Abstinence Syndrome (NAS) is defined as a group of health problems seen in newborns exposed to addictive opiate drugs in utero, including dependency of the newborn;

Whereas, The National Institute on Drug Abuse found that the average hospital stay for an infant born with NAS is 16.9 days as opposed to the 2.1 day average of non NAS infants, leading to an extra $1.5 billion in hospital expenses in the year 2012; which is a five-fold increase from 2000 to 2012; and

Whereas, Methadone and buprenorphine have been found to be effective and safe opioid maintenance therapies in pregnant and breastfeeding women; with negligible amounts of methadone transmission in breast milk, and not a large enough amount of buprenorphine transmitted via breast milk to produce acute adverse effects; and

Whereas, The benefits of breastfeeding with physician supervision has been found to supersede the risk of opioid exposure since it decreases the rate and severity of NAS in infants born to mothers undergoing opioid maintenance therapy; and is advised by The American Society of Addiction Medicine; and

Whereas, Seeking treatment for opioid addiction with the guidance of a physician is beneficial to newborn outcomes at any point during pregnancy and the AMA recognizes that breastfeeding is the optimal form of nutrition for breastfeeding infants (AMA Policy H-245.982); and

Whereas, Inadequate access to treatment for opioid addiction, limited options for medication-assisted programs during pregnancy and breastfeeding, lack of expertise among providers caring for opioid dependent pregnant and breastfeeding women and their opioid-exposed neonates, and insufficient resources to care for opioid-exposed neonates in low volume obstetric hospitals are challenges facing breastfeeding opioid dependent mothers, especially in rural and underserved communities; therefore be it

RESOLVED, That our American Medical Association’s Task Force to Reduce Opioid Abuse promote educational resources for opioid dependent mothers on the benefits and risks of breastfeeding while using opioid drugs or during maintenance therapy based on the most recent guidelines (New HOD Policy); and be it further

RESOLVED, That our AMA amend by addition existing AMA Policy H-420.962, “Perinatal Addiction - Issues in Care and Prevention,” to read as follows:

Perinatal Addiction - Issues in Care and Prevention H-420.962
Our AMA: (1) adopts the following statement: Transplacental drug transfer should not be subject to criminal sanctions or civil liability; (2) encourages the federal government to expand the proportion of funds allocated to drug treatment, prevention, and education. In particular, support is crucial for establishing and making broadly available specialized treatment programs for drug-addicted pregnant and breastfeeding women wherever possible; (3) urges the federal government to fund additional research to further knowledge about and effective treatment programs for drug-addicted pregnant and breastfeeding women, encourages also the support of research that provides long-term follow-up data on the developmental consequences of perinatal drug exposure, and identifies appropriate methodologies for early intervention with perinatally exposed children; (4) reaffirms the following statement: Pregnant and breastfeeding patients with substance use disorders should be provided with physician-led, team-based care that is evidence-based and offers the ancillary and supportive services that are necessary to support rehabilitation; and (5) through its communication vehicles, encourages all physicians to increase their knowledge regarding the effects of drug and alcohol use during pregnancy and breastfeeding and to routinely inquire about alcohol and drug use in the course of providing prenatal care. (Modify Current HOD Policy)

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

Received: 09/12/17

RELEVANT AMA POLICY

Perinatal Addiction- Issues in Care and Prevention H-420.962
Our AMA: (1) adopts the following statement: Transplacental drug transfer should not be subject to criminal sanctions or civil liability; (2) encourages the federal government to expand the proportion of funds allocated to drug treatment, prevention, and education. In particular, support is crucial for establishing and making broadly available specialized treatment programs for drug-addicted pregnant women wherever possible; (3) urges the federal government to fund additional research to further knowledge about and effective treatment programs for drug-addicted pregnant women, encourages also the support of research that provides long-term follow-up data on the developmental consequences of perinatal drug exposure, and identifies appropriate methodologies for early intervention with perinatally exposed children; (4) reaffirms the following statement: Pregnant and breastfeeding patients with substance use disorders should be provided with physician-led, team-based care that is evidence-based and offers the ancillary and supportive services that are necessary to support rehabilitation; and (5) through its communication vehicles, encourages all physicians to increase their knowledge regarding the effects of drug and alcohol use during pregnancy and breastfeeding and to routinely inquire about alcohol and drug use in the course of providing prenatal care. Citation: CSA Rep. G, A-92 Reaffirmation A-99 Reaffirmation A-09 Modified and Reaffirmed: CSAPH Rep. 1, A-09 Modified: Alt. Res. 507, A-16

See also: Education and Awareness of Opioid Pain Management Treatments, Including Responsible Use of Methadone D-120.985; Medical Direction of Methadone Treatment H-95.977; AMA Support for Breastfeeding H-245.982
Whereas, Over 420,000 children are within the foster care system according to the most recent data from the U.S. Department of Health & Human Services;¹ and

Whereas, A 2014 study indicates 48.3% of children within the foster care system experience four or more adverse family experiences, and these traumatic experiences lead to and include being removed from one’s home;² and

Whereas, Adults who had a history of being in the foster care system had significantly higher rates than the general population of post-traumatic stress disorder and toxic stress-related symptoms, such as attachment disorders, affect dysregulation, and behavior control issues;³,⁴ and

Whereas, Toxic stress and childhood trauma can impact a child’s immune system, neurodevelopment, and genome resulting in delays in cognitive, behavioral, and physical development, in addition to leading to poor health outcomes into adulthood, such as alcoholism, chronic obstructive pulmonary disease, depression, cancer, obesity, increase in suicide attempts, and ischemic heart disease;³,⁵,⁶,⁷,⁸ and

Whereas, Children within the foster system face unique legal and social barriers including limited healthcare records, difficulty in identifying who can consent to care for the child, court mandated treatments, and limited resources;⁹,¹⁰,¹¹,¹² and

Whereas, Screenings, such as the Ages and Stages Questionnaire, can double the detection rate of developmental delay and lead to earlier intervention among children in foster care.¹³ and

Whereas, The American Academy of Pediatrics identifies fifteen Models of Care which can be used for further creation of foster care clinics;\(^\text{14}\) and

Whereas, Existing foster care clinics, while limited in number, provide coordination of care, screenings regarding normal development, and transition support for the child and foster families;\(^\text{14,15}\) therefore be it

RESOLVED, That our American Medical Association advocate for comprehensive and evidence-based care that addresses the specific health care needs of foster care children. (New HOD Policy)

Fiscal Note: Minimal - less than $1,000.

Received: 09/20/17

**RELEVANT AMA POLICY**

**Child Protection Legislation H-60.948**  
**Promoting Physician Awareness of the Correlation Between Domestic Violence and Child Abuse D-515.982**

\(^{14}\) American Academy of Pediatrics. Healthy Foster Care America-Models of Care.  

Whereas, Studies have demonstrated that conventional and unconventional methods of oil extraction, including acidization, vertical and horizontal drilling, and drilling in urban areas releases volatile organic compounds and heavy metals into local communities, including but not limited to methanol, ozone, crystalline silica, methanol, hydrochloric acid, formaldehyde, hydrofluoric acid, naphthalene, xylene, and ethylbenzene;¹,² and

Whereas, Naphthalene, methanol, formaldehyde, hydrochloric acid and hydrofluoric acid are associated with damage to multiple organ systems, including but not limited to the skin, eyes, and lungs, ozone increases smog production and the incidence of asthma, and chronic exposure to crystalline silica causes lung and autoimmune diseases;³,⁴,⁵,⁶ and

Whereas, Urban oil wells, drilling and refining facilities are often located close to residences, schools, hospitals, and religious institutions, especially in low income communities and communities of color;⁷,⁸,⁹ and

Whereas, Proximity to oil and gas development activities has been associated with reproductive abnormalities including congenital heart abnormalities, premature birth, high risk pregnancies, and low birth weight;¹⁰,¹¹,¹² and

Whereas, Individuals within one kilometer (3,280 feet) of well stimulation or other urban oil and gas development activities demonstrate higher rates of self-reported skin and respiratory symptoms including asthma, headache, nausea, epistaxis, experience greater ambient noise levels, and have a higher incidence of leukemia and a higher hazard index for chronic disease;¹³,¹⁴,¹⁵,¹⁶ and

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⁵ McConnell, R. et al. Childhood Incident Asthma and Traffic-Related Air Pollution at Home and School. Environmental Health Perspectives; 2014, 118 (7): 1021–26
⁶ Bang, KM. et al. Silicosis mortality trends and new exposures to respirable crystalline silica—United States 2001-2010. CDC M&M Weekly Report; 2015, 64:5. Available at:
Whereas, Numerous states, cities, and towns have enacted buffer zones or setbacks ranging from 150 to 1,500 feet (45 to 407 meters) between well stimulation and sensitive public land uses, commissioned research into buffer zone distances, or banned drilling activities completely;¹⁷,¹⁸,¹⁹ therefore be it

RESOLVED, That our American Medical Association amend Policy H-135.949 by addition and deletion to read as follows:

**Support of Clean Air and Reduction in Power Plant Emissions H-135.949**

Our AMA supports (1) federal legislation and regulations that meaningfully reduce the following four major power plant emissions: mercury, carbon dioxide, sulfur dioxide and nitrogen oxide; and (2) efforts to limit carbon dioxide emissions through the reduction of the burning of coal in the nation's power generating plants, efforts to improve the efficiency of power plants, substitution of natural gas in lieu of other carbon-based fossil fuels, and continued development, promotion, and widespread implementation of alternative renewable energy sources in lieu of carbon-based fossil fuels. (Modify Current HOD Policy);

and be it further

RESOLVED, That our AMA support the implementation of buffer zones between oil and gas development sites and residences, schools, hospitals, and religious institutions. (New HOD Policy)

Fiscal Note: Minimal - less than $1,000.

Received: 09/20/17

RELEVANT AMA POLICY

Green Initiatives and the Health Care Community H-135.939

Our AMA supports: (1) responsible waste management policies, including the promotion of appropriate recycling and waste reduction; (2) the use of ecologically sustainable products, foods, and materials when possible; (3) the development of products that are non-toxic, sustainable, and ecologically sound; (4) building practices that help reduce resource utilization and contribute to a healthy environment; and (5) community-wide adoption of 'green' initiatives and activities by organizations, businesses, homes, schools, and government and health care entities. CSAPH Rep. 1, I-08 Reaffirmation A-09 Reaffirmed in lieu of Res. 402, A-10 Reaffirmed in lieu of: Res. 504, A-16

See also: Global Climate Change: The "Greenhouse Effect" (H-135.977); AMA Advocacy for Environmental Sustainability and Climate (H-135.923); Green Initiatives and the Health Care Community (H-135.939); The Health Risks of Hydraulic Fracturing (H-135.931); Environmental Health Programs (H-135.969); Stewardship of the Environment (H-135.973); Modern Chemicals Policies (H-135.942); Clean Air (H-135.991); Reducing Sources of Diesel Exhaust (D-135.996); The Need for Increased Research and Development in Nuclear Fusion to Reduce Environmental Pollution (H-460.956); Air Pollution and Public Health (H-135.941); Air Pollution and Public Health (D-135.985); Expense of Biohazardous Waste Removal (H-135.953); Pollution Control and Environmental Health (H-135.996); AMA Position on Air Pollution (H-135.998); Clean Air (H-135.979); Risks of Nuclear Energy and Low-Level Ionizing Radiation (H-455.994); Childhood Anaphylactic Reactions (D-60.976); Asthma Control (H-160.932); Protective NAAQS Standard for Fine Particulate Matter ((PM-2.5) (H-135.946)); Support the Health-Based Provisions of the Clean Air Act (H-135.950); Protective NAAQS Standard for Fine Particulate Matter ((PM-2.5) (D-135.983)); Protective NAAQS Standard for Particulate Matter ((PM 2.5 and PM 10) (D-135.978)); Support of Clean Air and Reduction in Power Plant Emissions (H-135.949); Federal Clean Air Legislation (H-135.984)

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¹⁷ McKenzie, LM. et al. Human health risk assessment of air emissions from development of unconventional natural gas


Whereas, The opioid epidemic continues to ravage most of the nation; and
Whereas, Deaths from opioid overdose are rising; and
Whereas, Fentanyl and carfentanil are increasingly mixed with the heroin being sold by drug dealers, with an associated increased risk of fatal overdose; and
Whereas, The use of fentanyl and carfentanil increases the likelihood that the overdose state will return after successful revival with the first dose of naloxone; and
Whereas, The average opioid-addicted individual relapses multiple times and often overdoses multiple times before successful sobriety; and
Whereas, Individuals who have undergone the training program as laypersons typically receive only one dose of intranasal naloxone; and
Whereas, As opioid use grows, there is an increasing risk of overdoses occurring in crowded public areas and events; therefore be it
RESOLVED, That our American Medical Association study the practicality and utility of Naloxone rescue stations (public availability of Naloxone through wall-mounted display/storage units that also include instructions). (Directive to Take Action)
Fiscal Note: Modest - between $1,000 - $5,000.
Received: 09/26/17
Whereas, At least one in seven women experience anxiety or depression during pregnancy or in the first year after birth, making mental health disorders the most common complication of pregnancy;¹ and

Whereas, Despite the prevalence of anxiety and depression during pregnancy, maternal depression remains highly underdiagnosed and undertreated, with only 15 percent of women seeking professional evaluation for depressive symptoms (compared with 26% in the general population);¹ and

Whereas, Growing evidence has demonstrated that maternal depression during the antenatal and postpartum periods increases the risk for many adverse outcomes among women and their children (including, poor cognitive outcomes in offspring and increased suicide rates among postpartum women);² ³, and

Whereas, There may be missed opportunities for screening women in an outpatient setting;⁴ ⁵, and

Whereas, The American Congress of Obstetricians and Gynecologists recommends women be screened at least once for depression during pregnancy and once during the postnatal period;⁴ ⁵ and

Whereas, The American Academy of Pediatrics (AAP) recommends pediatricians screen mothers for depression at well-baby visits during the first six months;⁴ ⁵ and

Whereas, The AAP also recommends postpartum depression screening of mothers with low acuity complaints presenting to a pediatric emergency department with their child;⁴ ⁵ and

Whereas, Many obstetricians or pediatricians, who are often at the frontline of diagnosis, lack training in responding to maternal mental-health concerns;⁴ ⁵ and

Whereas, A statewide program called Massachusetts Child Psychiatry Access Program (MCPAP) for Moms provides a full-time consulting care coordinator available for pediatricians or other providers seeking advice on the appropriate treatment of a depressed pregnant or breastfeeding woman; and

Whereas, Treatments through MCPAP can include consultation with a perinatal psychiatrist, individual or group therapy geographically convenient for patients, medications, home visits by a nurse or social worker, or simply a follow-up phone call; therefore be it RESOLVED, That our American Medical Association work with stakeholders to encourage the implementation of a routine protocol for depression screening in pregnant and postpartum women presenting alone or with their child during prenatal, postnatal, pediatric, or emergency room visits (Directive to Take Action); and be it further

RESOLVED, That our AMA encourage the development of training materials related to maternal depression to advise providers on appropriate treatment and referral pathways (Directive to Take Action); and be it further

RESOLVED, That our AMA encourage the development of state-based care coordination programs (e.g., staffing a psychiatrist and care coordinator) to assure appropriate referral, treatment and access to follow-up maternal mental health care. (Directive to Take Action)

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

Received: 09/28/17

RELEVANT AMA POLICY

Improving Mental Health Services for Pregnant and Postpartum Mothers H-420.953
Our AMA: (1) supports improvements in current mental health services for women during pregnancy and postpartum; (2) supports advocacy for inclusive insurance coverage of mental health services during gestation, and extension of postpartum mental health services coverage to one year postpartum; (3) supports appropriate organizations working to improve awareness and education among patients, families, and providers of the risks of mental illness during gestation and postpartum; and (4) will continue to advocate for funding programs that address perinatal and postpartum depression, anxiety and psychosis, and substance use disorder through research, public awareness, and support programs.
Citation: Res. 102, A-12; Modified: Res. 503, A-17

Access to Mental Health Services D-345.997
Our AMA will: (1) continue to work with relevant national medical specialty societies and other professional and patient advocacy groups to identify and eliminate barriers to access to treatment for mental illness, including barriers that disproportionately affect women and at-risk populations; (2) advocate that psychiatrists and other physicians who provide treatment for mental illness be paid by both private and public payers for the provision of evaluation and management services, for case management and coordination efforts, and for interpretive and indirect services; and (3) advocate that all insurance entities facilitate direct access to a psychiatrist in the referral process.
Citation: CMS Rep. 9, A-01; Reaffirmed: CMS Rep. 7, A-11; Reaffirmed in lieu of Res. 804, I-13; Reaffirmed in lieu of Res. 808, I-14; Modified: Res. 503, A-17

See also: Access to Mental Health Services H-345.981

Whereas, Pregnancy-related deaths doubled in the United States in the past 25 years;¹ and

Whereas, An estimated 700 women die of pregnancy-related causes each year in the US and another 65,000 have serious health complications; many of these deaths and complications can be prevented²; and

Whereas, Leading causes of maternal deaths include cardiovascular disease, cardiomyopathy, thromboembolism, obstetric hemorrhage, preeclampsia, sepsis, hypertension and obesity, and more recently, drug overdose and maternal suicide;³ and

Whereas, The US lags far behind all other industrialized countries and is the only high-resource country with a rising maternal mortality rate;⁴ and

Whereas, There are significant and widening disparities in maternal mortality and morbidity, disproportionately impacting black women in the US;⁵ and

Whereas, There is a need to redouble efforts to prevent maternal deaths and national initiatives are underway to mobilize clinical and public health resources to improve safety in obstetric care, including establishing and strengthening state Maternal Mortality Review Committees; and

Whereas, The Centers for Disease Control and Prevention and ACOG recommend that all states have an active Maternal Mortality Review Committee; and

Whereas, Maternal Mortality Review Committees conduct systematic, confidential analysis of the medical and non-medical circumstances of deaths that occur during pregnancy or up to one year after--for the purpose of taking action to reduce the risk of women dying from complications of pregnancy; and

Whereas, Maternal Mortality Review Committees make specific, data-driven recommendations, identifying gaps in services and systems to prevent future deaths and near-misses as well as strengths in the systems of care that should be supported or expanded; and

Whereas, Review Committees conduct their confidential interviews and analysis of birth and
death certificates, autopsy, hospital ER, medical transport, social services, and mental health
records and reports within a culture of promoting safety—not to assign blame; and

Whereas, Maternal health and mortality are important indicators of the quality of health care and
are at the core of what it means to have healthy, vibrant communities; therefore be it

RESOLVED, That our American Medical Association support the important work of maternal
mortality review committees (New HOD Policy); and be it further

RESOLVED, That our AMA support work with state and specialty medical societies to advocate
for state and federal legislation establishing Maternal Mortality Review Committees (New HOD
Policy); and be it further

RESOLVED, That our AMA support work with state and specialty medical societies to secure
funding from state and federal governments that fully supports the start-up and ongoing work of
state Maternal Mortality Review Committees. (New HOD Policy)

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

Received: 10/05/17
AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 912
(I-17)

Introduced by: American College of Chest Physicians (CHEST)
Oklahoma
American Thoracic Society

Subject: Corrective Statements Ordered to be Published by Tobacco Companies for the Violation of the Racketeer Influenced and Corrupt Organizations Act

Referred to: Reference Committee K
(L. Samuel Wann, MD, Chair)

Whereas, Smoking is the leading preventable cause of death, killing an estimated 480,000 persons in the United States and costing an estimated $325 billion in medical expenses and lost productivity each year; and

Whereas, If current trends continue, an estimated 5.6 million children in the United States alive today will ultimately die prematurely from smoking; and

Whereas, On August 17, 2006, a U.S. federal district court issued a 1,682 page final ruling in the case of United States v. Philip Morris concluding that Philip Morris, Altria, R.J. Reynolds, and other tobacco companies were in violation of the United States Racketeer Influenced and Corrupt Organizations (RICO) Act, noting that their goal has been “to make money with little, if any, regard for individual illness and suffering, soaring health costs, or the integrity of the legal system”; and

Whereas, To successfully prosecute defendants for a violation of the RICO Act, it must be proved that they have an ongoing pattern of criminal activity and the court found that “the evidence in this case clearly establishes that Defendants have not ceased engaging in unlawful activity...” and that “…their continuing conduct misleads consumers in order to maximize Defendants revenues by recruiting new smokers (the majority of whom are under the age of 18), preventing current smokers from quitting, and thereby sustaining the industry”; and

Whereas, The tobacco companies were ordered to publish “corrective statements” regarding “(a) the adverse health effects of smoking; (b) the addictiveness of smoking and nicotine; (c) the lack of any significant health benefit from smoking ‘low tar,’ ‘light,’ ‘ultralight,’ ‘mild,’ and ‘natural,’ cigarettes; (d) defendants’ manipulation of cigarette design and composition to ensure optimum nicotine delivery; and (e) the adverse health effects of exposure to secondhand smoke”; and

Whereas, On May 22, 2009, a three-judge panel of the U.S. Court of Appeals issued a unanimous opinion affirming many of the findings of the lower court and all 4,088 findings of fact outlined in the ruling; and

Whereas, On June 28, 2010, the U.S. Supreme Court refused to hear appeals in the RICO verdict against the tobacco companies, thereby allowing the racketeering verdict to stand; and

Whereas, On April 25, 2017, a three-judge panel of the U.S. Court of Appeals unanimously ordered that the tobacco companies publish corrective statements; and
Whereas, The corrective statements will finally be published, beginning in November, in major newspapers, advertised during primetime on such national television channels as NBC, CBS, ABC or other channels with comparable reach; printed on “onserts” affixed to cigarette packages, and placed on the tobacco companies’ websites; and

Whereas, In all 50 U.S. states, one or more of the tobacco companies found to be in violation of RICO have retained lobbyists to influence state lawmakers; and

Whereas, Public support is strong for lawmakers to reject potential tobacco industry influences, particularly meals, gifts, or campaign contributions from tobacco companies or their lobbyists; and

Whereas, A strong majority of Americans think lawmakers shouldn’t trust tobacco companies as much as they trust other companies and, further, that lawmakers shouldn’t trust tobacco company lobbyists to provide accurate information on tobacco issues; and

Whereas, When asked if a tobacco-related law was written or influenced by a tobacco company or a tobacco company lobbyist, very few Americans think lawmakers should “leave the law as it is” and a strong majority of Americans think lawmakers should either “revise the law” or “remove the law and start over”; and

Whereas, Internal tobacco industry documents reveal that that tobacco companies have written or heavily influenced tobacco-related public policies since at least 1967; and

Whereas, Interference by the tobacco industry in government policy-making is known to be an important reason for governments’ failure to adopt proven measures to reduce tobacco consumption; and

Whereas, There is strong public support for a wide range of public policies actively opposed by tobacco companies yet proven effective in reducing the harms of tobacco by preventing initiation of smoking among youth and/or encouraging cessation of smoking among current users; therefore be it

RESOLVED, That our American Medical Association collaborate with members, component societies, and other interested public health organizations such as the Campaign for Tobacco Free Kids, Truth Initiative, the American Cancer Society, the American Lung Association and the American Heart Association, to help educate the public and policymakers about the tobacco companies’ organized conspiracy to commit fraud leading to the federal court verdict finding them in violation of the Racketeer Influenced and Corrupt Organization Act (RICO) and resulting in the corrective statements as ordered by the U.S. Court of Appeals in United States vs. Philip Morris (Directive to Take Action); and be it further

RESOLVED, That our AMA encourage our component societies to work with appropriate public health organizations in their states to help identify public policies that may have been directly or indirectly influenced by tobacco companies or their lobbyists and encourage lawmakers to remediate all such influences, to reject any potential tobacco industry influences in the future, and to formally censure the tobacco companies for their fraudulent and harmful behavior. (New HOD Policy)

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

Received: 10/08/17
Whereas, Consistent increases in the life expectancy of the population of a country are  
expected and considered an indication of effective public health systems and health care and  
socio-economic well-being; and  

Whereas, Life expectancy for the U.S. population decreased by 0.1 year from 2014 (78.9 years)  
to 2015 (78.8 years), including a decrease of 0.2 years (76.5 years to 76.3 years) for males and  
a decrease of 0.1 years (81.3 years to 81.2 years) for females1; and  

Whereas, U.S. life expectancy is now lower than in most high-income countries and this gap is  
projected to increase2,3, and  

Whereas, Continuous decline in the age-adjusted death rate for the total population of a country  
is expected and considered a sign of public health progress, good health care, and socio-  
economic well-being; and  

Whereas, From 2014 to 2015, the age-adjusted death rate for the total population rose  
significantly for the first time since 1999, increasing by 1.2%, with age-adjusted death rate  
increases for non-Hispanic white males, non-Hispanic white females, and non-Hispanic black  
males1; and  

Whereas, Between 1999 and 2014, premature mortality increased in white individuals and in  
American Indians and Alaska Natives, and given that the magnitude of annual mortality  
increases in the USA is extremely unusual in high-income countries, a rapid public health  
response is needed to avert further premature deaths4; therefore be it  

RESOLVED, That our American Medical Association raise awareness of the recent reversals in  
the improvement of overall death rates and life expectancy with the message that these new  
problems in the United States are different from all other developed countries and that these  
trends need to be reversed promptly (Directive to Take Action); and be it further  

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1 CDC National Center for Health Statistics, Mortality in the United States, 2015.NCHS Data Brief No. 267, December 2016  
2 Kontis V, Bennett JE, Mathers CD, Li G, Foreman K, Ezzati M. Future life expectancy in 35 industrialized countries: projections  
3 Dowell D, Arias E, Kochanek K, Anderson R, Guy GP, Losby JL, Baldwin G. Contribution of opioid-involved poisoning to the  
4 Shiels MS, Chernyavskiy P, Anderson WF, Best AF, Haozous EA, et al. Trends in premature mortality in the USA by sex, race,  
10.1016/S0140-6736(17)30187-3.
RESOLVED, That our AMA call on the legislative and executive branches of the Federal
Government to fund and carry out investigations into the causes of these very unusual
decreases in life expectancy and increases in death rates in order to design multi-disciplinary
interventions to reverse these troubling changes (Directive to Take Action); and be it further

RESOLVED, That our AMA encourage state and local medical societies to raise awareness of
the new problems of decreasing life expectancy and increasing population death rates as
indicators of major public health problems and advocate for local investigation of the causes and
remedies for these disturbing problems. (New HOD Policy)

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

Received: 10/12/17
Whereas, A number of medical conditions have been associated with exposures to environmental chemicals in utero or during early development; and

Whereas, Differentiating likely causal connections from coincidental associations or confounders is complex and prone to misrepresentation; and

Whereas, Budgetary concerns threaten current and ongoing pediatric toxicological education and consultation services; and

Whereas, Socioeconomically disadvantaged and other susceptible populations are more likely to bear the health burden of many chemical exposures; therefore be it

RESOLVED, That our American Medical Association support the mission of and ongoing funding of academically-based regional Pediatric Environmental Health Specialty Units (PEHSU) by the Agency for Toxic Substances and Disease Registry of the Centers for Disease Control and Prevention (ATSDR/CDC) and the Environmental Protection Agency (EPA) (New HOD Policy); and be it further

RESOLVED, That our AMA support educational and consultative activities of the PEHSU program with local pediatricians, medical toxicologists, obstetricians, and others providing care to pregnant patients (New HOD Policy); and be it further

RESOLVED, That our AMA encourage the continuing training of physicians specializing in pediatric environmental health. (New HOD Policy)

Fiscal Note: Minimal - less than $1,000.

Received: 10/11/17
Whereas, Inequalities in determinants of health and health outcomes continue to exist, with the color of a patient’s skin determining, at least in part, the quality of their health care; and

Whereas, Some of these disparities are due to differential treatment and care by physicians; and

Whereas, An ever-increasing number of patients in the United States identify as a member of a minority group, including approximately 38% of the current population; and

Whereas, Recognition of implicit bias and training in diversity and inclusion may mitigate both intentional and unintentional disparities in the provision of care to minority patients; and

Whereas, Reducing disparities requires national leadership to coordinate thoughtful, intentional action by leaders at each medical school and residency training program; therefore be it

RESOLVED, That our American Medical Association: (1) actively support the development and implementation of training implicit bias, diversity and inclusion as a component of medical education in all medical schools and residency programs; (2) identify and publicize effective strategies for educating residents in all specialties about disparities in their fields according to race and ethnicity, with particular regard to access to care and health outcomes; and (3) support research to identify the most effective strategies for educating physicians on how to eliminate disparities in health outcomes according to race and ethnicity. (Directive to Take Action)

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

Received: 09/06/17

11. Our AMA will advocate for the tracking and reporting to interested stakeholders of demographic information on education.

10. Our AMA will recommend that medical school admissions committees use holistic assessments of admission applicants that take into account the diversity of preparation and the variety of talents that applicants bring to their work.

9. Our AMA will create and support pipeline programs and encourage support services for URM college students that will support them as they move through college, medical school and residency programs.

8. Our AMA will create and support programs that introduce elementary through high school students, especially those from groups that are underrepresented in medicine, to healthcare careers.

7. Our AMA will provide on-line educational materials for its membership that address diversity issues in patient care creating a diverse physician population.

6. Our AMA will develop an internal education program for its members on the issues and possibilities involved in compliance with its requirements for a diverse student body and faculty.

5. Our AMA will partner with key stakeholders (including but not limited to the Association of American Medical Colleges, Association of American Indian Physicians, Association of Native American Medical Students, We Are Healers, and the Indian Health Service) to study and report back by July 2018 on why enrollment in medical school for Native Americans is declining in spite of an overall substantial increase in medical school enrollment, and lastly to propose remedies to solve the problems identified in the AMA study.

4. Our AMA will encourage the Liaison Committee on Medical Education to assure that medical schools demonstrate compliance with its requirements for a diverse student body and faculty.

3. Our AMA will take a leadership role in efforts to enhance diversity in the physician workforce, including engaging in broad-based efforts that involve partners within and beyond the medical profession and medical education community.

2. Our AMA will work to obtain full restoration and protection of federal Title VII funding, and similar state funding programs, for the Centers of Excellence Program, Health Careers Opportunity Program, Area Health Education Centers, and other programs that support physician training, recruitment, and retention in geographically-underserved areas.

1. Our AMA, independently and in collaboration with other groups such as the Association of American Medical Colleges (AAMC), will actively work and advocate for funding at the federal and state levels and in the private sector to support the following: a. Pipeline programs to prepare and motivate members of underrepresented groups to enter medical school; b. Diversity or minority affairs offices at medical schools; c. Financial aid programs for students from groups that are underrepresented in medicine; and d. Financial support programs to recruit and develop faculty members from underrepresented groups.

RELEVANT AMA POLICY

Strategies for Enhancing Diversity in the Physician Workforce D-200.985

1. Our AMA, independently and in collaboration with other groups such as the Association of American Medical Colleges (AAMC), will actively work and advocate for funding at the federal and state levels and in the private sector to support the following: a. Pipeline programs to prepare and motivate members of underrepresented groups to enter medical school; b. Diversity or minority affairs offices at medical schools; c. Financial aid programs for students from groups that are underrepresented in medicine; and d. Financial support programs to recruit and develop faculty members from underrepresented groups.

2. Our AMA will work to obtain full restoration and protection of federal Title VII funding, and similar state funding programs, for the Centers of Excellence Program, Health Careers Opportunity Program, Area Health Education Centers, and other programs that support physician training, recruitment, and retention in geographically-underserved areas.

3. Our AMA will take a leadership role in efforts to enhance diversity in the physician workforce, including engaging in broad-based efforts that involve partners within and beyond the medical profession and medical education community.

4. Our AMA will encourage the Liaison Committee on Medical Education to assure that medical schools demonstrate compliance with its requirements for a diverse student body and faculty.

5. Our AMA will partner with key stakeholders (including but not limited to the Association of American Medical Colleges, Association of American Indian Physicians, Association of Native American Medical Students, We Are Healers, and the Indian Health Service) to study and report back by July 2018 on why enrollment in medical school for Native Americans is declining in spite of an overall substantial increase in medical school enrollment, and lastly to propose remedies to solve the problems identified in the AMA study.

6. Our AMA will develop an internal education program for its members on the issues and possibilities involved in creating a diverse physician population.

7. Our AMA will provide on-line educational materials for its membership that address diversity issues in patient care including, but not limited to, culture, religion, race and ethnicity.

8. Our AMA will create and support programs that introduce elementary through high school students, especially those from groups that are underrepresented in medicine (URM), to healthcare careers.

9. Our AMA will create and support pipeline programs and encourage support services for URM college students that will support them as they move through college, medical school and residency programs.

10. Our AMA will recommend that medical school admissions committees use holistic assessments of admission applicants that take into account the diversity of preparation and the variety of talents that applicants bring to their education.

11. Our AMA will advocate for the tracking and reporting to interested stakeholders of demographic information pertaining to URM status collected from Electronic Residency Application Service (ERAS) applications through the National Resident Matching Program (NRMP).

12. Our AMA will continue the research, advocacy, collaborative partnerships and other work that was initiated by the Commission to End Health Care Disparities.

See also: Reducing Racial and Ethnic Disparities in Health Care D-350.995, Diversity in the Physician Workforce and Access to Care D-200.982
AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 953
(I-17)

Introduced by: Virginia

Subject: Fees for Taking Maintenance of Certification Examination

Referred to: Reference Committee K
(L. Samuel Wann, MD, Chair)

Whereas, The process of board certification has a central role in self-regulation of physician quality standards; and
Whereas, Each specialty has established non-profit organizations to administer this required evaluation to obtain and maintain board certification; and
Whereas, These organizations charge fees for the examination process that averages $110.00/year for family medicine to $610.00 per year for colon-rectal surgery; and
Whereas, The physicians taking the examination incur other costs such as review courses, travel expenses, and lost wages from their current practice; and
Whereas, Physician reimbursement has declined for many and further complicates the process involved in the cost of taking the exam; and
Whereas, The cumulative net assets of the various certifying organizations as stated in the reference below, is excessive and totals more than 584 million dollars (JAMA, August 1, 2017, Volume 318, #5: pages 477-479); therefore be it
RESOLVED, That our American Medical Association request reductions in Maintenance of Certification examination fees so as to work towards a balanced/neutral budget of ABMS medical boards given their status as non-profit organizations. (Directive to Take Action)

Fiscal Note: Minimal - less than $1,000.

Received: 09/18/17

The topic of this resolution is currently under study by the Council on Medical Education
WHEREAS, Approximately 70% of the determinants of health status can be traced to environmental, preventive and life-style factors that are influenced by both primary care - patient and public health - community interventions of physicians; and

WHEREAS, There is a shortage of expertise in both such specialties, especially in rural communities; and

WHEREAS, Although many primary care physicians serve as “health officers”, other non-physician (even non-health professional) individuals with limited public health knowledge and skills lead the public health community effort in most rural communities; and

WHEREAS, Many primary care physicians have expressed a desire to greatly expand their public health/population health capacities, competencies and community leadership involvement but are not in a position to leave their practices for long periods to obtain board eligibility in preventive medicine and public health; and

WHEREAS, Many of these physicians have expressed a willingness to obtain the requisite public health board competencies through alternate “experiential” preceptorships, short didactic courses and other arrangements, while still maintaining the integrity of their practice; and

WHEREAS, The development of such expertise would greatly improve public health leadership, competencies and performance in such communities while, also, increasing physician presence and influence in overall community health policy and activities; therefore be it

RESOLVED, That our American Medical Association study, with the participation of the appropriate educational and certifying entities, innovative approaches that could be developed and/or implemented to promote interested physicians to obtain board eligibility in preventive medicine/public health to strengthen public health leadership, especially in rural communities.

(Directive to Take Action)

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

Received: 09/01/17
Whereas, The current Electronic Residency Application Service (ERAS) Residency Application should conform to the requirements of the U.S. Equal Employment Opportunity Commission (EEOC) by blinding the ERAS Residency Application to the “applicant’s age, race, religion, national origin”;¹ and

Whereas, The ERAS Residency Application has non-academic identifiers (including a picture) that may identify or suggest age, race, religion, and/or national origin, placed at the beginning of the application which may contribute to bias including, but not limited to, the priming effect;²⁻⁶ and

Whereas, Conscious and unconscious bias, that may influence the selection of a resident, may be associated with many identifiers revealed at the beginning of the ERAS Residency Application including, but not limited to, age, race, religion, national origin, weight, gender, sexual orientation, transgender status, and attractiveness;⁷⁻¹⁰ and

Whereas, Bias has been associated with school admissions and hiring;⁶,¹⁰ and

Whereas, This bias should be minimized to ensure fairness in residency trainee selection; therefore be it

RESOLVED, That our American Medical Association advocate for the formation of an Electronic Residency Application Service (ERAS) Residency Application Bias Minimization Committee to examine the role of bias in the residency training selection process¹¹ (Directive to Take Action); and be it further

RESOLVED, That our AMA advocate for the modification of the ERAS Residency Application to minimize its bias in accordance with the suggestions of the ERAS Residency Application Bias Minimization Committee. (Directive to Take Action)

Fiscal Note: Minimal - less than $1,000.

Received: 09/22/17
References:

RELEVANT AMA POLICY

Gender-Based Questioning in Residency Interviews H-310.976
The AMA (1) opposes gender-based questioning during residency interviews in both public and private institutions for the purpose of sexual discrimination; (2) supports inclusion in the AMA Fellowship and Residency Interactive Database Access (FREIDA) system information on residency Family and Medical Leave policies; and (3) supports monitoring the Accreditation Council for Graduate Medical Education as it proposes changes to the "Common Requirements" and the "Institutional Requirements" of the "Essentials of Accredited Residencies," to ensure that there is no gender-based bias.

Eliminating Questions Regarding Marital Status, Dependents, Plans for Marriage or Children, Sexual Orientation, Gender Identity, Age, Race, National Origin and Religion During the Residency and Fellowship Application Process H-310.919
Our AMA:
1. opposes questioning residency or fellowship applicants regarding marital status, dependents, plans for marriage or children, sexual orientation, gender identity, age, race, national origin, and religion.
2. will work with the Accreditation Council for Graduate Medical Education, the National Residency Matching Program, and other interested parties to eliminate questioning about or discrimination based on marital and dependent status, future plans for marriage or children, sexual orientation, age, race, national origin, and religion during the residency and fellowship application process.
3. will continue to support efforts to enhance racial and ethnic diversity in medicine. Information regarding race and ethnicity may be voluntarily provided by residency and fellowship applicants.
Res. 307, A-09

Oppose Discrimination in Residency Selection Based on International Medical Graduate Status D-255.982
Our AMA:
1. Will request that the Accreditation Council for Graduate Medical Education include in the Institutional Requirements a requirement that will prohibit a program or an institution from having a blanket policy to not interview, rank or accept international medical graduate applicants.
2. Recognizes that the assessment of the individual international medical graduate residency and fellowship applicant should be based on his/her education and experience.
3. Will disseminate this new policy on opposition to discrimination in residency selection based on international medical graduate status to the graduate medical education community through AMA mechanisms.
Sub. Res. 305, A-08 Reaffirmation I-11

See also: Eliminating Religious Discrimination from Residency Programs H-310.923
WHEREAS, In order to practice clinical medicine in an unsupervised setting, all physicians (international medical graduates and domestic graduates) must be licensed by the medical licensing board of the state where they plan to practice; and

WHEREAS, International medical graduates (IMGs) must be certified by the Educational Commission for Foreign Medical Graduates (ECFMG) and must pass USMLE Steps 1, Step 2 CK and Step 2 CS; and

WHEREAS, When a physician receives ECFMG certification, he/she may apply for an ACGME accredited residency; and

WHEREAS, Many ECFMG-certified IMGs are waiting to get into a residency program, but are unable to obtain a residency due to the limited number of residency slots available; and

WHEREAS, A significant shortage of primary care physicians is predicted ranging between 8,700 and 43,100 physicians by 2030;¹ which will further impact the availability of physicians and health care providers to care for patients in underserved areas of the United States;² and

WHEREAS, The Florida State Medical Board has implemented policies and laws to allow hospitals to employ physicians who have limited medical licenses as “house physicians” to work under the direct supervision of a physician who has an active Florida medical license and provide care to patients³; therefore be it

RESOLVED, That our American Medical Association work with state legislators and other regulatory organizations to develop the category of “House Physicians” to help address the anticipated physician need and shortfall of available practitioners in underserved areas of the United States. (Directive to Take Action)

Fiscal Note: Minimal - less than $1,000.

Received: 09/22/17

References:
Whereas, Current Accreditation Council for Graduate Medical Education (ACGME) guidelines state that accredited obstetrics and gynecology (OB-GYN) residencies are required to provide access to abortion training in their curriculum, which the American Congress of Obstetricians and Gynecologists (ACOG) recognizes is a necessary component of women’s health care; and

Whereas, ACGME requires that all programs be held to the same high standards; however, ACOG reports that programs differ widely in scope and types of training offered; and

Whereas, There are many institutional barriers to medical education surrounding abortion, including legislative, societal, and monetary, all of which contribute to the limited access to family planning training opportunities; and

Whereas, Many institutions do not provide equal access to abortion training during OB-GYN residency training, only 54 percent of OB-GYN residents from 161 programs noted routine integrated abortion training, and 16 percent reported that elective training was not available; and

Whereas, In a 10-year study of Ryan Residency programs--which offer enhanced, integrated family planning education in OB-GYN residencies--there was a demonstrated 97 percent improved competency in abortion and contraceptive care, but they only make up 32 percent of all US OB-GYN residency programs; and

Whereas, Offering comprehensive, integrated training in abortion and family planning has shown to improve residents’ competency and proficiency in abortion, counseling, miscarriage management, and other reproductive care; and

Whereas, ACOG supports expansion of abortion training, and the improvement and integration of abortion education throughout all levels of medical education; and

Whereas, AMA policy supports the opportunity for residents to learn or opt-out of pregnancy termination procedures and opposes program measures aimed to interfere with or restrict the availability of this training; and

Whereas, AMA policy maintains that basic skills and competencies be determined solely by the medical profession; therefore be it
RESOLVED, That our American Medical Association encourage the Accreditation Council for Graduate Medical Education to better enforce compliance with the standardization of abortion training opportunities as per the American Congress of Obstetricians and Gynecologists’ recommendations. (Directive to Take Action)

Fiscal Note: Minimal - less than $1,000.

Received: 09/29/17

RELEVANT AMA POLICY

Medical Training and Termination of Pregnancy H-295.923
The AMA supports the education of medical students, residents and young physicians about the need for physicians who provide termination of pregnancy services, the medical and public health importance of access to safe termination of pregnancy, and the medical, ethical, legal and psychological principles associated with termination of pregnancy, although observation of, attendance at, or any direct or indirect participation in an abortion should not be required. Further, the AMA supports the opportunity for residents to learn procedures for termination of pregnancy and opposes efforts to interfere with or restrict the availability of this training.

Residency Program Responsibility for Resident Education H-295.915
The AMA affirms that the basic skills and competencies for the practice of medicine and its specialties must be determined solely by the medical profession.
Citation: Res. 313, A-96; Reaffirmed: CME Rep. 2, A-06; Reaffirmed: CME Rep. 01, A-16;

1 Accreditation Council for Graduate Medical Education. “ACGME program requirements for graduate medical education in obstetrics and gynecology.” (2013).
Whereas, The cellular biology, gene expression, and hormonal profile differs between sexes and genders, and influence the clinical presentation, progression, and outcome for a variety of diseases; and

Whereas, The Institute of Medicine supports the advent and implementation of sex and gender based medicine in daily practice of patient care due to its multifactorial impact on overall patient health and disease prognosis; and

Whereas, Sex and gender based medical education is a critical component in the pursuit of more personalized medicine; and

Whereas, The majority of current educational materials used in medical education have a gender-bias toward male patients, and educators must make the conscious decision to offer learning materials and teaching that is sex and gender based; and

Whereas, There are demonstrated sex and gender differences in drug responses to therapeutic doses due to variations in gene expression leading to increases in adverse effects disproportionately in the female sex; and

Whereas, Sex and gender-based medicine (SGBM) may not currently be addressed in undergraduate or graduate medical education, and medical students and residents may not fully understand the impact of these differences on patient care; and

Whereas, A recent study shows 96 percent of medical students are aware of differences in SGBM, and 94.2 percent believe including it in the curriculum improves their ability to care for future patients; and

Whereas, Some schools have already adapted their curriculum to include SGBM through integration into existing educational resources, including clinical cases and learning modules; and

Whereas, Over twenty national and international organizations and schools are already addressing sex and gender implications in medical education and continuing medical education curricula; and

Whereas, The AMA has recently expanded the definition of women’s health to be inclusive of all health conditions for which there is evidence that women’s risks, presentations, and/or responses to treatment are different from those of men, and encouraged physicians to use this in their training; and
Whereas, The AMA has previously resolved to encourage the research of sex and gender differences in medicine, and recommends that medical/scientific journals require sex based analysis of data when appropriate; therefore be it

RESOLVED, That our American Medical Association ask the AMA Council on Medical Education and Academic Physician Section to encourage the Accreditation Council for Graduate Medical Education, Liaison Committee on Medical Education, Commission on Osteopathic Accreditation, Association of American Medical Colleges, and Accreditation Council for Continuing Medical Education to assure the inclusion of sex and gender based medicine in medical education programs across the spectrum of learners nationwide. (Directive to Take Action)

Fiscal Note: Minimal - less than $1,000.

Received: 09/29/17

RELEVANT AMA POLICY

An Expanded Definition of Women’s Health H-525.976,
Our AMA recognizes the term "women's health" as inclusive of all health conditions for which there is evidence that women's risks, presentations, and/or responses to treatments are different from those of men, and encourages that evidence-based information regarding the impact of sex and gender be incorporated into medical practice, research, and training.

Citation: CSAPH Rep. 05, A-16;

See also: Medical Education and Training in Women's Health H-295.890, Sex and Gender Differences in Medical Research H-525.988

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11. Sex and Gender Women's Health Collaborative – Collaborators (http://sgwhc.org/participate/collaborators/#tslash.kkbSvcku.dbps)
Whereas, Four healthy lifestyle factors--never smoking, maintaining a healthy weight, exercising regularly, and following a healthy diet--together appear to be associated with as much as an 80 percent reduction in the risk of developing the most common and deadly chronic diseases, such as cardiovascular disease, cancer, and diabetes; and

Whereas, The Bipartisan Policy Center has called for improving medical education and training in “topics such as nutrition and physical activity that have an important role to play in the prevention and treatment of obesity and chronic diseases,” since “these topics have traditionally received little attention in formal medical school curricula”; and

Whereas, Many physicians and other healthcare providers are not adequately trained in nutrition and physical activity and other lifestyle components in a way that could mitigate disease development and progression; and

Whereas, In a report from 2010, only 25% of medical schools surveyed required a dedicated nutrition course (down from 30% in 2004) and only 27% of schools surveyed met the minimum 25 required hours of nutrition instruction set by the National Academy of Sciences (down from 38% in 2004); and

Whereas, Patients advised to quit smoking by their physicians are 1.6 times more likely to quit than patients not receiving physician advice; however, most smokers do not receive this advice when visiting their physicians; and

Whereas, Just 34% of U.S. adults reported exercise counseling at their last medical visit; and

Whereas, In a study of internal medicine physicians, less than half reported confidence in knowledge of local exercise facilities, American College of Sports Medicine (ACSM) guidelines, and behavior modification techniques; therefore be it

RESOLVED, That our American Medical Association support legislation that incentivizes and/or provides funding for the inclusion of lifestyle medicine education in medical school education, graduate medical education, and continuing medical education, including but not limited to education in nutrition, physical activity, behavior change, sleep health, tobacco cessation, alcohol use reduction, emotional wellness, and stress reduction. (New HOD Policy)
Fiscal Note: Minimal - less than $1,000.

Received: 10/12/17

RELEVANT AMA POLICY

Healthy Lifestyles H-425.972
Our AMA: (1) recognizes the 15 competencies of lifestyle medicine as defined by a blue ribbon panel of experts convened in 2009 whose consensus statement was published in the Journal of the American Medical Association in 2010; (2) will urge physicians to acquire and apply the 15 clinical competencies of lifestyle medicine, and offer evidence-based lifestyle interventions as the first and primary mode of preventing and, when appropriate, treating chronic disease within clinical medicine; and (3) will work with appropriate federal agencies, medical specialty societies, and public health organizations to educate and assist physicians to routinely address physical activity and nutrition, tobacco cessation and other lifestyle factors with their patients as the primary strategy for chronic disease prevention and management.

Citation: Res. 423, A-12

E-8.11 Health Promotion and Preventive Care

Medicine and public health share an ethical foundation stemming from the essential and direct role that health plays in human flourishing. While a physicians role tends to focus on diagnosing and treating illness once it occurs, physicians also have a professional commitment to prevent disease and promote health and well-being for their patients and the community. The clinical encounter provides an opportunity for the physician to engage the patient in the process of health promotion. Effective elements of this process may include educating and motivating patients regarding healthy lifestyle, helping patients by assessing their needs, preferences, and readiness for change and recommending appropriate preventive care measures. Implementing effective health promotion practices is consistent with physicians duties to patients and also with their responsibilities as stewards of health care resources. While primary care physicians are typically the patients main source for health promotion and disease prevention, specialists can play an important role, particularly when the specialist has a close or long-standing relationship with the patient or when recommended action is particularly relevant for the condition that the specialist is treating. Additionally, while all physicians must balance a commitment to individual patients with the health of the public, physicians who work solely or primarily in a public health capacity should uphold accepted standards of medical professionalism by implementing policies that appropriately balance individual liberties with the social goals of public health policies.

Health promotion should be a collaborative, patient-centered process that promotes trust and recognizes patients self-directed roles and responsibilities in maintaining health. In keeping with their professional commitment to the health of patients and the public, physicians should:

(a) Keep current with preventive care guidelines that apply to their patients and ensure that the interventions they recommend are well supported by the best available evidence.
(b) Educate patients about relevant modifiable risk factors.
(c) Recommend and encourage patients to have appropriate vaccinations and screenings.
(d) Encourage an open dialogue regarding circumstances that may make it difficult to manage chronic conditions or maintain a healthy lifestyle, such as transportation, work and home environments, and social support systems.
(e) Collaborate with the patient to develop recommendations that are most likely to be effective.
(f) When appropriate, delegate health promotion activities to other professionals or other resources available in the community who can help counsel and educate patients.
(g) Consider the health of the community when treating their own patients and identify and notify public health authorities if and when they notice patterns in patient health that may indicate a health risk for others.
(h) Recognize that modeling health behaviors can help patients make changes in their own lives.

Collectively, physicians should:

(i) Promote training in health promotion and disease prevention during medical school, residency and in continuing medical education.
(j) Advocate for healthier schools, workplaces and communities.
(k) Create or promote healthier work and training environments for physicians.
(l) Advocate for community resources designed to promote health and provide access to preventive services.
(m) Support research to improve the evidence for disease prevention and health promotion.
Not for consideration

Resolutions not for consideration

212  Physician Identification
602  Creation of LGBTQ Health Specialty Section Council
603  A Guide for Best Health Practices for Seniors Living in Retirement Communities
951  Financial Protections for Doctors in Training
Whereas, Health care facilities are inundated with personnel wearing white coats, scrubs or stethoscopes; and

Whereas, It can be difficult for our patients to distinguish physicians and nurses from other health facility personnel; and

Whereas, Because professional abbreviations are increasingly complex and confusing, they should not be used on health professional ID tags; therefore, be it

RESOLVED, That our American Medical Association adopt nationally standardized whole word labels to be used on health professional and health worker ID tags. (New HOD Policy)

Fiscal Note: Minimal - less than $1,000.

Received: 09/26/17
AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 602
(I-17)

Introduced by: GLMA

Subject: Creation of LGBTQ Health Specialty Section Council

Referred to: Reference Committee F
(Julia V. Johnson, MD, Chair)

Whereas, The AMA House of Delegates (HOD) allows for the creation of Specialty Section Councils composed of member organizations with common medical interests or specialty training (B-9.1); and

Whereas, The AMA HOD currently recognizes thirty-one (31) Specialty Section Councils within the House of Delegates (B-14.0.1); and

Whereas, LGBTQ Health has become a fully acknowledged subspecialty of medical practice, spanning a range of medical specialties including, but not limited to, internal medicine, pediatrics, geriatrics, obstetrics and gynecology, endocrinology, plastic surgery; and

Whereas, The study and practice of LGBTQ Health as a recognized subspecialty is vital due to the presence of well-established medical disparities that affect this population; and

Whereas, The AMA Foundation, recognizing the importance of LGBTQ specific medical training, has chosen to utilize the LGBT Honor Fund to establish the creation of subspecialty fellowship training programs in LGBTQ Health; therefore be it

RESOLVED, That our American Medical Association House of Delegates establish a Specialty Section Council on LGBTQ Health. (Directive to Take Action)

Fiscal Note: No significant fiscal impact.

Received: 09/28/17

RELEVANT AMA POLICY

B-9.1 Purpose.

9.1.1 Specialty Section Councils shall be established by the House of Delegates. Specialty Section Councils shall provide for deliberation and study of scientific educational and other appropriate interests and concerns of the specialty disciplines and the specialty societies representing these disciplines within the AMA.

9.1.2 The Section Council shall, on request, submit to the Board of Trustees nominations for AMA representatives to serve on approved Specialty Certifying Boards.
B-9.2 Composition.
9.2.1 National medical specialty societies represented in the House of Delegates may appoint representatives to the Specialty Section Councils for the medical specialty in which the specialty society participates. Such representatives must be members of the AMA.
9.2.2 Upon recommendation of the Specialty Section Council and approval of the Board of Trustees, national medical specialty societies that are not represented in the House of Delegates may appoint representatives to the Specialty Section Council for the medical specialty in which the specialty society participates. Such representatives must be members of the AMA.

B-9.3 Specialty Society Delegate.
The AMA delegate(s) and alternate delegate(s) from each national medical specialty society represented in the House of Delegates shall also serve in the Specialty Section Council of their respective specialty.

B-9.4 Chair and Vice Chair.
Each Specialty Section Council shall elect a Chair and Vice Chair from within its membership.

B-14.0.1 Glossary of Terms.
Section Council - Specialty Section Councils have been recognized by the House of Delegates for the following specialties: Allergy; Anesthesiology; Cardiovascular Disease; Clinical Pharmacology and Therapeutics; Dermatology; Digestive Diseases; Disease of the Chest; Emergency Medicine; Endocrinology; Family and General Practice; Federal and Military Medicine; General Surgery; Genetics; Internal Medicine; Neurological Surgery; Neurology; Nuclear Medicine; Obstetrics and Gynecology; Ophthalmology; Orthopedic Surgery; Otolaryngology-Head and Neck Surgery; Pain and Palliative Medicine; Pathology; Pediatrics; Physical Medicine and Rehabilitation; Plastic, Reconstructive and Maxillofacial Surgery; Preventive Medicine; Psychiatry; Radiology; and Urology.
Whereas, The AMA-Senior Physicians Section mission is to engage physicians age 65 and above, both active and retired, to promote policies, products and services relevant to senior physicians; and

Whereas, The number of seniors in the United States is growing exponentially, with currently 46 million people age 65 or older with the number expected to grow to 73 million in the next 15 years\(^1\); and

Whereas, The “Baby Boomer” generation (generally accepted as birth dates between 1946 to 1964) is 74.9 million\(^2\); and

Whereas, Large numbers of these groups live independently in retirement communities not subject to any state or federal regulations as are required for assisted living, extended care and nursing homes; and

Whereas, AARP has published its second edition of “Where We Live: Communities for All Ages” with a focus on communities in the forefront in addressing the needs of an aging population\(^3\); and

Whereas, Many senior physicians live in such communities and could be a resource for their communities in matters of health and wellness, enhancing the health of the community’s residents, were there a template of suggestions to guide their efforts; and

Whereas, Although there are guidelines for immunizations from the CDC and publications touting the validity of exercise programs for the elderly, they are not cohesive and in “one place;” and

Whereas, There are no guidelines for independent living communities (on activities) that could prevent communicable diseases or even save lives (e.g. alcohol/soap hand dispensers in communal areas, maintenance suggestions for decorative fountains and cooling towers, placement of AEDs [AEDs — automated external defibrillators — can be found in almost every school building and airport but how many are in senior living facilities?]); and

Whereas, Senior citizens have special needs that may include safety features (e.g. wider doorways, absence of area rugs, leveling of doorsills), accommodations for disabilities, improved bathroom accessibility and enhanced lighting; therefore be it

RESOLVED, That our American Medical Association, including other interested parties such as the public health community, geriatric specialties, and AARP, study the development of a document that could guide best health practices for the senior independent living community.

(Directive to Take Action)

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

Received: 09/29/17
Whereas, The AMA has guidelines that expect all institutions to provide retirement benefits; and

Whereas, With resident and fellowship matching, physicians do not have choice in the benefit package causing differences in retirement outcomes; and

Whereas, Physicians should be saving 15% of their funding towards retirements, but studies have shown that physicians have not been saving enough due to multiple reason including significant student debt, delayed start in professional life, and decreased financial literacy; and

Whereas, Evidence has shown that employers who match retirement savings, result in employees saving significantly more annual for retirement; therefore be it

RESOLVED, That our American Medical Association support retirement plans for all residents and fellows, which includes retirement plan matching in order to further secure the financial stability of physicians and increase financial literacy during training (New HOD Policy); and be it further

RESOLVED, That our AMA support that all programs provide financial advising to resident and fellows. (New HOD Policy)

Fiscal Note: Minimal - less than $1,000.

Received: 09/06/17

References:
3 https://www.mededpub.com/manuscripts/847/v1
4 http://www.plansponsor.com/Employer_Contributions_Important_to_Employee_Retirement_Savings.aspx
Informational Reports

BOT Report(s)
01 Redefining AMA's Position on ACA and Healthcare Reform
02 2017 AMA Advocacy Efforts
03 Removing Restrictions on Federal Funding for Firearms Violence Research
04 Limitations on Reports by Insurance Carriers to the National Practitioner Data Bank Unrelated to Patient Care
08 2018 Strategic Plan
09 Parental Leave
11* Anti-Harassment Policy

CEJA Opinion(s)
01 Amendment to E-2.3.2, "Professionalism in Social Media"

CME Report(s)
02 A National Continuing Medical Education Repository
03* Impact of Immigration Barriers on the Nation's Health

Report of the Speakers
01 Recommendations for Policy Reconciliation

* included in the Handbook Addendum
REPORT OF THE BOARD OF TRUSTEES

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. BOT 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.

EFFORTS TO REPEAL THE ACA

Efforts to repeal and replace the ACA have consumed the vast majority of health system reform efforts of the 115th Congress and, to date, have been largely unsuccessful. The AMA engaged directly with members of Congress in an effort to shape the outcome of the discussion along the lines of specified principles set forth in AMA policy and approved by the HOD. These were that any legislation should:

- Ensure that individuals currently covered do not become uninsured and take steps toward coverage and access for all Americans;
- Maintain key insurance market reforms, such as pre-existing conditions, guaranteed issue and parental coverage for young adults;
- Stabilize and strengthen the individual insurance market;
- Ensure that low/moderate income patients are able to secure affordable and meaningful coverage;
- Ensure that Medicaid, CHIP and other safety net programs are adequately funded;
- Reduce regulatory burdens that detract from patient care and increase costs;
- Provide greater cost transparency throughout the health care system;
- Incorporate common sense medical liability reforms; and
- Continue the advancement of delivery reforms and new physician-led payment models to achieve better outcomes, higher quality and lower spending trends.

A number of factors played into the inability of Congress to advance repeal of the ACA, including the decision to act under the limitations imposed by the budget reconciliation process and efforts to go beyond ACA reform to include significantly restructuring the financing of the Medicaid program without hearings or stakeholder input. Ideological differences among Republican members of Congress and discomfort with projections of significant increases in the number of Americans without health insurance as a result of Congressional action further compromised any pathway to repeal.
The “American Health Care Act” (AHCA) was reported by the House Budget committee on March 20, 2017 and considered by the House of Representatives on March 24. As considered by the House, the bill made numerous changes to the Medicaid program, most significantly eliminating federal funding for ACA Medicaid expansion populations and converting Medicaid financing into a per-capita allotment. The AHCA effectively eliminated the individual and employer mandates established by the ACA and replaced the current premium assistance tax credit for purchasing health coverage which was based on age, income and the affordability of coverage with an advanceable, refundable credit based primarily on age and phasing out for individuals with higher incomes. Actuarial requirements for plans were eliminated and the permissible variation of premiums by age was increased from 3:1 to 5:1. To compensate for the greater instability in the individual market caused by the elimination of penalties for failure to maintain coverage and other changes, the bill established a Patient and State Stability Fund and required insurers to charge a 30 percent premium surcharge to individuals who failed to maintain coverage for more than 62 days during the previous year. The Congressional Budget Office (CBO) estimated that the bill would result in 14 million fewer Americans with health insurance coverage in 2018, increasing to 26 million by 2026. It would also reduce federal Medicaid expenditures by more than $800 billion over the next decade. Lacking the necessary support, House leadership pulled the bill from consideration prior to a vote.

On May 4, 2017, the House considered a revised version of the AHCA, incorporating amendments by both conservative and moderate members of the House Republican Conference, including: allowing the establishment of Medicaid work requirements; allowing a state to receive Medicaid funding as a block grant; increased funding for maternity coverage, newborn care, and services for those with mental health or substance use disorders; establishment of a risk sharing program for insurers; increased stability funding; state waiver of essential health benefits; and allowing insurers to vary premiums by health status for individuals who had a break in coverage. The modified legislation, considered prior to the availability of a CBO score, was passed by a vote of 217-213. On May 24, the CBO estimated that the House-passed bill would result in 14 million fewer Americans with health insurance coverage in 2018 and 23 million fewer in 2026 while reducing federal Medicaid expenditures by more than $800 billion.

Lacking Senate support for the House-passed AHCA, Senate Republican leadership undertook the drafting of revised legislation. A discussion draft, the “Better Care Reconciliation Act” (BCRA) was released on June 26, 2017. The Medicaid per-capita cap was maintained, though with a more generous growth rate in the short term and a lower allowed growth rate in later years. Funding for Medicaid expansion was also eliminated, though over a longer period of time. Premium tax credits in the Senate bill more closely reflected those in the ACA and a single actuarial benchmark of 58 percent was established for plans. As opposed the AHCA’s 30 percent premium surcharge for those with a gap in coverage, the Senate bill established a six month waiting period before coverage could begin. CBO estimated that the proposal would result in 15 million fewer Americans with health coverage in 2018 and 22 million fewer by 2026. Federal Medicaid expenditures would be reduced by more than $770 billion over the decade.

Despite these efforts, Senate leadership was unable to attract the necessary 50 votes for the proposal from the 52 Republican Senators. While moderate members, especially those from states that had successfully expanded Medicaid, remained concerned with the impact on coverage, a modified draft released on July 13 moved the Senate product decidedly to the right. The proposed amendment would allow insurers to offer plans outside of the exchanges that were exempt from ACA requirements including essential health benefits and pre-existing condition protections, as long as they also offered other compliant plans on the exchanges. To compensate for the impact on the risk pool within the exchange, additional stability funding was included. The measure also
increased funding for opioid abuse treatment and allowed Health Savings Account funds to be used
for premiums. Some conservative members continued to argue that the Senate proposal largely
kept the structure of the ACA intact – contrary to campaign promises to completely repeal the law.
On July 19, another proposal was released called the “Obamacare Repeal Reconciliation Act”
(ORRA). The ORRA largely reflected the reconciliation bill passed by the previous Congress but
veted by President Obama. ORRA would repeal all elements of the ACA allowed under
reconciliation, essentially wrecking the individual markets by repealing penalties for failure to
maintain coverage while maintaining requirements that insurers offer coverage to all individuals at
community rated premiums with no preexisting condition exclusions. CBO estimate that 17 million
fewer Americans would have coverage under the ORRA in 2018, increasing to 32 million by 2026.
Furthermore, for those purchasing coverage on the exchange, premiums would be double those
projected under current law by 2026 and three-quarters of all Americans would live in areas with
no plans offered in the non-group market. Federal Medicaid expenditures would be reduced by
more than $840 billion over the decade.

On July 25, 2017, the Senate voted 51-50 to proceed to consideration of H.R. 1628, the American
Health Care Act. Republican Senators Susan Collins of Maine and Lisa Murkowski of Alaska
voted no. Vice President Mike Pence cast the tie-breaking vote. Over the next two days the Senate
considered a number of secondary amendments from both sides of the aisle. On July 25, the Senate
considered and rejected the “Better Care Reconciliation Act” by a vote of 43-57, with 9
Republicans joining all Democrats in opposition. The following day, the Senate also rejected the
“Obamacare Repeal Reconciliation Act” by a vote of 45-55.

Still lacking the necessary 50 votes to advance ACA repeal and facing a growing backlog in the
Senate agenda, Senate Majority Leader McConnell offered one last alternative, the “Health Care
Freedom Act” (HCFA) or so-called skinny repeal. The HCFA reflected common provisions of
previous versions – elimination of individual and employer mandate penalties, eliminate funding
for the Prevention and Public Health Fund, extension of the moratorium on the device tax though
2020, a temporary increase in HSA contribution limits, increased section 1332 state waivers,
increased Community Health Center Funding, and prohibition of Medicaid payments to Planned
Parenthood clinics. While most of these provisions enjoyed unanimous support among Republican
senators (the Planned Parenthood provision being the exception), no Senator supported the HCFA
as the final Senate position on ACA repeal. Rather, leadership promoted the idea that passage of
the amendment would allow the Senate to advance ACA repeal to a conference with the House
where yet another new version of the bill could be written. Several Republican senators expressed
the concern that the House would instead take up the Senate-passed bill and send it directly to the
President. While the House leadership tried to assure the Senate that they would go to conference,
messaging from different quarters on the ultimate pathway was decidedly mixed. In the end, in the
eyarly morning hours of July 28, the Senate rejected the HCFA by a vote of 49-51, with Sen. John
McCain (R-AZ) joining Sens. Collins, Murkowski and all Democrats in voting no. With no viable
pathway forward, Sen. McConnell pulled the bill from consideration.

Throughout House and Senate consideration of the AHCA and the Senate substitutes, the AMA
consistently advocated that Congress reject proposals that would lead to fewer Americans with
access to quality, affordable health care coverage and that were inconsistent with the principles and
policies adopted by the House of Delegates. The AMA also consistently acknowledged that there
are shortcomings in the ACA and expressed our desire to engage with Congress and other
stakeholders in efforts to address those issues. In response to a May 12, 2017 request from Senate
Finance Committee Chairman Orrin Hatch (R-UT), the AMA offered a number of policy
suggestions to enhance plan affordability, stabilize the individual market, and protect the safety net.
The partisan nature of the debate and the limitations imposed by the budget reconciliation process,
however, made advancing those proposals highly unlikely as long as repeal of the ACA remained the primary objective.

At this writing, Congress is expected to turn to efforts to stabilize the current system in the short term, likely through continuing Cost Sharing Reduction payments to health plans and reinsurance. Efforts are also likely to incorporate additional flexibilities for states in administering components of the Affordable Care Act. Members on both sides of the aisle have acknowledged that successful legislative efforts will require regular order – committee hearings, consultation with stakeholders, and compromise on all sides. The AMA will remain engaged in these efforts consistent with the principles outlined above.

REPEAL AND APPROPRIATE REPLACEMENT OF THE SGR AND PAY-FOR-PERFORMANCE

Since the enactment of the Medicare Access and CHIP Reauthorization Act (MACRA), much of the policy making activity related to pay-for-performance programs has been subsumed by implementation activities surrounding that statute. Since the enactment of MACRA, the AMA has worked diligently with the Centers for Medicare & Medicaid Services (CMS) to ensure that the law was implemented in manner that encourages and enables successful participation of physician practices of all sizes and structures, including appropriate exemptions. Proposed rulemaking for 2018 offers further evidence of the success achieved by the AMA and organized medicine in this regard.

The 2018 proposed rule calls for important accommodations for small practices, including expanded low volume thresholds, creation of virtual groups, bonus points for small practices and a new hardship exemption from Advancing Care Information (ACI) (formerly meaningful use). New flexibilities have also been proposed for ACI, including the use of 2014 certified electronic health records technology for 2018. Quality performance will remain weighted at 60 percent and the cost category at zero.

The proposed rule also eliminates the cross cutting measure requirement, maintains the current data completeness threshold, and allows the reporting of improvement activities through attestation while maintaining the number of activities physicians must report.

On the legislative front, the AMA is engaged in efforts to ensure that CMS has the necessary flexibility to promote successful physician participation. This includes efforts to make sure measures of resource use are developed and tested prior to their required implementation and that ACI requirements do not become overly burdensome.

REPEAL AND REPLACE THE INDEPENDENT PAYMENT ADVISORY BOARD (IPAB)

The IPAB was created as part of the Affordable Care Act to reduce the per capita rate of growth in Medicare spending. Recommendations from the IPAB to reduce spending in Medicare are required should the Chief Actuary of CMS Services determine that per-capita spending exceeds a specified target. Should that occur, the IPAB would be required to make recommendations to Congress to bring spending back into line with targets. In doing so, the IPAB is generally prohibited from recommending changes to cost sharing or premiums, rationing care, or changing benefits or eligibility. These limits leave few tools for controlling spending outside of changes to provider payments. The statute also prescribes a specific time table for Congressional action on these recommendations which leaves Congress the option of replacing IPAB-recommended policies with
alternative savings, though Congress would still be required to produce total savings necessary to match the targets.

At this time, no members have been appointed to the IPAB nor are appointments expected. The statute contemplates this possibility by calling for the Secretary of U.S. Department of Health and Human Services (HHS) to make the recommendation directly to Congress in lieu of recommendations made by an appointed IPAB. However, it is not clear at this time what steps Secretary Price would take in response to the triggering of the IPAB requirement nor is the position of the Administration on this issue clear.

Six separate pieces of legislation have been introduced in the 115th Congress to repeal or otherwise discontinue the functions of the IPAB. Three of these bills, by Sen. John Cornyn (R-TX), Sen. Ron Wyden (D-OR), and Rep. Phil Roe, MD (R-TN) and Rep. Raul Ruiz, MD (D-CA) are consistent with legislation that has been introduced in each of the previous Congresses since the enactment of the ACA. In both the 113th and 114th Congress, bipartisan IPAB repeal legislation was considered and passed in the House of Representatives but not considered in the Senate. In each case, the bill was paired with provisions offsetting the cost that were not bipartisan in nature, therefore diminishing the opportunity for successful enactment.

The second set of proposals, introduced by the same sponsors as the IPAB repeal legislation, fulfills the requirements of an IPAB discontinuation process that was enacted as part of the IPAB itself. Section 3403 of the ACA establishes fast track procedures for discontinuing the IPAB process through a joint resolution that meets specific requirements. Unfortunately, the procedural advantages offered by these resolutions expired on August 15.

On July 13, 2017, the Medicare Trustees released their annual report. Included was the determination by the Actuary that spending targets have not been exceeded and therefore IPAB recommendations are not triggered this year, contrary to earlier predictions. While it is certainly positive that no cuts are currently required, the lack of a direct threat of cuts has tempered the urgency of repealing IPAB.

The longer Congress waits to repeal the IPAB, the more expensive it will become given the fact that the Congressional Budget Office predicts accelerating Medicare spending in future years, increasing the likelihood of required cuts that must then be offset as part of repeal legislation. This is unfortunate in that the true urgency lies not in the immediate threat of cuts but in the growing cost of IPAB repeal.

SUPPORT FOR MEDICAL SAVINGS ACCOUNTS, FLEXIBLE SPENDING ACCOUNTS, AND THE MEDICARE PATIENT EMPOWERMENT ACT

Our AMA continues to seek opportunities to expand the use of health savings accounts and remove ACA imposed limitations on the allowed use of Flexible Spending Account funds.

Our AMA continues to work with the Health Choices Coalition in support of the “Restoring Access to Medications Act” which has been reintroduced by Rep. Lynn Jenkins (R-KS), Rep. Ron Kind (D-WI), Sen. Pat Roberts (R-KS) and Sen. Heidi Heitkamp (D-ND). This legislation would repeal ACA-imposed limitations on the use of Flexible Spending Account funds to purchase over-the-counter medications without a prescription.

Our AMA also continues to pursue opportunities to expand the availability of Health Savings Accounts (HSA) consistent with AMA objectives for continuing health system reform. In
suggestions provided to Sen. Hatch on improving health care affordability, for example, the AMA
suggested allowing individuals who are eligible for cost sharing reductions to forgo those
reductions and instead enroll in a bronze plan with a prefunded HSA and allow those funds to roll
over from year to year. We also proposed providing individuals not eligible for cost sharing
reductions with a moderately funded HSA.

The Medicare Patient Empowerment Act has not been reintroduced in the 115th Congress. AMA
will continue to seek opportunities, however, to increase private contracting opportunities under the
Medicare program without penalty to the patient or physician.

STEPS TO LOWER HEALTH CARE COSTS

Beyond AMA’s extensive efforts to prevent chronic disease currently underway through the
Improving Health Outcomes initiative, there are multiple opportunities in the policy arena to bring
down the cost of care, among them are focusing on the rising cost of prescription drugs and the
opportunity to lower the cost of providing care through regulatory reforms.

Though Congress’ attention has been focused on the Affordable Care Act, the AMA continues to
work to build support for addressing the high costs of prescription drugs. Drawing on policies
adopted by the House of Delegates in 2015 and 2016, and the work of an AMA task force
consisting of AMA councils, state medical associations and national medical specialty associations,
the AMA continues to explore opportunities to increase transparency in the pharmaceutical sector.
These efforts include a website, TruthinRx.org where patients can access information and share
their stories as well as sign an online petition. We believe that Congress will turn its attention to
pharmaceutical pricing in the near future and the AMA is ready to fully engage at that time.

Achieving lower cost care is also dependent on reducing the cost to the physician to provide care
by eliminating administrative burdens that do not contribute to better care. Our AMA continues to
engage both Congress and the new Administration on a variety of proposals to reduce regulatory
burden in the areas of certification and documentation, Medicare Advantage, Part D prior
authorization requirements, Appropriate Use Criteria, Meaningful Use and Electronic Health
Records, Program Integrity, DEA requirements, and FDA regulation of laboratory developed tests
and compounding, to name a few. Some success can already be seen in the MACRA proposals
noted above as well as a recent request for information on regulatory reform ideas that was part of
the 2018 Medicare Physician Fee Schedule proposed rule released in July. Additionally, the House
Committee on Ways and Means has initiated an effort to collect suggestions for both statutory and
regulatory changes to “deliver relief from unnecessary and burdensome mandates that impede
innovation, drive up costs, and ultimately stand in the way of delivering better care for Medicare
beneficiaries.” The AMA is participating fully in these and other efforts to reduce regulatory
burdens.

REPEAL NON-PHYSICIAN PROVIDER NON-DISCRIMINATION PROVISIONS OF THE
ACA

Guidance released by the Department of Health and Human Services in 2014 included a positive
interpretation of health plan requirements under section 2706(a) of the ACA, specifically clarifying
that the section does not require “that a group health plan or health insurance issuer contract with
any provider willing to abide by the terms and conditions for participation.” Nevertheless, the
AMA will continue to seek legislative opportunities to repeal this provision.
CONCLUSION

To date, much of the effort surrounding health system reform in the 115th Congress has been focused on efforts to repeal the Affordable Care Act. While we are pleased that those proposals have been unsuccessful to date, we will remain engaged in efforts to address the shortcomings of the ACA by vigorously pursuing the adoption of AMA policies on health care coverage and health system reform. Additionally, we will continue to seek opportunities both in the legislative and regulatory arenas to advance policies promoting the successful implementation of MACRA, the reduction of regulatory burdens on physicians, the repeal of IPAB, lowering of health care costs and other policies adopted by the House of Delegates.
EXECUTIVE SUMMARY

Policy G-640.005, “AMA Advocacy Analysis,” calls on the Board of Trustees (BOT) 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 BOT has prepared the following report to provide an update on 2017 American Medical Association (AMA) advocacy activities.

The AMA had another strong year on the advocacy front. We were able to advance patient and physician interests in several areas. We were also able to defend against potential rollbacks of hard fought gains. Our efforts centered on the following issues.

- The AMA led medicine’s effort to protect coverage and access to quality, affordable health care for patients which were threatened in the 115th Congress.
- The AMA sought and attained numerous improvements to the implementation regulations for the Medicare Access and CHIP Reauthorization Act (MACRA) – or Quality Payment Program (QPP) as it is now known.
- The AMA continued to educate and create tools for physicians to help them with the transition to MACRA/QPP.
- The AMA pursued legislative and regulatory initiatives to reduce administrative burdens on physician practices to improve efficiency and reduce burnout.
- The AMA, in conjunction with our Federation colleagues, played a major role in the defeat of two health insurer mega-mergers – one of which could have led to physician payment cuts of $500 million per year.
- The AMA has successfully called on the Centers for Medicare & Medicaid Services to provide coverage for the Medicare Diabetes Prevention Program which directly addresses one of our nation’s most prevalent diseases.
- The AMA continues to address the opioid epidemic, and our main recommendations on physician use of Prescription Drug Monitoring Programs, continuing medical education, naloxone, and others are having positive results. However, the overdose and death rates remain staggering.
- The AMA is working to limit the inappropriate use of prior authorization which is a major impediment for physicians as they seek to provide optimal care to their patients.
- The AMA has also launched a campaign calling for greater transparency in the pricing process for prescription drugs by pharmaceutical companies, pharmacy benefit managers, and health insurers.

Staff note: This report was prepared in September 2017, and may be updated prior to the Interim Meeting based on more recent advocacy developments.
Subject: 2017 AMA Advocacy Efforts

Presented by: Gerald E. Harmon, MD, Chair

BACKGROUND

Policy G-640.005, “AMA Advocacy Analysis,” calls on the Board of Trustees (BOT) 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 BOT has prepared the following report to provide an update on 2017 American Medical Association (AMA) advocacy activities.

DISCUSSION OF 2017 ADVOCACY EFFORTS

Health System Reform

When the 115th Congress convened on Jan. 3, 2017, it was clear that health system reform would be a top priority for both chambers. In anticipation of the coming debates, the AMA outlined our key objectives for health system reform which are based on AMA policy and sent them to the Administration and Congress urging them to align any legislative proposals with these objectives.

• Ensure that individuals currently covered do not become uninsured and take steps toward coverage and access for all Americans;
• Maintain key insurance market reforms, such as pre-existing conditions, guaranteed issue and parental coverage for young adults;
• Stabilize and strengthen the individual insurance market;
• Ensure that low/moderate income patients are able to secure affordable and meaningful coverage;
• Ensure that Medicaid, CHIP and other safety net programs are adequately funded;
• Reduce regulatory burdens that detract from patient care and increase costs;
• Provide greater cost transparency throughout the health care system;
• Incorporate common sense medical liability reforms; and
• Continue the advancement of delivery reforms and new physician-led payment models to achieve better outcomes, higher quality and lower spending trends.

Subsequently, the House and the Senate both introduced legislation at various points that would repeal key portions of the Affordable Care Act (ACA). The AMA analyzed the House bill, the American Health Care Act (AHCA), and the Senate bill, the Better Care Reconciliation Act (BCRA), in relation to our health reform objectives and determined that both bills fell short when compared to those objectives. According to the Congressional Budget Office (CBO), the AHCA and BCRA would both have led to over 20 million or more Americans losing their health care coverage. The bills included per capita caps on Medicaid funding, which the AMA opposes based on explicit policy adopted at our 2017 Annual Meeting. The bills would have also led to increased costs for patients. Therefore, the AMA opposed the bills as originally introduced and as they were
amended through the process (as did a long list of other health organizations). The AHCA eventually passed the House in May by a vote of 217-213. The Senate efforts, BCRA and other repeal bills, have stalled in the Senate as of this writing.

The AMA launched a vibrant and effective campaign to oppose both of these bills.

- The AMA created a website, PatientsBeforePolitics.org, to serve as our grassroots platform for patient and physician engagement on these issues.
- The AMA also launched an extensive grassroots campaign involving telephone calls, emails, social media contacts and meetings with key Senators. The results were very strong: 6,290,404 digital/social media engagements; 380,264 emails; and 33,618 phone calls as of this writing.
- The AMA commissioned public opinion polls in select states, revealing that registered voters support Medicaid and opposed the proposed repeal/replace bills.
- The AMA joined collaborative efforts with patient groups, hospitals and other providers for media events held in Colorado, Ohio, Nevada, and West Virginia to share personal stories about the impact that access to affordable, meaningful health insurance coverage has had on individuals, families and communities.

The AMA will continue to offer short-term and long-term recommendations and solutions to Congress as it revisits the health reform debate. We are on the record that the status quo is unacceptable and that problems with the ACA must be fixed. The immediate focus is individual insurance market stability to provide affordable coverage and choice. We are working with both parties in Congress to advance these and other interventions.

**MACRA/QPP Implementation**

Addressing practice sustainability is a major objective for the AMA. The Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 (being implemented as the Quality Payment Program [QPP]) repealed the Sustainable Growth Rate and made several improvements over previous law including aligning and reforming a number of existing Medicare programs such as Meaningful Use, Physician Quality Reporting System (PQRS) and the Value-based Modifier (VM). It also created a way for physicians to participate in alternative payment models (APMs) and provided a path to advance them. Since MACRA’s enactment, the AMA has been advocating to the Centers for Medicare & Medicaid Services (CMS) to ensure that the QPP regulations implementing MACRA are workable for physician practices and do not create new hurdles. The AMA has also launched an extensive campaign to educate physicians about MACRA and to help them prepare for the transition.

On the regulatory implementation front, the AMA, working with our Federation partners, attained several major improvements in the QPP for physicians in last year’s QPP rule. For example, CMS instituted the Pick Your Pace program for 2017. Under Pick Your Pace, physicians will not face a potential four percent payment reduction in 2019 if they report on one measure for one patient in 2017. Only physicians who do not report any data to Medicare in 2017 will receive a penalty. To help physicians understand how to report, the AMA created a video that explains in detail how to report and avoid the penalty. While this year’s QPP rule included several positive aspects, we continued to make recommendations to CMS on how to further improve the program.

In the QPP proposed rule for the 2018 performance period, CMS has proposed several more improvements in response to issues raised by the AMA, including several concerns facing small practices.
Expanding significantly the low-volume threshold to $90,000 or less in Medicare Part B allowed charges OR 200 or fewer Medicare Part B patients (previously the threshold was $30,000 in allowed charges or 100 patients) – CMS estimates that only 37 percent of clinicians who bill Medicare will be subject to the Merit-based Incentive Payment System (MIPS);

Allowing the establishment of virtual groups to assist small practices;

Adding five bonus points to the final MIPS scores for practices of 15 or fewer clinicians;

Adding a hardship exception from the Advancing Care Information (previously Meaningful Use) category for practices of 15 or fewer clinicians; and

Allowing the use of 2014 edition certified electronic health records technology (CEHRT) past 2017, and CMS will not mandate that physicians update their EHRs in 2018.

The proposed rule also contains a number of other positive provisions, such as:

Eliminating the cross cutting measure reporting requirement;

Not increasing the data completeness threshold requirement;

Proposing a zero weight for costs again in the 2018 performance/2020 payment year;

Allowing physicians to report on Improvement Activities (IA) through simple attestation;

Not increasing the number of IAs physicians must report;

Developing additional IAs; and

Keeping the revenue standard for Alternative Payment Models for more than nominal financial risk at 8 percent of revenues.

The AMA continues to provide educational resources to physicians and their staff as they prepare for the QPP transition, including webinars, ReachMD podcasts, and the development of resource material. An APM workshop was held in March to convene physicians engaged with their specialties in practice model development to stimulate innovation and share strategies for addressing common problems and concerns. A second workshop is planned for October in Chicago. The Interactive MIPS 2017 Action Plan launched in July and the Payment Model Evaluator will be updated in the fall to reflect changes stemming from the 2018 final rule. For more information, please visit the AMA MACRA/QPP page.

Regulatory Relief

Regulatory relief is a high priority for the AMA. It is also a top initiative for the Trump Administration. To take advantage of this enhanced opportunity to address long-standing concerns with a burgeoning regulatory burden, the AMA established a Federation work group to help pinpoint the key regulatory relief issues the AMA should pursue with the Federal government. Some of the issues include: prior authorization, Medicare beneficiary identification numbers, Medicare documentation and certification requirements, appropriate use criteria (AUC), electronic health records, physician office lab reporting, and program integrity audits. In addition, the AMA, along with members of the Federation, agreed to urge the Administration to modify prior requirements and consequently the 2018 penalties of the PQRS, MU, and VM programs. Such changes would bring these policies more in line with the design of MIPS. Concerns and solutions for these and other administrative burdens have been shared and discussed with various arms of the Administration.

As a result of these efforts, some issues are already being successfully resolved. AMA places streamlining and aligning QPP at the top of our regulatory relief agenda. As outlined above, CMS continues to respond positively to AMA advocacy by modifying QPP. In addition due to direct AMA advocacy, the Administration agreed to create a look up database for new Medicare beneficiary identification numbers that will replace the current Social Security number identifiers.
The Social Security Number Removal Initiative (SSNRI), which will be phased in over a 12-month period starting in April, 2018, will affect all Medicare beneficiaries and their physicians. Consequently, agreement by CMS to establish the database and a communication plan to educate both patients and physicians is an important achievement. The Food and Drug Administration has initiated a process to reduce the administrative barriers that generic drug manufacturers face when entering the market. CMS also decided to delay public reporting of new pain measures until 2020. The AMA and other physician groups convinced the US Pharmacopeia to establish a sub-committee to more thoughtfully consider in-office compounding. Also there were several positive regulatory relief developments in the annual proposed Physician Fee Schedule rule, including reductions in 2018 PQRS, MU and VM penalties, further delays in implementation of AUC, and requests for comments on the burden associated with new physician lab reporting requirements.

In addition to these proposed policy modifications, the 2018 fee schedule proposed rule as well as several other regulations released by the Administration have also launched a broad request for information on regulatory relief. The more concrete and immediate proposals in the proposed rule represent a down payment on these broader initiatives, and while there could be modifications when a final rule is issued in November, the proposals do signal a clear intent to make a significant dent in regulatory burden in the future. The AMA will file comments on the proposed Fee Schedule rule in early September.

A number of bills have been introduced to repeal the Independent Payment Advisory Board (IPAB). Although the controversial panel has never been formally appointed, the mandate to impose Medicare cuts through a fast-track process when total program spending exceeds a target amount remains. Although actuaries projected that recent Medicare spending trends would trigger the mandate in 2017, it did not happen this year. If it had been triggered, then provider payment rate cuts would have gone into effect in 2019 unless Congress acted. The AMA supports legislation to repeal the IPAB provisions of the Affordable Care Act, which has been introduced by Sens. John Cornyn (R-Texas) as S. 260, and Ron Wyden (D-Ore.) as S. 251. In the House, Reps. Phil Roe, MD (R-Tenn.) and Raul Ruiz (D-Calif.) introduced H.R. 849. We also submitted a statement for the record calling for IPAB repeal to the U.S. House of Representatives Committee on Energy and Commerce Subcommittee on Health on July 20, 2017.

Preventing type 2 diabetes is a major goal for the AMA and our partners. We received positive news toward this goal on July 10, 2017, when CMS released the 2018 Medicare Physician Fee Schedule (PFS) proposed rule. CMS proposes payment for the Medicare Diabetes Prevention Program (MDPP), with a maximum payment per beneficiary of $810 over three years for the set of MDPP core and maintenance sessions. CMS also proposes a two-year time limit on Medicare coverage for ongoing maintenance sessions. AMA comments on the previous CMS proposal had expressed concern that the proposed payment model was too restrictive in linking payments to patient adherence in attending sessions and health outcomes as measured by weight loss in a short period of time. The new proposal attempts to address these concerns by providing more flexibility to DPP providers in supporting patient engagement and attendance and by making performance-based payments available if patients meet weight-loss targets over a longer period of time. CMS also defers coverage for virtual programs to a CMMI demonstration, which has to be defined. CMS proposes to delay the start date of the MDPP for three months to April 1, 2018 from January 1, 2018. We will provide comments to CMS on the proposed rule expressing support for the
provisions that align with AMA objectives, and we will continue to offer suggestions to improve
the proposed rule on issues where we still have concerns.

At the state level, the AMA continues to advocate for insurance coverage of the DPP, including
through state Medicaid programs. This year, California enacted a budget bill allocating $5 million
from the state general fund to cover the DPP for Medicaid beneficiaries beginning on July 1, 2018.

**Insurer Mergers**

The AMA, with the help of 17 state medical association antitrust coalition partners from across the
country, achieved two huge victories in 2017 when federal trial court judges blocked these massive
insurance company mergers: the $37 billion Aetna-Humana merger and $54 billion Anthem-Cigna
merger. Soon after losing at trial, Aetna abandoned the merger. Anthem, though, appealed the trial
court judge’s decision to the U.S. Court of Appeals in Washington DC. On April 28, the federal
appeals court affirmed the trial court’s decision to block the Anthem-Cigna merger. Throughout the
appeal, the AMA and its coalition partners continued to vigorously oppose the Anthem-Cigna
merger. On May 12, Anthem dropped the merger.

At trial, Anthem’s own expert stated that this mega-merger would have reduced provider payments,
annually, by $2.4 billion. According to an analysis provided to the AMA, this $2.4 billion cut
included physician payment cuts of at least $500 million per year.

Our efforts to block the two mergers included:

- Utilizing the AMA’s updated gold standard Competition in Health Insurance: A
  Comprehensive Study of U.S. Markets;
- Preparing detailed state-specific market analysis of both the Anthem-Cigna and Aetna-Humana
  mergers;
- Sending comprehensive, evidence-based advocacy statements to the U.S. Department of
  Justice (DOJ) after the mergers were announced in July 2015 urging the DOJ to challenge both
  mergers;
- Leading a 17-state medical society coalition and engaging likeminded stakeholders, including
  the American Hospital Association and various patient coalitions;
- Testifying with the California Medical Association before the California Department of
  Insurance (DOI) opposing the Anthem-Cigna merger and filing a joint statement—the
  California DOI ended up opposing both mergers;
- Filing an evidenced-based advocacy letter with the Missouri DOI opposing the Aetna-Humana
  merger—the Missouri DOI later blocked the merger;
- Working closely with the Indiana State Medical Association, filed a statement with the Indiana
  DOI challenging the Anthem-Cigna merger;
- Supporting numerous other state medical associations in their efforts to oppose the mergers;
- Engaging the National Association of Attorneys General in an effort to convince key state AGs
  to join the DOJ in opposing the mergers;
- Conducting extensive physician surveys to gauge impact on patient care (in conjunction with
  the AMA’s state medical association partners);
- Marshaling nationally-recognized economists/legal experts in support of our arguments;
- Filing an amicus brief with the federal appeals court arguing against the Anthem/Cigna merger;
  and
- Facilitating another amicus brief from a group of nationally-renowned health care economists.
In response to these recent merger efforts and the potential for more proposed mergers, the AMA has developed a state level campaign to ensure fairness and transparency as states evaluate future merger proposals. It will also protect physicians from retaliation by health insurers.

**Opioid Epidemic**

The nation’s opioid epidemic continues to claim many lives, and according to the most recent Centers for Disease Control and Prevention data, deaths due to heroin and illicit fentanyl (12,957 and 9,549, respectively) outnumbered and were rising faster than deaths due to prescription opioids (12,728) in 2015. These numbers show that the nature of the epidemic is changing and that significant work still needs to be done to address the epidemic’s full scope. The rising mortality due to heroin and illicit fentanyl also makes it imperative to directly address the need for further treatment resources and access to treatment for patients who have an opioid use disorder.

In 2016, the AMA strongly supported federal legislation that recently led to $485 million being sent to states to help fund state-based treatment programs. We look forward to learning which efforts are most successful so we can build best practices throughout the nation. The AMA is also urging full funding of the Comprehensive Addiction and Recovery Act so even more resources will be available to fight the epidemic.

The AMA Opioid Task Force recently released its yearly progress report on physicians’ efforts to reverse the epidemic, showing:

- Physicians and other health care professionals queried their state prescription drug monitoring program (PDMP) more than 136 million times in 2016 – a 121 percent increase over 2014. Registration to use state PDMPs has nearly tripled since 2014 to more than 1.3 million registered users in 2016. Most state-specific increases occurred prior to new policies mandating PDMP use.
- More than 118,000 physicians accessed, attended or completed continuing medical educational and other courses offered by the AMA, American Osteopathic Association, and the American Dental Association and the nation’s state and specialty societies on safe opioid prescribing, pain management, addiction and related areas in 2015 and 2016.
- More than 37,000 physicians are now certified to provide office-based medication-assisted treatment for opioid use disorders across all 50 states – including more than 10,000 in the past year.
- While there remains work to do in ensuring comprehensive treatment for patients with pain, there was a national 17 percent decrease in opioid prescribing from 2012 to 2016 with decreases seen in every state. Nearly all decreases occurred prior to new state laws restricting the prescribing of opioids to certain dose and/or quantity limits.
- Nearly all 50 states have naloxone access laws, and in the first two months of 2017, more than 32,000 naloxone prescriptions were dispensed – a record 340 percent increase from 2016. Most of the new state laws were based, in part, on AMA model state legislation.

The AMA also created a new End the Opioid Epidemic Microsite to provide physicians with the state- and specialty-specific education and training to help end the nation’s opioid epidemic, the AMA—in concert with the Opioid Task Force—has identified nearly 300 resources for the new [AMA opioid microsite](#). The resources are organized so that physicians and other health care professionals can access practical, relevant information about:
• How PDMPs can help improve patient care;
• State- and specialty-specific information to ensure that physicians’ education is meaningful and relevant to their practice and patient population;
• Key resources to help improve pain management for acute and chronic, non-cancer pain;
• Becoming certified to provide in-office buprenorphine to patients with an opioid use disorder;
• Incorporating overdose prevention and treatment strategies in one’s practice;
• Practical information about naloxone;
• How to better talk with patients about safe storage and disposal of unwanted and unused opioid analgesics and all medications; and
• New research published in *JAMA*, and new resources developed by the Centers for Disease Control and Prevention, Substance Abuse and Mental Health Services Administration and other stakeholders.

**Prior Authorization**

The AMA has identified prior authorization as a major impediment for physicians as they seek to provide optimal care for their patients. In response, the AMA, in collaboration with a coalition of 16 other organizations representing physicians, hospitals, medical groups, pharmacists, and patients, released the **Prior Authorization and Utilization Management Reform Principles** in late January 2017. The 21 common sense principles form the foundation of a multi-pronged campaign to “right-size” health plan prior authorization and utilization management programs. More than 100 other provider and patient organizations have requested to be listed as supporters of the principles, and this number continues to grow. The principles have received extensive press coverage and have generated nearly 300 earned media citations.

The first wave of outreach on the principles to health plans, pharmacy benefit managers, and accreditation organizations has been very productive with mutual interest in this issue from many of these groups. Further, this advocacy is making an impact across the country. Just in the last year, at least eight states have enacted laws that limit prior authorization or step therapy, and insurers are starting to change their practices.

To further our efforts, the AMA partnered with the University of Southern California Schaeffer Center for Health Policy & Economics on an academic research project to assess the growing impact of prior authorization on physician practices and patients through analysis of Medicare claims data. This project has generated two manuscripts: the first provides a broad analysis of overall prior authorization trends and the effect of utilization management policies on medication use, while the second is a case study examining the impact of prior authorization for a specific class of drugs and disease state on patient outcomes and overall medical costs. Both manuscripts have been submitted for publication to peer-reviewed journals. The anticipated articles will strengthen and enhance the AMA’s advocacy on this issue.

**Pharmaceutical Cost Transparency**

Our recent work on the pharmaceutical cost issue stems from a series of resolutions at I-15 calling on the AMA to tackle spiking pharmaceutical costs and the detrimental effect this trend has on patients. In response, the AMA formed a task force in 2016 consisting of representatives of AMA policy councils, state medical associations, and national medical specialty societies to develop principles to guide advocacy and grassroots efforts aimed at addressing pharmaceutical costs and adherence to medically necessary drug regimens. The task force discussed a variety of possible approaches, including Medicare drug price negotiation and re-importation, but ultimately recommended implementation of a grassroots campaign focused on increasing drug pricing.
transparency. This approach aligns with long-standing AMA policy encouraging prescription drug price and cost transparency among pharmaceutical companies, pharmacy benefit managers (PBMs) and health insurance companies.

To implement this campaign, the AMA launched an interactive grassroots campaign microsite, TruthInRx.org, in November 2016 as the online hub for the AMA pharmaceutical pricing transparency campaign, where patients can tell stories and activists can access further tools and resources to make their voices heard with members of Congress and state legislators through email and social media communications. We also created an online petition calling on pharmaceutical companies, PBMs and health plans to be more transparent on pricing decisions. The petition has been promoted through the AMA’s Patient Action Network and other cause-oriented websites (e.g., standunited.org and care2.org), and to date, over 154,000 people have signed it. We are prepared to activate this group when federal legislation is introduced. Also, to address this issue at the state level, the Board of Trustees recently approved a new model state bill that would increase pharmaceutical price transparency and increase related areas for PBMs and health plans. The model bill has been distributed to all 50 state medical associations and national medical specialty societies, and the AMA will work with any interested society to advance this legislation.

Network Adequacy/Out-of-Network Bills

Ensuring that provider networks offer access to timely, quality care continues to be a concern in many states, as narrow networks become the norm and changes to networks take place throughout the year. This continues to be a major area of focus for the AMA at the state level. This year, Illinois was able to enact a comprehensive network adequacy bill that incorporated many provisions of the AMA’s model bill. Also, Maryland, which enacted strong legislation last year that also included many AMA model provisions, is now going through the regulatory process to implement these positive changes. Draft regulations released earlier this year suggest Maryland may end up with some of the strongest provider network requirements in the country.

State and specialty societies continue to work through legislative proposals with the AMA’s guidance that would include prohibitions on anticipated out-of-network bills or “surprise” bills. While some states proactively offered solutions that involved strong patient protections and fair out-of-network payment to physicians, most states ended up fighting problematic bills that undercut any incentives for insurers to offer physicians fair in-network contracts. In fact, more than half of all states had at least one proposal this year on this topic, but only a handful ended up being enacted. Bills in Arizona, Indiana, Louisiana, and New Hampshire focused largely on disclosure and/or study committees. Texas expanded its current mediation process; while Maine and Oregon enacted broader bans on out-of-network billing. A problematic bill passed both chambers in Nevada, but was ultimately vetoed by the governor. The AMA sent a letter to Governor Brian Sandoval supporting the Nevada State Medical Association effort to defeat the bill.

Physician-owned Hospitals

Currently, federal self-referral limitations effectively ban construction of physician-owned hospitals and place restrictions on expansion of already-existing facilities. The Patient Access to Higher Quality Health Care Act of 2017, introduced by Rep. Sam Johnson (R-TX) and Senator James Lankford (R-OK) as H.R. 1156 and S. 113, respectively, would repeal these limits and level the playing field for physician-owned hospitals allowing them to remain competitive and continue their solid record of providing the highest quality health care to patients. The AMA is supporting these bills based on our policy against this prohibition.
Medical Liability Reform

At the federal level, the AMA offered our support for the Protecting Access to Care Act of 2017 (PACA) (H.R. 1215). H.R. 1215 is a comprehensive medical liability reform bill that would help repair our nation’s liability system, reduce the growth of health care costs, and preserve patients’ access to medical care. The bill passed the House by a vote of 218 to 210. PACA provides the right balance of reforms by promoting speedier resolutions to disputes, maintaining access to courts, maximizing patient recovery of damage awards with unlimited compensation for economic damages, while limiting noneconomic damages to a quarter million dollars. Importantly, H.R. 1215 includes language to protect medical liability reforms enacted at the state level. The CBO determined that H.R. 1215 would reduce federal health care spending by $44 billion over 10 years and reduce the deficit by $50 billion over the same period. At the time of this writing, PACA has not been acted on in the Senate.

The AMA continues to advocate for and defend medical liability reform at the state level as well. State legislatures in 2017 considered bills that promoted a variety of reforms, including expert witness guidelines, affidavit of merit requirements, collateral source reform and bills that establish structures such as pretrial screening panels or health court systems. A handful of states also considered and defeated attempts to raise caps on noneconomic damages. Iowa enacted a comprehensive bill that includes a $250,000 limit on noneconomic damages in most cases, stronger expert witness standards, a requirement for a certificate of merit in all medical liability lawsuits, and an expansion of the state’s previously passed communication and resolution framework. In addition, Arkansas’ legislature approved a ballot initiative proposing an amendment to the state constitution to limit damage awards and attorneys’ fees. Finally, Florida and Wisconsin both had disappointing judicial outcomes regarding their caps on noneconomic damages.

Team-based Care/Scope of Practice

State legislatures in 2017 considered over 750 bills seeking to eliminate team-based care models of health care delivery and/or expand the scope of practice of non-physician health care professionals. Though tough fights in all cases, most bills that threatened passage have been defeated with the support of the AMA and – as is often the case with scope bills – a coordinated state and specialty effort. State medical associations had particular success in defeating psychologist and naturopath prescribing legislation. In addition, the AMA and the Federation were largely successful in fending off the over 175 bills filed to expand the scope of practice of advanced practice nurses. For example, bills were defeated in Arkansas, California, Florida, Kentucky, Indiana, Mississippi, Missouri, Montana, Tennessee, Texas, and Virginia. The AMA continues to monitor state legislative activity on these and all other established and emerging scope of practice issues.

Telemedicine

The AMA actively negotiated with congressional staff and other major digital medicine stakeholders provisions of a recently introduced federal bill that would expand Medicare coverage of telehealth services. On May 3, 2017, S. 1016, the “Creating Opportunities Now for Necessary and Effective Care Technologies (CONNECT) for Health Act of 2017” was introduced by Sen. Brian Schatz (D-HI). Subsequently, the companion bill, H.R. 2556 was introduced by Rep. Diane Black (R-TN) and Rep. Peter Welch (I-VT) on May 19, 2017. The legislation would expand Medicare coverage by removing a number of Medicare restrictions to coverage that are widely criticized as being antiquated including originating site restrictions that prevent delivery of telehealth to a beneficiary’s home as well as the geographic limitation which limits access to
telehealth services to rural locations, among a host of other provisions. The AMA secured changes from the draft versions to ensure: (1) state-based licensure requirements were retained; (2) telehealth was not used for Medicare Advantage network adequacy determinations; and (3) other provisions aligned closely with AMA policy. The AMA continues to work with various coalitions to advance this legislation as well as S. 870, the “Creating High-Quality Results and Outcomes Necessary to Improve Chronic (CHRONIC) Care Act of 2017” which contains a number of provisions that parallel the CONNECT for Health Act provisions concerning waiver of Medicare restrictions for accountable care organizations, Medicare Advantage plans, telesstroke, and home dialysis. On May 18, 2017, the U.S. Senate Finance Committee unanimously passed this bipartisan legislation. Moving forward, the AMA is actively working with Senate staff to craft another bill that would confer CMS with expanded waiver authority of current coverage restrictions conditioned on the CMS Chief Actuary certifying that the expansion would be cost neutral or costs saving in an effort to overcome Congressional Budget Office scoring obstacles that stymie passage of legislation that enjoys strong bipartisan support.

Following release of AMA model telemedicine legislation, states saw a flurry of activity in the area, with dozens of laws and regulations proposed to address telemedicine licensure, reimbursement, and practice standards. While most attention was given to debates over how to establish a patient-physician relationship via telemedicine – in person, face-to-face or over the phone – states continue to make gains in passage of coverage parity laws, ensuring that physicians will be compensated for treating their patients via telemedicine. Many of these laws were based on the AMA Telemedicine Act, which addresses these and other issues related to telemedicine.

**Immigration/Travel Ban**

The Trump administration’s executive order entitled “Protecting the Nation from Foreign Terrorist Entry into the United States” created significant uncertainty for the medical community and the ability to freely travel to the United States to either receive or provide care. The AMA swiftly reacted to this new policy by issuing letters to the Administration and Department of Homeland Security asking for clear exemptions for international medical graduates (IMGs), patients, and others who attend medical conferences or conduct medical research. In a joint letter with the Association of American Medical Colleges (AAMC), the AMA also noted the chilling effect this policy could have on foreign physicians entering the National Resident Matching Program (NRMP) or “Match,” and urged support for IMGs given the important role they play in providing care to rural and underserved areas. While the Supreme Court ruling clarified that students, residents, fellows, and lecturers should not be barred entry, the AMA continues to monitor the impact of the travel ban and seek greater exemptions for physicians and patients.

In addition, the AMA offered its support for S. 128, the “Bar Removal of Individuals who Dream and Grow our Economy Act” (BRIDGE Act), which would provide employment authorization and temporary relief from deportation for undocumented young immigrants who have Deferred Action for Childhood Arrivals (DACA) status. The AMA also worked to reinstate the premium processing of H-1B visas, which ensures that those in the Conrad 30 program can work in the United States without returning to their home country.

**Graduate Medical Education (GME)**

Congress has re-introduced GME legislation from previous sessions, entitled the Resident Physician Shortage Reduction Act (H.R. 2267/S.1301), which would create 15,000 additional Medicare-funded GME positions over five years. While this legislation appears promising, and the AMA has supported these bills, they are unlikely to be enacted given the significant cost and lack
of financial offsets. Instead, Congress continues to consider cuts to GME, especially indirect medical education (IME) payments. As a result, the AMA continues advocacy efforts to maintain and protect current GME funding levels. Thus far, the AMA has avoided any significant cuts to current federal funding and is working to continue to educate lawmakers about the need for greater support for GME.

In addition to supporting legislation in Congress to increase GME funding, the AMA has established an effective grassroots campaign to educate the public about the importance of GME. Our SaveGME website has generated significant public attention as well as media response targeted at policymakers. This website allows anyone interested in supporting GME to send letters to members of Congress in support of maintaining GME funding and increasing the number of Medicare-funded residency positions. The AMA has also drafted a compendium of GME policy alternatives. This resource can be used by legislators to consider innovative ways to increase GME funding and training positions. The AMA is also working with states to find other-payer solutions to GME funding. Examples of state laws that have been enacted include: Maryland established a tax credit for physicians or nurse practitioners who serve workforce shortage areas; Mississippi provided support for the creation of ACGME-accredited training programs based on a needs analysis of what residency programs might be necessary, while maintaining a strong and continued priority focus on family medicine; and West Virginia created a scholarship fund for medical students who commit to serve underserved areas of the state.

Conrad 30 Program

The Conrad 30 Program allows IMGs to remain in the United States in exchange for providing care in underserved areas. Currently, resident physicians from other countries working in the United States on J-1 visas are required to return to their home country after their residency has ended for two years before they can apply for another visa or green card. The Conrad 30 program allows these physicians to remain in the U.S. without having to return home if they agree to practice in an underserved area for three years. Many communities, including rural and low-income urban areas, have problems meeting their patient care needs and depend on the physicians in the Conrad 30 program to provide health care services. The program was set to expire this year if Congress did not act. On May 4, 2017, Congress passed an appropriations bill to fund the federal government through Fiscal Year 2017. This bill extended the Conrad 30 program through September 30, 2017. There is also bicameral legislation, S.898/HR. 2141 the “Conrad State 30 and Physician Access Reauthorization Act,” to extend the program for an additional three years. This bill would also make improvements to the program by requiring more transparency in employment contract terms and creating additional waivers per state. The AMA has issued support for this bill and is advocating for it to be passed by Congress.

Veterans Issues

The 115th Congress has held a number of hearings regarding the extension and improvement of the VA Choice program. The program was originally set to expire in August, 2017. In April, the President signed legislation to remove the sunset date and allow the program to continue to operate until those funds are expended. Recognizing that Congress was unlikely to act to reauthorize the program prior to the expiration of funding, the House in July passed additional legislation to provide more than $2 billion in interim funding for the VA Choice program. Congress is working its way through numerous issues as part of efforts to reauthorize the VA Choice program – including the consolidation of various VA purchased care programs, appropriate provider payment levels, the use of tiered networks and value-based reimbursement, the appropriate role of telemedicine, and the interoperability of electronic medical records. The AMA will continue to
work with the House and Senate Committees on Veterans Affairs to ensure that the emerging VA Choice reauthorization reflects the policy and priorities established by the HOD.

2017 AMPAC ACTIVITIES

AMPAC has once again worked closely with its state medical association PAC partners this election cycle on contribution support decisions for candidates running for the U.S. House of Representatives and Senate. A report summarizing AMPAC activities will be distributed at the Interim Meeting in Hawaii.

ADVOCACY RESEARCH

The AMA has also conducted/is conducting the following studies to assist in our efforts:

- The AMA will release an updated Economic Impact Study in December, 2017, which quantifies physicians’ economic impact on the state and national economies on four key economic indicators: economic output, jobs, wages and benefits and state and local tax revenue.
- This fall, the AMA published the 2017 Update to Competition in Health Insurance: A Comprehensive Study of U.S. Markets, its 16th edition of that work. This study provides detailed estimates of the degree of competition among health insurers in different markets. The study identifies areas where health insurer mergers may harm consumers and providers of care. Data from the two previous editions of the study were instrumental in AMA’s advocacy efforts that successfully blocked the Anthem-Cigna and Aetna-Humana proposed mergers.
- The AMA’s Physician Practice Benchmark Surveys, conducted in the fall of 2012, 2014, and 2016, provide nationally representative physician-level information that supports many of the AMA’s advocacy efforts. 2017 reports based on the Surveys focused on physicians’ practice arrangements (e.g., ownership and practice type and size); physicians’ patient-base and how the mix of patients was affected by the ACA; participation in accountable care organizations, medical homes and alternative payment models; and how frequently physicians are subject to medical liability claims.

CONCLUSION

This year has been a very successful one for the AMA on the advocacy front once again. We led the fight to protect coverage and access to quality, affordable health care for patients. We have made excellent strides on MACRA regulatory improvements, and the AMA is at the forefront of helping physicians to prepare for this transition. We also are continuing to make progress in reducing various regulatory burdens that hamper practice efficiency and contribute to physician burnout. Our collaborative effort with the Federation was vital to the defeat of the health insurer mega-mergers and stopped further insurer consolidation which would have had a host of negative effects. The AMA has also continued to make progress on public health issues such as halting the national opioid epidemic and helping physicians to provide resources to their patients at risk of developing diabetes. The AMA thanks our Federation partners for their collaboration and support, and we look forward to tackling medicine’s biggest issues again in 2018.
REPORT OF THE BOARD OF TRUSTEES

B of T Report 3-I-17

Subject: Removing Restrictions on Federal Funding for Firearms Violence Research
(Resolution 201-I-16)

Presented by: Gerald E. Harmon, MD, Chair

At the 2016 Interim Meeting, the House of Delegates (HOD) adopted Policy D-145.994,
“Removing Restrictions on Federal Funding for Firearms Violence Research,” which called on our
American Medical Association (AMA) to “provide an informational report on recent and current
organizational actions taken on our existing AMA Policies (e.g., H-145.997) regarding removing
the restrictions on federal funding for firearms violence research, with additional recommendations
on any ongoing or proposed upcoming actions.” This report fulfills that directive.

BACKGROUND ON RESTRICTIONS ON FEDERAL FUNDING FOR FIREARMS
VIOLENCE RESEARCH

Since the late 1990s, language has been inserted into either annual funding bills for the
Departments of Labor, Health and Human Services, and Education or included into omnibus
appropriations bills that has effectively limited federally-funded research related to firearm
violence. Under the Public Health Service Act (PHSA), the Centers for Disease Control and
Prevention (CDC), the lead public health agency for the federal government, is charged with
conducting and providing grants for research “relating to the causes, mechanisms, prevention,
diagnosis, treatment of injuries, and rehabilitation from injuries…. (42 U.S.C. § 280b(a)). From
1985 until 1996, the CDC’s National Center for Injury Prevention and Control (Injury Center)
researched firearm violence or funded research that studied firearm violence as part of CDC’s
statutory mandate. Many of these studies researched questions related to gun ownership and use. In
1993, after a CDC-funded study published in The New England Journal of Medicine concluded that
guns in the home put people at greater risk of homicide, the National Rifle Association (NRA)
argued that the CDC was advocating for gun control and that the Injury Center should be stripped
of all funding.

Congress eventually decided to retain the Injury Center, but redirected $2.6 million (the exact
amount spent on gun research the previous year) from its budget. Subsequently, in September
1996, Congress included a rider in the Omnibus Consolidated Appropriations Bill for Fiscal Year
(“FY”) 1997 that stated that “none of the funds made available for injury prevention and control at
the [CDC] may be used to advocate or promote gun control” (P.L. 104-208; September 30, 1996;
110 Stat. 3009, 3009-244). This language was sponsored by the late Representative Jay Dickey
(R-AR) and is known as the Dickey Amendment or Rider. The Dickey amendment language has
been included in each subsequent funding bill. Although in recent years such bills have rarely
actually become law, the Dickey amendment has been included in the continuing resolutions or
omnibus funding bills at the end of the year. For FY 2012, Congress expanded this limitation so
that it applies to National Institutes of Health (NIH) funding as well. While attempts have been
made to delete the amendment language, including in the immediate aftermath of the Charleston,
South Carolina church shooting that killed nine people, such attempts have been rejected by
appropriators.

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While the Dickey amendment does not specifically prohibit research on the causes of firearm violence, for the past 20 years the language has had a chilling effect on the CDC. The Obama Administration maintained the position that research on the causes of firearm violence does not constitute “advocacy” and that such research would not be in violation of the Dickey amendment, and in fact directed the CDC to conduct such research. However, the CDC did not do so. According to a white paper prepared in August 2016 by the law firm of Covington & Burling LLP for the Law Center to Prevent Firearm violence, “CDC’s interpretation of the appropriations rider has had a dramatic effect on firearm research by effectively halting federally funded research on gun-related injuries. From 1996 to 2013, CDC funding for firearm injury prevention fell 96 percent.”

AMA ADVOCACY ACTIVITIES

AMA Policy and advocacy activities have strongly urged Congress to take action on curbing firearm violence generally, and to allow and fund firearm violence research specifically. In April of 2016, the AMA, along with over 100 other medical organizations, sent a joint letter to Congress urging federal funding for research on firearm violence. In response to policy adopted at A-16 (D-145.995), the AMA issued a public statement that firearm violence represents a public health crisis that requires a comprehensive public health response and solution. That same policy directed the AMA to actively lobby Congress to lift the firearm violence research ban. Consequently, on June 15, 2016, the AMA sent a letter to the entire Senate advocating for federal support for research into the epidemiology of firearm violence and effective methods to reduce injury and death. Furthermore, the AMA continues to support two federal bills (S. 834 and H.R. 1832) that would authorize federal funds to the CDC for conducting or supporting research on firearm violence prevention.

AMA policy (H-145.975) also supports increased funding for the expansion of the National Violent Death Reporting System (NVDRS) to all 50 states and U.S. territories, to inform state and federal health policy. NVDRS is a state-based surveillance system that provides jurisdictions with a better understanding of violent deaths to guide decisions about violence prevention and track progress over time. In FY 2016, CDC received funding to expand NVDRS to a total of 42 jurisdictions. The FY 2017 omnibus appropriations bill provided level funding for NVDRS. Despite the fact that the FY 2018 President’s budget request for CDC was an estimated $1.2 billion (17 percent) below the FY 2017 continuing resolution level, the budget request maintained level funding for NVDRS.

In addition, AMA policy supports state research on firearm-related injuries and deaths (H-145.975). In the absence of federal funding for firearm violence research, at least one state has passed a budget that allocates funding for firearm violence research. In 2016, the California legislature allocated $5 million for the creation of a Firearm Violence Research Center at the University of California, Davis.

Policy was adopted at the 2016 Annual Meeting supporting a waiting period and background check for all firearm purchasers (H-145.996). As a result, the AMA endorsed a call to action on firearm-related injury and death in the U.S. issued in 2014 by eight medical organizations—including the American College of Physicians, the American Academy of Family Physicians, and the American Academy of Pediatrics—and the American Bar Association (ABA). More than 50 organizations have since endorsed the call to action, which includes a recommendation supporting federally-funded firearms research. On March 24, 2017, the AMA and the ABA, along with a number of local, state, and specialty medical societies, presented a program in Chicago on Preventing Firearm violence: Moving from Crisis to Action. The program explored a workable public health response to reducing firearm violence, including priorities for a research agenda.
The AMA continues to seek opportunities to advocate for federally-funded firearm violence research. The current leadership in Congress and the current Administration, however, oppose federal funding for such research. Thus, in the current political environment there is little expectation that federal legislation, such as S. 834 and H.R. 1832, could pass in Congress, or that the Administration would direct the CDC to conduct such research. Your Board has reviewed our extensive policy and believes that the AMA is well positioned to support any future legislative or regulatory proposals to provide funding for research, and to engage with other stakeholders to continue to educate policy leaders and the public that firearm violence remains a public health crisis and requires a comprehensive public health response and solution. Therefore, the Board is not recommending additional policy on this topic at this time.
Subject: Limitations on Reports by Insurance Carriers to the National Practitioner Data Bank Unrelated to Patient Care

Presented by: Gerald E. Harmon, MD, Chair

At the 2016 Interim Meeting, the House of Delegates (HOD) adopted Policy D-355.996, “Limitations on Reports by Insurance Carriers to the National Practitioner Data Bank Unrelated to Patient Care,” with a progress report back at the 2017 Interim Meeting. This policy asks that:

- Our AMA will seek legislation and/or regulation that would require the Health Resources and Services Administration (HRSA) to clarify that reports to the National Practitioner Data Bank (NPDB) of medical malpractice settlements by physicians be limited to those cases in which the named physician was directly involved in the provision of or failure to provide healthcare services.

- Our AMA will seek legislation and/or regulation that would require HRSA to audit the NPDB for reports on physicians who were not involved in the treatment of a plaintiff, but were reported as a result of a healthcare entity’s settlement of a claim that included the names of those physicians in their administrative roles at the entity.

- Our AMA will seek legislation and/or regulation that would require HRSA to remove reports from the NPDB of any physician who was reported as the result of the settlement of a claim by a healthcare entity where the physician was not involved in the treatment of the plaintiff.

- Our AMA will provide a report to the House of Delegates at the 2017 Interim Meeting regarding our AMA’s interactions with HRSA and detailing the actions taken or planned by HRSA to eliminate inappropriate reporting of physicians to the NPDB.

In addition to this resolution, the HOD also adopted new policy at the 2017 Annual Meeting that directly relates to reporting on physicians who were not involved in treatment or patient care.

Policy H-355.976(7), “National Practitioner Data Bank,” states that:

- Our AMA will: (a) request that the Health Resources and Services Administration (HRSA) clarify that reports of medical staff appointment denial of physicians be (i) contingent upon competency or conduct related to the physicians’ provision of or failure to provide healthcare services that adversely affect the health or welfare of a patient, and (ii) only based on a professional review action and not for administrative or eligibility reasons; and (b) advocate that HRSA remove the name of any physician from the National Practitioner Data Bank reported for reasons not related to competence or conduct that adversely affected the health or welfare of a patient.

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This report provides background on the NPDB, including its history and the integration of the Healthcare Integrity and Protection Data Bank into the NPDB; analyzes the reporting requirements in medical liability payments and medical staff appointments; highlights related AMA policy; and discusses AMA’s interactions with HRSA.

BACKGROUND: NATIONAL PRACTITIONER DATA BANK

The NPDB is a United States Government program that collects certain negative information on health care providers, including adverse licensure or clinical privileges actions, medical malpractice actions, and exclusion from participation in Medicare and Medicaid. The NPDB provides access to this negative information to only authorized users, such as hospitals and medical boards, but not the general public. The NPDB is managed by the Bureau of Health Workforce of the Health Resources and Services Administration in the U.S. Department of Health and Human Services.

History

The NPDB was created by Congress to restrict the ability of health care providers to move from state to state without disclosure or discovery of the provider’s previous disciplinary actions, licensure restrictions, or settled or adjudicated liability lawsuits. In addition, due to the threat of private money damages liability under federal laws, Congress wanted to provide incentives and protection for health care providers engaging in effective professional peer review.

The NPDB was established by the Health Care Quality Improvement Act of 1986 (HCQIA)\(^1\) and subsequent laws expanded the information collected and disclosed by the NPDB and modified its operations.

- Section 1921 of the Social Security Act\(^2\) authorizes the federal government to collect information concerning certain adverse licensure actions taken against any authority of the state responsible for the licensing of such practitioners or entities and reporting any negative action or finding that a state licensing authority, a peer review organization, or a private accreditation entity had taken against a health care practitioner or health care entity.
- Section 1128E of the Social Security Act\(^3\) established a national care fraud and abuse data collection program for the reporting and disclosing of certain final adverse actions taken against the health care provides. This data bank was known as the Healthcare Integrity and Protection Data Bank (HIPDB).
- Section 6403 of the Affordable Care Act\(^4\) amended sections 1128E and 1921 of the Social Security Act to eliminate duplication between the HIPDB and the NPDB. It also required the transferring of data collected in the HIPDB to the NPDB and to cease HIPDB operations. Information previously collected and disclosed by the HIPDB is now collected and disclosed by the NPDB. The transition of data from the HIPDB to the NPDB was completed in May 2013. This transition means that the NPDB jurisdiction is broader than its original intent and now includes all adverse actions from a medical licensing authority and any health care-related civil judgments or criminal convictions.\(^5\)

When a health care provider is subject of a NPDB report, the individual can—at any time—add a statement to the report or initiate a dispute. The statement becomes part of the report and remains with the report unless the individual edits or removes it. The statement is sent to the reporting entity, all queriers who received a copy of the report within the past three years, and is included in the future query responses.
An individual can also initiate a dispute and enter the report into “dispute status” to disagree with either the factual accuracy of the report or whether the report was submitted in accordance with NPDB requirements. Once in dispute status, the individual must contact the reporting entity and attempt to resolve the dispute directly. If the reporting entity fails to respond or responds unsatisfactorily, the individual can elevate the case to “dispute resolution.” In dispute resolution, HRSA will review and determine whether the information is accurate and reportable to the NPDB. If the information is inaccurate, HRSA will direct the reporting entity to revise or void the report.

While NPDB was established to improve health care quality, protect the public from incompetent providers, and reduce health care fraud and abuse, HRSA needs to provide clarification to stop unnecessary reporting to the NPDB when the physician’s conduct or competency in question is not related to the health or welfare of a patient. Unnecessary reporting is damaging to a physician’s reputation, employment status, hospital medical staff privileges, and future employment opportunities. Specifically, AMA policy shows concerns regarding unnecessary reporting of medical liability payments and medical staff appointment denials.

**Reporting of Malpractice Payments**

The NPDB requires medical malpractice payers to report medical malpractice payments. The payment is for the benefit of a health care provider in settlement of a written claim or judgment for medical malpractice against that practitioner. A payment made as a result of a suit or claim solely against an entity (e.g., hospital) that does not identify an individual practitioner should not be reported to the NPDB. Medical malpractice payments are limited to exchanges of money and must be the result of a written complaint or claim demanding monetary payment for damages. A medical malpractice payer also reports a supervisory practitioner that is named in a complaint based on the actions of a subordinate practitioner (e.g., resident, student).

The written complaint or claim must be based on a provider’s provision of or failure to provide health care services. However, the NPDB statute, regulation, guidebook, or FAQs do not further define “provision of or failure to provide health care services.” Without any further clarification from HRSA, malpractice payers are reporting instances to the NPDB where the physician serves in an administrative only capacity and has no direct contact or relationship with the plaintiff that is demanding payment. In these instances, physicians are not providing health care services or failing to provide health care services. Therefore, these payments should not be reported to the NPDB because NPDB’s statutes and regulations limit the filing of medical malpractice reports based on whether a physician provided or failed to provide health care services.

**Reporting Medical Staff Appointment Denials**

The NPDB requires hospitals and other health care entities to report adverse clinical privileges actions. An adverse action includes any professional review action that adversely affects the clinical privileges of a physician for a period of more than 30 days. It also includes the acceptance of the surrender or restriction of clinical privileges while the physician is under investigation relating to possible incompetence or unprofessional conduct or when the surrender occurs in lieu of conducting an investigation. Clinical privileges include privileges, medical staff membership, and other circumstances in which a physician is permitted to furnish medical care by a health care entity. Thus, a medical staff denial is a type of clinical privilege.

Adverse clinical privileges actions are based on a physician’s competence or professional conduct that adversely affects, or could adversely affect, the health or welfare of a patient. Whether an action affects or could affect patient health or welfare is generally a determination that must be
made by the hospital or other entity taking the action. If, in the opinion of the entity, the provider’s actions could adversely affect the health or welfare of a patient, and the action is the result of a professional review, the action must be reported to the NPDB. Potential actions include lying on an application, not completing medical records, outbursts of anger, throwing charts and instruments in the operating room, and cutting and pasting notes and lab results from one patient’s electronic health record (EHR) to another patient’s EHR.

Administrative actions that do not involve a professional review action should not be reported to the NPDB. Thus, if an individual is denied clinical privileges because the individual failed to meet a hospital’s established threshold criteria (e.g., board certification), the hospital should not report this action to the NPDB. Furthermore, matters not related to the professional competence or professional conduct of a practitioner should not be reported. For example, adverse actions based primarily on a practitioner’s advertising practices, fee structure, salary arrangement, affiliation with other associations or health care professionals, or other competitive acts intended to solicit or retain business are excluded from NPDB reporting requirements.

While the NPDB Guidebook states that actions that do not involve a professional review action should not be reported, physicians are still being reported based on administrative and eligibility reviews. HRSA needs to provide further clarification as to what constitutes a professional review action and what constitutes an administrative or eligibility-based action. In addition, although HRSA states that it is the opinion of the reporting entity as to whether an action affects or could affect patient health or welfare, it would be beneficial to both reporting entities and health care providers to state factors that a hospital should consider in making this determination.

AMA OUTREACH WITH HRSA

AMA has consistently reached out to HRSA involving the NPDB, including proposed rule and guidebook comments. Because of the duplicative reports and often misleading information that can be found in the NPDB, previous correspondence has helped ensure that the NPDB remains unavailable for public access. Moreover, AMA’s comments on the draft guidebook ensured that censures, reprimands, or admonishments are not reported to the NPDB. Furthermore, AMA advocacy led to inclusion of the following language in the 2015 revision to the NPDB guidebook: “Medical malpractice payments are limited to exchanges of money and must be the result of a written complaint or claim demanding monetary payment for damages. The written complaint or claim must be based on a practitioner’s provision of or failure to provide health care services.”

In August 2017, the AMA sent a letter to HRSA seeking clarification regarding malpractice payments and medical staff appointment denials and reiterating concerns surrounding the surrendering of clinical privileges while a provider is unaware of an ongoing investigation. The letter also requests a meeting between AMA and HRSA to discuss these issues. While Policy D-355.996 suggests that the AMA also seek potential legislation, advocating for a legislative change would provide an opportunity for some members of Congress and other groups to open the NPDB to the general public. Your Board believes a more prudent and practical approach is to continue to work with HRSA to provide the necessary clarifications for reporting to the NPDB.

CONCLUSION

As of the date this report was drafted, HRSA has not responded to AMA’s request for a meeting. The AMA will continue to urge HRSA to provide clarification and potentially remove individuals who were improperly reported to the NPDB.
REFERENCES

1 42 U.S.C. 11101 et seq.
2 Section 1921 of the Social Security Act as amended by section 5(b) of the Medicare and Medicaid Patient and Program Protection Act of 1987, Public Law 100–93, and as amended by the Omnibus Budget Reconciliation Act of 1990, Public Law 101–508.
4 Section 6403 of the Patient Protection and Affordable Care Act of 2010, Public Law 111–148.
7 Comment Letter from AMA to HRSA, Notice of Proposed Rulemaking Concerning Privacy Act; Exempt Record System, Apr. 18, 2011; Letter from AMA to HRSA; The National Practitioner Data Bank Public Data File, Sept. 23, 2011; Comment Letter from AMA to HRSA, Elimination of Duplication Between the Healthcare Integrity and Protection Data Bank and the National Practitioner Data Bank, Apr. 16, 2012; Comment Letter from AMA to HRSA, Draft Revised Guidebook for the National Practitioner Data Bank; Jan. 31, 2014; Comment Letter from AMA to HRSA, National Practitioner Data Bank Surrendering of Privileges, Nov. 8, 2016.
8 Letter from AMA to HRSA, NPDB Clarification on Medical Malpractice Payments and Adverse Clinical Privileges Actions, August 3, 2017.

APPENDIX – CURRENT AMA POLICY

Policy H-355.976, “National Practitioner Data Bank”
1. Our AMA believes that (A) the National Practitioner Data Bank requirements should be modified so that settlements and judgments of less than $30,000 are not reported or recorded; (B) reports, other than licensure revocation, in the Data Bank should be purged after five years; (C) proctoring of physicians for the purpose of investigation should not be reportable; (D) physicians should not be required to turn over copies of their Data Bank file to anyone not authorized direct access to the Data Bank; and (E) any physician’s statement included in the Data Bank file should automatically accompany any adverse report about that physician in distributions from the Data Bank.
2. Our AMA will (a) work with HHS to establish a mechanism to inform physicians when an inquiry to the Data Bank has been made; and (b) support efforts to require the same Data Bank reporting requirements for physicians, dentists and other licensed health care practitioners.
3. Our AMA: (a) opposes all efforts to open the National Practitioner Data Bank to public access; (b) strongly opposes public access to medical malpractice payment information in the National Practitioner Data Bank; and (c) opposes the implementation by the National Practitioner Data Bank of a self-query user fee.
4. Our AMA supports using all necessary efforts to direct the National Practitioner Data Bank to send all notifications to physicians by certified mail return receipt requested, and supports using all necessary efforts at the federal level to direct the National Practitioner Data Bank to begin the sixty day appeal process from the date the physician receives notification.
5. Our AMA will work with the appropriate federal agencies to ensure that the National Practitioner Data Bank reflects all disciplinary actions on appeal, and to remove from the physician’s record reported decisions which have been overruled.
6. Our AMA will continue to monitor the issue of reporting impaired physicians to the National Practitioner Data Bank and will seek further clarification of ambiguities or misinterpretations of the reporting requirements for impaired physicians.
7. Our AMA will: (a) request that the Health Resources and Services Administration (HRSA) clarify that reports of medical staff appointment denial of physicians be (i) contingent upon competency or conduct related to the physicians’ provision of or failure to provide healthcare services that adversely affect the health or welfare of a patient, and (ii) only based on a professional review action and not for administrative or eligibility reasons; and (b) advocate that HRSA remove the name of any physician from the National Practitioner Data Bank reported for reasons not related to competence or conduct that adversely affected the health or welfare of a patient.
Policy H-355.975, “Opposition to the National Practitioner Data Bank”
1. Our AMA communicates to legislators the fundamental unfairness of the civil judicial system as it now exists, whereby a jury, rather than a forum of similarly educated peers, determines if a physician has violated the standards of care and such results are communicated to the National Practitioner Data Bank; and impresses on our national legislators that only when a physician has been disciplined by his/her state licensing agency should his/her name appear on the National Practitioner Data Bank.
2. Our AMA affirms its support for the Federation of State Medical Boards Action Data Bank and seeks to abolish the National Practitioner Data Bank.
3. Our AMA urges HHS to retain an independent consultant to (A) evaluate the utility and effectiveness of the National Practitioner Data Bank, (B) evaluate the confidentiality and security of the reporting, processing and distribution of Data Bank information, and (C) provide the findings and recommendations to the National Practitioner Data Bank Executive Committee and the General Accounting Office.
4. Our AMA will take appropriate steps to have Congress repeal Section 4752 (f) of OBRA 1990 requiring peer review organizations and private accreditation entities to report any negative action or finding to the Data Bank.
5. Our AMA seeks to amend the Health Care Quality Improvement Act of 1986 to allow a physician, at the time the physician notifies the Data Bank of a dispute, to attach an explanation or statement to the disputed report;
6. Our AMA opposes any legislative or administrative efforts to expand the Data Bank reporting requirements for physicians, such as the reporting of a physician who is dismissed from a malpractice suit without any payment made on his or her behalf, or to expand the entities permitted to query the Data Bank such as public and private third party payers for purposes of credentialing or reimbursement.
7. Our AMA (A) urges HHS to work with the Federation of State Medical Boards to refine its National Practitioner Data Bank breakdown of drug violation reporting into several categories; (B) urges the HHS to analyze malpractice data gathered by the Physician Insurance Association of America and recommend to Congress that a threshold of at least $30,000 for the reporting of malpractice payments be established as soon as possible; (C) will continue to work with HHS to allow physicians an expanded time period to verify the accuracy of information reported to the Data Bank prior to its release in response to queries; (D) will work with HHS and the Office of Management and Budget to reduce the amount of information required on the request for information disclosure form and to improve the design of the form to allow for more efficient processing of information; and (E) will continue to work with HHS to improve its mechanism to distribute revisions and clarifications of Data Bank policy and procedure.
8. Our AMA will review questions regarding reportability to the Data Bank and will provide periodic updates on this issue to the AMA House of Delegates.

Policy H-355.990, “National Practitioner Data Bank”
(1) The AMA shall continue to pursue vigorously remedial action to correct all operational problems with the National Practitioner Data Bank (NPDB).
(2) The AMA requests that the Health Resources and Services Administration (a) prepare and disseminate to physician and hospital organizations a white paper addressing its plans to enhance the confidentiality/security provisions of the reporting and querying process no later than December 1992; (b) conduct a statistically valid sample of health care entities, other than hospitals, on the entity file to determine if entities that are not eligible to query under the statute and regulation have gained access to the NPDB information, and disseminate the results to the NPDB Executive Committee no later than December 1992; (c) implement appropriate steps to ensure and maintain the confidentiality of the practitioner’s self-query reports no later than December 1992; (d) recommend to the Congress that small claims payments, less than $30,000, no longer be reported to the NPDB and provide the Executive Committee members the opportunity to attach their comments on the report that goes to the Congress; (e) allow by January 1, 1993, the practitioner to append an explanatory statement to the disputed report; and (f) release the evaluation report, prepared by Dr. Mohammad Akhter, on the NPDB’s first year of operation to the AMA by July 1992.
(3) The AMA will reevaluate at the 1992 Interim Meeting the progress on these issues. If the preceding requests are not met by the established due date and the House of Delegates is not satisfied with the progress on these issues, the AMA will again reevaluate the implementation of Policy H-355.991.
Policy H-355.974, “National Practitioner Data Bank”

1. Our AMA will advocate to the Health Resources and Services Administration that a physician’s surrender of clinical privileges or failure to renew clinical privileges while under investigation should not be reported to the National Practitioner Data Bank unless the physician has been notified that an investigation is underway.

2. Our AMA: (a) recommends that medical staff bylaws require that physicians be notified in writing prior to the start of any investigation; and (b) include this recommendation in our AMA Physician’s Guide to Medical Staff Organization Bylaws.
Subject: 2018 Strategic Plan

Presented by: Gerald E. Harmon MD, Chair

Our AMA continues to execute its multi-year strategy to achieve significant positive impact for physicians, medical students and patients. The strategy, launched in 2013, identified three areas of emphasis in our mission focused areas: Improving Health Outcomes, Accelerating Change in Medical Education, and Shaping Care Delivery and Payment for Professional Satisfaction and Practice Sustainability. These focus areas provide for tangible and meaningful implementation of our AMA’s mission to promote the art and science of medicine and the betterment of public health.

Through this report, the Board of Trustees affirms AMA’s multi-year strategic focus. This report is devoted to what is on the horizon for each of the focus areas in 2018 and highlights other work to modernize the means through which physicians can engage in advancement of the mission.

CARE DELIVERY AND PAYMENT:
PROFESSIONAL SATISFACTION AND PRACTICE SUSTAINABILITY

With the successful repeal of the sustainable growth rate (SGR) in 2015 through the Medicare and CHIP Reauthorization Act of 2015 (MACRA), our work has refocused—with even greater intensity—to ensure that MACRA’s implementation supports a health care system that delivers better care and more visible value while also supporting a sustainable and professionally satisfying practice environment. The goal is to create a pathway for physicians to choose from a broad array of alternative payment and health care delivery models, including viable fee-for-service options.

Successful navigation and implementation of evolving public and private payment systems requires heightened physician awareness, informed assessment of options, and, potentially, new strategic and operating methods to optimize success. To support physicians through this changing landscape and improve care delivery and professional satisfaction, AMA will work in 2018 to:

- Advocate for legislative and regulatory changes that enhance prospects for physicians to succeed.
- Generate awareness and encourage physicians to prepare for evolving payment model changes.
- Provide multi-modal, multi-channel physician education about what new payment model options mean for physicians and patients.
- Guide physicians toward the best outcome in value-based care systems and establish the AMA as a valued source of support on issues spanning a wide range of care delivery and payment models.
- Expand the resources delivered through the STEPS Forward: Practice Improvement Strategies program and other tools to help physicians in a variety of practice settings learn new techniques to improve practice workflow, patient care and professional satisfaction.
- Increase the awareness and importance of professional satisfaction and support the Quadruple Aim through additional research, partnerships, and resources to assist physicians throughout the various settings and stages of their careers.
- Discover and promote the physician perspective across health technology sectors, directing development for improved usability, productive access to data, and respect for the patient-physician relationship.
In addition taking the longer perspective in 2018 AMA will build on its 2017 research and development work to further assess opportunities for diagnostic, prognostic, and predictive tools for patient care that will modernize health and medical information systems to give physicians access to data needed for enhanced clinical, operational, and administrative effectiveness.

IMPROVING HEALTH OUTCOMES (IHO)

Initiatives focused on health outcomes, particularly in the area of prevention and management of chronic care, underscore AMA’s foundational commitment to improving the health of the nation. Concentrating on risk factors for cardiovascular disease and type 2 diabetes, our AMA is working with physicians and care teams to bring new approaches for anticipating, preventing, and managing widely prevalent chronic conditions.

To achieve the scale required for this ambitious set of programs, AMA has developed multi-year strategic relationships with the Centers for Disease Control and Prevention (CDC) and the American Heart Association (AHA), whose national reach and influence reinforce and complement AMA resources. Our shared goals with the CDC and the AHA include significantly increasing the number of physician practices, health care systems and federally qualified health centers that:

- Screen patients for prediabetes and refer eligible patients to CDC-recognized diabetes prevention programs (DPPs) as the preferred option for preventing type 2 diabetes, and
- Improve care for patients with hypertension to achieve and sustain 70 percent or higher blood pressure control rates within the communities they serve.

AMA’s partnerships with the CDC and AHA are solid and we are complementing them with collaborations with medical societies, business groups, payers, technology companies, and medical schools (through the ACE consortium) to offer evidence-based products, tools and services to support physicians, care teams, health system leaders and medical students in achieving the health outcomes we seek. Materials have been developed and distributed for use in practice settings ranging from small private practices to large integrated systems. The material and programs have been empirically demonstrated to be effective and our main focus is to create the environmental, distribution, and awareness elements conducive to widespread scaling. In this regard, we continue to define and promote the “business case” for public and private payer coverage of proven interventions such as diabetes prevention programs (for which Medicare announced coverage in 2016) and self-measured blood pressure monitoring devices.

Public and physician awareness is a key ingredient to success. Beginning in 2017 and extending through 2018, we will refresh the successful pre-diabetes public campaign launched in 2016 and add a physician oriented pre-diabetes awareness campaign. A blood pressure awareness program is planned for 2018.

ACCELERATING CHANGE IN MEDICAL EDUCATION (ACE)

Since 2013 the AMA has supported a Consortium of medical schools, now 32 in number, to accelerate change in medical education by creating a system that trains physicians to meet the needs of today's patients and to anticipate future changes. Facilitated by the AMA through individual and collaborative work the consortium schools have created new and innovative programs and technologies that are increasingly adopted by medical schools throughout the nation. Of particular note is the successful application of the chronic care curriculum based on work done in our Improving Health Outcomes area. This is an example of the growing application of work emanating from one strategic area to another critical arena.
Highlights of major plans for 2018 include:

- Ensuring the ongoing viability and maintenance of the Consortium beyond the termination of the AMA funding cycle.
- Building on the AMA Consortium health system science textbook to create a product and service line applicable to all stages of physician and other health care providers’ lifelong learning.
- Collaborating with other focus areas on student and trainee wellness; resilience/burnout; and new models for linking students, physicians and communities in shared goals of chronic disease management and health equity.
- Based on the experience and learning from the work in undergraduate medical education, plans will be developed for subsequent work in graduate medical education likely emphasizing the transition from undergraduate to residency status.

ENGAGING PHYSICIANS IN ADVANCEMENT OF THE MISSION

Effective and responsive lifelong physician professional development is a cornerstone to activating the focus area objectives. These objectives and other national imperatives--such as reducing opioid-related harm and increasing access to treatment for patients with opioid use disorders, responding to physician burnout and wellness issues, responding to the quality and cost issues in our health care environment--require AMA to provide physicians and their team members pragmatic educational offerings, tools, and leadership training designed to address real-world practice and care delivery issues.

The AMA’s Education Center portal and platform is a crucial component of AMA’s commitment to lifelong professional development. New capabilities and an improved user experience were introduced in 2017. The GME Competency Education Program (formerly Introduction to the Practice of Medicine), currently deployed in approximately 150 residency settings across the country, was modernized and incorporated into the Education Center in 2017. As the multi-year effort progresses, our physician stakeholders will have access to educational tools and resources from diverse sources through a highly functional platform tailored to individual needs, accessible from desktops and mobile devices, with streamlined support for transcripts, reporting to boards, employers and payers to serve credentialing, licensing and certification requirements. We anticipate completing the majority of the Education Center refresh in 2018.

Evidence of AMA mission impact continues to grow, creating an opportunity for AMA to refresh its brand identify among physicians and other stakeholders. We will achieve this by linking relevant offerings and activities throughout the career lifecycle of students, residents, and practicing physicians and more refined approaches to identifying and responding to the particular interests and needs of the physician population. The goal is to strengthen the AMA brand through deeper stakeholder engagement. Traditional and interactive/social/digital media will be deployed to create new connections, awareness, and opportunities to interact with the AMA. More sophisticated monitoring of interactions also will yield insight into physician preferences so that we can continuously improve services to physicians, residents and fellows, and medical students so as to retain and grow our membership base. In 2018 we will build on our initial experience with social networks and community groups started in 2017 by further refined exploration and integration of this strategy into our overall physician engagement effort.

The three focus areas have made much progress since their inception in 2013. As they have matured and moved from the early stages of innovation and learning to more operative models of impact and scaling we have begun to extend the conceptualization and connection of their work to other important aspects of our AMA’s efforts under three general strategic arcs: 1) Vital practice resources; 2) Lifelong professional development; and 3) Improving the health of nation. Closer connection of the focus areas with other critical AMA activities will stimulate more collaborative and synergistic planning and operations enhancing our effectiveness and impact.
The momentum that supports this multi-year strategy is a reflection of collaboration and shared commitment across the AMA and the Federation of medicine, academic institutions, public and private health sector organizations, technology innovators, physicians, and physicians in training. Together we will chart a course for health care delivery that will improve the health of the nation.
Subject: Parental Leave

Presented by: Gerald E. Harmon, MD, Chair

INTRODUCTION

At the 2016 Interim Meeting of the House of Delegates (HOD), Policy H-405.954, “Parental Leave,” was adopted. The policy states the American Medical Association (AMA) will: (1) encourage 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) a reduction in the number of employees from 50 employees; (b) an increase in the number of covered weeks from 12 weeks; (c) creating a new benefit of paid parental leave; and (2) study the effects of FMLA expansion on physicians in varied practice environments. This report serves as a summary of the FMLA, proposed expansion of the law and potential for study of the effects of future expansion, with a focus on the effects on physicians.

BACKGROUND

The FMLA provides certain employees with up to 12 weeks of unpaid, job-protected leave per year. Eligible beneficiaries of FMLA include employees who have been employed by their employer at least 12 months, worked at least 1,250 hours over the past 12 months, and work at a location where the company employs 50 or more employees within 75 miles. Private employers with at least 50 employees (employed for at least 20 weeks in the preceding or current calendar year) and public employers with any number of employees are covered by the FMLA.1 Several proposals for expansion of the FMLA at the federal level have been considered. Expansion of employee eligibility, covered leave time or employer requirements would undoubtedly result in various impacts on employees and employers,2 including physicians who are employed or employ others. Another proposed form of expansion, the creation of a required paid parental leave benefit, would also have significant implications for employers, employees, and new parents and infants.3-6

AMA POLICY

AMA policy supports voluntary employer policies that provide employees with reasonable job security and continued availability of health plan benefits in the event leave becomes necessary due to documented medical conditions (Policy H-420.979). The AMA recognizes the public health benefits of paid sick leave and other paid time off, although mandatory paid sick leave is not specifically endorsed by the AMA. Council on Medical Service Report (CMS) 3-A-16 provided a comprehensive review of sick leave and paid leave policies. The HOD adopted the recommendations in the report that established policy supporting employer policies that provide employees with unpaid sick days to care for themselves or a family member (Policy H-440.823).

The AMA recognizes that physicians, as employees and employers, are impacted by the FMLA and other medical leave regulations. AMA Policies for Parental, Family and Medical Necessity

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Leave (Policy H-405.960) established guidelines that encourage 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. This policy also encourages staff scheduling to allow for coverage during a physician’s leave without creating intolerable increases in other physicians’ workloads, particularly in residency programs, and that physicians should be able to return to their practices or training programs after taking parental leave without the loss of status.

**DISCUSSION**

**Expansion of the FMLA**

Proposals to expand the FMLA have been presented by legislators and advocacy organizations who assert that the U.S. lags behind other industrialized nations in its existing laws related to employee leave. On the federal level, proposals for expansion have attempted to:\(^\text{2}\)

1. expand employee eligibility by removing the 1,250 hour requirement, eliminating the requirement that an employee work for the employer for at least 12 months, or lowering the employer threshold of 50 employees within 75 miles;
2. cover more employers by including those with 15 or 25 employees;
3. increase the number of covered weeks; and
4. establish a mandated paid leave benefit.

One proposed federal expansion law is the Family and Medical Insurance Leave Act (the FAMILY Act) S. 337/H.R. 947, which would, among other things:

- create a national program to provide all workers, regardless of company size, with up to 12 weeks of partially paid leave; and
- enable workers to receive up to 66 percent of their monthly wages, up to a capped amount, during their time of leave.

Many states have already enacted laws that provide benefits in excess of those provided under the FMLA. Currently, three states—California, New Jersey and Rhode Island—have required paid family leave. New York will be the fourth in 2018 when its Paid Family Leave Benefits Law will be effective. Additionally, five states and several cities have implemented paid sick leave laws. The laws in these cities and states go beyond the required unpaid leave of the FMLA to provide employees with guaranteed pay during various types of approved medical leave. Benefits to both employees and employers have been reported in the states providing paid family leave.

In California, for example, the Paid Family Leave program provides employees with up to six weeks of paid leave to care for a new child or ill family member. The program is funded by employee payroll contributions, so while employers do not face financial burden as a result of the law, they are faced with ensuring the employees’ workload is covered and that gaps in staffing are filled. The program in California, however, does not assure job protection during leave, provides wage replacement at only 55 percent, and does not cover care for grandparents, grandchildren, parents-in-law, or siblings. A 10-year review of California’s expansion demonstrated that the Paid Family Leave benefit promoted family well-being, improved family economic security, equalized access to leave across occupations and income levels, and bolstered businesses by reducing workforce turnover. It was also noted that overall awareness of the program among those most likely to utilize it was low, implying that utilization rates could be higher if education and outreach were improved upon.\(^\text{7-10}\)

Similar outcomes have been reported for other cities and states.\(^\text{7-10}\)
Existing Research

There is an abundance of literature about the benefits of employee access to medical leave provided under existing law, much of which was summarized in CMS Report 3-A-16.11 For example, studies show that children recover faster from illness when cared for by a parent,12 and the presence of a parent has been shown to reduce hospital stay duration by 31 percent.13 A national health impact assessment demonstrated that paid sick leave policy would result in more workers taking needed leave to recover from illness, receive preventive care, and care for ill children.14 These actions would reduce transmission of influenza, foodborne disease, and gastrointestinal infections in health care facilities.14 Some proponents of paid sick leave policies claim companies can experience cost savings, increased productivity, and disease and illness prevention when employees are able to take time off when they or a family member are ill.15

In addition to evidence showing the benefits of leave policies, lack of paid sick leave can have significant and adverse effects on public health. Workers without paid sick leave are more likely to work while ill and delay medical care, which can lead to prolonged illness and likelihood of worsening otherwise minor health issues.16 One study revealed that lack of workplace policies, such as paid sick leave, was correlated with a higher incidence of influenza-like illness.17 A 2007 study estimated that the annual flu season results in over 3 million hospitalized days and costs employers $10.4 billion in direct medical costs for hospitalizations and outpatient visits.18

Also outlined in CMS Report 3-A-16 are the concerns employers and employer groups have expressed with the prospect of expanding medical leave benefits. Some employer groups oppose expanding FMLA benefits due to the potential for increased costs. Others claim paid leave policies or policies that provide coverage for more employees may burden and negatively impact employer operations,11 with hospitals and physician practices being no exception.

Although it is limited, research does exist that demonstrates projected effects of various types of expansion upon family leave policies. An analysis published by IMPAQ International, Inc. and the Institute for Women’s Policy Research summarizes a simulation of five paid family and medical leave model programs based on working programs in three states and a federal proposal, all applied to the national workforce. The findings suggest that upon expansion of FMLA laws, through covering more eligible workers, replacing a larger percentage of usual earnings, and offering more weeks of paid leave increase the estimated costs. If based on any of the five models in the simulation, the cost for benefits would range from $31 billion to $43 billion. This report also projects that a national paid family and medical leave policy, depending on the type of expansion, would increase the amount of leave taken by 6 to 11 percent annually.19

Another report by the Institute for Women’s Policy Research estimates costs for a series of policy scenarios for employers in New Hampshire. Using a simulation model, the authors estimated the total program costs for the Family Medical Leave Insurance (FMLI) policy proposal if the law was changed to require all employers to provide benefits, only firms with 25 or more employees, and only firms with 50 or more (current policy). The total costs were estimated at $163.5 million when all employees are covered, $133.8 million when only firms with 25 or more employees are covered, and $124.1 million when only firms with 50 or more employees are covered. In addition to the cost implications of covering more employees, the authors projected an increase in the number of leaves taken and a decrease in the average weekly benefit.20 Similar research has been reported for the District of Columbia.21
Implications for Physicians

Expansion of FMLA benefits to include more employers or employees would undoubtedly affect physicians who employ others or are employed. Upon any form of expansion of FMLA, physicians who employ others and physicians in small practices would be expected to experience some changes in the operations of their practices. In 2016, 37.9 percent of U.S. physicians worked in practices with less than five physicians, 19.9 percent in practices with five to 10 physicians, and 13.3 percent with 11 to 24 physicians.22

As of 2016, most physicians (57.8 percent) work in practices with 10 or fewer physicians. Given there is an average of four full-time support staff for every full-time practicing physician,23 it would likely be the practices with 10 or fewer physicians that would be impacted by any reduction in the threshold to include more employees under FMLA. (Those with 11 or more physicians are already likely covered under current legislation.) For example, if FMLA coverage were expanded to include employers with 25 or more employees, or all employers regardless of size, these practices with 10 or fewer physicians may be required to make changes in scheduling, staffing processes or other aspects of practice operations. Reports on business’ experiences with FMLA compliance are limited and mixed, suggesting that these changes could be burdensome for some practices, but may pose no issues for others. One survey concluded employers report little negative impact of complying with FMLA,24 but another report indicates a high number of complaints about the record keeping and coordination of state and federal leave policies.25

A study conducted by the National Federation of Independent Business (NFIB) used a regulatory impact model to calculate the projected costs of an expanded FMLA leave program on small businesses. Their findings showed small businesses would be faced with an additional cost of approximately $30,000 to $50,000 in reduced sales, mandatory overtime payments, and diversion of management attention.25 This study focused on manufacturing, construction, and various service industries and did not include data for health care employers; therefore, assuming correlations that suggest similar impacts in health care settings is cautioned against.

As outlined in the previously mentioned reports, the effects on employees, including physicians, would be dependent on many factors including practice size and whether expansion of the law would change the employer’s existing coverage. As more and more physicians move from solo or small practices to employment within health systems or hospitals, some may gain coverage under FMLA law. The personal effects of FMLA expansion on physicians would likely be similar to the

<table>
<thead>
<tr>
<th>Number of physicians in practice</th>
<th>Distribution of physicians by practice size22</th>
<th>Estimated full-time employee count*</th>
<th>Affected by expansion in FMLA coverage from 50 to 25 minimum FTE</th>
<th>Affected by expansion in FMLA coverage to ALL employees</th>
</tr>
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<tr>
<td>1-4</td>
<td>37.9%</td>
<td>5-20</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>5-10</td>
<td>19.9%</td>
<td>25-50</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>11-24</td>
<td>13.3%</td>
<td>55-120</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>25-49</td>
<td>7.4%</td>
<td>125-245</td>
<td>No</td>
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<td>50+</td>
<td>13.8%</td>
<td>250+</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

*Number of full-time staff members per physician varies according to specialty, practice setting and other factors. This full-time employee count assumes an average of four full-time staff members per full-time physician and includes the physicians.23
overall public health benefits described earlier in this report and in CMS Report 3-A-16. There is no research or literature to suggest that physicians employed by organizations subjected to expanded FMLA requirements would experience benefits that are significantly different than those experienced by employees in other professions.

CONCLUSION

Our review of existing research has demonstrated that expansion of FMLA laws could increase the cost of benefits to employers. Depending on the type of expansion, the costs could range from $31 billion to $43 billion. A national paid family and medical leave policy, depending on the type of expansion, would increase the amount of leave taken by 6 to 11 percent annually. Finally, any expansion of FMLA coverage would likely predominantly affect physician practices with 10 or fewer physicians.

The first directive in Policy H-405.954 states the AMA will encourage the study of the health implications among patients if the FMLA law was modified. The AMA recognizes the importance of effects changes in the law may have on patient outcomes. In addition to the federal law, states may have, or may enact in the future, any variety of family leave laws that provide benefits to more employees. Patient demographics and health care needs also vary across states and regions. It is for these reasons that the AMA will continue ongoing collaborations with state medical societies to observe and track the variety of local and state family leave laws and study the related health implications for patients.

The second directive of Policy H-405.954 states the AMA will study the effects of FMLA expansion on physicians. Upon enactment of federal laws that provide more expansive coverage or coverage to a larger number of people, there should be opportunities to study the effects on physicians and health care employers more expansively than the simulations discussed herein.

The AMA recognizes the importance and benefits of access to medical and family leave, and existing policies H-420.979 and H-405.960 are demonstrative of this cognizance. While the AMA does not endorse policies requiring paid leave, it does encourage medical group practices to incorporate leave policies, including parental, family, and medical leave policies, in their standard benefit structure.
REFERENCES

At the 2017 Annual Meeting, the American Medical Association (AMA) House of Delegates adopted Policy H-140.837, “Anti-Harassment Policy” (see Appendix for full text), which provided that:

 Upon adoption of the Anti-Harassment Policy, the Board will establish a formal process by which any delegate, AMA Entity member or AMA staff member who feels he/she has experienced or witnessed conduct in violation of this policy may report such incident. Additionally, the Board will consider and prepare for future consideration by the HOD, potential corrective action and/or discipline for conduct in violation of this policy, which may include, but shall not be limited to, referral of the matter to the applicable delegation, expulsion from AMA meetings, or expulsion from the HOD.

The policy was proffered by Board of Trustees Report 23-A-17, which noted that AMA Human Resources policies establish zero tolerance regarding harassment with respect to AMA personnel, agents, and nonemployees, including AMA members. This informational report of the Board of Trustees provides an update to the House of Delegates. At the 2018 Annual Meeting, the Board will recommend procedures to fully implement the anti-harassment policy with respect to conduct during meetings of the House of Delegates, councils, sections, and all other AMA entities, such as the RVS Update Committee (RUC) and CPT Editorial Panel.

DISCUSSION

Professional associations’ anti-harassment policies are designed to support the open exchange of ideas central to their mission and to ensure that those who participate in association activities “enjoy an environment free from all forms of discrimination, harassment, and retaliation” [1]. Surprisingly few professional associations have published anti-harassment policies. These Associations have established mechanisms to address allegations of harassment that designate the association officer(s) or other association authority to whom incidents should be reported, provide for confidential investigation of alleged inappropriate conduct, and define sanctions that may be imposed if conduct is found to violate association policy [1-5].

The AMA recently extended mandatory recurring anti-harassment training to include not only staff, but also members of all AMA councils. The Board believes such training is appropriate for section governing councils and Board members as well. It is the Board’s hope that this training will eliminate harassing behavior in connection with meetings of AMA entities, but given our zero tolerance policy for such behavior we believe that a formal process for reporting, investigation and resolution should be established.

There are numerous complexities involved in implementing processes for reporting and investigation and discipline in the event of harassment complaints. The Board is studying best practices and reviewing potential avenues for the above called for in Policy H-140.837. Myriad issues have arisen with any of the types of processes discussed. Thus, the Board will make recommendations on reporting, investigating, and enforcing instances of harassment at the 2018 Annual Meeting.
REFERENCES


APPENDIX

**AMA Policy H-140.837, “Anti-Harassment Policy”**

1. Our AMA adopts the following policy:

**Anti-Harassment Policy Applicable to AMA Entities**

It is the policy of the American Medical Association that any type of harassment of AMA staff, fellow delegates or others by members of the House of Delegates or other attendees at or in connection with HOD meetings, or otherwise, including but not limited to dinners, receptions and social gatherings held in conjunction with HOD meetings, is prohibited conduct and is not tolerated. The AMA is committed to a zero tolerance for harassing conduct at all locations where AMA delegates and staff are conducting AMA business. 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.

**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 other protected group status, 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.

2. Our AMA's Board of Trustees will establish a formal process by which any delegate, AMA Entity member or AMA staff member who feels he/she has experienced or witnessed conduct in violation of this policy may report such incident; and consider and prepare for future consideration by the House of Delegates, potential corrective action and/or discipline for conduct in violation of this policy, with report back at the 2017 Interim Meeting.
INTRODUCTION

At the 2017 Annual Meeting, the American Medical Association House of Delegates adopted the recommendations of Council on Ethical and Judicial Affairs Report 1-A-17, “Amendment to E-2.3.2, Professionalism in Social Media.” 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-2.3.2 Professionalism in Social Media

The Internet has created the ability for medical students and physicians to communicate and share information quickly and to reach millions of people easily. Participating in social networking and other similar opportunities can support physicians’ personal expression, enable individual physicians to have a professional presence online, foster collegiality and camaraderie within the profession, provide opportunities to widely disseminate public health messages and other health communication. Social networks, blogs, and other forms of communication online also create new challenges to the patient-physician relationship. Physicians should weigh a number of considerations when maintaining a presence online:

(a) Physicians should be cognizant of standards of patient privacy and confidentiality that must be maintained in all environments, including online, and must refrain from posting identifiable patient information online.

(b) When using social media for educational purposes or to exchange information professionally with other physicians, follow ethics guidance regarding confidentiality, privacy and informed consent.

(c) When using the Internet for social networking, physicians should use privacy settings to safeguard personal information and content to the extent possible, but should realize that privacy settings are not absolute and that once on the Internet, content is likely there permanently. Thus, physicians should routinely monitor their own Internet presence to ensure that the personal and professional information on their own sites and, to the extent possible, content posted about them by others, is accurate and appropriate.
(d) If they interact with patients on the Internet, physicians must maintain appropriate boundaries of the patient-physician relationship in accordance with professional ethics guidance just as they would in any other context.

(e) To maintain appropriate professional boundaries physicians should consider separating personal and professional content online.

(f) When physicians see content posted by colleagues that appears unprofessional they have a responsibility to bring that content to the attention of the individual, so that he or she can remove it and/or take other appropriate actions. If the behavior significantly violates professional norms and the individual does not take appropriate action to resolve the situation, the physician should report the matter to appropriate authorities.

(g) Physicians must recognize that actions online and content posted may negatively affect their reputations among patients and colleagues, may have consequences for their medical careers (particularly for physicians-in-training and medical students), and can undermine public trust in the medical profession. (I, II, IV)
REPORT OF THE COUNCIL ON MEDICAL EDUCATION

CME Report 2-I-17

Subject: A National Continuing Medical Education Repository

Presented by: Lynne M. Kirk, MD, Chair

It is a physician’s professional responsibility to participate in continuing medical education (CME) activities in order to sustain life-long learning and improve the care provided to patients. Often, CME credits can be used to meet the CME requirements of state medical and osteopathic boards, medical specialty societies, specialty boards, hospital medical staffs, and insurance networks. Yet the tools with which physicians track their CME vary widely by state, specialty, and institution.

In a previous report, the American Medical Association (AMA) Council on Medical Education noted that while a central repository/online reporting system that would allow a physician to track/store CME credits would be very useful for meeting requirements for licensure, certification, and credentialing, many specialty and state medical societies and other organizations already provide such services, and a central repository was perceived as duplicative (or not warranted). Additionally, research indicated that the cost of a centralized service would almost invariably be borne by physicians. Furthermore, all CME providers would need to agree upon technical and data security proposals in order to proceed with a centralized repository, and questions about which entity(ies) would fund and maintain such a service remained unanswered. Pursuant to more recent Council on Medical Education discussions, however, members agreed that a follow-up review was warranted, given the time elapsed since the adoption of the previous report.

BACKGROUND

There are three major credit systems in the United States: (1) The AMA Physician Recognition Award (PRA) credit system; (2) American Academy of Family Physicians (AAFP) credit system; and (3) American Osteopathic Association (AOA) credit system. These three established credit systems facilitate physician credentialing and the renewal of licensure by providing metrics to demonstrate that a physician has maintained a commitment to study, apply, and advance scientific knowledge through participation in appropriate CME activities. There is strong communication and cooperation among the AMA, AOA, and AAFP, and although there are differences in how credits are categorized, the CME rules followed are similar in many ways. However, there is no centralized data repository to track all CME credits earned by a physician, and physicians are generally personally responsible for tracking and documenting their earned CME credits when verification is required for licensure or other credentialing purposes.

CREDIT SYSTEMS AND ACCREDITING BODIES

AMA, ACCME, and State/Territory Medical Societies

In 2016, more than 1,800 CME providers accredited by the Accreditation Council for Continuing Medical Education (ACCME) and state/territory medical societies produced almost 159,000 educational activities that were certified for *AMA PRA Category 1 Credit.*AMA PRA requirements mandate that all accredited CME providers maintain records for each physician who
participates in their CME activities and verify this participation if requested by the physician. The vast majority of CME providers do not report the actual number of credits awarded to individual physicians at the participant level. An exception to this is a new partnership between the ACCME and three American Board of Medical Specialties’ (ABMS) Member Boards. The American Board of Anesthesiology (ABA), American Board of Internal Medicine (ABIM), and American Board of Pediatrics (ABP) have established a relationship with the ACCME’s Program and Activity Reporting System (PARS). Through this partnership, CME providers upload physician-level data to the ACCME PARS system, which then can be transmitted directly to the specialty board. However, this transmission occurs only in those instances in which the credits are accepted by the specialty boards to meet their MOC requirements.

AMA PRA policy encourages physicians to report to the AMA any accredited CME provider that fails to provide documentation to a physician of his or her earned AMA PRA Category 1 Credits. Additionally, physicians can choose to apply for the AMA PRA, which many state licensing boards accept as demonstrating compliance with state CME requirements.

AOA

The AOA works with approximately 170 AOA-accredited sponsors that provide AOA Category 1 credit. It is the responsibility of the sponsor to report all CME credit earned by individual physicians to the AOA. For non-osteopathic-sponsored CME activities, it is the responsibility of the physician to provide documentation to the AOA. A certificate of attendance or letter of verification from the CME sponsor must be provided. The AOA tracks earned CME credits for individual physicians in a centralized online repository, the AOA “traCME” system. AOA members may view their CME profile/activity report online or contact the AOA for an electronic copy.

AAFP

AAFP members usually self-report CME credits to the AAFP. However, this is strictly voluntary. The AAFP does not require CME providers to provide certificates to CME participants; however, the AAFP encourages providers to offer certificates, since many members need them for state licensing and credentialing. CME providers are required to have a mechanism in place to document learner participation.

Comparison of Accrediting Bodies

Appendix A reviews the credit-related services currently offered by the three major CME credit systems.

CME TRACKING SERVICES

State Medical Societies

In preparation for the writing of this report, the Council canvassed state medical societies regarding their efforts to assist physicians with tracking CME to meet state licensure requirements. Of those who responded, four indicated that they offer related services beyond providing a transcript for their own CME activities:

- The Pennsylvania Medical Society (PMS) ([www.pamedsoc.org/Tracker](http://www.pamedsoc.org/Tracker)) allows physicians to enter their AMA PRA Category 1 Credits and AMA PRA Category 2 Credits into an
electronic tracking system called Tracker. This system shows physicians when they have met
the state’s licensing requirements and the PMS’s CME certificate requirements.

- The California Medical Association’s Institute for Medical Quality (IMQ) CME Certification
  Program (www.imq.org/continuingmedicaleducation/cmecertification.aspx) records and
  verifies AMA PRA Category 1 Credit™ for California-licensed physicians to meet the state
  medical board’s requirements for licensure. CME credits can be reported using an online form
  and CME transcripts can be viewed and printed from the IMQ online site. Physicians who
  participate in this program are not required to undergo an independent audit of their CME
  activities by the California Medical Board.

- The Florida Medical Association (FMA) tracks all CME it provides directly in each
  physician’s record in its membership database http://www.floridahealth.gov/licensing-and-
  regulation/ce.html). This allows the FMA to generate a transcript with all FMA directly-
  provided CME that a physician (member or non-member) has completed over a specific period
  of time. The FMA also electronically reports its CME attendance data to CE Broker, which is
  the official continuing education (CE) tracking system for the state of Florida. Any educational
  provider that is specifically approved by a medical licensing board in Florida is statutorily
  required to report its attendance data to CE Broker. Although organizations accredited through
  the ACCME system are not statutorily required to report attendance (as their approval is from
  an entity other than the medical licensing board), many ACCME and FMA-accredited CME
  providers in Florida choose to do this.

- The South Carolina Medical Association (SCMA) receives information from its accredited
  CME providers on a quarterly basis that is uploaded into its database, which also contains data
  from SCMA’s own CME activities. The SCMA provides, on a biennial basis, a report to the
  state Board of Medical Examiners of members who have submitted their CME for tracking and
  met the minimum standard for license renewal (https://www.scmedical.org/education). The
  SCMA also tracks all South Carolina physicians who participate in its online opioid courses
  and reports this biennially to the Board of Medical Examiners.

Specialty Societies

Specialty societies are more likely than state medical societies to offer CME tracking tools and
capabilities to their members, and this tracking is more likely to relate to MOC requirements.
Appendix B summarizes information obtained from 2013 and 2017 surveys of Council of Medical
Specialty Societies (CMSS) member organizations.

Personal Digital Strategies

A number of mobile apps and online services are available to track CME credit. A simple search of
the phrases “continuing medical education tracker” and “CME Tracker” in Apple’s App Store and
Google Play generated multiple hits, including JoyCE, CEAgent, CE Vault Healthcare Edition,
CME Tracker, eeds Mobile, My CE, and DocIt, among others. Online membership groups, such as
Doximity, and products, such as UpToDate, also offer some level of CME tracking. However, the
ability of these products to interface with accrediting bodies is unclear, and the product in many
cases seems to be more reflective of a transcript, rather than of a comprehensive tracking system.
Institutional Tracking Systems

Some hospital systems and institutions also offer a type of CME tracking through their credentialing offices or other similar bodies, although this credit tracking may apply only to credit granted for the health system’s own events/CME offerings, and there does not appear to be aggregated information regarding which systems offer these services at the national level. The Association of American Medical Colleges (AAMC) does not officially track which of its member institutions offer CME tracking as a physician employee benefit. However, the Alliance for Continuing Education in the Health Professions (ACEHP) notes that at least one of its major hospital system members, the Cleveland Clinic, offers its employed physicians a free database tool for tracking CME (although it is the responsibility of individual physicians to manage their CME).

DISCUSSION

Perceived Need for a National Repository

As noted in a previous report, the AMA recognizes that a centralized repository and online reporting system for CME credit would be very useful to today’s physicians. However, in addition to the duplicative nature of such a service, some CME providers might resist requirements to report information to an additional central repository as they already provide this service to their members. Furthermore, as noted, some specialty societies already have developed working relationships with their certifying boards as a member service. In addition, each CME provider is required to keep records of the credits it issues to meet the requirements of the AMA PRA Credit System, and this could create additional administrative work for their staff.

The 2013 survey of CME directors from CMSS member organizations found that the majority of specialty societies that manage a database of CME credits earned by their physician members would not prefer a centralized credit database in lieu of their services, as they considered their own CME tracking services to be a valuable member benefit. At that time, specialty societies also were concerned about the potential data integrity/ownership/security issues that could arise with the development of a centralized database.

A 2017 survey of CMSS member societies reinforced this group’s lack of support for the creation of centralized repository; respondents cited multiple reasons for their opinions. “Creating a centralized database would only create additional work for us to copy the records we have to keep into an outside system and answer member questions when the centralized system has errors or the information we provide doesn’t upload correctly,” wrote one respondent. Another noted, “We want to incentivize physicians to see our learning center as their digital home for medical education. Centralizing CME credits elsewhere would fracture that experience.” Others noted the difficulties inherent in creating and maintaining such a system: “This could potentially be a real benefit for physicians. However, it will only be beneficial if there is 100% participation by CME providers, and 100% adoption by the organizations who require CME or coordinate MOC and other elements with CME. The amount of coordination and resources it would take on the part of all organizations involved should not be underestimated.” Another responded, “We understand the AMA’s desire for greater centralization of the data. We request that a large organization like the AMA take into consideration the butterfly effect. One phrase mandating change may seem like a small improvement for the CME enterprise, but will most certainly have a significant impact on the budget for each CME provider.”
Barriers

Additional barriers to the implementation of a centralized tracking system include funding, staffing, and technical and security requirements. In order to create a central repository, all CME providers would need to agree upon technical and data security proposals to ensure interoperability and determine who would pay for database development and maintenance. On several previous occasions, the AMA has considered development of a central repository, but in-depth analysis indicated that such a repository would be impractical due to complexity and cost. A system that includes AAFP and AOA credit would be more complex still.

Opportunities

Suggestions have been made that a remedy could be achieved through the creation of a single web link, which, when followed, directs users to a page with additional links to all specialty society, state medical society, AAFP, AMA, and AOA CME pages (and their vendors that handle CME reporting services). This potentially could reduce the amount of time and frustration physicians currently experience when attempting to access multiple sites. However, this solution would place responsibility on these groups to ensure all links are accurate and up-to-date. Furthermore, simply creating a page of links to reporting sites does not ensure that all credits a physician reports to these sites are automatically shared with licensing bodies.

The AMA is currently developing its Education Center, which aims to improve health and health care and enhance professional competency and satisfaction through trusted, innovative educational resources. The Education Center will deliver education that is based on user needs and focuses on user experience. Today, the Education Center includes routine transcript functionality. In the near term, it will be developing and testing features that support improved and expanded CME tracking and reporting.

RELEVANT AMA POLICY

The AMA Code of Medical Ethics (Opinions on Professional Self-Regulation, E-9.2.6 “Continuing Medical Education”) and existing AMA policy support lifelong learning. Related policies include the following:

- The AMA Principles of Medical Ethics state, V.) A physician shall continue to study, apply, and advance scientific knowledge, maintain a commitment to medical education, make relevant information available to patients, colleagues, and the public, obtain consultation, and use the talents of other health professionals when indicated.
- Policy D-300.999, “Registration of Accredited CME Sponsors,” states that our AMA will: (1) continue cooperative efforts to assure that accredited sponsors of continuing medical education adhere to AMA Physician’s Recognition Award (PRA) policy when designating AMA PRA credit; and (2) remind all accredited CME providers of their responsibility, as stated in the AMA PRA requirements, to provide documentation to participating physicians of the credit awarded at the request of the physician.
- Policy H-300.980, “Focused Continuing Education Programs for Enhanced Clinical Competence,” states that the AMA: (1) encourages state and, where appropriate, local medical societies to respond to the needs of physicians who have been identified as requiring focused continuing medical education; (2) encourages state and county medical societies to cooperate with organizations and agencies concerned with physician competence, such as state licensing boards, and to assist in providing opportunities for physicians to participate in focused continuing education programs; (3) supports the collection and dissemination of information on
focused continuing medical education programs that have been developed or are in the process
of development; and (4) recommends that organizations with responsibilities for patient care
and patient safety request physicians to engage in content-specific educational activities only
when there is a reasonable expectation that the CME intervention will be appropriate for the
physician and effective in improving patient care or increasing patient safety in the context of
the physicians’ practice.

- Policy H-300.958, “Support for Continuing Medical Education,” states that the AMA:
  (1) Supports the concept of lifelong learning by recognizing the importance of continuing
  medical education as an integral part of medical education, along with undergraduate and
  graduate medical education; (2) Encourages physicians to maintain and advance their clinical
  competence and keep up with changes in health care delivery brought about by health system
  reform; (3) Assists and supports the expansion and enhancement of funding resources for
  continuing medical education on a local, regional, and national basis through foundations,
  private industry, health care organizations and appropriate government agencies;
  (4) Encourages U.S. medical schools to integrate continuing medical education into the
  continuum of undergraduate and graduate medical education; (5) Supports and assists medical
  schools, teaching institutions, and other health-related organizations in developing and
  facilitating implementation of health policy that supports research in continuing medical
  education, relevant to the needs of practicing physicians; and (6) Supports efforts to facilitate
  and speed development of computer-based interactive and distance learning technologies to
  support learning needs of practicing physicians regardless of their geographic location.

- Policy H-275.924, “Maintenance of Certification,” states in part that: (10) In relation to MOC
  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.

CONCLUSION AND AREAS FOR FURTHER STUDY

CME credit is currently tracked and monitored to a varying degree by a wide variety of
organizations at the state, specialty society, and institutional level, but as a result, physicians lack a
single tool to track all types of earned CME credit, including credit earned from multiple CME
providers or CME earned from one provider that is applied for multiple purposes (such as state
licensing renewal and MOC). Because the nature of tracking and monitoring CME credit can be so
specialized, the creation and maintenance of a centralized repository—while helpful for
physicians—may not be feasible at this time due to a myriad of factors. Despite these challenges,
however, appropriate departments within the AMA should continue to monitor advancements in
technology and changes in the CME environment that may inform future deliberations on this
topic, and the AMA should continue to actively work with the ABMS, ACCME, the CME provider
community including state medical and professional societies, and other CME stakeholders to
address these and related issues.
APPENDIX A: CREDIT-RELATED SERVICES OFFERED BY THE THREE MAJOR CREDIT SYSTEMS

<table>
<thead>
<tr>
<th></th>
<th>Is tracking provided for participants of credit system activities?</th>
<th>Which types of activities are tracked for inclusion in the transcript/CME report?</th>
<th>Is there a fee for tracking?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Members</td>
<td>Non-members</td>
<td>Credit system’s own activities as a CME provider</td>
</tr>
<tr>
<td>AAFP¹</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>AMA²</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>AOA³</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>

¹ The AAFP directly certifies CME activities offering AAFP credit; these activities are listed on the AAFP website. Activity providers can report activity completion, including credits earned by members. This is optional, and not all activity providers do this; however, if done, the credits are automatically entered into the members’ AAFP transcripts. Individual physician members can also report activity completion and credits earned, and the information is entered into their AAFP transcript. For activities for which the AAFP is the accredited CME provider, the credit is automatically included in the transcript. Non-members receive a letter of participation for each activity, but not a transcript.

² AMA transcripts include credit for CME activities for which the AMA is the accredited CME provider. However, AMA PRA Category 1 Credits™ awarded by the AMA for credit conversions through international agreements, international conference recognition program conferences, and direct credit categories are not included in the transcript at this time. Anyone can self-report AMA PRA Category 1 Credit™ activities from other accredited CME providers and activities for other types of credit.

³ The AOA tracks AOA credits for DO members and non-members, but only DO members are provided access to their CME report, which reflects the credits. AOA credits are reported by the AOA sponsors and posted to the CME activity report. DO members also self-report AMA PRA Category 1 Credits™ and AAFP credits, and these are included on the CME activity report.
APPENDIX B: SURVEY OF CMSS MEMBER SOCIETIES REGARDING CME TRACKING

<table>
<thead>
<tr>
<th>Does your society maintain a database of CME credits earned annually for any of the following? Please check all that apply.</th>
<th>2013 (N = 17)</th>
<th>2017 (N = 14)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Member physicians, for CME offered by your society</td>
<td>15 (93.8)</td>
<td>14 (100.0)</td>
</tr>
<tr>
<td>Non-member physicians in your specialty, for CME offered by your society</td>
<td>11 (68.8)</td>
<td>12 (92.3)</td>
</tr>
<tr>
<td>Member physicians, for CME offered by any CME provider</td>
<td>6 (37.5)</td>
<td>6 (50.0)</td>
</tr>
<tr>
<td>Non-member physicians in your specialty, for CME offered by any CME provider</td>
<td>3 (18.8)</td>
<td>3 (25.0)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>If your membership organization offers this service, is there an additional fee associated with tracking the CME?</th>
<th>2013</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>0 (0.0)</td>
<td>16 (100.0)</td>
<td>0 (0.0)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Would you prefer a centralized database of CME credits earned by all physicians in lieu of managing such a database through your society?</th>
<th>2013</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
<td>Unsure</td>
</tr>
<tr>
<td>2 (12.5)</td>
<td>9 (56.3)</td>
<td>5 (31.2)</td>
</tr>
</tbody>
</table>

*Percentages calculated based on the number of respondents answering the individual question.
REFERENCES


8 Personal communication, Stacia Gueriguian, Director of Meetings, Association of American Medical Colleges. July 12, 2017.

9 Personal communication, Laurie Kendall-Ellis, Executive Director and CEO, Alliance for Continuing Education in the Health Professions. July 12, 2017.
EXECUTIVE SUMMARY

The recently issued executive order instituting new limitations on immigration to the United States introduced great uncertainty into the lives of many physicians in training, physician scientists, medical researchers, hospital administrators, and patients. The health care community expressed immediate concern regarding the impacts of the order, especially during a time when physician shortages are predicted and the number of patients with multiple chronic conditions is growing.

Widespread media coverage of the order and multiple court rulings regarding its legality, combined with the overall complexity of existing U.S. visa regulations, have contributed to public confusion regarding this complicated topic and its multiple implications.

This comprehensive review characterizes the orders’ potential impacts on physicians and patients, and seeks to educate physicians so they can appropriately advocate for their patients and their profession. The report explains the content of the executive order; characterizes the reaction from physicians and scientists; reviews visa implications; discusses potential impacts to international research and data sharing; describes institutional staffing and patient access implications; and offers suggestions regarding areas for further study.

The introduction of the order has prompted extensive and very public discussions regarding the physician workforce in multiple venues, all of which provide an excellent opportunity to educate the American people regarding the crucial, life-saving role played in this country by foreign-born physicians. Additional dialogue regarding the importance of collaborative, international research is also valuable and necessary. The Council on Medical Education will continue to follow this issue and report back to the House of Delegates as necessary.
American Medical Association (AMA) Policy D-255.980, “Impact of Immigration Barriers on the Nation’s Health,” was adopted by the AMA House of Delegates (HOD) at its 2017 Annual Meeting. It states the following:

1. Our American Medical Association (AMA) recognizes the valuable contributions and affirms our support of international medical students and international medical graduates and their participation in U.S. medical schools, residency and fellowship training programs and in the practice of medicine.

2. Our AMA will oppose laws and regulations that would broadly deny entry or re-entry to the United States of persons who currently have legal visas, including permanent resident status (green card) and student visas, based on their country of origin and/or religion.

3. Our AMA will oppose policies that would broadly deny issuance of legal visas to persons based on their country of origin and/or religion.

4. Our AMA will advocate for the immediate reinstatement of premium processing of H-1B visas for physicians and trainees to prevent any negative impact on patient care.

5. Our AMA will advocate for the timely processing of visas for all physicians, including residents, fellows, and physicians in independent practice.

6. Our AMA will work with other stakeholders to study the current impact of immigration reform efforts on residency and fellowship programs, physician supply, and timely access of patients to health care throughout the U.S.

7. Our AMA will update the House of Delegates by the 2017 Interim Meeting on the impact of immigration barriers on the physician workforce.

During the HOD meeting, Reference Committee C heard universal support for the timely and salient resolutions that were introduced regarding these topics, which sought to address and rectify the multiple implications of restricting U.S. travel for foreign-born physicians, trainees, and researchers. Testimony also noted that any travel restrictions could negatively affect patient access to care, especially in areas of need. These same implications hold true for patients served by other foreign-born clinicians and trainees employed in this country.

Restricting travel on the basis of country of origin or religion goes against the principles and policy of our AMA, which has worked to enhance physician diversity and to address the quality of care received and experienced by diverse patients and populations. Additionally, many communities, including rural and low-income areas, face challenges attracting physicians to meet their health needs.
care needs. International medical graduates (IMGs) often fill these openings. Currently, one out of
every four physicians practicing in the United States is an IMG. In certain specialties, that number
is even higher. These physicians are trained and licensed by the same stringent requirements
applied to U.S. medical school graduates. They are more likely to practice in underserved and poor
communities, and in primary care and other specialties that face significant workforce shortages.

Concerns related to additional limitations on immigration also have been voiced by the biomedical
research community. Restriction of travel can constrain the free flow of ideas and hamper the
international cooperation that has historically led to advancements in the delivery of care.

AMA delegates collectively introduced seven related resolutions to the HOD for the 2017 Annual
Meeting; an umbrella resolution, which incorporated elements of all seven resolutions, was
subsequently adopted. This report addresses Resolves 6 and 7 of that umbrella resolution. The issue
of physician immigration also was highlighted by the Council on Medical Education during the
Annual Meeting—with support from the Council on Science and Public Health, Academic
Physicians Section, International Medical Graduates Section, Integrated Physician Practice Section,
and Medical Student Section—through development of an educational session that called attention
to and addressed these important concerns.

Individuals eligible for Deferred Action for Childhood Arrivals (DACA) status face related, but not
entirely similar, concerns. Council on Medical Education Report 4-A-17, “Evaluation of DACA-
Eligible Medical Students, Residents, and Physicians in Addressing Physician Shortages,” offers a
comprehensive review of DACA-eligible individuals, their prospects, and their potential impact on
the U.S. workforce. This report was submitted to and adopted by the HOD (see D-350.986), and
interested parties are encouraged to review the report and its findings. The Council on Medical
Education continues to monitor DACA and will report back to the HOD as needed.

INTRODUCTION

The executive order issued by President Donald J. Trump on January 27, 2017—“Protecting the
Nation from Foreign Terrorist Entry into the United States”—introduced great uncertainty into the
lives of physicians in training, physician scientists, other medical researchers, and hospital
administrators. Many in the health care community expressed immediate concern regarding the
impacts of the proposed order on physicians, institutions, researchers, and patients on multiple
levels, especially during a time when physician shortages are predicted and the number of patients
with multiple chronic conditions is growing.

A recent article published in JAMA effectively frames these legitimate concerns. The article notes,
“At least 1 in 4 physicians [in the U.S.] are foreign born. Research demonstrates that foreign-born
physicians offer high-quality care, with low mortality rates among their patients. Due to critical
health worker shortages, special visas are offered to foreign physicians who practice for 3 years in
rural, underserviced communities. More than 13,000 physicians from the 6 Muslim-majority
countries with suspended entry practice in the United States, including 9,000 from Iran and 3,500
from Syria. In 2015 alone, 453 foreign nationals from these countries were admitted to residency
programs. If this group of physicians were not replaced, given the size of the average primary care
patient panel (2,500 patients), the ban could affect more than 1 million patients nationally.”
UNDERSTANDING THE ORDERS: “PROTECTING THE NATION FROM FOREIGN
TERRORIST ENTRY INTO THE UNITED STATES”

• On January 27, 2017, President Donald J. Trump signed the executive order titled
“Protecting the Nation from Foreign Terrorist Entry into the United States.” The order
barred entry to the United States to all individuals with immigrant and non-immigrant visas
from Iraq, Iran, Libya, Somalia, Sudan, Syria, and Yemen for a period of 90 days.
Refugees worldwide were subject to an entry ban for 120 days, and refugees from Syria
were indefinitely banned. In subsequent days, federal lawsuits were filed in New York,
Massachusetts, Virginia, and Washington on behalf of travelers denied entry into the U.S.
from one of the seven affected countries.

• On February 3, a Federal District Court halted the implementation of the executive order
with a temporary restraining order; also that day, the state of Hawaii filed a lawsuit asking
the court to block the order’s implementation.

• On February 4, the Department of Justice appealed the February 3 restraining order to the
Ninth Circuit Court of Appeals.

• On February 9, the Ninth Circuit Court of Appeals unanimously ruled to deny the Justice
Department’s request for a stay.

• On March 6, rather than continue to litigate the first executive order, President Trump
withdrew the first executive order and signed a revised order, which was intended to go
into effect on March 16. The revised order removed Iraq from the list of countries facing
the 90-day travel ban. Additionally, the order removed the indefinite ban on Syrian
refugees and clarified that individuals with a valid visa to enter the U.S. would be
permitted to do so, regardless of their country of origin.

• On March 8, Hawaii filed another legal challenge to this revised ban.

• On March 15, a U.S. District Judge issued a temporary restraining order, blocking the
executive order from taking effect on March 16. On March 16, a second judge issued a
preliminary injunction related to the order.

• On March 29, a federal judge in Hawaii extended an order that blocked the ban from
nationwide implementation until Hawaii’s lawsuit was decided.

• On June 12, the Ninth Circuit Court largely upheld the injunction on the revised travel ban.

• On June 26, the U.S. Supreme Court allowed parts of the revised order to go into effect;
oral arguments are scheduled to be heard in October 2017 (after drafting of this report).
The Supreme Court’s decision upholds the revised order with the exception of those with
“any bona fide relationship with a person or entity in the United States,” which is being
defined as those with certain family connections in the U.S. (guidance from the State
Department indicated that only parents, step-parents, spouses, children, step-children, adult
sons/daughters, sons-/daughters-in-law, and siblings apply, but later added fiancées and
grandparents as well); students accepted by a U.S. university; individuals with job offers
at U.S. companies; and lecturers invited to address an American audience.

• The partial ban went into effect the evening of Thursday, June 29, and expired on
September 24. A new ban was then instituted, scheduled to take effect on October 18,
which struck the country of Sudan from the list but added Chad, North Korea, and
Venezuela (limited to government officials and their families).

• On October 10, the U.S. Supreme Court dismissed one of two pending lawsuits related to
the travel ban based on the argument that the ban in question had expired.

• On October 17, a federal judge in Hawaii blocked the revised travel ban, scheduled to go
into effect on October 18. As of the writing of this report, restrictions on North Korea and
Venezuela will be permitted to go into effect.
REACTION TO THE ORDER

The U.S. medical and scientific community responded immediately and forcefully to both executive orders. Leading national medical groups, including the AMA,9,10 Accreditation Council for Graduate Medical Education (ACGME),11 American Association of Colleges of Osteopathic Medicine (AACOM),12 Association of American Medical Colleges (AAMC),13,14 American Hospital Association (AHA),15,16 American Medical Student Association (AMSA),17 American Osteopathic Organization (AOA),18 Committee of Interns and Residents (CIR),19 and National Medical Association (NMA)20 all registered their serious concerns, often multiple times, over the following months. The Educational Commission for Foreign Medical Graduates (ECFMG), the body that evaluates and certifies qualified graduates of foreign medical schools prior to their entry into the U.S. graduate medical education system, dedicated an entire page of resources on its website related to the executive order.21

Individual specialty societies also spoke out. The American College of Cardiology (ACC),22 American College of Physicians (ACP),23 American Society for Clinical Oncology (ASCO),24 American Academy of Family Physicians (AAFP),25 and American Academy of Pediatrics (AAP),26,27 among others, all expressed unease with the content and implications of the executive orders.

On June 12, the AAMC filed an amicus brief with the Supreme Court in opposition to the government’s petition for a stay against lower court injunctions against the executive order. Twenty-one organizations joined the brief: the AAFP; AAP; American Association of Colleges of Nursing (AACN); American Association of Colleges of Pharmacy (AACP); American College of Healthcare Executives (ACHE); American College of Obstetricians and Gynecologists (ACOG); ACP; American Dental Education Association (ADEA); American Nurses Association (ANA); American Psychiatric Association (APA); American Public Health Association (APHA); Association of Academic Health Centers (AAHC); Association of Schools and Programs of Public Health (ASPPH); Association of Schools of Allied Health Professions (ASAHP); Association of University Programs in Health Administration (AUPHA); Greater New York Hospital Association; Hispanic-Serving Health Professions Schools, Inc. (HSHPS); NMA; National Resident Matching Program (NRMP); Physician Assistant Education Association (PAEA); and Society of General Internal Medicine (SGIM).

As the brief noted, “Individuals from outside the United States play a critical role in the delivery of healthcare in America... Non-U.S. health professionals hail from around the world, including from the six countries subject to the Executive order’s suspension of entry. Economists estimate that more than seven thousand physicians currently working in the United States received training in the six countries, and that those doctors collectively provide fourteen million patient visits each year...Physicians from outside the United States ‘situate [themselves] on the front lines of medical need,’ including rural and other underserved communities, Native American communities, and U.S. Department of Veterans Affairs hospitals. In Alabama, for example, ‘Syria ranks fourth as a source of doctors for medically-needey areas . . . behind India, Pakistan and the Philippines’.”28

The brief goes on to describe additional implications: “Collaborative international efforts, especially strengthening the capacity of national health systems, are essential to prevent and prepare for an array of threats, from infectious disease pandemics to the silent killers of chronic non-communicable diseases. Any constraint on the participation of recognized experts in the free exchange of scientific research and collaboration impairs the collective knowledge of our healthcare community and jeopardizes American lives.”29
Innovation and medical research were also highlighted in the brief: “The Executive order also has the potential to adversely affect patient care by constraining medical research and innovation. In 2016, all six American winners of the Nobel Prize in economics and scientific fields were immigrants. Moreover, since 2000, immigrants have been awarded 40%—or 31 of 78—of the Nobel Prizes won by Americans in chemistry, medicine, and physics. An analysis of the U.S. Patent and Trademark Office’s online database shows that 76% of patents awarded to the top ten patent-producing U.S. universities in 2011 listed at least one inventor who had been born in another country. During that same period, 56% of all patents were awarded to inventors who were students, postdoctoral fellows, or staff researchers from another country. Because non-U.S. post-doctorate students are increasingly relied upon to counter a decrease in U.S. students pursuing biomedical research in this nation, chilling their participation could adversely affect biomedical research and our health security.”

VISA IMPLICATIONS

As noted in Council on Medical Education Report 11-A-09, “Rationalize Visa and Licensure Process for IMG Residents,” the two most commonly used temporary, nonimmigrant classifications by IMGs are the J-1 Exchange Visitor program and the H-1B Temporary Worker classification.

Most IMGs in graduate medical education (GME) programs arrive under the J-1 Exchange Visitor Program, although the H-1B Temporary Worker category has been increasingly utilized. Data collected via the AMA’s National GME Census reflect changes in the ease or difficulty of obtaining different visas. Between 2001 and 2008, there was an increase in IMGs in residency programs under H status from 1,474 to 4,777. Meanwhile, IMGs under J status declined over the same period from 5,473 to 4,152. Since then, however, more IMGs have been training with J-1 visas. In 2012 there were 4,059 residents with H visas, and 5,200 with J visas; by 2015 there were 2,889 IMG residents with H visas and 6,394 with J visas. Additional analysis of the AMA’s National GME Census reveals that during the 2016/2017 academic year, 2,477 physicians who were born in the seven countries affected by the original executive order were participating in GME in the U.S. Of those, 615 (24.8 percent) were training here with a visa.

The J-1 visa is a temporary, non-immigrant visa, meant to enhance educational and cultural exchange and promote mutual understanding between the U.S. and other countries. The ECFMG is the only authorized J-1 visa sponsor of foreign national physicians in U.S. clinical training programs. In 2016/2017, the ECFMG sponsored more than 10,000 individuals who are training in U.S. GME programs in 48 states plus the District of Columbia and Puerto Rico. The majority of these physician trainees were in primary care programs: 50 percent in internal medicine, 10 percent in pediatrics, and 7 percent in family medicine. The ECFMG also reports that in the 2017 NRMP Match, while the overall match rate of non-U.S. citizen IMGs increased slightly, fewer IMGs participated in the Match process.

The ECFMG further reports that the number of J-1 visa applications it has received for the 2017/2018 year has declined 33 percent from Iran and 60 percent from Syria, while remaining flat in Libya and Yemen. As of August 15, 2017, 97.8% of the 2,766 physicians initially sponsored by ECFMG for J-1 visa status had successfully secured this status and arrived at their U.S. training programs. Of the 57 initially-sponsored J-1 physicians who are nationals of the countries identified in Executive Order 13780, 50 (87.7%) have successfully secured J-1 status and reported to their training program. Of the 7 (12.3%) who have not yet reported to their programs in J-1 status, 5
already are in the United States in another visa status and awaiting a change of status through U.S. Citizenship and Immigration Services.36

A program known as the Conrad 30 Waiver program, which is intended to lessen physician shortages in medically underserved areas, allows physicians with J-1 status to apply for a waiver for the two-year residence requirement upon completion of the J-1 program (individuals with J-1 status are otherwise required to return to their country of last permanent residence for two consecutive years prior to being permitted to apply for permanent resident status in the U.S.). Participants in the Conrad 30 Waiver program are required to practice medicine for a minimum of three years in an area designated by the U.S. Department of Health and Human Services (HHS) as a health professional shortage area (HPSA), medically underserved area (MUA), or medically underserved population (MUP). At the conclusion of that three-year period, waiver recipients can apply for an immigrant visa and permanent resident status.37

The Conrad State 30 and Physician Access Act (S. 898 and H.R. 2141) is intended to address the most recent extension of the Conrad State 30 Program, which was scheduled to expire on April 28. The AMA strongly supports adoption of the Act, writing that “J-1 visa waivers play a significant role in placing physicians in communities that face healthcare access challenges. Many communities, including rural and low-income urban areas, struggle to attract physicians to meet their patient needs. This legislation will help ensure continued access to care in medically underserved communities across the U.S.”38 As of the writing of this report, these bills had been referred to both the Senate and House Committees on the Judiciary.

**J-1 Visas and the 2017 Match**

The timing of the executive order was extremely disruptive to IMGs applying for residency training programs through the NRMP match, as well as for institutions and program directors seeking to fill their slots. The NRMP was concerned enough to issue a February 3 statement: “We ask the medical education community to support all international medical graduates and their families during these difficult times. Please be assured that NRMP will do all it can to address the uncertainties the order has created. As for the current Match cycle, we hope that applicants and programs will continue to rank each other in the order of true preference, based on the qualifications and qualities each seeks in the other.”39 Although no data exist to support this claim, the Council on Medical Education has heard anecdotally that some GME programs struggled to justify ranking qualified applicants from the list of countries affected by the executive order because of concerns about filling their programs and having enough resident staff on hand to fully serve their local patient populations.

**H-1B Visas**

In March, U.S. Citizenship and Immigration Services (USCIS) reported that it would temporarily suspend premium processing of H-1B visas beginning on April 3.40 H-1B visas grant temporary work status for immigrants who work for a specific employer. A recent *JAMA* article41 noted that physicians practicing in the U.S. with H-1B status accounted for 1.4% of all physicians actively delivering patient care nationwide in 2016 (more than 10,000 physicians). Physicians with this visa status, however, make up much larger percentages of the practicing physician workforce in certain states. For example, of practicing physicians in the following states, 4.7 percent in North Dakota are authorized to work through the H-1B visa program, 4 percent in Rhode Island, 3.9 percent in Michigan, and 3.6 percent in Delaware. It is worth noting, however, that USCIS typically suspends premium processing annually. The primary difference in this suspension, and likely the reason why
it garnered more attention, is that this year’s suspension period was longer (potentially up to six months).

On June 23, USCIS announced that the department would resume the expedited processing of H-1B visas for physicians seeking such status under the Conrad 30 waiver program. As of the writing of this report, premium processing remains suspended for other categories of H-1B petitions.

IMPLICATIONS FOR RESEARCHERS AND GLOBAL DATA SHARING

Physician scientists and researchers were quick to note the obstacles the executive order would introduce into the heretofore collaborative nature of scientific research, which has led to life-saving medical advancements at home and abroad. There were concerns that existing research partnerships might be threatened or terminated, and that the next generation of U.S. researchers and biomedical engineers might be depleted as talented individuals from other countries choose to settle and work outside of the U.S.

A group of almost 200 organizations, ranging from professional scientific, engineering, and education societies, as well as leading research universities, signed a letter to President Trump vocalizing their concerns regarding the January executive order. The letter notes, “Scientific progress depends on openness, transparency, and the free flow of ideas and people, and these principles have helped the United States attract and richly benefit from international scientific talent…The Executive order will discourage many of the best and brightest international students, scholars, engineers and scientists from studying and working, attending academic and scientific conferences, or seeking to build new businesses in the United States. Implementation of this policy will compromise the United States’ ability to attract international scientific talent and maintain scientific and economic leadership.”

Furthermore, since the first order was signed in January, more than 41,000 academics and researchers from a variety of fields, including 62 Nobel Laureates, have signed a statement attesting that “The EO [Executive order] significantly damages American leadership in higher education and research…The proposed EO limits collaborations with researchers from these nations by restricting entry of these researchers to the US and can potentially lead to departure of many talented individuals who are current and future researchers and entrepreneurs in the US. We strongly believe the immediate and long term consequences of this EO do not serve our national interests.”

As noted in a recent article in the New England Journal of Medicine, “Whether we are concerned about the competence of the physicians who will care for us when we are ill, the biomedical enterprise that represents one sixth of our economy, the jobs created by academic medical centers, or our global leadership position in health and health care, immigration policy that blocks the best from coming to train and work in the United States and blocks our trainees and faculty from safely traveling to other countries is a step backward, one that will harm our patients, colleagues, and America’s position as a world leader in health care and innovation.”

INSTITUTIONAL IMPLICATIONS AND PATIENT ACCESS TO CARE

According to research generated by The Immigrant Doctors Project, physicians from Iran, Libya, Somalia, Sudan, Syria and Yemen provide 14 million doctors’ appointments each year, and almost all Americans (94%) reside in a community that hosts at least one doctor from one of the countries specified in the executive order.
As previously noted, concerns have been voiced that regardless of country of origin, qualified non-US citizen IMGs will in the future pursue training and employment in other countries. Yet we know that higher proportions of IMGs, compared to U.S. medical school graduates, provide care to socioeconomically disadvantaged patients, and health care systems and patients rely heavily on foreign-born physicians. According to a recent article in the New York Times, “in Coudersport, Pa., a town in a mountainous region an hour’s drive from the nearest Walmart, Cole Memorial Hospital counts on two Jordanian physicians to keep its obstetrics unit open and is actively recruiting foreign specialists. In Fargo, N.D., a gastroenterologist from Lebanon — who is among hundreds of foreign physicians in the state — has risen to become vice president of the North Dakota Medical Association. In Great Falls, Mont., 60 percent of the doctors who specialize in hospital care at Benefis Health System, which serves about 230,000 people in 15 counties, are foreign doctors on work visas.”

Findings from a recent survey from a physician recruiting agency further highlight this country’s need for foreign-born physicians, noting that just over eight percent of practicing physicians and less than three percent of trainees believe that practicing in a rural area is desirable.

Some specialties rely more heavily on IMGs. According to data from the 2017 NRMP Match, primary care continues to depend on foreign-born physicians. Of 7,233 positions offered in internal medicine, 2,003 were filled by non-U.S. IMGs. Of 3,356 positions offered in family medicine, 337 were filled by non-U.S. IMGs, and of 2,738 positions offered in pediatrics, 253 were filled by non-U.S. IMGs. Certain subspecialties also depend heavily on non-U.S. citizen graduates of international medical schools. The NRMP notes that in 2017, these individuals filled 45.1% of nephrology fellowship positions, 41.6% of vascular neurology positions, 39.3% of endocrinology/diabetes/metabolism positions, 37% of interventional pulmonology positions, and 35.3% of abdominal transplant surgery positions.

RELEVANT AMA POLICY

Policy D-255.991, “Visa Complications for IMGs in GME,” directs our AMA to work with the ECFMG to minimize delays in the visa process for international medical graduates applying for visas to enter the U.S. for GME and/or medical practice; promote regular communication between the Department of Homeland Security and AMA IMG representatives to address and discuss existing and evolving issues related to the immigration and registration process required for international medical graduates; and work through the appropriate channels to establish effective contacts with the State Department and the Department of Homeland Security, in order to prioritize and expedite the necessary procedures for qualified residency applicants and reduce the uncertainty associated with considering a non-citizen or permanent resident IMG for a residency position. It also calls on our AMA to study, in collaboration with the ECFMG and the ACGME, the frequency of such J-1 Visa reentry denials and their impact on patient care and residency training, and, with other stakeholders, to advocate for unfettered travel for IMGs for the duration of their legal stay in the US in order to complete their residency or fellowship training to prevent disruption of patient care.

Policy D-255.985, “Conrad 30 - J-1 Visa Waivers,” directs our AMA to advocate for solutions to expand the J-1 Visa Waiver Program to increase the overall number of waiver positions in the U.S. in order to increase the number of IMGs who are willing to work in underserved areas to alleviate the physician workforce shortage; work with the Educational Commission for Foreign Medical Graduates and other stakeholders to facilitate better communication and information sharing among Conrad administrators, IMGs, US Citizenship and Immigration Services and the State Department; and continue to communicate with the Conrad 30 administrators and IMG members to share information and best practices in order to fully utilize and expand the Conrad 30 program.
CONCLUSIONS AND AREAS FOR FURTHER STUDY

Ultimately, the real impact of the executive order will not be known until it becomes clear how the language of the revised ban is interpreted and applied at U.S. points of entry both at home and in consular offices abroad. The Supreme Court’s ruling would seem to imply that practicing physicians and resident physicians with a job offer from a U.S. institution will indeed be permitted to travel to and from the United States. However, anecdotal evidence indicates that several incoming resident trainees have either not been able to obtain a visa or have experienced significant delays, preventing them from starting residency on July 1; also, an Iranian researcher with a valid J-1 visa and job offer as a visiting scholar was prevented from entering the country on July 11.67,68

As noted previously, even the specter of immigration limitations can have an effect on individuals seeking to enter the United States. As a recent article observes, “Even with the travel restrictions on hold, admissions from the six nations fell dramatically in March and April, government data show. Compared with a year earlier, the number of people admitted from Iran, Libya, Somalia, Sudan, Syria and Yemen was down by about half year over year. It was unclear whether that was primarily due to fewer people seeking to travel to the U.S. or to the administration rejecting more applications.”69

Although not the focus of this report, what is less clear at this time is how the ruling will apply to foreign students seeking to apply to U.S. medical schools. As a parallel, we might look to the immigration environment immediately following the 2001 terrorist attacks. As one recent article notes, “Student visa applications dropped by 25 percent between 2001 and 2002, and the number of rejections rose from 25 to 34 percent between 2001 and 2003; and perhaps as a result of those post-9/11 policies, the number of international students enrolled at universities dropped for several years, says the 2009 report by the Council on Foreign Relations. ‘Overall, the number of foreign students attending American universities would have been about 25 percent higher if the pre-9/11 growth rates had continued,’ the report says. During that same time period, the report continues, international enrollment in the United Kingdom, France, Australia, Japan, and Germany surged as students went elsewhere.”70 The effects of the executive order on medical school enrollment bear monitoring, as a diverse body of medical students is critical to the creation and retention of a diverse physician workforce.

If there is a bright side to the executive orders, it is this: extensive and very public discussions are taking place in multiple venues, all of which provide an excellent opportunity to educate the American people regarding the crucial, life-saving role played in this country by foreign-born physicians. Additional dialogue regarding the importance of collaborative, international research is also valuable and necessary. The Council on Medical Education therefore will continue to follow this issue and report back to the House of Delegates as necessary.
REFERENCES


Ibid.

Ibid.


Personal Communication from Sarah Brotherton, Director, Data Acquisition Services, American Medical Association.

Personal Communication from William Pinsky, President and CEO, Educational Commission for Foreign Medical Graduates.

Ibid.

Ibid.


58 Ibid.


REPORT OF THE SPEAKERS

Speakers’ Report 1-1-17

Subject: Recommendations for Policy Reconciliation

Presented by: Susan R. Bailey, MD, Speaker
Bruce A. Scott, MD, Vice Speaker

Policy G-600.111, “Consolidation and Reconciliation of AMA Policy,” states in relevant part that
the Speakers should “present one or more reconciliation reports for action by the House of
Delegates relating to newly passed policies from recent meetings that caused one or more existing
policies to be redundant and/or obsolete.”

Your Speakers present this report, the second of 2017, to deal with policies that were affected by
actions taken at this past June’s Annual Meeting.

Suggestions on other policy statements that are thought to be outdated or needing revision for any
other reason should be sent to hod@ama-assn.org. That address may also be used to contact your
Speakers on any House-related matter.

RECOMMENDED RECONCILIATIONS

The following changes will delete references to reports that have been completed but otherwise do
not affect existing policy.

1. Policy D-405.988, “The Preservation of the Private Practice of Medicine,” includes a reference
to a report that was considered by the House at the 2015 Annual Meeting as Board of Trustees
Report 16. That reference will be stricken, but the remainder of the policy unchanged.

Policy D-405.988, “The Preservation of the Private Practice of Medicine”
Our AMA: (1) supports preserving the value of the private practice of medicine and its benefit
to patients; (2) will utilize its resources to protect and support the continued existence of solo
and small group medical practice, and to protect and support the ability of these practices to
provide quality care; (3) will advocate in Congress to ensure adequate payment for services
rendered by private practicing physicians; (4) will work through the appropriate channels to
preserve choices and opportunities, including the private practice of medicine, for new
physicians whose choices and opportunities may be limited due to their significant medical
education debt; (5) will work through the appropriate channels to ensure that medical students
and residents during their training are educated in all of medicine’s career choices, including
the private practice of medicine; (6) will create, maintain, and make accessible to medical
students, residents and fellows, and physicians, resources to enhance satisfaction and practice
sustainability for physicians in private practice, with a progress report at the 2015 Annual
Meeting; and (7) will create and maintain a reference document establishing principles for
entering into and sustaining a private practice, and encourage medical schools and residency
programs to present physicians in training with information regarding private practice as a viable option.

2. Policy G-600.035, “The Demographics of the House of Delegates” includes a directive that has been accomplished. The Council on Long Range Planning and Development provided the requested information in Report 2-A-17. Having been completed, the directive will be dropped.

Policy G-600.035, “The Demographics of the House of Delegates”
1. A report on the demographics of our AMA House of Delegates will be issued annually and include information regarding age, gender, race/ethnicity, education, life stage, present employment, and self-designated specialty. 2. As one means of encouraging greater awareness and responsiveness to diversity, our AMA will prepare and distribute a state-by-state demographic analysis of the House of Delegates, with comparisons to the physician population and to our AMA physician membership every other year. 3. Future reports on the demographic characteristics of the House of Delegates will identify and include information on successful initiatives and best practices to promote diversity, particularly by age, of state and specialty society delegations.

4. Our AMA will convene a group of stakeholders at a forum in conjunction with the 2016 Annual Meeting to identify viable solutions with which to promote diversity, particularly by age, of state and specialty society delegations, with a summary of the findings to be included in the next CLRPD report on the demographic characteristics of the House of Delegates.

3. H-110.987, “Pharmaceutical Cost,” calls for a progress report on a “drug pricing advocacy campaign at the 2016 Interim Meeting.” That report was delivered in Board of Trustees Report 10, AMA Initiatives on Pharmaceutical Costs. Hence the specific call for the report will be removed from policy.

H-110.987, “Pharmaceutical Cost”
1. Our AMA encourages Federal Trade Commission (FTC) actions to limit anticompetitive behavior by pharmaceutical companies attempting to reduce competition from generic manufacturers through manipulation of patent protections and abuse of regulatory exclusivity incentives. 2. Our AMA encourages Congress, the FTC and the Department of Health and Human Services to monitor and evaluate the utilization and impact of controlled distribution channels for prescription pharmaceuticals on patient access and market competition. 3. Our AMA will monitor the impact of mergers and acquisitions in the pharmaceutical industry. 4. Our AMA will continue to monitor and support an appropriate balance between incentives based on appropriate safeguards for innovation on the one hand and efforts to reduce regulatory and statutory barriers to competition as part of the patent system. 5. Our AMA encourages prescription drug price and cost transparency among pharmaceutical companies, pharmacy benefit managers and health insurance companies. 6. Our AMA supports legislation to require generic drug manufacturers to pay an additional rebate to state Medicaid programs if the price of a generic drug rises faster than inflation. 7. Our AMA supports legislation to shorten the exclusivity period for biologics. 8. Our AMA will convene a task force of appropriate AMA Councils, state medical societies and national medical specialty societies to develop principles to guide advocacy and grassroots efforts aimed at addressing pharmaceutical costs and improving patient access and adherence to medically necessary prescription drug regimens. 9. Our AMA will generate an advocacy campaign to engage physicians and patients in local and national advocacy initiatives that bring attention to the rising price of prescription drugs and help to put forward solutions to make prescription drugs more affordable for all patients, and will report back to the House of Delegates regarding the progress of the drug pricing advocacy campaign at the 2016 Interim Meeting.
Policies to be rescinded in full

Five policies should be rescinded in full because they have been superseded by newer policies and, where necessary, bylaws amendments. Three policies deal with specialty society representation, a process that has been completely revised over the last year. Two other policy statements are directives dealing with the Council on Ethical and Judicial Affairs; both have been accomplished and should be rescinded.

4. Two policies deal with the now abandoned balloting system used for apportioning delegates to specialty societies. In light of amendments to the bylaws and Policy G-600.027 at the 2017 Annual Meeting, these older policies should be rescinded. The first is Policy G-600.023, “Designation of Specialty Societies for Representation in the House of Delegates,” which was adopted at the 2013 Interim Meeting. Although the final paragraph of the policy has some merit, your Speakers believe that it is incumbent on them to monitor the delegate allocation process and no explicit requirement is needed. Moreover, in the event of a perceived problem, any delegate may propose a resolution to address the matter. As such, the policy as a whole is no longer viable and will be rescinded.

Policy G-600.023, “Designation of Specialty Societies for Representation in the House of Delegates”

1. Specialty society delegate allocation in the House of Delegates shall be determined in the same manner as state medical society delegate allocation based on membership numbers allowing one delegate per 1,000 AMA members or fraction thereof. 2. Specialty society membership data shall be submitted annually by all societies with more than one delegate or societies seeking to obtain an additional delegate or delegates as part of a two-year pilot program with a report back at the 2016 Annual Meeting of our AMA House of Delegates. 3. The current specialty delegation allocation system (ballot and formula) will be continued until the pilot program is completed and the 2016 Annual Meeting report is acted upon by the House of Delegates. 4. This system shall be tested with all specialty societies with more than one delegate seated in the House of Delegates. 5. Organizations that would lose or gain one or more delegates through this pilot delegate allocation system shall assist our AMA with documenting the impact. However, no actual changes to delegation allocation other than those which occur through the five-year review and balloting system will be implemented until the data are collected and presented for acceptance to our AMA House of Delegates at the 2016 Annual Meeting. 6. In the future, any system of delegate allocation will continue to be monitored and evaluated for improvements.

5. Likewise, Policy G-600.021, “Specialty Society Representation in our AMA House,” which dates from 1996 and was altered in 2012, will be rescinded.

Policy G-600.021, “Specialty Society Representation in our AMA House”
The number of AMA delegate positions allocated to the specialty societies in our AMA/Federation House will be determined in the following manner: (1) The number of delegates and alternate delegates allocated to a specialty society will be on the basis of one delegate and one alternate delegate for each 1000 AMA members, or portion of 1000 AMA members, who select that a particular specialty society on the annual ballot and return the ballot to our AMA; and (2) Each specialty society that meets the eligibility criteria and is represented in our AMA/Federation House will be assured of at least one delegate and alternate delegate position regardless of the number of AMA members who select the society on the ballot and return the ballot to the AMA. (3) Our AMA will: (a) continue to include the ballot postcard in the Member Welcome Kit; (b) continue to promote the online ballot application to
increase specialty society designations; (c) work with all willing specialty societies to solicit additional specialty society designations, using both printed ballots and electronic communications vehicles; and (d) continue to send email ballot solicitations to members who have not yet cast a ballot. (4) The current ballot system will remain in place while the Speakers, working with the Specialty and Service Society, examine other options for ensuring that each member of the American Medical Association is adequately represented by both a state medical association and national medical specialty society.

6. Policy G-600.135, “Specialty Society Delegate Representation in the House of Delegates,” will be rescinded as it has been superseded by the new procedure to apportion specialty society delegates that will be implemented in 2018.

1. Our AMA will continue efforts to expand awareness and use of the designation mechanism for specialty society representation, working wherever possible with relevant members of the Federation. 2. The system of apportioning delegates to specialty societies be enhanced by a systematic allocation of delegates to specialty societies by extrapolating from the current process in which members designate a specialty society for representation. The recommended model will: (a) establish annual targets for the overall proportion of AMA members from whom designations should have been received; (b) adjust actual designations by increasing them proportionately to achieve the overall target level of designations; (c) limit the number of delegates a society can acquire to the number that would be obtained if all the society’s AMA members designated it for representation; (d) be initiated with delegate allocations for 2008, following the expiration of the freeze, which ends December 31, 2007; and (e) be implemented over five years because this will result in the least disruption to the House of Delegates and allow the process to unfold naturally. 3. The Board of Trustees will prepare annual reports to the House describing efforts undertaken to solicit designations from members, characterizing progress in collecting designations, and recommending changes in strategies that might be required to implement existing policy on representation of specialty societies. In addition, the Board should, in these or other reports: (a) develop a system for use among direct members to solicit their designations of specialty societies for representation, with an eye on how that system might be expanded or adapted for use among other members; and (b) engage in discussions with specialty societies that will lead to enhanced data sharing so that delegate allocations for both state and specialty societies can be handled in parallel fashion. 4. Our AMA will include in the specialty designation system an option to permit those members who wish to opt out of representation by a specialty society to do so when any automatic allocation system is used to provide representation for specialty societies that are represented in the House of Delegates. 5. If any specialty society loses delegates as a result of the apportionment process, the specialty society shall have a one-year grace period commencing January 1, 2008. At the expiration of this one-year grace period, a phase-in period shall be implemented such that the number of delegate seats lost will be limited to one seat per year for the succeeding three years. In the fourth year, any remaining reduction of seats will be implemented. 6. AMA Bylaw 2.11111 grants state societies a one-year grace period following the freeze expiring December 31, 2007 (per Bylaw 2.121). At the end of the grace period, a phase-in period will be implemented such that the number of delegate seats lost will be limited to one seat per year for the succeeding three years. In the fourth year, any remaining reduction of seats will be implemented.

7. The multi-year effort by the Council on Ethical and Judicial Affairs to modernize the *Code of Medical Ethics* culminated with the adoption of CEJA Report 2-A-16. At that same meeting, and partly because of the lengthy and somewhat tortuous effort to achieve consensus on the
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Code, the House also adopted Policy D-600.957 calling for an evaluation of the deliberative processes surrounding CEJA reports. The initial response to that policy came in CEJA Report 3-I-16, which was referred because important underlying issues of the relationship between the Council and the HOD required further study. At the 2017 Annual Meeting, the Board of Trustees submitted Report 19, providing the requested evaluation and establishing Policy G-600.009, “CEJA and House of Delegates Collaboration.” Given the Board’s report, the following policy has been accomplished and will be rescinded.

D-600.957, “CEJA and House of Delegates Deliberation”

1. Our AMA will evaluate how the collaborative process between the House of Delegates and the Council on Ethical and Judicial Affairs can best be improved to allow HOD input to CEJA deliberation while still preserving CEJA autonomy and report back at the 2016 Interim Meeting. 2. Our AMA will evaluate how a periodic review of Code of Medical Ethics guidelines and reports can best be implemented, and report back.

Policy D-478.969, “Social Media Trends and the Medical Profession,” asked that CEJA examine how physicians may ethically use social media for educational and advocacy purposes. CEJA submitted Report 2 at this past June’s meeting, which included a section dealing specifically with uses of social media for education or advocacy. The policy will be rescinded as having been completed.

D-478.969, “Social Media Trends and the Medical Profession”

Our AMA will ask the Council on Ethical and Judicial Affairs to reconsider AMA Ethical Opinion E-9.124, Professionalism in the Use of Social Media.

Policies to be modified

The most recent policy dealing with the apportionment of specialty society delegates requires relatively minor modifications to bring it up to date.

G-600.027, “Designation of Specialty Societies for Representation in the House of Delegates,” was modified at 2017 Annual Meeting to clarify the formula that will be used to apportion delegates to specialty societies in the House of Delegates. The policy will be modified to delete a call to study bylaws changes necessitated by the policy change and the date of the initiation of the policy as those elements are no longer relevant.

1. The current specialty society delegation allocation system (using a formula that incorporates the ballot) will be discontinued; and specialty society delegate allocation in the House of Delegates will be determined so that the total number of national specialty society delegates shall be equal to the total number of delegates apportioned to constituent societies under section 2.1.1 (and subsections thereof) of AMA bylaws, and will be distributed based on the latest available membership data for each society, which is generally from the society's most recent five year review, but may be determined annually at the society's request.

2. Specialty society delegate allocation will be determined annually, based on the latest available membership data, using a two-step process:
   (a) First, the number of delegates per specialty society will be calculated as one delegate per 1,000 AMA members in that society, or fraction thereof.
   (i) At the time of this calculation, any specialty society that has applied for representation in the HOD, and has met SSS criteria for representation, will be apportioned delegates in anticipation of its formal acceptance to the HOD at the
subsequent Annual Meeting. Should the society not be accepted, the delegate seat(s) apportioned to that society will remain vacant until the apportionment of delegates occurs the following year.

(b) Second, the total number of specialty society delegates will be adjusted up or down to equal the number of delegates allocated to constituent societies.

(i) Should the calculated total number of specialty society delegates be fewer than the total number of delegates allocated to constituent societies, additional delegates will be apportioned, one each, to those societies that are numerically closest to qualifying for an additional delegate, until the total number of national specialty society delegates equals the number of constituent society delegates.

(ii) Should the calculated total number of specialty society delegates be greater than the number of delegates allocated to constituent societies, then the excess delegates will be removed, one each, from those societies numerically closest to losing a delegate, until the total number of national specialty society delegates equals the number of constituent society delegates.

(iii) In the case of a tie, the previous year’s data will be used as a tie breaker. In the case of an additional delegate being necessary, the society that was closest to gaining a delegate in the previous year will be awarded the delegate. In the case of a delegate reduction being necessary, the society that was next closest to losing a delegate in the previous year will lose a delegate.

3. The Council on Constitution and Bylaws will investigate the need to change any policy or bylaws needed to implement a new system to apportion national medical specialty society delegates.

4. This new specialty society delegate apportionment process will be implemented at the first Annual Meeting of the House of Delegates following the necessary bylaws revisions.

5. Should a specialty society lose representation during a meeting of the HOD, the delegate seat(s) apportioned to that society will remain vacant until the apportionment of delegates occurs the following year.

The policy below requires a slight change to use the preferred language consistently. The change is presented here in the interest of transparency. The original sponsor favors the change.

10. In June the House adopted policy supporting the use of “person-first” language in addressing the needs of patients affected by obesity, which is catalogued as Policy H-440.821, “Person-First Language for Obesity.” The language in the third paragraph is slightly inconsistent as adopted and will be changed from “patient-first” to “person-first.”

Our AMA: (1) encourages the use of person-first language (patients with obesity, patients affected by obesity) in all discussions, resolutions and reports regarding obesity; (2) encourages the use of preferred terms in discussions, resolutions and reports regarding patients affected by obesity including weight and unhealthy weight, and discourage the use of stigmatizing terms including obese, morbidly obese, and fat; and (3) will educate health care providers on the importance of person-first language for treating patients with obesity; equipping their health care facilities with proper sized furniture, medical equipment and gowns for patients with obesity; and having patients weighed respectfully.

The changes outlined above do not reset the sunset clock and will be implemented when this report is filed.

Fiscal note: $250 to edit policy database.