

REPORTS OF THE BOARD OF TRUSTEES

The following reports, 1–33, were presented by Jack Resneck, Jr., MD, Chair.

1. ANNUAL REPORT

Reference committee hearing: see report of Reference Committee F.

HOUSE ACTION: FILED

The Consolidated Financial Statements for the years ended December 31, 2018 and 2017 and the Independent Auditor's report have been included in a separate booklet, titled "2018 Annual Report." This booklet is included in the Handbook mailing to members of the House of Delegates and will be discussed at the Reference Committee F hearing.

2. NEW SPECIALTY ORGANIZATIONS REPRESENTATION IN THE HOUSE OF DELEGATES

Reference committee hearing: see report of Reference Committee on Amendments to Constitution and Bylaws.

HOUSE ACTION: RECOMMENDATIONS ADOPTED REMAINDER OF REPORT FILED

See Policy D-600.984

The Board of Trustees (BOT) and the Specialty and Service Society (SSS) considered the applications of the American Academy of Sleep Medicine and the American Society of Cytopathology for national medical specialty organization representation in the American Medical Association (AMA) House of Delegates (HOD). The applications were first reviewed by the AMA SSS Rules Committee and presented to the SSS Assembly for consideration.

The applications were considered using criteria developed by the Council on Long Range Planning and Development and adopted by the HOD (Policy G-600.020). (Exhibit A)

Organizations seeking admission were asked to provide appropriate membership information to the AMA. That information was analyzed to determine AMA membership, as required under criterion 3. A summary of this information is attached to this report as Exhibit B.

In addition, organizations must submit a letter of application in a designated format. This format lists the above-mentioned guidelines followed by each organization's explanation of how it meets each of the criteria.

Before a society is eligible for admission to the HOD, it must participate in the SSS for three years. Both organizations have actively participated in the SSS for more than three years.

Review of the materials and discussion during the SSS meeting at the 2018 Interim Meeting indicated that the American Academy of Sleep Medicine and the American Society of Cytopathology meet the criteria for representation in the HOD.

RECOMMENDATION

Therefore, the Board of Trustees recommends that the American Academy of Sleep Medicine and the American Society of Cytopathology be granted representation in the AMA House of Delegates and that the remainder of the report be filed.

APPENDIX

Exhibit A - Guidelines for Representation in & Admission to the House of Delegates: National Medical Specialty Societies

1. The organization must not be in conflict with the constitution and bylaws of the American Medical Association by discriminating in membership on the basis of race, religion, national origin, sex, or handicap.
2. The organization must (a) represent a field of medicine that has recognized scientific validity; and (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:
 - 1,000 or more AMA members;
 - At least 100 AMA members and that twenty percent (20%) of its physician members who are eligible for AMA membership are members of the AMA; or
 - Have been 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 5 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.

Responsibilities of National Medical Specialty Organizations

1. To cooperate with the AMA in increasing its AMA membership.
2. To keep its delegate to the House of Delegates fully informed on the policy positions of the organizations so that the delegate can properly represent the organization in the House of Delegates.
3. To require its delegate to report to the organization on the actions taken by the House of Delegates at each meeting.
4. To disseminate to its membership information to the actions taken by the House of Delegates at each meeting.
5. To provide information and data to the AMA when requested.

Exhibit B - Summary Membership Information

Organization	AMA Membership of Organization's <u>Total Eligible Membership</u>
American Academy of Sleep Medicine	1,202 of 5,185 (23%)
American Society of Cytopathology	286 of 1,371 (21%)

3. 2018 GRANTS AND DONATIONS

Informational report; no reference committee hearing.

HOUSE ACTION: FILED

This informational financial report details all grants or donations received by the American Medical Association during 2018.

**American Medical Association
Grants & Donations Received by the AMA
For the Year Ended December 31, 2018
Amounts in thousands**

Funding Institution	Project	Amount Received
Agency for Healthcare Research and Quality (subcontracted through Northwestern University)	Midwest Small Practice Care Transformation Research Alliance	\$ 141
Agency for Healthcare Research and Quality (subcontracted through RAND Corporation)	Health Insurance Expansion and Physician Distribution	67

**American Medical Association
Grants & Donations Received by the AMA
For the Year Ended December 31, 2018
Amounts in thousands**

Funding Institution	Project	Amount Received
Centers for Disease Control and Prevention (subcontracted through National Association of Chronic Disease Directors)	Diabetes Technical Assistance and Support	156
Centers for Disease Control and Prevention (subcontracted through YMCA)	Diabetes Prevention Program	71
Centers for Medicare & Medicaid Services	Transforming Clinical Practices Initiative — Support and Alignment Networks	549
National Institutes of Health (subcontracted through HCM Strategist, LLC)	All of Us Research Program	64
Substance Abuse and Mental Health Services Administration (subcontracted through American Academy of Addiction Psychiatry)	Providers Clinical Support System for Opioid Therapies	<u>69</u>
Government Funding		<u>1,117</u>
American Association of Colleges of Osteopathic Medicine	Accelerating Change in Medical Education Initiative	13
American Heart Association, Inc.	Target: Blood Pressure Initiative	94
American College of Emergency Physicians	Accelerating Change in Medical Education Initiative	<u>13</u>
Nonprofit Contributors		<u>120</u>
Contributions less than \$5,000	International Medical Graduates Section Reception	<u>5</u>
Other Contributors		<u>5</u>
Total Grants and Donations		\$ 1,242

4. AMA 2020 DUES

Reference committee hearing: see report of Reference Committee F.

**HOUSE ACTION: RECOMMENDATIONS ADOPTED
REMAINDER OF REPORT FILED
*See Policy G-635.130***

Our American Medical Association (AMA) last raised its dues in 1994. AMA continues to invest in improving the value of membership. As our AMA’s membership benefits portfolio is modified and enhanced, management will continuously evaluate dues pricing to ensure optimization of the membership value proposition.

RECOMMENDATION

2020 Membership Year

The Board of Trustees recommends no change to the dues levels for 2020, that the following be adopted and that the remainder of this report be filed:

Regular Members	\$ 420
Physicians in Their Second Year of Practice	\$ 315
Physicians in Military Service	\$ 280
Physicians in Their First Year of Practice	\$ 210
Semi-Retired Physicians	\$ 210
Fully Retired Physicians	\$ 84
Physicians in Residency Training	\$ 45
Medical Students	\$ 20

5. UPDATE ON CORPORATE RELATIONSHIPS

Informational report; no reference committee hearing.

HOUSE ACTION: FILED

PURPOSE

The purpose of this informational report is to update the House of Delegates (HOD) on the results of the Corporate Review process from January 1 through December 31, 2018. Corporate activities that associate the American Medical Association (AMA) name or logo with a company, non-Federation association or foundation, or include commercial support, currently undergo review and recommendations by the Corporate Review Team (CRT) (Appendix A).

BACKGROUND

At the 2002 Annual Meeting, the HOD approved revised principles to govern the American Medical Association's (AMA) corporate relationships, HOD Policy G-630.040 "Principles on Corporate Relationships." These "Guidelines for American Medical Association Corporate Relationships" were incorporated into the corporate review process, are reviewed regularly, and were reaffirmed at the 2012 Annual Meeting. AMA managers are responsible for reviewing AMA projects to ensure they fit within these guidelines.

YEAR 2018 RESULTS

In 2018, eighty new activities were considered and approved through the Corporate Review process. Of the 80 projects recommended for approval, 33 were conferences or events, nine were education, content or grants, 24 were collaborations or affiliations, 12 were member service provider programs, one was an American Medical Association (AMA) Alliance activity and one was an American Medical Association Foundation (AMAF) program. (Appendix B).

CONCLUSION

The Board of Trustees (BOT) continues to evaluate the CRT review process to balance risk assessment with the need for external collaborations that advance the AMA's strategic focus.

APPENDIX A - Corporate Review Process Overview

The Corporate Review Team (CRT) includes senior managers from the following areas: Strategy, Finance, Health Solutions Group (HSG), Advocacy, Federation Relations, Office of the General Counsel, Medical Education, Publishing, Ethics, Enterprise Communications (EC), Physician Engagement (PE), and Health and Science.

The CRT evaluates each project with the following criteria:

- Type, purpose and duration of the activity;
- Audience;
- Company, association, foundation, or academic institution involved (due diligence reviewed);
- Source of external funding;
- Use of the AMA logo;
- Fit or conflict with AMA Corporate Guidelines;
- Editorial control/copyright;
- Exclusive or non-exclusive nature of the arrangement;
- Status of single and multiple supporters; and
- Risk assessment for AMA.

The CRT reviews and makes recommendations regarding the following types of activities that utilize AMA name and logo:

- Industry-supported web, print, or conference projects directed to physicians or patients that do not adhere to Accreditation Council for Continuing Medical Education (ACCME) Standards and Essentials.
- AMA sponsorship of external events.
- Independent and company-sponsored foundation supported projects.

- AMA licensing and publishing programs. (These corporate arrangements involve licensing AMA products or information to corporate or non-profit entities in exchange for a royalty and involve the use of AMA's name, logo, and trademarks. This does not include database or CPT licensing.)
- Member service provider programs such as new affinity or insurance programs and member benefits.
- Third-party relationships such as joint ventures, business partnerships, or co-branding programs directed to members.
- Non-profit association collaborations outside the Federation. The CRT reviews all non-profit association projects (Federation or non-Federation) that involve corporate sponsorship.
- Collaboration with academic institutions only if there is corporate sponsorship.

For the above specified activities, if the CRT recommends approval, the project proceeds.

In addition to CRT review, the Executive Committee of the Board must review and approve CRT recommendations for the following AMA activities:

- Any activity directed to the public with external funding.
- Single-sponsor activities that do not meet ACCME Standards and Essentials.
- Activities involving risk of substantial financial penalties for cancellation.
- Upon request of a dissenting member of the CRT.
- Any other activity upon request of the CRT.

All Corporate Review recommendations are summarized annually for information to the Board of Trustees. The BOT informs the HOD of all corporate arrangements at the Annual Meeting.

APPENDIX B - Summary of Corporate Review Recommendations for 2018

Project No.	Project Description	Corporations	Approval Date
CONFERENCES/EVENTS			
22738	TEDMED 2018 – Continue TEDMED conference sponsorship with name and logo	TEDMED, LLC	6/5/2018
23524	HIMSS18 Annual Conference – Sponsorship with AMA name and logo.	Health Information and Management Systems Society (HIMSS)	1/9/2018
27797	Sandy Hook Gala Event 2018 – Continue sponsorship with AMA name and logo.	Sandy Hook Promise Akin Gump Straus Hauer & Feld, LLP Amalgamated Bank Anthem, Inc. Blue Cross Blue Shield Association Genentech, Inc. Heather McHugh Liberty Partners Group, LLC Managed Funds Association Mehlman Castagnetti Rosen & Thomas National Association of Broadcasters (NAB) National Multifamily Housing Council Pacific Gas & Electric Company (PG&E) The Sorenson Family Diageo, PLC Wine and Spirits Wholesalers of America, Inc. Aetna Inc. Air Line Pilots Association (ALPA) American Health Care Association (AHCA) AT&T Inc. (American Telephone and Telegraph) The Bank of America Corporation Boehringer-Ingelheim, GmbH CVS Health (Consumer Value Store) Deloitte Touche Tohmatsu Limited Discovery Communications, Inc. Lockheed Martin Corporation Lumina Foundation Merck & Co., Inc.	4/6/2018

Project No.	Project Description	Corporations	Approval Date
		Verizon Wireless Charter Communications, Inc. S&P Global Inc. (Standard & Poor) PepsiCo, Inc. Comcast Corporation Centene Corporation Pharmaceutical Research and Manufacturers of America (PhRMA) Alexion Pharmaceuticals, Inc. General Dynamics Corporation Association for Accessible Medicine	
27981	Alliance for Health Policy – Continue sponsorship of event dinner with AMA name and logo.	Pharmaceutical Research and Manufacturers of America (PhRMA) Health Is Primary (Family Medicine for America’s Health) Aetna, Inc. Anthem Insurance Companies, Inc. Ascension Health Blue Cross Blue Shield Association Cambia Health Foundation GSK (GlaxoSmithKline) Welsh Carson Anderson & Stowe (WCAS) Bristol-Myers Squibb Company (BMS) Amgen, Inc. (Applied Molecular Genetics) Association of Community Affiliated Plans (ACAP) Novartis International, A.G. Biotechnology Innovation Organization (BIO) Blue Shield of California DaVita, Inc. UCB, Inc. (Union Chimique Belge) Vertex Pharmaceuticals, Inc.	5/11/2018
29472	Sling Health 2018 Demo Day – Sponsorship with AMA name and logo.	Sling Health National Network Pharmaceutical Research and Manufacturers of America (PhRMA) Husch Blackwell, LLP The Boston Consulting Group, Inc. (BCG) Cortex Innovation Community St. Louis Metropolitan Medical Society St. Louis Regional Chamber Barnes-Jewish Christian HealthCare (BJC) Inventr InSite Washington University in St. Louis St. Louis Development Partnership Penn HealthX University of Michigan Medical School EVNTUR Cambridge Innovation Center (CIC) Louisiana State University Health (LSU Health) Foundation Brown Smith Wallace, LLP	4/10/2018
29760	8 th Annual Diversity Inclusion and Health Equity Symposium – Sponsorship with AMA name and logo.	Center for Healthcare Innovation (CHI) Genentech, Inc. Abbott Laboratories Edelman Digital AbbVie, Inc. Salesforce, Inc. West Monroe Partners, LLC. The University of Chicago Medicine Gilead Sciences, Inc. Northwestern University Upsher-Smith Laboratories, LLC	5/9/2019

<u>Project No.</u>	<u>Project Description</u>	<u>Corporations</u>	<u>Approval Date</u>
		Drinker Biddle & Reath LLP Aurora Health Care Sanofi, S.A. SoPE (Society of Physician Entrepreneurs) Chiltern International Limited	
29938	2018 Personal Connected Health (PCH) Alliance Conference – Continue sponsorship with AMA name and logo.	Connected Health Conference Personal Connected Health (PCH) Alliance	6/25/2018
31205	2018 25 th Annual Princeton Conference – Sponsorship with AMA name and logo.	Princeton University	1/22/2018
31322	AMA Global Health Challenge – AMA to rebrand Timmy Global Health Challenge as AMA Global Health Challenge.	Timmy Global Health Med Plus Advantage International Medical Group (IMG)	2/8/2018
31368	AMA Sponsored Journalist Training on Opioid/Addiction Epidemic – AMA sponsorship of training program for journalists.	American Society of Addiction (ASAM) National Press Foundation (NPF)	2/19/2018
31391	2018 Women Business Leaders in Healthcare (WBL) Summit – Sponsorship with AMA name and logo.	Women Business Leaders in Healthcare (WBL) Tivity Health, Inc. MCG Health, LLC, part of the Health Network UnitedHealth Group, Inc. Medecision, Inc. American Mobile Nurses (AMN) Healthcare McKesson Corporation Tabula Rasa Healthcare Catholic Health Initiatives Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. Amgen, Inc. Highmark, Inc. Trustmark National Bank Healthcare Leadership Council (HLC) Navigant Consulting, Inc. Dobson DaVanzo & Associates, LLC	2/13/2018
32602	Northern Connecticut and Western Massachusetts Juvenile Diabetes Research Foundation (JDJRF) Annual Promise Ball – AMA sponsorship with name and logo.	Northern Connecticut and Western Massachusetts Juvenile Diabetes Research Foundation (JDJRF) Optum, Inc. Travelers (The Travelers Indemnity Company) Aetna, Inc. Aspen RE (Reinsurance) Cigna (Global Health Service Company) HealthPlan Services, Inc. Mandell Family Foundation (Foundation Center) Accenture, Inc. Convey Health Solutions Pratt & Whitney (United Technologies Corporation) Travelers Championship (The Greater Hartford Community Foundation) Bartlett, Brainard, Eacott (BBE) Inc. Covington & Burling, LLP Prudential Financial, Inc. The Hartford Financial Services Group, Inc. Klynveld Peat Marwick Goerdeler (KPMG) International Cooperative Barnes Group, Inc. Concentrix Corporation	

<u>Project No.</u>	<u>Project Description</u>	<u>Corporations</u>	<u>Approval Date</u>
		Hartford Yard Dogs (Minor League Baseball Team) Lilly Diabetes (Lilly USA, LLC) Marcum Accountants (Marcum LLP) New Britain Bees (Atlantic League of Professional Baseball Team) New England Development, Inc. PRO Unlimited, Inc. People's United Bank, N.A.	
32603	National Minority Quality Forum Leadership Summit 2018 – Sponsorship with AMA name and logo.	National Minority Quality Forum, Inc.	4/2/2018
32761	AMA Physician Innovation Network (PIN)/Health:Further Conference Collaboration –Speaking opportunity for AMA Physician Innovation Network (PIN) with AMA name and logo at Health: Further Conference.	Health:Further	5/4/2018
32899	Big Data and Healthcare Analytics Forum – Sponsorship with AMA name and logo.	Big Data and Healthcare Analytics Forum Health Information and Management Systems Society (HIMSS) Media, LLC Purestorage, Inc. General Electric (GE) Microsoft Corporation DataRobot, Inc. Sirius Healthcare (Sirius Computer Solutions, Inc.) 3M (Minnesota Mining and Manufacturing Company) Qlik Healthcare (QlikTech International AB) American Health Information Management Association (AHIMA) HealthDataViz, LLC Roche Diagnostics Information Solutions (F. Hoffmann-La Roche Ltd)	5/21/2018
33070	American Health Information Management Association (AHIMA)/AMA Clinical Documentation Improvement (CDI) Summit – AMA to co-brand and sponsor the summit with AHIMA.	Clinical Documentation Improvement (CDI) Summit American Health Information Management Association (AHIMA)	6/25/2018
33195	2018 Connected Health Conference & Personal Connected Health (PCH) Alliance – AMA to continue sponsorship with name and logo for 2018 event.	2018 Connected Health Conference Personal Connected Health (PCH) Alliance Health Information and Management Systems Society (HIMSS)	7/20/2018
33238	2018 Midwest LGBTQ Health Symposium Reception –Sponsorship of reception with AMA name and logo.	2018 Midwest LGBTQ Health Symposium Howard Brown Health Center for Education, Research and Advocacy	7/26/2018
33239	2018 Health 2.0 Annual Fall Conference – AMA to continue sponsorship with name and logo for 2018 event.	Health 2.0, LLC Health Information and Management Systems Society (HIMSS)	7/26/2018
33422	National Association Medical Staff Services (NAMSS) Annual Meeting – AMA name, logo and sponsorship of key (room) cards for meeting.	National Association Medical Staff Services (NAMSS)	8/24/2018
33423	Systematized Nomenclature of Medicine – Clinical Terms (SNOMED CT) Expo 2018 – AMA to continue sponsorship with name and logo for 2018 event.	Systematized Nomenclature of Medicine – Clinical Terms (SNOMED CT)	8/24/2018

<u>Project No.</u>	<u>Project Description</u>	<u>Corporations</u>	<u>Approval Date</u>
33424	Health Information and Management Systems Society (HIMSS) Saudi Arabia Conference & Exhibition 2018 – Sponsorship with AMA name and logo.	Health Information and Management Systems Society (HIMSS)	8/28/2018
33425	Health Information and Management Systems Society (HIMSS) Big Data and Healthcare Analytics Forum – Sponsorship with AMA name and logo.	Health Information and Management Systems Society (HIMSS) Initiate Government Solutions (IGS), LLC Rapid Insight, Inc.	8/24/2018
33428	American Health Information Management Association (AHIMA) World Congress 2018 – Sponsorship with AMA name and logo to reinforce CPT brand awareness internationally.	American Health Information Management Association (AHIMA) Cleveland Clinic Abu Dhabi 3M (Minnesota Mining and Manufacturing Company) Health Information Systems DML (Data Manipulation Language) Consulting, Inc.	8/28/2018
33479	American Health Information Management Association (AHIMA) Annual Clinical Coding Meeting – Sponsorship with AMA name and logo.	American Health Information Management Association (AHIMA)	9/4/2018
33494	Predictive Analytics Innovation Summit – Speaking engagement including sponsorship with AMA name and logo.	The Predictive Analytics Innovation Summit (The Innovation Enterprise Ltd) Visier, Inc. Women Who Code Decideo CrowdReviews, LLC Datafloq, B.V. Visibility Magazine	9/21/2018
33568	2018 Chicago United – Sponsorship with AMA name and logo for “Leaders for Change” 2018 gala event.	Chicago United	9/24/2018
33654	HIMSS 2019 Agreement – Collaboration for HIMSS Global Conference, with use of AMA name and logo.	Health Information and Management Systems Society (HIMSS)	10/5/2018
33672	PCPI Fall Conference 2018 – AMA IHMI sponsorship with AMA name and logo.	PCPI National Quality Registry Network (NQRN)	10/8/2018
33830	Arab Health 2019 Conference – Sponsorship with the AMA name and logo to establish CPT in Middle East healthcare market.	Arab Health (Informa Exhibitions, LLC)	10/31/2018
33859	2019 National Rx Drug Abuse & Heroin Summit – Sponsorship with AMA name and logo.	The National Rx Drug Abuse & Heroin Summit	11/2/2018
34034	E-Health Conference 2019 – Speaking engagement, booth and sponsorship with AMA name and logo to establish CPT in Canadian healthcare market.	Digital Health Canada Canada Health Infoway Canadian Institute for Health Information (CIHI)	11/13/2018
34269	2019 National Quality Forum (NQF) Annual Conference – Sponsorship with AMA name and logo.	National Quality Forum (NQF)	12/6/2018
EDUCATION, CONTENT OR GRANTS			
30540	Gaples Institute for Integrative Cardiology Collaboration – Gaples nutrition curriculum to be featured on the AMA Education Center.	Gaples Institute for Integrative Cardiology	12/6/2018
31526	Validated Blood Pressure Device Criteria and Listing (VDL) – Guidance to physicians on AMA/AHA Target:BP website regarding a list of devices	American Heart Association (AHA) National Opinion Research Center	4/23/2018

<u>Project No.</u>	<u>Project Description</u>	<u>Corporations</u>	<u>Approval Date</u>
	demonstrating validation for clinical accuracy (VDL).		
31533	“Distributed by” branding for American Medical Association / American Heart Association Target:BP Materials – Listing of “distributed by Telligen” on AMA and AHA co-branded Target:BP materials.	American Heart Association (AHA) Telligen, Inc.	3/28/2018
32931	American Hospital Association’s Health Research and Educational Trust (HRET) – AMA Improving Health Outcomes (IHO) royalty free license for diabetes prevention white paper development and dissemination.	Health Research and Educational Trust (HRET) American Hospital Association (AHA)	6/5/2018
33836	American Hospital Association (AHA) and AMA “Blood Pressure Measure Accurately” Module – AMA to co-create and co-brand education program to train primary care team members.	American Hospital Association (AHA)	10/31/2018
33885	MedStar/AMA EHR Usability Comparison Research Microsite – AMA name and logo use on EHR visibility website featuring videos.	Cerner Corporation Allscripts MEDITECH NextGen Epic (Electronic Privacy Information Center) Modernizing Medicine, Inc. CureMD Healthcare eClinicalworks Athenahealth, Inc. Kareo, Inc. General Electric (GE) Healthcare (Centricity)	11/5/2018
33896	Physician Burnout Assessment Crosswalk Research - AMA to distribute a physician burnout survey with incentive to physician population.	Amazon.com, Inc. The American Red Cross	11/2/2018
34154	Target: BP Initiative Data Platform – AMA/American Heart Association logo use on select pages of a chronic disease ambulatory platform with the vendor IQVIA.	American Heart Association (AHA) IQVIA, Inc	12/12/2018
	2019 Historically Black Colleges and Universities (HBCU) Calendar and Resource Guide – Participation in calendar and resource guide.	Historically Black Colleges and Universities (HBCU)	7/12/2018
COLLABORATIONS/AFFILIATIONS			
25493	Heka Health Collaboration – Updated AMA collaboration on a self-measured blood pressure (SMBP) phone app pilot.	AllScripts Healthcare Solutions, Inc. Heka Health, Inc. eClinicalWorks	8/8/2018
30260	AMA Physician Innovation Network (PIN) Collaborators –AMA Physician Innovation Network (PIN) collaboration agreements with limited AMA name and logo use.	AngelMD, Inc. Physician Entrepreneur Summit Redox, Inc. Tincture.io Center for Digital Innovation (CDI-NEGEV) Further Fund Springboard Enterprises	9/13/2018
30327	AMA IHMI Collaborators – IHMI collaboration agreements with limited AMA name and logo use.	ACT - The App Association Elimu Medstro Association Forum Ingenious Med, Inc.	4/24/2018

<u>Project No.</u>	<u>Project Description</u>	<u>Corporations</u>	<u>Approval Date</u>
31531	AMA IHMI Google Innovation Challenge with Medstro – Collaboration with Google and Medstro on the IHMI Google Innovation Challenge to enhance IHMI common data model.	Google, LLC Medstro	9/10/2018
32591	AMA Physician Innovation Network (PIN)/Massachusetts Institute of Technology (MIT) Hacking Medicine Collaboration – AMA Physician Innovation Network (PIN) to create a sub-community for Massachusetts Institute of Technology (MIT) Hacking Medicine events and workshops.	Massachusetts Institute of Technology (MIT) Hacking Medicine	4/2/2018
32732	“All of Us” Precision Medicine Digital Physician Engagement Campaign – AMA name and logo use to announce collaboration.	National Institute of Health (NIH) Figure 1	4/30/2018
32807	American Foundation for Firearm Injury Reduction in Medicine (AFFIRM) – AMA support, name and logo for AFFIRM’s steering committee. AMA not involved in fundraising.	American Foundation for Firearm Injury Reduction in Medicine (AFFIRM)	5/15/2018
32975	AMA Physician Innovation Network (PIN)/Georgetown StartupHoyas Collaboration– AMA Physician Innovation Network (PIN) to create a sub-community for Georgetown StartupHoyas.	Georgetown University School of Business	6/8/2018
33354	FitGate Health Collaboration Agreement with IHMI – IHMI collaboration agreement with limited AMA name and logo use.	FitGate, Inc.	8/13/2018
33355	Knowledge-Action-Change (KAC) Health Collaboration Agreement with IHMI – IHMI collaboration agreement with limited AMA name and logo use.	Knowledge-Action-Change (KAC) Health, LLC	8/22/2018
33421	AMA Digital Health Implementation Playbook – AMA branded website with links to collaborator websites and newsletters.	Egg Strategy, Inc. Advocate Health Care, Inc. Avia, Inc. Baylor Scott & White Health Boston Medical Center (BMC) CareMore Health System (a subsidiary of Anthem, Inc.) Columbia University Medical Center Eccles School of Business Enlightening Results, LLC Epharmix, Inc. Inception Health, LLC Harvard Medical School Partners Healthcare Brigham and Women’s Hospital Health2047, Inc. Healthbox, LLC HealthPartners Henry Ford Health System (HFHS) Illinois Gastroenterology Group/SonarMD, LLC Intermountain Healthcare IQVIA, Inc. John Hopkins Medicine (JHM) Kaiser Permanente (Kaiser Foundation Health Plan, Inc.) Lucro Global, LLC	8/30/2018

Project No.	Project Description	Corporations	Approval Date
		Marshfield Clinic MassChallenge, Inc. Matter Health Mount Sinai Health System National Association of Community Health Centers NODE (Network of Digital Evidence) Health New York University (NYU) Langone Health Ochsner Health System OSF (Order of Saint Francis) Healthcare Partners Connected Health Partners HealthCare (Connected Health) Pharos Innovations, LLC Philips (Koninklijke Philips, N.V.) Privia Medical Group Providence Health & Services Rock Health Rx Health (Responsive Health) Samsung SLUCare Physician Group Stanford Health Care (SHC) The Dartmouth Institute The Research And Development (RAND) Corporation University of California San Francisco University of Colorado Health University of Mississippi Medical Center Penn Medicine (University of Pennsylvania Health System) University of Pittsburgh Medical Center Vivify Health, Inc.	
33446	Propeller Health Collaboration Agreement with IHMI – IHMI collaboration agreement with limited AMA name and logo use.	Propeller Health	8/30/2018
33555	Medfusion Collaboration Agreement with IHMI – IHMI collaboration agreement with limited AMA name and logo use.	Medfusion, Inc.	9/19/2018
33557	PharmaSmart Collaboration Agreement with IHMI - IHMI collaboration agreement with limited AMA name and logo use.	PharmaSmart International, Inc.	9/19/2018
33600	PatientPoint Collaboration Agreement with IHMI – IHMI collaboration agreement with limited AMA name and logo use.	PatientPoint, LLC	9/27/2018
33627	Prevention Strategy Collaboration with Health Care Organizations (HCOs) – AMA name and logo will appear alongside these HCOs for national diabetes prevention program.	Marshfield Clinic Hattiesburg Clinic North Mississippi Health System Trinity Health Ascension Health, Inc. University of Florida Health Greenville Health System (GHS) Family Christian Health Center Loyola University Medical Center Matthew Walker Comprehensive Health Center, Inc. Mercy Community Health Care Riverbend Medical Group, Inc. University of Pittsburgh, PA (UPMC)	1/8/2018

<u>Project No.</u>	<u>Project Description</u>	<u>Corporations</u>	<u>Approval Date</u>
		Midwest Health's Midwest Heart & Vascular Specialists Aledade, Inc. Banner University Medical Center Harris Health System Health Management Services Organization Holy Cross Health Kelsey-Seybold Clinic Mercy Physician Network (Mercy Health System) Nashville University Priority Health Care South Illinois University Vanderbilt University Medical Center Wisconsin Women's Health Foundation Regents of the University of California University of Connecticut University of Michigan University of North Dakota University of Pittsburgh Medical Center (UPMC) Community Medicine, Inc.	
33671	Fitbit, Higi Collaboration Agreement with IHMI – IHMI collaboration agreement with limited AMA name and logo use.	Fitbit, Inc. Higi, SH, LLC	10/8/2018
33794	NAM Opioid Action Collaborative – AMA name, logo and sponsorship of public-private partnership to disseminate evidence based solutions to reduce opioid abuse.	National Academy of Medicine Action Collaborative (NAM Opioid Collaborative)	10/24/2018
33835	Core Quality Measure Collaborative – AMA participation and logo use in coalition to identify core sets of quality measures that payers will commit to use for reporting.	Core Quality Measure Collaborative (CQMC) National Quality Forum (NQF) The Centers for Medicare & Medicaid Services (CMS) AHIP (America's Health Insurance Plans)	10/25/2018
33884	AMA Physician Innovation Network (PIN)/EHR Sub-Community – AMA to display logos of organizations that agree to collaborate in an online community that connects physicians, vendors, healthcare and IT leaders on EHR best practices.	Cerner Corporation Allscripts Healthcare Solutions, Inc. MEDITECH (Medical Information Technology, Incorporated) NextGen Healthcare Information Epic Modernizing Medicine CureMD eClinicalworks Athenahealth Kareo General Electric (GE) Healthcare (Centricity) Cerner Corporation Allscripts	11/5/2018
33936	TechSpring Collaboration Agreement with IHMI – IHMI collaboration agreement with limited AMA name and logo use.	TechSpring Health	11/7/2018
33988	Persona Informatics Collaboration Agreement with IHMI – IHMI collaboration agreement with limited AMA name and logo use.	Persona Informatics, Inc.	11/21/2018
34069	The Collaborative for Healing and Renewal in Medicine (CHARM) - The AMA logo will be associated with the Charter and the "CHARM" friends" on	The Collaborative for Healing and Renewal in Medicine (CHARM) Association of American Medical Colleges (AAMC)	11/21/2018

<u>Project No.</u>	<u>Project Description</u>	<u>Corporations</u>	<u>Approval Date</u>
	AMA and Arnold P. Gold Foundation websites.	Society for Hospital Medicine Council of Residency Directors in Emergency Medicine Accreditation Council of CME (Continuing Medical Education) American College of Osteopathic Internists American Psychiatric Association National Hispanic Medical Association Institute for Healthcare Improvement Society for General Internal Medicine American College of Physicians ACLGIM (Association of Chief and Leaders of General Internal Medicine) National Medical Association AAIM (Alliance for Academic Internal Medicine) ABIM (American Board of Internal Medicine) American Society of Anesthesiology Arnold P. Gold Foundation	
	Partnership for America's Future Website logo request – AMA name and logo use to announce collaboration.	America's Health Insurance Plans (AHIP) Pharmaceutical Research and Manufacturer's Association (PhRMA) Biotechnology Innovation Organization (BIO) Blue Cross, Blue Shield Association (BCBS) Association of Accessible Medicines (AAM) Federation of American Hospitals	5/31/2018
MEMBER SERVICE PROVIDER PROGRAMS			
31423	Mirador Financial Inc. – AMA Affinity program for small practice lending services.	Mirador Financial, Inc. Core Innovation Capital Cuna Mutual Group Epic Ventures Collaborative Fund Jump Capital Crosslink Capital NYCA (New York Court of Appeals) Partners	2/27/2018
31459	Relish Labs, LLC – AMA Affinity program for home meal kits.	Relish Labs, LLC d/b/a Home Chef The Kroger Co.	6/13/2018
32694	Laurel Road Bank – AMA Affinity program for student loan refinance.	Laurel Road Bank (f/k/a Darien Rowayton Bank "DRB") Credible Labs, Inc.	4/25/2018
32786	SimpliSafe, Inc. – AMA Affinity program for security monitoring offices and homes.	SimpliSafe, Inc.	5/14/2018
33256	Headspace, Inc. – AMA Affinity program for discounted subscription to meditation and mindfulness mobile application.	Headspace, Inc.	8/14/2018
33257	Gympass U.S., LLC – AMA Affinity program for discounted fitness memberships.	Gympass U.S., LLC	8/6/2018
33258	Intersections, Inc. – AMA Affinity program for discounted identity theft protection and data breach readiness subscriptions.	Intersections, Inc. d/b/a Identity Guard	8/14/2018
33615	GE Appliances – AMA Affinity program for discounted home appliances.	General Electric (GE) Appliances Meridian One Corporation	10/3/2018

Project No.	Project Description	Corporations	Approval Date
33615	Meridian One Acquisition by Arthur J. Gallagher – Arthur J. Gallagher purchases Meridian One, an AMA Affinity program partner for GE home appliances.	Meridian One Corporation Arthur J. Gallagher & Co. Gallagher Affinity	12/12/2018
33619	Dell Marketing L.P. – AMA Affinity program for discounted computer technology.	Dell Marketing L.P.	5/7/2018
33734	AMA Affinity Hotel Program – AMA Affinity program for international hotels.	Choice Hotels International, Inc.	10/3/2018
	AMA-sponsored Med Plus Advantage (MPA) with Employee Assistance Program – AMA Insurance Agency program for employee mental health counselling services through AMA-sponsored Med Plus Advantage (MPA) program.	Standard Insurance Company Morneau Shepell, Ltd.	9/24/2018
AMA ALLIANCE			
	AMA Alliance Video Program: “Community Approaches to Combat the Opioid Epidemic” – AMA Alliance and Independent Television News (ITN) Productions Industry News to co-brand and collaborate on an AMA Alliance promotional video, with AMA Alliance name and logo use.	AMA Alliance Independent Television News (ITN) Productions Industry News	5/7/2018
AMA FOUNDATION			
	AMA Foundation (AMAF) Corporate Roundtable Fundraising – Phase One – Phase one corporate fundraising campaign to increase AMA Foundation Corporate Roundtable members.	AbbVie, Inc. Actelion Pharmaceuticals US (J&J/Janssen Co.) Alexion Pharmaceuticals, Inc. America’s Health Insurance Plans (AHIP) Amneal Pharmaceuticals, Inc. Argus Health Systems, Inc. AstraZeneca, PLC Biogen, Inc. BioMarin Pharmaceutical, Inc. Biotechnology Innovation Organization (BIO) Blue Cross Blue Shield Boehringer-Ingelheim, GmbH Bracco Diagnostics, Inc. Bristol-Myers Squibb Company Centene Corporation Cerner Corporation Change Healthcare Corporation Cigna Corp. Cigna Pharmacy Benefit Management Cipla USA, Inc. Citizens Rx, LLC CVS (Consumer Value Store) Caremark Daiichi Sankyo Company, Limited Eli Lilly and Company EnvisionRx Options (Envision Pharmaceuticals, LLC) Express Scripts Holding Company GE Foundation (General Electric) Genentech, Inc. Gilead Sciences, Inc. GlaxoSmithKline, PLC Henry Schein, Inc.	10/25/2018

Project No.	Project Description	Corporations	Approval Date
		Horizon Pharma, PLC Humana, Inc. IBM Watson Health (International Business Machines) Incyte Corporation Insulet Corporation Ionis Pharmaceuticals Livongo Health, Inc. Lupin Pharmaceuticals, Inc. Mallinckrodt, LLC Masimo Corporation MedImpact Healthcare Systems, Inc. Merck and Company, Inc. MeridianRx, LLC Navitus Health Solutions Novartis International, AG Novo Nordisk A/S Oak Street Health, LLC Otsuka America Pharmaceutical, Inc. PerformRx, LLC Pernix Therapeutics Holdings Pfizer, Inc. Philips Healthcare Company Phoenix Benefits Management, LLC PhRMA (Pharmaceuticals Research and Manufactures) Prime Therapeutics, LLC ProCare RX Regeneron Pharmaceuticals, Inc. The Risk Authority – Stanford Sanofi Shionogi, Inc. Shire U.S. Solera Health (Solera Network) Sun Pharmaceutical Industries, Inc. Takeda Pharmaceuticals Company, LTD Terumo Medical Corporation Teva North America (Teva Pharmaceuticals, USA, Inc.) UnitedHealth Group, Inc. Vertex Pharmaceuticals, Inc. Walgreens (Walgreen Company) WellDyneRx, LLC World Wide Technology, Inc.	

6. REDEFINING AMA’S POSITION ON ACA AND HEALTHCARE REFORM

Informational report; no reference committee hearing.

HOUSE ACTION: FILED

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.

IMPROVING THE AFFORDABLE CARE ACT, AND AN UPDATE ON MEDICARE EXPANSION EFFORTS

Efforts are currently underway on Capitol Hill to enact polices to support the ACA and address recent efforts to weaken the law. The termination of cost sharing payments, for example, has increased premiums for those not eligible for the ACA's premium subsidies, resulting in significant decreases in enrollment among that population. In March, the House Committee on Energy and Commerce began efforts to enact legislation to support state reinsurance programs or to provide financial assistance to reduce out-of-pocket costs for those enrolled in qualified plans. Separate legislation would reverse cuts to the ACA Navigator program and expand program duties as they relate to Medicaid and the Medicare, Medicaid, Children's Health Insurance Program (CHIP). The committee will also consider legislation to again make funding available for the establishment of state-based marketplaces. The AMA remains engaged on this and other efforts to preserve current coverage options and make improvements where necessary.

Following the mid-term Congressional elections in 2018, a great deal of attention has been paid to efforts to enact legislation creating a Medicare for All program. As proposed, this single-payer system would replace the Affordable Care Act (ACA), CHIP and all private health insurance options available through employers or the individual market.

Our AMA is currently engaged in efforts with other partners across the health care sector to raise the awareness of the shortcomings of single-payer systems and, consistent with AMA policy, to continue to promote improvements to the current system which provides quality coverage to more than 90 percent of Americans while working to expand options to cover those who remain uninsured. Though polling on the general topic shows strong public support, that support quickly erodes when the details of a such a system are explained and people begin to comprehend the significant disruptions that would occur to the coverage and access to care they currently enjoy.

MERIT-BASED INCENTIVE PAYMENT SYSTEM (MIPS) AND ALTERNATIVE PAYMENT MODELS

Our AMA continues to work to make refinements to the Merit-based Incentive Payment System (MIPS) that was established by the Medicare Access and CHIP Reauthorization Act (MACRA). Work has proceeded through workgroups comprised of policy staff from state and national medical specialty societies as well as a CEO Working Group. At this writing, several policy modifications have been discussed which would not require statutory changes, while others would require Congressional action. Among proposals which can be implemented without Congressional action are:

- Keeping cost weighted at 15 percent for at least one additional year while new episode-based measures are developed and tested and phase in new measures.
- Ultimate elimination of the Total Per Capita Cost (TPCC) and Medicare Spending Per Beneficiary (MSPB) measures which double count costs and will potentially triple count costs once the cost-based episode measures are in place.
- Improve the accountability of cost measures so that physicians can make informed decisions about their cost effectiveness without being inappropriately penalized for care outside of their control or for caring for medically and socially complex patients.
- Reduce the requirements for reporting quality measures and propose a reporting option based on clinical continuums of care.
- Revise the quality measure benchmark methodology.
- Modify policies to encourage reporting via Qualified Clinical Data Registries (QCDRs).
- Increase transparency in the Improvement Activities category.
- Accept activity modifications and new activities on an accelerated timeline to reflect the pace of change in medicine.
- Allow multi-category credit for activities and measures that overlap performance categories to simplify the scoring methodology and make the program more clinically relevant.
- Propose (as opposed to seeking comment on) alternative scoring methodologies for promoting interoperability.
- Further simplify and reduce physician reporting burden through a yes/no measure attestation and leverage health IT vendors' reporting on utilization of Certified EHR Technology – Centers for Medicare & Medicaid Services (CMS) functionality.

Proposals which would likely require statutory changes by Congress include:

- Implement positive updates for physician payment rates for 2020-2025.

- Extend CMS' flexibility to set the performance threshold lower than the mean or median beyond 2021 performance year or permanently remove the "mean or median" requirement.
- Update the Promoting Interoperability category by including language that explicitly allows vendors as well as eligible professionals to submit the data necessary for eligible professionals to be considered a "meaningful user" and decouple the Promoting Interoperability performance category from the old EHR Meaningful Use program.
- Adopt a provision granting CMS explicit flexibility to base scoring on multi-category measures to reduce silos between each of the four MIPS categories and create a more unified program.
- Aid smaller practices by adding provisions that allow more flexibility for the development of virtual groups if CMS sees low numbers of physicians joining virtual groups in the first two years of the program.
- Remove the requirement that episode-based cost measures account for half of all expenditures under Parts A and B.
- Align benchmark/reporting language for the Quality performance category in MIPS and physician compare.

On March 1, 2019, the AMA wrote to Health and Human Services Secretary Alex Azar and CMS Deputy Administrator for Quality and Innovation Adam Boehler to put forth policy recommendations for HHS and CMS to consider as a means of generating more successful alternative payment models (APMs) that will achieve better outcomes for patients and more savings for Medicare. The recommendations fell into six policy areas:

- Limiting accountability to costs and outcomes that physicians can control;
- Making payment models simple but flexible;
- Providing physicians with the data needed to deliver high-value care;
- Encouraging the implementation of APMs developed by practicing clinicians;
- Trying multiple approaches to delivery and payment reform; and
- Extending MACRA APM incentives for a longer period.

Our AMA will continue to work with the Administration and Congress as appropriate to implement these and other steps that can improve the environment surrounding payment and delivery system reform efforts for physicians.

STEPS TO LOWER HEALTH CARE COSTS

As a follow up to multiple hearings over the summer of 2018, the Chairman of the Senate Committee on Health, Education, Labor and Pensions, Sen. Lamar Alexander of Tennessee, requested information from a broad range of stakeholders on specific steps that could be taken to reduce the cost of health care. In a March 1 response to the Chairman, the AMA put forth several recommendations.

One area in which the AMA made recommendations was the high administrative costs in the health care system, particularly related to burdensome prior authorization requirements and the enormous amount of physician and staff time spent in these tasks that add little to patient care and in many cases, delay medically necessary care. Other areas addressed to the committee were:

- Increased price and data transparency to empower patients;
- Prescription drug price and cost transparency;
- Value-Based Insurance Design;
- Alternative Payment Models; and
- Lowering health care costs with an increased focus on prevention, particularly the AMA's work on preventing diabetes and controlling hypertension.

CONCLUSION

Our AMA will remain engaged in efforts to improve the health care system through policies outlined in Policy D-165.938 and other directives of the House of Delegates.

7. AMA PERFORMANCE, ACTIVITIES AND STATUS IN 2018

Informational report; no reference committee hearing.

HOUSE ACTION: FILED

Policy G-605.050, “Annual Reporting Responsibilities of the AMA Board of Trustees,” calls for the Board of Trustees to submit a report at the American Medical Association (AMA) Annual Meeting each year summarizing AMA performance, activities, and status for the prior year.

INTRODUCTION

The AMA’s mission is to promote the art and science of medicine and the betterment of public health. As the physician organization whose reach and depth extends across all physicians, as well as policymakers, medical schools, and health care leaders, the AMA is uniquely positioned to deliver results-focused initiatives that enable physicians to answer a national imperative to measurably improve the health of the nation.

Attacking the dysfunction in health care

Insurer Practices

Abusive insurer practices continue to plague patients and physicians, but the AMA convinced Anthem to reverse course when Anthem announced a change in its modifier 25 policy that could have cost physician practices an estimated \$100 million annually. The AMA also combatted Anthem/BCBS policies that deny coverage for emergency care, including supporting enactment of state legislation in Missouri.

The AMA created a consensus statement - adopted by industry stakeholders - to “right size” the prior authorization process.

- Supported by: AMA, American Hospital Association, America’s Health Insurance Plans, American Pharmacists Association, Blue Cross Blue Shield Association and Medical Group Management Association
- AMA successfully collaborated to enact utilization management reforms (step therapy and prior authorization) in three states (IN, NM and WV)

The AMA’s grassroots website, FixPriorAuth.org, launched in 2018 to educate the general public about the problems associated with prior authorization and to gather stories from physicians and patients about how they have been affected by it.

Physician Payment

Due to AMA advocacy, physicians averted an E/M code collapse that would have implemented dramatic reductions in physician payment. An AMA-convened physician workgroup developed a new E/M coding proposal to be considered by the CPT Editorial Panel in early 2019.

The AMA fought successfully for Congress to eliminate the Independent Payment Advisory Board.

CMS expanded coverage for services using telecommunications technology, strongly supported by the AMA.

AMA has been working with specialty societies and individual physicians to promote testing of new alternative payment models. Over the past 12 months, the federal Physician-focused Payment Model Technical Advisory Committee (PTAC) has recommended to the HHS Secretary five alternative payment models that were strongly supported by the AMA. These models aim to significantly improve care for patients that need emergency department care, oncology care, palliative care, advanced primary care, and those transitioning from chronic to end-stage renal disease. As AMA has strongly advocated, the CMS Innovation Center has indicated that it plans to implement three of these physician-focused payment models early in 2019.

AMA continued to successfully seek Quality Payment Program (QPP) improvements:

- Medicare Part B drug costs will be excluded from the Merit-based Incentive Payment System (MIPS) payment adjustments and from the low-volume threshold determination
- CMS may reweight the MIPS cost performance category to not less than 10 percent for the third, fourth and fifth program years (rather than requiring a weight of 30 percent in the third year)
- CMS has more flexibility in setting the MIPS performance threshold for years three through five to ensure a gradual and incremental transition to the performance threshold being set at the mean or median performance level in the sixth year

Regulatory Relief

The AMA secured significant improvements to the Promoting Interoperability component of the QPP (formerly known as the EHR Meaningful Use Program).

Congress eliminated the requirement that the federal electronic health record (EHR) program become more stringent over time.

State efforts

Working with state medical societies, the AMA helped secure over 85 state legislative and regulatory victories (issues include opioids, stabilizing the individual market, balance billing, Anthem ER policy, PBM regulation, utilization management, Medicaid expansion, banning of conversion therapy, scope of practice, medical liability reform, telemedicine, and more.)

Practice Transformation (Operational)

To support the operational components of physician practices, [Professional Satisfaction and Practice Sustainability \(PS2\)](#) relaunched, updated and expanded the STEPS Forward™ Practice Improvement Strategies collection as part of the AMA Ed Hub™, focused on creating the organizational structures that can result in more satisfied and productive physicians.

PS2 continues to partner with health systems, large practices, state medical societies, and graduate medical education programs to assess physician burnout utilizing the Mini-Z Burnout Assessment. Many of these burnout assessments were done in collaboration with the AMA's Physician Engagement unit as a key component of our offering for group membership.

The AMA, in partnership with Stanford WellMD and Mayo Clinic, led research to evaluate the latest trends in prevalence of burnout and satisfaction with work-life integration among physicians, to assess progress relative to 2011 and 2014 studies.

PS2 co-hosted a successful International Conference on Physician Health held October 2018 in Toronto with the Canadian Medical Association and British Medical Association, and will convene the second American Conference on Physician Health in Fall 2019 with our partners Stanford WellMD and Mayo Clinic.

In 2018, PS2 made a significant investment in research to expand the body of “practice science,” championing evidence-based interventions to improve the delivery models of care at the practice and system levels. This robust body of research, entitled the AMA Practice Transformation Initiative (PTI), will be conducted in collaboration with health systems, practices, and medical societies to study interventions at various practice types and sizes, with the goal of improving patient care by improving clinician satisfaction.

PS2 and Advocacy have partnered to provide new resources for physicians to provide clear guidance on commonly misunderstood regulatory guidelines that impact day-to-day clinical practice on pressing topics like [Computerized Process Order Entry \(CPOE\)](#) and [Medical Student Documentation](#).

Digital Health (Technological)

PS2 continued to support the quadruple aim by convening the health care innovation ecosystem to advance the adoption of safe, effective electronic health records (EHRs) and digital health solutions - led by the physician and patient voice - in support of the quadruple aim.

PS2's work included the July 2018 publishing of "A Usability and Safety Analysis of Electronic Health Records: A Multi-Center Study" in the Journal of the American Medical Informatics Association. This followed the release of a guide with recommendations for improving the safety and usability of EHRs as well as safety test case scenarios.

PS2 continued to support and expand the influence of Xcertia, the collaboration dedicated to improving the quality, safety, and effectiveness of mobile health applications.

The AMA's Physician Innovation Network (PIN) continues to expand to amplify further the physician voice in health tech innovation by connecting physicians with health tech innovators and entrepreneurs.

PS2 launched the AMA Digital Health Implementation Playbook in Fall 2018 to improve the clinical integration and scaling of digital health tools. These tools, when leveraged effectively, can remove obstacles to delivering quality patient care and reduce physician burnout. The Playbook was brought to life with the support of over 30 collaborators, and it includes general best practices relevant for implementing any technology solution in practice as well as a chapter specifically focused on remote patient monitoring. The Playbook will be expanded in 2019 to include additional chapters emphasizing the implementation of additional specific digital health solutions.

Physician Payment and Quality (Financial)

The financial performance and sustainability of physician practices continues to be a focus of PS2's work to update our comprehensive collection of payment and quality reporting resources, available on the AMA website, to reflect the current Medicare Quality Payment Program (QPP) program year.

In Fall 2018, the AMA and RAND Corporation partnered again to publish a follow-up study to our 2014 research on the effects of payment models on physician practices, hospitals and health plans. With this research, the AMA is positioned to better understand and shape alternative payment models and develop our strategic plan in this area to inform our investments in research, educational resources, and activities that enable physicians to adapt, lead and thrive in a value-based health care system.

A grant from the Centers for Medicare and Medicaid Services (CMS) Transforming Clinical Practices Initiative, through which the AMA is providing technical assistance and educational resources for multiple Practice Transformation Network (PTN) practices, was renewed for 2019. Under the auspices of the grant, the AMA will continue to convene experts to tackle the challenges associated with Qualified Clinical Data Registry reporting and quality measurement.

Litigation Center

Azar v. Allina Health Services: In 2018, the AMA Litigation Center filed an amicus brief before the US Supreme Court to argue for Medicare to use notice and comment rulemaking for significant payment rule changes.

Bell v. Mackey: A psychiatrist who discharged a patient who later committed suicide was shielded from liability under state law because the physician performed a good faith examination and favored his patient's autonomy vs. involuntary commitment. The Litigation Center filed a brief supporting the physician.

Mayo v. IPFCF: The Wisconsin Supreme Court upheld the constitutionality of Wisconsin's statutory cap on damages in medical malpractice suits. The Litigation Center filed an amicus brief in support of reinstating the cap.

Texas v. U.S.: The AMA filed an amicus brief defending the constitutionality of the ACA.

Tulare Hospital Medical Staff v. Tulare Local Healthcare District: The AMA supported the California Medical Association in reinstating a hospital medical staff and recovering certain damages after an unjust ousting from the hospital administration.

Sexual Orientation and Gender Identity (SOGI)

As directed by the House of Delegates, Policy G-635.125, asked the AMA, with input from the LGBTQ Advisory Committee, to expand the collection of demographic information from AMA members to include sexual orientation and gender identity. The initial roll-out of the SOGI data collection effort was successfully completed ahead of the 2018 AMA membership recruitment efforts and allows members and non-members to voluntarily submit SOGI information. Post-launch improvements were recently implemented to better capture and represent the diversity of the physician member population. The focus, now, will be to encourage participation and to develop a white paper on how the AMA implemented SOGI data collection for our members.

DMPAG

The Digital Medicine Payment Advisory Group made great progress towards its goal of integrating digital medicine technologies into clinical practice. This includes proposing new CPT codes for Remote Physiologic Monitoring and Interprofessional Internet Consultations. These codes were published in 2018 and will be covered and paid by Medicare and other payers in 2019.

CPT/RUC Workgroup

The CPT/RUC Workgroup on Evaluation and Management built a new coding structure for E/M Office Visit coding in response to changes to E/M proposed by CMS. The group has developed a consensus coding structure that will be proposed to the CPT Panel in February 2019. Given the progress made by the workgroup CMS has delayed implementation of any changes to E/M until 2021.

Reinventing medical education, training and lifelong learning

Beta launch of AMA Ed Hub

In 2018, the AMA introduced the AMA Ed Hub™ (amaedhub.com), AMA's new education delivery platform. Designed to support lifelong learning, licensure and certification needs, the AMA Ed Hub reflects the AMA's deep and longstanding commitment to lifelong professional development that helps physicians and the broader health care team achieve real-world outcomes of better health care and better health.

The AMA Ed Hub brings together the many excellent sources of education from across the AMA under one unified umbrella including JN Learning™, STEPs Forward™ and other AMA education. Serving as a powerful discovery channel for trusted education, the AMA Ed Hub provides physicians and other learners with simple, intuitive access to high quality education on any device, in many formats and at any time of the day. It delivers increasingly personalized learning experiences, serving up recommendations based on user interests and behaviors. It also features a consolidated learner transcript and seamless claiming, tracking and reporting of credit.

JAMA

The JAMA Network continued to expand into new channels and content types, such as podcasts (over 2.7 million downloads), Apple News feeds, and visual abstracts to increase the accessibility and reach of content for students, physicians, and researchers. This was highlighted by the launch of *JAMA Network Open* in 2018, the AMA's first online-only, fully open access clinical research journal. *JAMA Network Open* is a general medicine journal covering more than 40 topic areas, with the same commitment to quality and integrity as all the JAMA Network journals. In addition to content being freely available to all readers upon publication, *JAMA Network Open* aims to make content accessible to readers by including invited commentaries to put research in context, press releases, and article key points. As an online-only publication, *JAMA Network Open* will provide ongoing innovations around the publishing process and dissemination of content, which will benefit the entire JAMA Network as the landscape around scientific information continues to evolve.

Accelerating Change in Medical Education (ACE)

The major accomplishments of the ACE Consortium that work toward reimagining medical education, training, and lifelong learning for the digital age include:

- Celebrated the completion of the original five-year grant period
- All 32 consortium member institutions have committed to continue to collaborate, and will invite new members.
- Consortium innovations impact over 19,000 students throughout the US

A significant output of the consortium is the increasing incorporation of health systems science into medical education. Training in health systems science will prepare physicians to lead in another critical area of AMA's focus: *Attacking the dysfunction in health care by removing obstacles and burdens that interfere with patient care.*

- The Health Systems Science textbook, published by Elsevier in December 2016, has sold more than 4,300 copies and is used at more than two dozen academic institutions, both consortium and non-consortium members.
- The Health Systems Science Review book was completed in 2018 and will be published by Elsevier in April 2019.
- The consortium is developing the Health Systems Science Learning Series of online modules which will be used by medical students to learn health systems science topics.
- The inaugural Health Systems Science Faculty Development Workshop was held in September 2018 for medical school faculty to learn how to teach health systems science. Subsequent workshops are being planned.

The AMA awarded 15 Innovation grants of \$10,000 to \$30,000 to schools that will further the work to transform medical education.

The AMA announced the launch of and requested proposals for the Reimagining Residency Initiative. This \$15 million program will provide grants to projects that will transform graduate medical education to better train young physicians to meet the changing needs of patients, communities and our dynamic health care system.

Journal of Ethics

The *AMA Journal of Ethics* website was completely redesigned and relaunched in July 2018, making it more user friendly and accessible. For example, educators of medical students or resident physicians are now able to filter and download content based on the ACGME core competencies or by medical specialty area.

Augmented Intelligence

In 2018, our House of Delegates approved a new policy outlining the use of augmented intelligence in health care and medicine. The policy outlines important considerations for design, evaluation, implementation and oversight of AI systems use in health care. The AMA remains committed to ensuring the evolution of AI occurs in a manner that benefits patients, their physicians, and the health care community.

Improving the health of the nation

Opioids

While the opioid epidemic continues to have a devastating effect on our nation, the AMA Opioid Task Force notes progress as the result of its efforts, including:

- Between 2013 and 2017, the number of opioid prescriptions decreased by more than 55 million, or 22.2 percent.
- The number of physicians trained/certified to provide buprenorphine in-office continues to rise - more than 55,000 physicians are now certified - a 17,000+ increase since April 2017.
- Naloxone prescriptions more than doubled in 2017, from approximately 3,500 to 8,000 per week.
- More than 549,000 physicians and other health care professionals completed continuing medical education trainings and accessed other Federation education resources in 2017.

Congress provided nearly \$4 billion for prevention, treatment and law enforcement efforts, and reached agreement on additional comprehensive legislation to address the opioid epidemic, including many provisions supported by the AMA.

AMA's intensive technical analysis and other support was used in more than 20 states to ensure state medical societies had current opioid prescribing and PDMP data to fight back against mandates and overly restrictive bills as well as strengthening naloxone access and Good Samaritan laws. This resulted in wins in at least 15 states in 2018 that are instrumental in reversing the opioid epidemic.

The AMA, along with Pennsylvania Medical Society and Manatt Health, conducted a spotlight analysis in Pennsylvania to demonstrate best practices on a state's response to the opioid epidemic and to highlight next steps. One of the key achievements in Pennsylvania includes a landmark agreement between the governor's administration and the seven largest insurers in the state, fully removing prior authorization requirements for medication-assisted treatment (MAT) to treat substance use disorder, and moving MAT to the lowest cost-sharing tier.

Access to Health Care

Congress provided funding for the Children's Health Insurance Plan for 10 years with strong AMA support.

Gun Violence

The AMA is working to prevent gun violence by partnering with the American Foundation for Firearm Injury Reduction in Medicine (AFFIRM), a physician-led nonprofit organization that aims to counter the lack of federal funding for gun violence research by sponsoring gun violence research with privately raised funds, and pushing Congress to fund CDC gun violence research.

Drug Prices

With AMA support, Congress banned so-called gag clauses in contracts with insurers that prevented pharmacists from informing patients about less expensive options for purchasing their medications.

Liability

The AMA secured passage of Good Samaritan liability protections for physicians responding to health care needs in out-of-state disasters and emergencies.

Prediabetes Awareness

Prediabetes Campaign Refresh: In November 2018, the AMA in collaboration with the Centers for Disease Control and Prevention and the Ad Council launched a new creative edition to the national prediabetes public service (PSA) campaign. To date, more than one million people have self-screened for prediabetes thanks to the PSA campaign. Additionally, the national public awareness has increased by more than four percent since launching the national campaign two years ago.

Engagement with health care organizations

STAT Refresh: In December 2018, IHO launched a new digital Diabetes Prevention Guide that helps support health care organizations in defining and implementing evidence-based diabetes prevention strategies. Using a comprehensive and customized approach, this new digital experience brings AMA resources to health systems to help them identify patients with prediabetes and implement a type 2 diabetes prevention lifestyle change program that meets the needs of their unique patient populations.

Trinity Health System Collaboration: In 2018, the AMA engaged in a multi-state chronic disease prevention effort aimed at diabetes prevention with Trinity Health System, a national health system serving diverse communities in 93 hospitals in 22 states. Work includes assisting Trinity leadership in developing a strategic roadmap that engages physicians, care teams and residents, while also recognizing the need to create community linkages.

Target: BP: Over the past year, participation in the national Target: BP initiative - a joint endeavor with the American Heart Association that has a shared goal of improving blood pressure control to reduce the number of Americans who have heart attacks and strokes each year - increased to more than 1,600 health systems and physician practices nationwide. More than 8 million US adults are now being reached because of this national effort, which launched less

than three years ago. In 2018, we recognized more than 800 physician practices that have made prioritizing blood pressure (BP) control for their patient populations a priority, with nearly 350 achieving a BP control rate above 70 percent.

Eminence/Research

PCORI Grant: In collaboration with a team of researchers from UCSF, the AMA's web-based version of our Blood Pressure M.A.P. QI program was selected to be tested as part of a three-year PCORI grant.

NACHC Grant: In collaboration with the Centers for Disease Control and Prevention (CDC) and the National Association of Community Health Centers (NACHC), the AMA was selected in October 2018 to help establish up to three health center control networks across the country that will leverage health information technology to address undiagnosed high blood pressure and cholesterol, improve blood pressure control in African Americans, and use self-measured blood pressure (SMBP) monitoring to improve blood pressure control in all adults with hypertension through 2019.

ACPM Grant: In collaboration with CDC and American College of Preventive Medicine (ACPM), the AMA was selected in October 2018 to help up to three health care organizations address the needs of disproportionately affected populations to identify adults with prediabetes and refer those with the condition to evidenced-based Diabetes Prevention Programs through 2019.

The IHO team published nine papers in leading journals including the *American Journal of Preventative Medicine*, *Hypertension*, and *International Journal of Healthcare*.

Communications

The AMA rose to the top of critical debates on immigration, gun violence, reimaging medical education and the future of health care. In 2018, the AMA media relations team secured 65,354 placements across national, local and trade media - coverage that generated more than 25 billion media impressions worth \$232 million in estimated publicity value.

Membership

Membership grew for the 8th consecutive year, with a 3.4% increase in dues paying members in 2018, more than double the growth rate in 2017. Growth was fueled by an innovative and award-winning campaign, "Membership Moves Medicine™," which celebrates the powerful work of physician members and showcases how their individual efforts - along with the AMA - are moving medicine forward.

EVP Compensation

During 2018, pursuant to his employment agreement, total cash compensation paid to James L. Madara, MD, as AMA Executive Vice President was \$1,107,042 in salary and \$1,046,000 in incentive compensation, reduced by \$2,890 in pre-tax deductions. Other taxable amounts per the contract are as follows: a \$170,998 payment of prior years' deferred compensation, \$14,478 imputed costs for life insurance, \$7,620 imputed costs for executive life insurance, \$2,500 paid for health club fees, \$2,820 paid for parking and \$3,500 paid for a physical. An \$81,000 contribution to a deferred compensation account was also made by the AMA. This will not be taxable until vested and paid pursuant to provisions in the deferred compensation agreement.

For additional information about AMA activities and accomplishments, please see the "AMA 2018 Annual Report."

8. ANNUAL UPDATE ON ACTIVITIES AND PROGRESS IN TOBACCO CONTROL: MARCH 2018 THROUGH FEBRUARY 2019

Informational report; no reference committee hearing.

HOUSE ACTION: FILED

This report summarizes American Medical Association (AMA) activities and progress in tobacco control from March 2018 through February 2019 and is written pursuant to AMA Policy D-490.983, “Annual Tobacco Report.”

TOBACCO USE IN THE UNITED STATES: CDC MORBIDITY AND MORTALITY WEEKLY REPORTS (MMWR)

According to the Centers for Disease Control and Prevention (CDC) tobacco use remains the leading preventable cause of disease and death in the United States with an estimated 480,000 premature deaths annually, including more than 41,000 deaths resulting from secondhand smoke exposure. These data translate to about one in five deaths related to tobacco use annually, or 1,300 deaths every day. Each year, the United States spends nearly \$170 billion on medical care to treat smoking-related disease in adults. From March 2018 through February 2019, the CDC released 13 MMWRs related to tobacco use. These reports provide useful data that researchers, health departments, community organizations and others use to assess and develop ongoing evidence-based programs, policies and interventions to eliminate and/or prevent the economic and social costs of tobacco use.

2018: https://www.cdc.gov/tobacco/data_statistics/mmwr/byyear/2018/index.htm

2019: https://www.cdc.gov/tobacco/data_statistics/mmwr/byyear/2019/index.htm

Youth Smoking Rates and Trends

According to the June 8, 2018 MMWR, which was an analysis of data from the 2011-2017 National Youth Tobacco Surveys (NYTS), there were substantial increases in electronic cigarette (e-cigarette) and hookah use among high school and middle school students, whereas significant decreases were observed in the use of cigarettes, cigars, smokeless tobacco, pipe tobacco, and bidis. The NYTS is a cross-sectional, voluntary, school-based, pencil-and-paper questionnaire self-administered to US middle and high school students. A three-stage cluster sampling procedure generated a nationally representative sample of US students attending public and private schools in grades 6–12.

Analysis of the 2017 NYTS data demonstrated that e-cigarettes were the most commonly used tobacco product among high school (11.7%; 1.73 million) and middle school (3.3%; 0.39 million) students. E-cigarette use in high school students was followed by cigars (7.7%), cigarettes (7.6%), smokeless tobacco (5.5%), hookah (3.3%), pipe tobacco (0.8%), and bidis (0.7%). E-cigarettes were the most commonly used tobacco product among non-Hispanic white (14.2%) and Hispanic (10.1%) high school students, whereas cigars were the most commonly used tobacco product among non-Hispanic black (black) high school students (7.8%). Among high school students, current use of any tobacco product decreased from 24.2% (estimated 3.69 million users) in 2011 to 19.6% (2.95 million) in 2017. Among middle school students, current use of any tobacco product decreased from 7.5% (0.87 million) in 2011 to 5.6% (0.67 million) in 2017.

The authors highlight the need for sustained efforts to implement proven tobacco control policies and strategies that are critical to preventing youth use of all tobacco products. There is concern about the rising popularity of e-cigarettes and availability of flavored tobacco products. This concern was amplified by another MMWR publication reporting the prevalence of e-cigarette use among high school students using the 2018 NYTS data. These results were published in November 2018 prior to the publication of the full survey results. E-cigarette use among high-schoolers climbed from 11.7% in 2017 to 20.8% in 2018.

Adult Smoking Rates

According to a study in the November 9, 2018 MMWR, an estimated 14% of US adults (34.3 million) were current cigarette smokers in 2017, representing a 67% decline since 1965. However, in 2017, nearly nine in 10 (41.1 million) adult tobacco product users reported using a combustible tobacco product, with cigarettes being the product most

commonly used. To assess recent national estimates of tobacco product use among US adults aged 18 years or older, the CDC, the Food and Drug Administration, and the National Institutes of Health's National Cancer Institute analyzed data from the 2017 National Health Interview Survey (NHIS). The NHIS is an annual, nationally representative in-person survey of the noninstitutionalized US civilian population. The NHIS core questionnaire is administered to a randomly selected adult in the household (the sample adult).

According to the analysis, an estimated 47.4 million US adults (19.3%) currently used any tobacco product, including cigarettes (14.0%; 34.3 million); cigars, cigarillos, or filtered little cigars (3.8%; 9.3 million); electronic cigarettes (e-cigarettes) (2.8%; 6.9 million); smokeless tobacco (2.1%; 5.1 million); and pipes, water pipes, or hookahs (1.0%; 2.6 million). Among current tobacco product users, 19.0% (9.0 million) used 2 or more tobacco products.

Multiple tobacco product users are at increased risk for nicotine addiction and dependence. E-cigarettes were commonly used among multiple tobacco product users. Primary reasons for e-cigarette use among adults include curiosity, flavoring, cost, consideration of others, convenience, and simulation of cigarettes.

TOBACCO CONTROL NEWS

Newest E-cigarette is High in Nicotine and Appealing to Youth

From 2016-2017 Juul sales increased by 641% according to the CDC. The CDC analyzed e-cigarette sales from retail stores in the U.S. during 2013 to 2017. The study assessed the five top-selling manufacturers: Japan Tobacco, British American Tobacco, JUUL Laboratories, Altria and Imperial Tobacco, among others. Juul, unlike its e-cigarette competitors, does not look like a cigarette or smoking device. Juul is designed to look like a flash drive which makes it appealing to youth. It is easy to disguise and use discreetly. The popularity of JUUL among youth has helped the product account for 73% of e-cigarette sales in the U.S. and sales of Juul represent one in three e-cigarette sales nationally in retail locations.

In addition to its youth-appealing flavors and sleek design, one Juul cartridge contains the same amount of nicotine as a pack of cigarettes. The company's website claims the product delivers nicotine up to 2.7 times faster than other e-cigarettes. Many young people are not even aware that they are consuming nicotine when they use e-cigarettes. Results from an April 2018 Truth Initiative® study published in Tobacco Control show that nearly two-thirds of JUUL users between 15 and 24 years old did not know that the product always contains nicotine.

In November 2018 Forbes reported that the FDA was seeking nationwide restrictions on the sales of fruity-flavored nicotine vaping cartridges. Juul, likely aware of the impending FDA crackdown stopped sales of its fruit-flavored nicotine pods in retail stores (though it will continue to sell them online) and has shut down its Facebook and Instagram pages in the U.S.

Underage Smokers find Pharmacies an Easy Source for Cigarettes

A team of researchers led by Joseph Lee, PhD, MPH, East Carolina University, examined the inspections of tobacco sales to minors conducted by the US Food and Drug Administration (FDA) in approximately 13,200 pharmacies from January 2012 to December 2017. The violation rate for tobacco sales to youths in FDA inspections at the top US pharmacies varied by chain and was highest at Walgreens. The findings were published in *JAMA Pediatrics* (Lee JGL, Schleicher NC, Lea EC, et al. US Food and Drug Administration inspection of tobacco sales to minors at top pharmacies, 2012-2017. *JAMA Pediatr.* 2018;172(11):1089-1090. doi:10.1001/jamapediatrics. 2018.2150).

In February the FDA initiated enforcement action against Walgreens for underage tobacco sales. Twenty-two percent of Walgreens stores inspected have illegally sold tobacco products to minors, making it the top violator among pharmacies selling tobacco products.

Walgreens is not the only retail pharmacy violating sales to minors but they are the first one that the FDA seeks to bar all tobacco sales for 30 days. Since the FDA began inspecting retail locations in 2010, Walgreens has received more than 1,550 warning letters and 240 civil money penalty actions against its stores nationwide.

According to a research letter published in *JAMA Internal Medicine* (Krumme AA, Choudhry NK, Shrank WH, et al. Cigarette purchases at pharmacies by patients at high risk of smoking-related illness. *JAMA Intern Med.*

2014;174(12):2031-2032. doi:10.1001/jamainternmed.2014.5307) one in 20 patients who were taking medications for tobacco exacerbated diseases (asthma, COPD and hypertension) purchased cigarettes at a pharmacy.

Tobacco control advocates, public health organizations and medical associations, including the AMA, have called on Walgreens to no longer sell tobacco products. Selling tobacco products in a pharmacy whose primary business is to provide medications to treat and/or prevent diseases while selling products that contribute those diseases sends the wrong message to consumers.

AMA opposes sales of tobacco products in pharmacies and adopted its policy calling for a ban in 2009 and reaffirmed this policy in 2013.

AMA TOBACCO CONTROL ACTIVITIES

AMA Fights for FDA's authority to regulate tobacco products

The AMA joined with other physician groups, including the American Thoracic Society, American Academy of Family Physicians, American College of Cardiology and American College of Physicians, urging Congress to oppose any provisions to weaken or delay FDA's authority to regulate all tobacco products. An important part of the Family Smoking Prevention and Tobacco Control Act, which Congress enacted with bipartisan support in 2009, was a requirement that new tobacco products undergo a scientific review by FDA. Based on its scientific assessment, FDA can prohibit new tobacco products that are harmful to public health from the marketplace.

According to the co-signed letter, in recent years, the House has included provisions in the Agriculture-FDA appropriations bill to exempt thousands of tobacco products, including many candy- and fruit-flavored products, from FDA's scientific product review.

AMA Supports Efforts to Control Nicotine

The AMA was one of the medical and public health organizations signing on to a joint letter to Dr. Scott Gottlieb, then FDA commissioner, in support of the Agency's initiative to move toward a product standard to reduce the nicotine level in cigarettes to non-addictive or minimally addictive levels. Such a standard would have massive public health benefits. Tobacco use is still the number one preventable cause of death. Nicotine, the addictive ingredient in tobacco products, makes it difficult for many adults to quit and keeps youth smoking.

The AMA and others urged the FDA to go further and include all combustible tobacco products in the nicotine product standard, including those currently on the market and those that may come on the market in the future. Exemption of other combustible products would invite tobacco manufacturers to market existing and develop new non-cigarette substitutes that would lead cigarette smokers to substitute those products, like the small flavored cigars the industry introduced after flavored cigarettes were removed from the market. It also would make the exempted products a potential vehicle for youth initiation. Thus, we urge FDA to make any nicotine reduction product standard applicable to other combustible tobacco products to prevent the industry from circumventing the new rule just as they did after the ban on flavored cigarettes.

AMA Responds to Other Federal Register Notices on FDA Tobacco Regulations

As part of its regulatory authority over cigarettes and other tobacco products, the FDA was soliciting for public comments to assist the agency in implementing initiatives that would reduce the health harms associated with smoking and tobacco use. The AMA, as part of its collaboration with other national medical associations and public health groups, signed on to comments as well as issued its own.

The AMA reiterated its support for the FDA's initiative to create a standard for nicotine in combustible tobacco products but called on the Agency to include *all* tobacco products and create a non-addictive nicotine level standard for all tobacco products, not just cigarettes. Cigarettes are not the only addictive form of tobacco, and applying this standard across all tobacco products is essential to combating the leading cause of preventable death.

The AMA also responded to a Federal Register notice on therapies to reduce youth e-cigarette and other tobacco program use. According to a study in *JAMA Pediatrics* (Watkins LW, Glantz SA, Chaffee BW. Association of

noncigarette tobacco product use with future cigarette smoking among youth in the population assessment of tobacco and health (path) study, 2013-2015. *JAMA Pediatr.* 2018;172(2):181-187. doi:10.1001/jamapediatrics.2017.4173) use of e-cigarettes, hookah, non-cigarette combustible tobacco, or smokeless tobacco by youth is associated with cigarette smoking one year later. This dual use makes it very difficult for youth to quit. The AMA believes that while it is important to consider drug therapies for youth who are already addicted, preventing youth tobacco use and nicotine addiction must be the priority.

9. COUNCIL ON LEGISLATION SUNSET REVIEW OF 2009 HOUSE POLICIES

Reference committee hearing: see report of Reference Committee B.

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS REMAINDER OF REPORT FILED

At its 1984 Interim Meeting, the House of Delegates established a sunset mechanism for House policies (Policy G-600.110). Under this mechanism, a policy established by the House ceases to be viable after 10 years unless action is taken by the House to retain it.

The objective of the sunset mechanism is to help ensure that the American Medical Association (AMA) policy database is current, coherent, and relevant. By eliminating outmoded, duplicative, and inconsistent policies, the sunset mechanism contributes to the ability of the AMA to communicate and promote its policy positions. It also contributes to the efficiency and effectiveness of House of Delegates deliberations.

At its 2002 Annual Meeting, the House modified Policy G-600.110 to change the process through which the policy sunset review is conducted. The process now includes the following steps:

- In the spring of each year, the House policies that are subject to review under the policy sunset mechanism are identified.
- Using the areas of expertise of the AMA Councils as a guide, the staffs of the AMA Councils determine which policies should be reviewed by which Councils.
- For the Annual Meeting of the House, each Council develops a separate policy sunset report that recommends how each policy assigned to it should be handled. For each policy it reviews, a Council may recommend one of the following actions: (a) retain the policy; (b) rescind the policy; or (c) retain part of the policy. A justification must be provided for the recommended action on each policy.
- The Speakers assign the policy sunset reports for consideration by the appropriate reference committees.

Although the policy sunset review mechanism may not be used to change the meaning of AMA policies, minor editorial changes can be accomplished through the sunset review process.

In this report, the Board of Trustees presents the Council on Legislation's recommendations on the disposition of the House policies that were assigned to it. The Council on Legislation's recommendations on policies are presented in the Appendix to this report.

RECOMMENDATION

The Board of Trustees recommends that the House of Delegates policies listed in the Appendix to this report be acted upon in the manner indicated and the remainder of this report be filed.

APPENDIX - RECOMMENDED ACTIONS ON 2009 HOUSE POLICIES

Policy Number	Title	Text	Recommendation
D-160.939	Physician Supervision Over Certified Registered Nurse Anesthetists	Our American Medical Association will urge the federal government to repeal the opt-out provision of the Medicare Conditions of Participation that eliminated the long-standing requirement that certified registered nurse anesthetists practice under direct physician supervision. Citation: (Res. 213, I-09)	Retain. This policy remains relevant.

Policy Number	Title	Text	Recommendation
D-270.998	Oppose Scope of Limited English Proficiency Guidance	Our AMA BOT, to the fullest extent appropriate, will authorize further efforts necessary to actively oppose the inappropriate extension of the Limited English Proficiency Guidance issued by the US Department of Health and Human Services' Office of Civil Rights' to physicians in private practice <u>who receive Federal financial assistance from HHS.</u> Citation: (Res. 216, I-00; Reaffirmation A-09)	Retain, but make a technical edit.
D-275.996	Creation of AMA Data Bank on Interstate Practice of Medicine	Our AMA will: (1) continue to study interstate practice of medicine issues as they relate to the quality of care available to patients; (2) explore the provision of information on physician licensure, including telemedicine, to members and others through the World Wide Web <u>internet</u> and other media; and (3) continue to make information on state legal parameters on the practice of medicine, including telemedicine, available for members and others. Citation: (BOT Rep. 6, I-99; Reaffirmed: CLRPD Rep. 1, A-09)	Retain. This policy remains relevant, but modify the term "World Wide Web" for "internet."
D-315.993	Physicians as Patients: Their Right to Confidentiality	Our AMA will consider for possible intervention pending and future court cases in which the principles of informed consent are inappropriately expanded to require disclosure of a physician's impairment, including substance abuse problems, or information otherwise protected by laws governing patient privacy and confidentiality. Citation: (BOT Rep. 17, I-99; Reaffirmed: CEJA Rep. 8, A-09)	Retain. This policy remains relevant.
D-330.993	Explanation of Public-Private Partnerships that Exist between Government and the AMA	Our AMA: (1) continues to employ a variety of tactics to advocate CMS adoption of AMA policy positions; (2) continues to work cooperatively with CMS, when possible, to achieve its policy objectives; (3) when advocacy efforts directed at CMS fall short of achieving AMA policy objectives, the AMA continue to seek congressional action, including oversight hearings and enactment of legislation; and (4) use appropriate legal means, including suing CMS, when appropriate and warranted. Citation: (BOT Rep. 17, A-99; Reaffirmed: CLRPD Rep. 1, A-09)	Retain. This policy remains relevant.
D-385.965	Insurance Companies Use of Contractors to Recover Payments	1. Our AMA will seek legislation to limit insurance companies, their agents, or any contractors from requesting payment back on paid claims to no more than 90 days after payment is made. (a) Such legislation would require insurance companies, their agents, or any contractors to have a defined and acceptable process for physicians to dispute these maneuvers to get payment back on claims already processed, verified, and paid. (b) Such legislation would ban insurance companies, their agents or contractors from using re-pricers and re-reviewers and to adhere to their own pricing and reviewing guidelines as agreed upon in their contracts with physicians. 2. Our AMA will pursue legislation to regulate self-insured plans in this regard and apply the same rules to Medicare and other federal plans. Citation: (Res. 215, A-09)	Retain. This policy is remains relevant.
D-435.973	Quantifying Medical Tort Reform	Our American Medical Association will study the true costs of defensive medicine and the financial impact that tort reform would have on the entire health care system, with a report back and to be updated every ten years.	Rescind. Policy is implemented. AMA on an annual basis publicly issues MLR Now!, which includes

Policy Number	Title	Text	Recommendation
		Citation: (Res. 216, I-09)	costs of defensive medicine, financial impact, and state and federal efforts in liability reform.
D-455.994	Standardizing Portable Medical Imaging Formats to Enhance Safe, Timely, Efficient Care	<p>1. Our American Medical Association will participate in efforts to ensure implementation of the recommendations for imaging standards developed by the AMA-convened imaging safety and standards Panel, that the Radiological Society of North American (RSNA) endorsed and Integrating the Healthcare Enterprise (IHE) adopted and wrote into the portable data initiative standards.</p> <p>2. Our AMA will develop a strategy to inform the health care and imaging communities of the AMA’s work to improve Imaging Safety and Standards that includes the following:</p> <ul style="list-style-type: none"> a. Disseminate (widely) the AMA-convened Panel’s statement, “All medical imaging data distributed should be a complete set of images of diagnostic quality in compliance with those found in the IHE PDI (Portable Data for Imaging) Integration Profile;” b. Publish the Panel’s work; c. Increase hospital group, deeming organization, medical group, and survey certification group awareness of the AMA’s work; determine their role in developing infrastructure support for medical imaging safety per AMA recommendations and IHE-PDI standards; d. Expose the AMA’s work to the Office of the National Coordinator; e. Encourage industry to view physicians as developers rather than solely as adopters of technology and to include physicians, as end users, in the development and implementation of technology solutions; and, f. Encourage physicians, as end users of technology, to participate in development and implementation of technology to ensure its appropriate use and application at the point of care. <p>Citation: (BOT Rep. 1, I-09)</p>	Retain. This policy remains relevant.
D-478.986	Information Technology and Stimulus Money	<p>Our AMA: will (1) caution health care policy makers that the Health Care Information Technology stimulus money, as outlined in the American Recovery and Reinvestment Act, will cause a sudden rise in the demand for health care IT products and services which may result in inflated prices for physicians; and (2) advise physicians and health care policy makers that the ongoing maintenance of health care IT can be costly, and that this ongoing expense will fall to physicians long after the stimulus money is exhausted.</p> <p>Citation: (Res. 227, A-09; Reaffirmation I-09)</p>	Retain. This policy is remains relevant.
D-65.993	<u>Pain and Suffering in Darfur War Crimes as a Threat to Physicians’ Humanitarian Responsibilities</u>	<p>Our American Medical Association will write to Secretary of State Hillary Rodham Clinton, the World Medical Association, and the World Health Organization in reference to the complex situations in Darfur and Sri Lanka, stating (1) <u>our concerns related to implore all parties at all times to understand and minimize</u> the health costs of war on civilian populations generally and the adverse effects of physician persecution in particular, (2) that we support the efforts of physicians around the world to practice medicine ethically in any and all circumstances, including during wartime or episodes of civil strife, and that we condemn the military targeting of health care facilities and personnel and using denial of</p>	Retain as amended.

Policy Number	Title	Text	Recommendation
		medical services as a weapon of war <u>by any party, wherever and whenever it occurs, as has occurred in Darfur and Sri Lanka</u> , and (3) that our AMA will advocate for the protection of physicians' rights to provide ethical care without fear of persecution. Citation: (BOT Action in response to referred for decision Res. 620, A-09)	
D-70.997	Negotiated Rulemaking for Lab Tests	Our AMA: (1) reaffirms its policy to seek repeal of Section 4317 of the Balanced Budget Act of 1997 granting the Secretary of HHS authority to require submission of diagnosis codes with every lab test claim and with all claims for services provided by an entity other than the ordering physician; (2) continues to urge CMS to clarify and improve the Advanced Beneficiary Notice process; and (3) will work to modify the regulations forthcoming in the implementation of the Health Insurance Portability and Accountability Act (HIPAA) to conform with AMA policy. Citation: (BOT Rep. 11, A-99; Reaffirmed: BOT Rep. 23, A-09)	Retain. This policy remains relevant.
H-120.941	e-Prescribing of Scheduled Medications	Our American Medical Association supports action requiring that the US Drug Enforcement Administration move expeditiously to establish reasonable requirements enabling the use of e-prescribing for controlled substances. Citation: (Res. 211, I-09)	Rescind. The SUPPORT Act (Public Law 115-271) mandates DEA to improve its EPCS regulations.
H-120.959	DVA Non-Physician Prescribing Authority	Our AMA will continue to pursue appropriate regulatory, legislative and legal means to oppose any efforts to permit non-physician health care professionals to prescribe medications. Citation: (Sub. Res. 220, A-99; Reaffirmed: CMS Rep. 11, I-99; Reaffirmed: BOT Rep. 23, A-09)	Retain. This policy remains relevant.
H-120.996	Prescribing Eye Medications	Our AMA (1) reaffirms its policy that only physicians licensed to practice medicine and surgery are qualified to prescribe or apply eye medications; and (2) continues to urge that state medical societies oppose legislation or administrative attempts to give optometrists a license to prescribe or apply medications or to diagnose disease or injury or to diagnose the absence of disease or injury. Citation: (Sub. Res. 76, A-76; Reaffirmed: CLRPD Rep. C, A-89; Reaffirmation A-99; Reaffirmed: BOT Rep. 23, A-09)	Retain. This policy remains relevant.
H-125.999	Drug Substitutes	Our AMA (1) supports continued efforts to inform the public and the profession of the potential problems and risks should a physician's choice of therapeutic agents be delegated to non-physicians; and (2) asks that state medical associations provide scientific and economic reasons in support of this position to state legislatures considering enactment of laws on substitution of drug products other than those prescribed or agreed upon by an attending physician.	Retain. This policy remains relevant.
H-160.917	Federation Payment for Emergency Services for Undocumented Immigrants	Our American Medical Association supports federal legislation to extend Section 1011 of the Medicare Modernization Act (MMA, P.L. 108-173), which provides for federal funding to the states for emergency services provided to undocumented immigrants. Citation: (Res. 212, I-09)	Rescind. This directive is no longer needed. MMA §1011 provided \$250M per year for federal fiscal years 2005 through 2008 for payment to hospitals, physicians and ambulance providers for emergency health services provided to undocumented aliens and certain other specified aliens. The funding

Policy Number	Title	Text	Recommendation
			expired over a decade ago and has never been renewed.
H-160.936	Comprehensive Physical Examinations by Appropriate Practitioners	AMA policy supports the position that performance of comprehensive physical examinations to diagnose medical conditions be limited to licensed MDs/DOs or those practitioners who are directly supervised by licensed MDs/DOs; and the AMA will actively work with state medical societies and medical specialty associations, both in the courts and in the legislative and regulatory spheres, to oppose any proposed or adopted law or policy that would inappropriately expand the scope of practice of practitioners other than MDs/DOs. Citation: (Sub. Res. 210, I-96; Reaffirmed: BOT Rep. 34, A-06; Reaffirmed in lieu of Res. 235, A-09)	Retain. This policy remains relevant.
H-160.972	Physician Representation on State and National Health Care Advisory Bodies	The AMA urges Congress, and others who select members of state and national health advisory bodies, to increase the proportion of physicians in active clinical practice serving on these bodies, with selected members being recommended by state or national medical associations. Citation: (Sub. Res. 110, A-88; Reaffirmed: Sunset Report, I-98; Reaffirmed: BOT Rep. 23, A-09)	Retain. This policy remains relevant.
H-175.980	Anti-Kickback Implications of Ambulance Restocking	Our AMA: (1) supports federal legislation to create a safe harbor under the anti-kickback statute for ambulance restocking by hospitals, such as H.R. 3247, the "Community Safety Act of 1998;" and (2) urges the Office of the HHS Inspector General to change its position, as expressed in two existing advisory opinions, that hospital restocking of ambulances on a gratis basis may constitute a violation of the anti-kickback statute. Citation: (BOT Rep. 17, I-98; Reaffirmed: BOT Rep. 23, A-09)	Rescind. This policy has been implemented. In 2001, the Office of Inspector General finalized a regulatory safe harbor regarding ambulance restocking by hospitals (42 C.F.R. 1001.952(v); 66 Fed. Reg. 62979). This safe harbor is available for free (or gratis) restocking arrangements, as well as arrangements under which the ambulance provider pays some amount for the restocked drugs and supplies (whether or not the amount is fair market value).
H-215.974	Not-For-Profit Boards	Our AMA seeks by whatever appropriate means available to change IRS requirements to allow more than 50% of a not-for-profit health care entity and/or hospital Board to be interested parties who are MDs or DOs. Citation: (Res. 222, A-98; Reaffirmed: BOT Rep. 23, A-09)	Retain. This policy remains relevant.
H-220.932	Life Safety Code	Our AMA urges CMS to adopt the most current "Life Safety Code" as expeditiously as possible. Citation: (Res. 827, A-99; Reaffirmed: CMS Rep. 5, A-09)	Retain. This policy remains relevant.
H-275.925	Protection of the Titles "Doctor," "Resident" and "Residency"	Our AMA: (1) will advocate that professionals in a clinical health care setting clearly and accurately identify to patients their qualifications and degree(s) attained and develop model state legislation for implementation; and (2) supports state legislation that would make it a felony to misrepresent oneself as a physician (MD/DO). Citation: (Sub. Res. 232, A-08; Reaffirmation I-09; Reaffirmed: BOT Rep. 9, I-09)	Retain. This policy remains relevant.
H-275.943	Public Education about Physician Qualifications	The AMA will continue to develop programs to educate the public about the differences in education and professional standards between physicians and non-physician health care providers.	Retain. This policy remains relevant.

Policy Number	Title	Text	Recommendation
		Citation: (Res. 623, A-96; Reaffirmation A-99; Reaffirmed: CLRPD Rep. 1, A-09)	
H-285.937	Surgical Pathology in Managed Care	Our AMA will develop model legislative and regulatory language for states to insure that managed care plans: (1) which require surgical pathology specimens to be sent to specified laboratories, provide a list of qualified surgical pathologists and surgical pathology subspecialists associated with those laboratories to whom physicians may refer surgical pathology specimens or slides for consultation; and (2) allow clinicians in the plans access to qualified surgical pathologists and surgical pathology subspecialists for covered pathology services, when the plans do not have contracts with a specific laboratory or laboratories for such services or when the plan's contracted laboratory or laboratories cannot provide the appropriate surgical pathology services. Citation: (Res. 716, A-98; Reaffirmation A-99; Reaffirmed: BOT Rep. 23, A-09)	Retain. This policy remains relevant.
H-30.977	Alcoholism as a Disease	The AMA urges change in federal laws and regulations to require that the Veterans Administration determine benefits eligibility on the basis that alcoholism is a disease. Citation: (Res. 112, A-88; Reaffirmed: Sunset Report, I-98; Reaffirmed: BOT Rep. 23, A-09)	Retain. This policy remains relevant.
H-315.986	Confidentiality of Patient Records	Our AMA opposes the concept that filing a claim for medical insurance coverage constitutes a blanket waiver of a patient's right to confidentiality of his/her medical records for all purposes. The AMA will engage in a major initiative to educate patients about the implications and consequences of blanket medical records releases, and educate patients about the need for possible legislative modifications. Citation: (Res. 243, I-94; Appended: Res 231, I-97; Reaffirmation I-98; Reaffirmation I-99; Reaffirmed: CEJA Rep. 8, A-09)	Retain. This policy remains relevant.
H-330.986	Physician ("Doctors") Services Costs as Reported by HHS and Medicare	Our AMA urges HHS and CMS to, at all times, distinguish between MDs/DOs and non-MDs/DOs, and to discontinue the use of the broad term "provider" when reporting or referring to the cost of physician services. Citation: (Res. 71, A-88; Reaffirmed: Sunset Report, I-98; Reaffirmation I-99; Reaffirmation A-02; Reaffirmation I-09)	Retain. This policy remains relevant.
H-335.991	Medical Necessity Denial Screens	Our AMA supports pursuing all available means to effect release of the data necessary for physicians to comply with the onerous provisions of the Medical Necessity Denial/Refund law. Citation: (Res. 272, A-89; Reaffirmed: Res. 239, A-99; Reaffirmed: BOT Rep. 23, A-09)	Retain. This policy remains relevant.
H-340.898	Medicare Review Activities: Peer Review Organization Sixth Scope of Work, Medicare Integrity Program, and Carrier Post-Payment Audit Processes	Our AMA: (1) strongly urges CMS to provide physician organizations with the opportunity for significant comment and input in <u>on</u> the development of Medicare Integrity Program task orders before they are implemented; (2) continues to oppose any type of "bounty" system for compensation to any Medicare contractor, including those in the Medicare Integrity Program, and instead urge CMS to base compensation on the proper repayment of claims, rather than on the numbers of resulting referrals to law enforcement agencies; (3) continues to advocate for the ongoing involvement of physician organizations and hospital and organized medical staffs in refining and implementing <u>any Medicare</u>	Retain in part. This policy remains relevant; but modify terms to reflect the current practices of CMS regarding contractor review activities. For example, the Sixth Scope of Work referenced in this policy was finalized in 1999. The original policy was written prior to Medicare Administrative Contractors or Recovery Audit Contractors.

Policy Number	Title	Text	Recommendation
		<p><u>review contractor’s activities</u> the Medicare Peer Review Organization (PRO) Sixth Scope of Work, especially the Payment Error Prevention Program, and the need to emphasize physician education and clinical improvements;</p> <p>(4) urges CMS to delete all “incentives” or other “award fees” for <u>any Medicare review contractor</u> from the Payment Error Prevention Program in the Medicare PRO Sixth Scope of Work; and</p> <p>(5) urges CMS to clarify <u>that in any Statement of Work or contract with a Medicare review contractor</u> the PRO Sixth Scope of Work that: (a) extrapolation should not occur unless it is to develop educational or compliance program interventions; and (b) referrals to the Office of the Inspector General should not occur unless a hospital does not respond to intervention or when significant evidence of fraud exists.</p> <p>Citation: (CMS Rep. 11, A-99; Reaffirmed: CMS Rep. 14, I-99; Reaffirmed: CMS Rep. 5, A-09)</p>	
H-340.928	Quality Improvement Organization Physician Advisory Confidentiality	<p>The AMA petitions third party payers and CMS (1) to require QIOs and carriers to publish and forward annually to the quality assurance chairman and the chief of staff of all hospitals under their jurisdictions as well as all state medical associations, the names of physician reviewers, their credentials, and their specialties, and (2) to require that the physician reviewers reveal their identity by signing the letter submitted to a physician placed under review.</p> <p>Citation: (Sub. Res. 200, A-91; Reaffirmation A-99; Modified and Reaffirmed: CMS Rep. 5, A-09)</p>	Retain. This policy remains relevant.
H-345.989	Psychologist Prescribing	<p>The AMA: (1) opposes the prescribing of medication by psychologists; (2) strongly urges through mail and electronic communications technology that all state medical societies work closely with local psychiatric societies to oppose legislative or ballot initiatives authorizing the prescribing of medications by psychologists; and (3) supports and will work in concert with the American Academy of Child and Adolescent Psychiatry, the American Psychiatric Association, and with state and other appropriate medical societies in order to defeat initiatives that authorize psychologist prescribing prescription medication..</p> <p>Citation: (Sub. Res. 214, A-89; Res. 204, A-97; Reaffirmation A-99; Reaffirmed: CMS Rep. 5, A-09)</p>	Retain. This policy remains relevant.
H-35.969	Practice Agreements Between Physicians and Advance Practice Nurses and the Physician to Advance Practice Nurse Supervisory Ratio	<p>Our AMA will: (1) continue to work with the Federation in developing necessary state advocacy resource tools to assist the Federation in: (a) addressing the development of practice agreements between practicing physicians and advance practice nurses, and (b) responding to or developing state legislation or regulations governing these practice agreements, and that the AMA make these tools available on the AMA Advocacy Resource Center Web site; and (2) support the development of methodologically valid research comparing physician-APRN practice agreements and their respective effectiveness.</p> <p>Citation: (BOT Rep. 28, A-09)</p>	Retain. This policy remains relevant.
H-35.976	Channeling of Eye Examinations to Optometrists	<p>The AMA issue a letter <u>advocates</u> to all third party payers stating organized medicine’s strong opposition to: (a) channeling enrollees to optometrists and other non-physicians; (b) designating optometrists as primary eye care providers; (c) shifting patients from ophthalmologists to optometrists; and (d) excluding ophthalmologists from performing refractive eye examinations, routine eye</p>	Retain in part. The reference to the letter is no longer relevant.

Policy Number	Title	Text	Recommendation
		examinations, or primary eye care. The AMA, state medical societies, and national medical specialty societies seek introduction of legislation prohibiting third party payers from mandating that routine and refractive examinations be performed by optometrists rather than by ophthalmologists. Citation: (Res. 213, A-98; Reaffirmed: BOT Rep. 23, A-09)	
H-360.985	Performance of Diagnostic X-Rays by Nurses Without Physician Supervision	Our AMA continues to vigorously oppose rules by CMS which lower the standard of training required for performance of diagnostic x-ray or other complex and potentially hazardous tests. Citation: (Res. 201, I-99; Reaffirmed: CMS Rep. 5, A-09)	Retain. This policy remains relevant.
H-383.991	Right to Privately Contract	Our AMA includes in its top advocacy priorities: (1) the enactment of federal legislation that ensures and protects the fundamental right of patients to privately contract with physicians, without penalties for doing so and regardless of payer within the framework of free market principles with the goal of accomplishing this by 2010; (2) the restoration of fairness to the current health care marketplace through changes in statutes and regulations so that physicians are able to negotiate (individually and as defined groups) fair contracts with private sector and public sector health plans. Citation: (Res. 203, A-09)	Retain. This policy remains relevant.
H-385.969	Assistants at Surgery	The AMA (1) opposes any effort by Medicare or any other third party payer to limit payment for medically necessary care, especially in the area of assistants at surgery; (2) supports and participates in, as appropriate, the efforts of state and specialty societies to develop guidelines for appropriate use of physicians as assistants at surgery; and (3) continues to oppose and seek regulatory and/or legislative relief from the discriminatory downgrading or elimination of Medicare payments for assistants at surgery. Citation: (Sub. Res. 229, A-91; Reaffirmed: BOT Rep. 32, A-99; Reaffirmed: CMS Rep. 5, A-09)	Retain. This policy remains relevant.
H-405.967	Truth in Corporate Advertising: Using Professional Degrees in Advertising Listings	The AMA opposes US West Yellow Pages or any other corporation which misrepresents physicians by failing to list their professional degrees in the corporation's advertising directory. Citation: (Sub. Res. 4, I-95; Reaffirmed with change in title: CLRPD Rep. 1, A-05; Reaffirmation I-09)	Retain. This policy remains relevant.
H-405.968	Clarification of the Term "Provider" in Advertising, Contracts and Other Communications	1. Our AMA supports requiring that health care entities, when using the term "provider" in contracts, advertising and other communications, specify the type of provider being referred to by using the provider's recognized title which details education, training, license status and other recognized qualifications; and supports this concept in state and federal health system reform. 2. Our AMA: (a) considers the generic terms "health care providers" or "providers" as inadequate to describe the extensive education and qualifications of physicians licensed to practice medicine in all its branches; (b) will institute an editorial policy prohibiting the use of the term "provider" in lieu of "physician" or other health professionals for all AMA publications not otherwise covered by the existing JAMA Editorial Governance Plan, which protects editorial independence of the Editor in Chief of JAMA and The JAMA Network journals; and (c) will forward to the editorial board of JAMA the	Retain. This policy remains relevant.

Policy Number	Title	Text	Recommendation
		recommendation that the term “physician” be used in lieu of “provider” when referring to MDs and DOs. Citation: (Sub. Res. 712, I-94; Reaffirmed: Res. 226, I-98; Reaffirmation I-99; Res. 605, A-09; Reaffirmed: CLRPD Rep. 1, A-09; Modified: Speakers Rep., A-15)	
H-405.997	Physician-Patient Relationship	Our AMA: (1) believes the terms “physician” and “patient” should be used rather than vendor, provider, recipient or consumer in order to maintain optimum physician-patient relationships and will do so in its medical publications; and (2) encourages third parties, including the U.S. Department of Health and Human Services and federal and state legislative bodies, to use the terms “physician” and “patient” where appropriate in actions, statements and reports. Citation: (Res. 9, A-77; Reaffirmed: CLRPD Rep. C, A-89; Reaffirmed: Sub. Res. 102, I-94; Reaffirmation I-99; Reaffirmation A-02; Reaffirmation A-07; Reaffirmation I-09)	Retain. This policy remains relevant.
H-406.990	Work of the Task Force on the Release of Physician Data	Release of Claims and Payment Data from Governmental Programs The AMA encourages the use of physician data to benefit both patients and physicians and to improve the quality of patient care and the efficient use of resources in the delivery of health care services. The AMA supports this use of physician data only when it preserves access to health care and is used to provide accurate physician performance assessments. Raw claims data used in isolation have significant limitations. The release of such data from government programs must be subject to safeguards to ensure that neither false nor misleading conclusions are derived that could undermine the delivery of appropriate and quality care. If not addressed, the limitations of such data are significant. The foregoing limitations may include, but are not limited to, failure to consider factors that impact care such as specialty, geographic location, patient mix and demographics, plan design, patient compliance, drug and supply costs, hospital and service costs, professional liability coverage, support staff and other practice costs as well as the potential for mistakes and errors in the data or its attribution. Raw claims and payment data resulting from government health care programs, including, but not limited to, the Medicare and Medicaid programs should only be released: 1. when appropriate patient privacy is preserved via de-identified data aggregation or if written authorization for release of individually identifiable patient data has been obtained from such patient in accordance with the requirements of the Health Insurance Portability and Accountability Act (HIPAA) and applicable regulations; 2. upon request of physicians [or their practice entities] to the extent the data involve services that they have provided; 3. to law enforcement and other regulatory agencies when there is reasonable and credible reason to believe that a specific physician [or practice entity] may have violated a law or regulation, and the data is relevant to the agency’s investigation or prosecution of a possible violation; 4. to researchers/policy analysts for bona fide research/policy analysis purposes, provided the data do not identify specific physicians [or their practice entities] unless the researcher or policy analyst has (a) made a	Retain. This policy remains relevant. [Note: grammatical correction—delete the word “the” before the word “their” in the last sentence.]

Policy Number	Title	Text	Recommendation
		<p>specific showing as to why the disclosure of specific identities is essential; and, (b) executed a written agreement to maintain the confidentiality of any data identifying specific physicians [or their practice entities];</p> <p>5. to other entities only if the data do not identify specific physicians [or their practice entities]; or</p> <p>6. if a law is enacted that permits the government to release raw physician-specific Medicare and/or Medicaid claims data, or allows the use of such data to construct profiles of identified physicians or physician practices. Such disclosures must meet the following criteria:</p> <p>(a) the publication or release of this information is deemed imperative to safeguard the public welfare;</p> <p>(b) the raw data regarding physician claims from governmental healthcare programs is:</p> <p>(i) published in conjunction with appropriate disclosures and/or explanatory statements as to the limitations of the data that raise the potential for specific misinterpretation of such data. These statements should include disclosure or explanation of factors that influence the provision of care including geographic location, specialty, patient mix and demographics, health plan design, patient compliance, drug and supply costs, hospital and service costs, professional liability coverage, support staff and other practice costs as well as the potential for mistakes and errors in the data or its attribution, in addition to other relevant factors.</p> <p>(ii) safeguarded to protect against the dissemination of inconsistent, incomplete, invalid or inaccurate physician-specific medical practice data.</p> <p>(c) any physician profiling which draws upon this raw data acknowledges that the data set is not representative of the physicians' entire patient population and uses a methodology that ensures the following:</p> <p>(i) the data are used to profile physicians based on quality of care provided - never on utilization of resources alone - and the degree to which profiling is based on utilization of resources is clearly identified.</p> <p>(ii) data are measured against evidence-based quality of care measures, created by physicians across appropriate specialties, such as the AMA-convened Physician Consortium for Performance Improvement.</p> <p>(iii) the data and methodologies used in profiling physicians, including the use of representative and statistically valid sample sizes, statistically valid risk-adjustment methodologies and statistically valid attribution rules produce verifiably accurate results that reflect the quality and cost of care provided by the physicians.</p> <p>(d) any governmental healthcare data shall be protected and shared with physicians before it is released or used, to ensure that physicians are provided with an adequate and timely opportunity to review, respond and appeal the accuracy of the raw data (and its attribution to individual physicians) and any physician profiling results derived from the analysis of physician-specific medical practice data to ensure accuracy prior to the their use, publication or release.</p> <p>Citation: (BOT Rep. 18, A-09)</p>	

Policy Number	Title	Text	Recommendation
H-415.988	Informed Choice for Patients	Our AMA in order to protect patient choice of health care providers, supports state and federal legislation mandating that patients be notified of who will provide their medical care, and be given the choice of who will provide their medical care. Citation: (Res. 215, A-98; Reaffirmed: BOT Rep. 23, A-09)	Retain. This policy remains relevant.
H-435.947	Liability Reform in Health Care Reform	Our American Medical Association: (1) supports that best clinical practice guidelines represent a medical guideline not a legal one and recognize and encourage that such guidelines do not supplant clinical judgment and that failure to follow each and every clinical guideline should not be used to create a presumption of negligence; and (2) will strongly advocate for clarification in any legislation or regulation relating to risk management, utilization review, and/or cost containment to ensure that any provision does not lead to new theories of liability, such as presumption of negligence in cases of hospital acquired conditions, or inadvertently create new legal causes of action against physicians. Citation: (Res. 206, I-09)	Retain. This policy remains relevant.
H-435.961	Prohibition of Forum Shopping	Our AMA will continue to support laws which limit a plaintiff's right to sue to the state of the defendant's residence or the state where at least a substantial element of the alleged professional negligence arose. Citation: (BOT Rep. 8, I-98; Reaffirmed: BOT Rep. 23, A-09)	Retain. This policy remains relevant.
H-450.955	Education of the General Public on the Role of Physician and Non-Physician Health Care Providers	The AMA will educate the general public and legislators to the differences between physician and non-physician providers of clinical services regarding their unique training, experience, broad based knowledge, ability and expertise, which impacts on their ability to provide high quality clinical care. Citation: (Res. 308, A-98; Reaffirmation A-99; Reaffirmed: CMS Rep. 5, A-09)	Retain. This policy remains relevant.
H-485.991	Identification of Physicians by the Media	It is the policy of our AMA to communicate to the media that when a physician is interviewed or provides commentary he or she be specifically identified with the appropriate initials "MD" or "DO" after his or her name; and that others be identified with the appropriate degrees after their names. Citation: (Res. 601, I-01; Reaffirmation I-09)	Retain. This policy remains relevant.
H-65.972	Repeal of "Don't Ask, Don't Tell"	Our American Medical Association will advocate for repeal of "Don't Ask, Don't Tell," the common term for the policy regarding gay and lesbian individuals serving openly in the U.S. military as mandated by federal law Pub.L. 103-160 and codified at 10 U.S.C. 654, the title of which is "Policy concerning homosexuality in the armed forces." Citation: (Sub. Res. 917, I-09; BOT Action in response to referred for decision Res. 918, I-09; Reaffirmed in lieu of Res. 918, I-09)	Rescind. This policy is no longer relevant as the "Don't Ask, Don't Tell" Policy is no longer in effect since the law was repealed in 2010.

10. CONDUCT AT AMA MEETINGS AND EVENTS

Reference committee hearing: see report of Reference Committee F.

HOUSE ACTION: RECOMMENDATIONS ADOPTED REMAINDER OF REPORT FILED

See Policy H-140.837

At the 2018 Interim Meeting, the American Medical Association (AMA) House of Delegates adopted Policy D-140.954, “Harassment Issues Within the AMA,” which provided:

That our American Medical Association immediately engage outside consultants to evaluate current processes and, as needed, implement new processes for the evaluation and adjudication of sexual and non-sexual harassment claims involving staff, members, or both with report back regarding said processes and implementation at the 2019 Annual Meeting.

In furtherance of Policy D-140.954, the AMA immediately engaged two outside consultants, Amy L. Bess, Esq. of Vedder Price PC and Sherry Marts of S*Marts Consulting, to review, evaluate and provide recommendations as to the AMA Policy H-140.837, “Anti-Harassment Policy,” including the investigative and disciplinary processes thereunder, as previously adopted by the House of Delegates (see Appendix A for the consultants’ professional biographies). This report of the Board of Trustees summarizes the evaluation and joint recommendations provided by the consultants and recommends revisions to the procedures implementing the anti-harassment policy with respect to conduct during meetings of the House of Delegates, councils, sections, and all other AMA entities. The Board of Trustees believes that these recommendations will result in significant improvements to help ensure that AMA meetings are safe, welcoming and free of inappropriate conduct.

BACKGROUND

At the 2017 Annual Meeting, the AMA House of Delegates adopted Policy H-140.837, “Anti-Harassment Policy.” The policy communicates the AMA’s commitment to zero tolerance for harassing conduct at or in conjunction with AMA-sponsored meetings and events, and provides a clear definition of what constitutes harassing conduct (see Appendix B for full text). The policy was proffered by Board of Trustees Report 23-A-17, 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.

At the 2018 Annual Meeting, the Board of Trustees presented Board of Trustees Report 20-A-18, which recommended 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), CPT Editorial Panel and JAMA Editorial Boards. Such recommended procedures included:

- Mechanisms by which any persons who believe they have experienced or witnessed conduct in the AMA House of Delegates or in other meetings and activities hosted by the AMA (e.g., meetings of AMA councils, sections, the RVS Update Committee (RUC), CPT Editorial Panel, or JAMA Editorial Boards) in violation of Anti-Harassment Policy H-140.837 could promptly notify the presiding officer(s) of such AMA meeting or activity, the Chair of the Board and/or the AMA Office of General Counsel, or report such violation by means of a telephonic or online hotline (with the option to report anonymously).
- Prompt and thorough investigation of harassment complaints to be conducted by AMA Human Resources, with AMA Human Resources responsible for making determinations as to whether a violation of Anti-Harassment Policy H-140.837 has occurred.
- The establishment of a three-member disciplinary committee comprised of the Chair of the Board of Trustees, the Immediate Past President of the AMA and the President-Elect of the AMA, to which violations of Anti-Harassment Policy H-140.837 would be referred for disciplinary and/or corrective action, including but not

limited to expulsion from the relevant AMA meetings or activities and/or referral to the Council on Ethical and Judicial Affairs (CEJA) for further review and action.

At the 2018 Annual Meeting, following extensive testimony concerning the recommended procedures set forth in Board of Trustees Report 20-A-18, the AMA House of Delegates adopted *with amendment* the recommendations of the Board of Trustees as to disciplinary action. In particular, the House of Delegates modified the recommendations of the Board of Trustees whereby all violations of Anti-Harassment Policy H-140.837 would be referred immediately to the Council on Ethical and Judicial Affairs (CEJA) for disciplinary action, rather than to the three-member disciplinary committee recommended by the Board of Trustees, as follows:

If AMA Human Resources shall determine that a violation of Anti-Harassment Policy H-140.837 has occurred, AMA Human Resources shall (i) notify the Speaker and Vice Speaker of the House or the presiding officer(s) of such other AMA -associated meeting or activity in which such violation occurred, as applicable, of such determination, (ii) refer the matter to the Council on Ethical and Judicial Affairs (CEJA) for disciplinary and/or corrective action, which may include but is not limited to expulsion from the relevant AMA-associated meetings or activities, and (iii) provide CEJA with appropriate training.

If a Delegate or Alternate Delegate is determined to have violated Anti-Harassment Policy H-140.837, CEJA shall determine disciplinary and/or corrective action in consultation with the Speaker and Vice Speaker of the House.

If a member of an AMA council, section, the RVS Update Committee (RUC), or CPT Editorial Panel is determined to have violated Anti-Harassment Policy H-140.837, CEJA shall determine disciplinary and/or corrective action in consultation with the presiding officer(s) of such activities.

At the 2018 Interim Meeting, CEJA presented Council on Ethical and Judicial Affairs Report 4-I-18, “CEJA Role in Implementing H-140.937, ‘Anti-Harassment Policy,’” expressing concerns about the scope of responsibilities delegated to CEJA under Anti-Harassment Policy H-140.837(3), Disciplinary Action, as modified and adopted by the House of Delegates at the 2018 Annual Meeting, and requesting that Policy H-140.837(3), Disciplinary Action, be reconsidered. The House of Delegates did not accept CEJA’s recommendation, but did adopt Policy D-140.954, as noted above.

DISCUSSION

In furtherance of Policy D-140.954, two external consultants with substantial expertise in this area were immediately engaged. The purpose of engaging two separate consultants was to ensure that legal and operational points of view were both considered, and that any recommendations would reflect a common view of best practice, rather than a single evaluation. The consultants reviewed and evaluated Policy H-140.837, “Anti-Harassment Policy,” and compared it to current best practices as well as policies and procedures currently in use by other membership societies. The consultants’ review considered the policy in two parts – i) the anti-harassment policy itself, and ii) the procedures to implement the policy.

The consultants observed that the AMA’s existing anti-harassment policy includes the critical elements of an effective policy (the first of the two parts mentioned above): a clear definition of unacceptable conduct; a clear statement of when, where, and to whom the policy applies; a statement that retaliation for reporting violations of the policy is itself a violation of the policy; and a statement that reports of violations will be kept confidential to the extent possible. Thus, the consultants were complimentary of this first portion of the policy, and recommended only modest changes (see “*Consultants’ recommendations for revision of the policy,*” below). However, the consultants noted that the current policy also includes material that more properly belongs in a detailed “enforcement procedures” document, and that the implementation procedures described in the existing policy (the second of the two parts mentioned above) do not entirely reflect current best practices. The consultants therefore recommended more substantive revisions to these procedural aspects of the policy (see “*Consultant recommendations for changes to implementation and enforcement of the policy – Operational Guidelines,*” below.)

Below are the consultants’ specific observations and joint recommendations.

Consultants' recommendations for revision of the policy

The consultants recommend that the name of the policy be changed to “Policy on Conduct at AMA Meetings and Events.” The reasons for this recommendation are:

- It more accurately captures a comprehensive objective to promote respectful, professional, and collegial behavior at AMA meetings and events and to effectively address violations of the policy.
- It avoids confusion as to what the policy covers. Most people equate “anti-harassment” policies or trainings with anti-*sexual* harassment. Although this policy addresses sexual harassment, it is much broader in scope and includes a prohibition of harassment on the basis of characteristics other than sex or gender.

The consultants recommend that the current policy be retained, with the following additions:

- A statement that the purpose of the policy is to protect participants in AMA activities from harm
- A description of desired behavior in interactions, for example:
 - Exhibit professional, collegial behavior at all times
 - Exercise consideration and respect in your speech and actions, including while making formal presentations to attendees
 - Be mindful of one’s surroundings and of fellow participants
 - Alert meeting Chair or meeting organizer of violations of the anti-harassment policy – even if they seem inconsequential
- A statement about potential consequences for violation of the policy. For example: If a participant engages in unacceptable behavior at an AMA meeting or event, AMA reserves the right to take any action deemed appropriate based on the outcome of the incident investigation(s). This action may include but is not limited to:
 - Removing the violator from the AMA event or activity, without warning or refund;
 - Prohibiting the violator from attending future AMA events or activities;
 - Removing the violator from leadership or other roles in AMA activities;
 - Prohibiting the violator from assuming a future leadership or other role in AMA activities;
 - Revoking the violator’s membership in the AMA, following the CEJA processes for taking such an action;
 - Notifying the violator’s employer of the actions taken by AMA; and/or
 - Notifying law enforcement.

The consultants recommend the implementation of processes and tactics to help ensure that attendees of AMA meetings and events are made aware of the policy and consequences for violations of the policy, and mechanisms by which attendees affirmatively acknowledge and assent to the policy.

The consultants recommend that the sections of the policy beginning with “1. Reporting a complaint of harassment” through “3. Disciplinary Action” be replaced with Operational Guidelines as described below.

Consultant recommendations for changes to implementation and enforcement of the policy – Operational Guidelines

The current policy includes detailed procedures for reporting, investigation, and enforcement of the policy. However, the procedures described in the policy do not entirely reflect current best practices in implementation and enforcement of such a policy. In addition, implementation of these procedures would be cumbersome and unlikely to bring about the desired outcome of making AMA meetings and events safer and more welcoming to all participants.

Current best practices for implementation and enforcement include:

1. Ensuring awareness, acknowledgement and acceptance of the policy by meeting/event participants
2. Simple and straightforward ways to report violations of the policy at the time of (or very close in time to) the incident in question.
3. Independence and neutrality in investigation of violations of the policy.
4. Avoidance of even the appearance of conflicts of interest in decisions on consequences for violations of the policy.
5. Assurance that all reports of violation and the outcomes of investigations will be reported to the organization’s counsel.
6. Assurance that reports, investigations, and outcomes will be kept confidential to the fullest extent possible, consistent with usual business practices.

The consultants further recommend that the policy be amended to reflect the need for flexibility in procedures for receiving reports, investigating incidents, and making decisions on consequences. This flexibility is necessary because of the wide range of meetings and activities covered by the policy, including consideration of the purpose, size and duration of meetings and activities.

Specifically, the consultants recommend adoption of the following operational guidelines for reporting, investigation, and enforcement of the policy.

Violation Reporting Procedures

In order to encourage individuals who are targets of harassment to report incidents, it is important to have a simple, straightforward, and easily publicized reporting mechanism. Ideally, reports should be taken and investigated by a single individual who is unlikely to face conflicts of interest in this role.

The consultants recommend that the AMA bring in an independent consultant to act as the Conduct Liaison for larger meetings and events. This should be someone who is trained and experienced in handling incidents of harassment and bullying. The Conduct Liaison should be the primary point of contact for event participants to report violations of the policy, and responsible for any on-site investigations of those violations. The Conduct Liaison should provide recommendations for immediate action to the Event Chair or other senior designated AMA officer or representative involved in the AMA meeting in question, and should provide a formal report with recommendations for any further action to the Committee on Conduct at AMA Meetings and Events (CCAM, see below). All reported violations of the policy, and the outcomes of investigations by the Conduct Liaison, should be provided to the Office of General Counsel.

For smaller meetings, the role of the Conduct Liaison may be assumed by an individual designated by the AMA Office of General Counsel and trained in advance of assuming such role, who may or may not be physically on-site at the meeting. If not on-site, the Conduct Liaison should be on-call.

The consultants recommend retaining the requirement for a reporting hotline in addition to the Conduct Liaison, which will be an alternative source for meeting attendees to lodge complaints regarding conduct at meetings.

Investigation of Incidents

Whenever possible, the Conduct Liaison should conduct incident investigations on-site during the event. This allows for immediate action at the event to protect the safety of event participants. When this is not possible, the Conduct Liaison may continue to investigate incidents following the event in order to provide recommendations for action to the CCAM.

Investigations should consist of structured interviews with the person reporting the incident (the reporter), the person targeted (if they are not the reporter), any witnesses that the reporter or target identify, and the alleged violator.

Committee on Conduct at AMA Meetings and Events (CCAM)

The consultants recommend the establishment of a Committee on Conduct at AMA Meetings and Events (CCAM), to include 5-7 members who are nominated by the Office of General Counsel (or through a nomination process facilitated by the Office of General Counsel) and approved by the Board of Trustees. The consultants recommend that the CCAM should include one member of the Women Physicians Section (WPS), and one member of the Council on Ethical and Judicial Affairs (CEJA). The remaining members may be appointed from AMA membership generally. Emphasis should be placed on maximizing the diversity of membership.

The consultants recommend that the CCAM receive reports on all violations of the policy arising from any AMA meeting or event. When an incident is significant enough that it requires action beyond those taken on-site at the event, the CCAM reviews the incident reports, performs further investigation if needed, and makes recommendations regarding further commensurate sanctions to the Office of General Counsel and to the appropriate AMA body (e.g., meeting or event organizers, appropriate AMA staff, and/or CEJA).

To prevent possible retaliatory action against CCAM members, all proceedings of the CCAM should be kept as confidential as practicable.

CONCLUSION

As noted above, consultants engaged by the AMA in furtherance of Policy D-140.954 have reviewed and evaluated the AMA's current Anti-Harassment Policy (Policy H-140.837) and confirmed that this existing policy includes many of the critical elements of an effective anti-harassment policy. However, while the current policy includes detailed procedures for reporting, investigation, and enforcement, several amendments to the policy are necessary to bring it fully in line with current best practices in implementation and enforcement. The consultants suggested that implementation of the existing procedures would be cumbersome and unlikely to bring about the desired outcome of making AMA meetings and events safer and more welcoming.

The consultants have recommended modifications to ensure that the policy itself, and the procedures for reporting, investigation and enforcement of the policy, reflect current best practices. In particular, the consultants' recommended modifications are intended to ensure 1) simple ways to report violations, 2) prompt investigation and resolution of alleged violations, 3) independence and neutrality in investigation of violations, and the avoidance of conflicts of interest, and 4) flexibility in procedures for receiving reports, investigating incidents, and making decisions on consequences of the policy (recognizing the nature, number and varying size of AMA meetings conducted each year).

The Board of Trustees has carefully considered the recommendations of the consultants, and believes that these recommendations are consistent with the goals and objectives of the AMA's current Anti-Harassment Policy and will result in significant improvements to help ensure that AMA meetings and events are safe and welcoming to all participants. The Board of Trustees also believes that these recommendations are responsive to comments and concerns expressed at the 2018 Interim Meeting. Therefore, the Board of Trustees is recommending corresponding modifications to Policy H-140.837, "Anti-Harassment Policy," as set forth below.

RECOMMENDATION

The Board of Trustees recommends the following, and that the remainder of this report be filed:

1. That Policy D-140.954, "Harassment Issues Within the AMA," be rescinded as having been fulfilled by the report.
2. That Policy H-140.837, "Anti-Harassment Policy," be renamed "Policy on Conduct at AMA Meetings and Events" and further amended by insertion and deletion as follows:

~~**Anti-Harassment Policy Applicable to AMA Entities**~~
Policy on Conduct at AMA Meetings and Events

It is the **policy** of the American Medical Association that all attendees of AMA hosted meetings, events and other activities are expected to exhibit respectful, professional, and collegial behavior during such meetings, events and activities, including but not limited to dinners, receptions and social gatherings held in conjunction with such AMA hosted meetings, events and other activities. Attendees should exercise consideration and respect in their speech and actions, including while making formal presentations to other attendees, and should be mindful of their surroundings and fellow participants.

~~a~~Any type of harassment of any attendee of an AMA staff, fellow delegates or others by members of the House of Delegates or hosted meeting, event and other attendees at or in connection with HOD meetings, or otherwise activity, including but not limited to dinners, receptions and social gatherings held in conjunction with HOD meetings, an AMA hosted meeting, event or activity, is prohibited conduct and is not tolerated. The AMA is committed to a zero tolerance for harassing conduct at all locations where AMA delegates and staff are conducting AMA business is conducted. This zero tolerance **policy** also applies to meetings of all AMA sections, councils, committees, task forces, and other leadership entities (each, an "AMA Entity"), as well as other AMA-sponsored events. The purpose of the policy is to protect participants in AMA-sponsored events from harm.

Definition

Harassment consists of unwelcome conduct whether verbal, physical or visual that denigrates or shows hostility or aversion toward an individual because of his/her race, color, religion, sex, sexual orientation, gender identity, national origin, age, disability, marital status, citizenship or otherwise ~~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.

Operational Guidelines

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

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

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

The AMA shall establish and maintain a Committee on Conduct at AMA Meetings and Events (CCAM), to be comprised of 5-7 AMA members who are nominated by the Office of General Counsel (or through a nomination process facilitated by the Office of General Counsel) and approved by the Board of Trustees. The CCAM should include one member of the Council on Ethical and Judicial Affairs (CEJA). The remaining members may be appointed from AMA membership generally, with emphasis on maximizing the diversity

of membership. Appointments to the CCAM shall ensure appropriate independence and neutrality, and avoid even the appearance of conflict of interest, in decisions on consequences for policy violations. Appointments to the CCAM should be multi-year, with staggered terms.

2. Reporting Violations of the Policy

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

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

These reporting mechanisms will be publicized to ensure awareness.

3. Investigations

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

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

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

4. Disciplinary Action

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

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

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

- Prohibiting the violator from attending future AMA events or activities;

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

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

5. Confidentiality

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

6. Assent to Policy

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

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

1. Reporting a complaint of harassment

Any persons who believe they have experienced or witnessed conduct in violation of Anti Harassment Policy H 140.837 during any AMA House of Delegates meeting or associated functions should promptly notify the Speaker or Vice Speaker of the House or the AMA Office of General Counsel.

Any persons who believe they have experienced or witnessed conduct in other activities associated with the AMA (such as meetings of AMA councils, sections, the RVS Update Committee (RUC), or CPT Editorial Panel) in violation of Anti Harassment Policy

H 140.837 should promptly notify the presiding officer(s) of such AMA associated meeting or activity or either the Chair of the Board or the AMA Office of General Counsel.

Anyone who prefers to register a complaint to an external vendor may do so using an AMA compliance hotline (telephone and online) maintained on behalf of the AMA. The name of the reporting party will be kept confidential by the vendor and not be released to the AMA. The vendor will advise the AMA of any complaint it receives so that the AMA may investigate.

2. Investigations

Investigations of harassment complaints will be conducted by AMA Human Resources. Each complaint of harassment or retaliation shall be promptly and thoroughly investigated. Generally, AMA Human Resources will (a) use reasonable efforts to minimize contact between the accuser and the accused during the pendency of an investigation and (b) provide the accused an opportunity to respond to allegations. Based on its investigation, AMA Human Resources will make a determination as to whether a violation of Anti-Harassment Policy H 140.837 has occurred.

3. Disciplinary Action

~~If AMA Human Resources shall determine that a violation of Anti Harassment Policy H 140.837 has occurred, AMA Human Resources shall (i) notify the Speaker and Vice Speaker of the House or the presiding officer(s) of such other AMA associated meeting or activity in which such violation occurred, as applicable, of such determination, (ii) refer the matter to the Council on Ethical and Judicial Affairs (CEJA) for disciplinary and/or corrective action, which may include but is not limited to expulsion from the relevant AMA associated meetings or activities, and (iii) provide CEJA with appropriate training.~~

~~If a Delegate or Alternate Delegate is determined to have violated Anti Harassment Policy H 140.837, CEJA shall determine disciplinary and/or corrective action in consultation with the Speaker and Vice Speaker of the House.~~

~~If a member of an AMA council, section, the RVS Update Committee (RUC), or CPT Editorial Panel is determined to have violated Anti Harassment Policy H 140.837, CEJA shall determine disciplinary and/or corrective action in consultation with the presiding officer(s) of such activities.~~

~~If a nonmember or non AMA party is the accused, AMA Human Resources shall refer the matter to appropriate AMA management, and when appropriate, may suggest that the complainant contact legal authorities.~~

4. Confidentiality

~~To the fullest extent possible, the AMA will keep complaints, investigations and resolutions confidential, consistent with usual business practice.~~

APPENDIX A - Biographies

AMY L. BESS, JD, has practiced in the area of employment defense for more than thirty years and currently serves as Chair of the global Labor and Employment practice group for Vedder Price and is a member of firm's Board of Directors.

Her employment litigation experience includes the representation of employers before U.S. state and federal courts and administrative agencies, defending against claims of race, sex, disability and age discrimination; sexual harassment; whistleblower retaliation; restrictive-covenant disputes; wrongful termination; and wage and hour violations. She regularly counsels clients in all of these areas, drafts and negotiates employment and severance agreements, conducts on-site workplace investigations, presents training seminars and speaks to employer groups on avoiding workplace problems. Ms. Bess is an author and frequent speaker on a variety of employment topics, most notably on the impact of the #MeToo movement and anti-harassment laws and best practices organizations should undertake to prevent and resolve harassment concerns. She is regularly quoted in the media on these and related topics.

Select Publications

"A Four-Part Series: Addressing Sexual Harassment in the #MeToo Era" ("Best Practices for Investigating Allegations", "The Rights of the Alleged Harasser", "The Superstar Harasser-Is Anyone Really Too Big to Lose?" and "The Same Old Workplace Training Won't Cut It") Corporate Compliance Insights, February 8, March 28, May 4 and June 21, 2018

"Oops, He (or She) Did It Again! Implementing a Best-In-Class Harassment-Free Workplace Program to Help Your Company Stay Out of the Headlines" Employee Relations Law Journal, Winter 2017

"Gender Identity Discrimination Claims on the Rise at State and Federal Levels" The National Law Review, March 3, 2016

Select Speaking Engagements

Conference Co-Chair/Moderator, "Employment Law Lessons Learned from Recent Scandals" PLI Employment Law Institute 2018, October 2018, New York, NY

"Vedder Talk: Lessons Learned from the #MeToo Movement" 2018 Vedder Works Employment Law Series, October 2018, Washington, D.C.

"Advising Clients on Sexual Harassment Law in the #MeToo Era" DC Bar, July 12, 2018

"Harassment in the Workplace, Part 2 - Community and Resources: Hearing Voices & Exploring Conversation Strategies" American Institute of Architects Conference on Architecture 2018, June 23, 2018, New York, NY

"Employee Relations in the #MeToo Era: Creating a Culture of Respect" 2018 Vedder Works Employment Law Series: April 24, Chicago, IL and June 1, Chicago-O'Hare, IL, June 14, New York, NY

"Sexual Harassment: Lessons Learned from Recent Scandals" PLI Sexual Harassment Webcast, November 2017

"Conducting and Documenting Investigations and Termination Actions" 2014 Vedder Price Employment Law Update: Rosemont, IL

SHERRY A. MARTS, PhD, CEO of S*Marts Consulting LLC, is a former association CEO with a wide-ranging background in biomedical research, nonprofit management, public education, and research advocacy, Sherry provides expert consulting services

to nonprofits and academic institutions on diversity and inclusion, harassment and bullying, and interpersonal communication. Her work includes a particular focus on harassment and bullying at professional society meetings and conferences. She provides training for society and association staff on how to implement and enforce meeting codes of conduct. She also leads workshops on active bystander intervention, harassment resistance, and ally skills. Her interest in the issue of harassment and bullying lies at the intersection of her professional life as a woman in science, and her previous experience as a women's self-defense instructor.

Sherry is the recipient of the 2018 MIT Media Lab Disobedience Award.

Select Publications

"Open Secrets and Missing Stairs: Sexual and Gender-Based Harassment at Scientific Meetings," available at <http://bit.ly/osmspdf>

"Include is a Verb: Moving from Talk to Action on Diversity and Inclusion," available at <http://bit.ly/2peWwP0>

"The Book of How: Answers to Life's Most Important Question."

Dr. Marts received her B.Sc. (Hons.) in Applied Biology from the University of Hertfordshire, and her Ph.D. in Physiology from Duke University.

APPENDIX B - 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.

**11. POLICY AND ECONOMIC SUPPORT FOR EARLY CHILD CARE
(RESOLUTION 416-A-17)**

Reference committee hearing: see report of Reference Committee D.

**HOUSE ACTION: RECOMMENDATIONS ADOPTED
IN LIEU OF RESOLUTION 416-A-17
REMAINDER OF REPORT FILED**
See Policies H-405.954 and H-440.823

INTRODUCTION

At the 2017 Annual Meeting of the House of Delegates (HOD), Resolution 416-A-17 was referred. Introduced by the New England Delegation and the Minority Affairs Section, Resolution 416-A-17 asked that our American Medical Association (AMA) advocate for: (1) improved social and economic support for paid family leave to care for newborns, infants and young children; and (2) federal tax incentives to support early child care and unpaid child care by extended family members. Board of Trustees Report 27 was submitted to the HOD at the 2018 Annual Meeting.

Reference Committee D received testimony that supported the general policy intent of the original resolution and also the recommendations in BOT Report 27-A-18. Testimony was also received pointing out that that smaller employers (including small practices) could face potential challenges in running their businesses if they were required to comply with new time off policies that may be more appropriate for larger employers as was pointed out in the original Board Report. There was further testimony and suggestions that the House go back to the original language in Resolution 416-A-17. The HOD referred BOT 27-A-18 back to the Board for additional study.

This report addresses the recommendations of Reference Committee D, and discusses the language in the original resolution, and any new developments in additional research. It also adopts by reference the analysis and recommendations of the original BOT Report 27-A-18 and provides additional recommendations.

The Background, policy discussion, research and legislative activities noted below are from the original BOT Report 27-A-18 and are considered still relevant to the issue today. New information in response to the testimony and referral from Reference Committee D is in italics in the discussion and recommendation portion of this Board Report.

BACKGROUND (From: BOT Report 27-A-18)

Increases in paid parental leave were associated with decreases in perinatal, neonatal, post-neonatal, infant, and child mortality in a sample of 18 Organization for Economic Co-operation and Development countries.¹

Unpaid maternal leave provided through the Family and Medical Leave Act of 1993 (FMLA) in the US was associated with decreases in neonatal, post-neonatal, and infant mortality, but only among women who were married and had graduated from college, suggesting that women of lower socioeconomic position were unable to benefit from unpaid leave.

Although the FMLA requires larger employers to provide unpaid job-protected time off, there is no current federal law that requires employers to provide paid time off for the birth or care of children. About 38 percent of employers offer paid parental leave for employees who are new parents.² Paid parental leave is distinct from other paid-leave programs such as short-term disability, sick days, and government-funded disability or insurance payments.³ Smaller employers in particular are less likely to provide meaningful paid time off beyond generic vacation or sick time. Further, much of the time off that is provided as it relates to children is oriented toward the period surrounding the birth of a child and typically does not extend to infants and young children as contemplated by Resolution 416-A-17. What success there has been in providing paid parental leave has been primarily at the state and local level and with a small number of high profile employers. For example, IBM offers 20 weeks of paid maternity leave to both salaried and hourly workers who are birth mothers and offers 12 weeks of paid paternity leave for all other parents.⁴ A few states have enacted paid medical and family leave laws – California, New Jersey, New York and Rhode Island. Additionally, a number of cities have enacted paid leave policies but most are oriented toward paid sick leave. While upwards of 20 other states have proposed their own paid leave laws, none have yet enacted a law. Regarding tax incentives to support early child care, tax law changes for 2018 raised child care tax credits up to a maximum of \$2000

per child. The amount of the credit is indexed by income level. The credits do not differentiate between medically-related child care and general day care. This provision of the tax code already allows amounts paid to certain extended family members to be considered in the tax credit calculation under certain circumstances. For instance, if a child was sick at home and both parents had to work, a grandmother could provide care and if paid, the expense could be considered in the credit calculation, but the expenses are still subject to the maximums.

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 (CMS) Report 3-A-16 provided a comprehensive review of sick leave and paid leave policies. The HOD adopted the recommendations in the report, which established policy supporting employer policies that provide employees with unpaid sick days to care for themselves or a family member (Policy H-440.823).

As it relates specifically to physician practices, AMA Policies for Parental, Family and Medical Necessity 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.

Existing AMA policy also includes Policy H-405.954, "Parental Leave." BOT Report 9-I-17 was written and filed as an informational report, primarily to address possible expansion of the FMLA, but also made reference to paid parental leave. Policy H-405.954 states that the 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."

RESEARCH AND LEGISLATIVE ACTIVITIES

Currently, federal law does not require employers to provide paid family or parental leave. The FMLA requires employers of a certain size to provide medically-related unpaid time off.

The most recent effort at the federal level to provide a broad paid parental leave approach is currently stalled. The Family and Medical Insurance Leave Act ("FAMILY Act," H.R. 947/S. 337) was introduced in Congress in 2017. The bill would, among other things, provide paid family and medical leave to individuals who meet certain criteria. It would be financed through a tax on every individual and employer, and all self-employment income. Thus far, the bill has been supported by Democratic members of Congress and has seen little action since introduction. The bill as originally drafted would:

- 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.

The AMA has not taken a position on this bill. In 2016 the Society for Human Resources Management (SHRM) partnered with the Families and Work Institute to conduct a National Study of Employers (NSE) practices on workplace benefits, and paid parental leave was part of that study.⁵ The study seems to be the most recent and relevant broad-based employer analysis of what policies are in place today for parental leave as well as trends for the future.

The NSE's surveys have been conducted five times since 2005, providing both snapshots in time and current trends in employer practices and attitudes. The 2016 study samples 920 employers with more than 50 employees, with a blend of for-profit and non-profit as well as single and multi-site locations. Note that the findings cited below all relate to employers with more than 50 employees.

The NSE noted that despite announcements of expanded parental leave benefits from Netflix, Amazon, Microsoft, Johnson & Johnson, Ernst & Young and a few others, “The media blitz over the past few years regarding paid parental leave was not representative of the majority of U.S. employers with 50 or more employees in 2016.”⁵ It also noted that the average maximum number of weeks of parental and caregiving leaves did not change significantly between 2012 and 2016, and in fact the average number of weeks provided had slightly declined when looking back to pre-recession 2005. 2016 data showed that employers seemed to be more supportive of easing the transition of a parent back into the workforce upon the birth of child (81% of employers), and more supportive of work from home options (40 percent of employers), but the percentage of employers allowing at least some employees to take time off during the workday for family or personal needs without loss of pay had declined from 87 percent to 81 percent.

Another finding demonstrated that employer support for flexible work arrangements had dropped dramatically from 31 percent in 2005 to 14 percent in 2016. While definitive research was not available to explain this change, it may be that many employers had narrowed benefit offerings during the prolonged period of economic difficulty that began in 2008. While the study tended to focus more on whether employers provided time off, it did note that of those employers providing at least some pay to women during maternity leave, most (78 percent) did so by providing some type of short term disability pay. The survey also indicated that for those employers that do offer pay, 6 percent of employers offered full pay, 39 percent offered partial pay, and 11 percent said it depends on the situation. Forty-two percent of the employers responding offered no pay at all. However, in contrast to those findings, the same report indicated that 39 percent of employers allowed employees to take time off (at least 5 days) to care for *mildly ill* children without having to use vacation days or losing pay. The implication of this particular data is that employer policies on paid time off lack consistency.

As articulated in Board of Trustees Report 9-I-17, 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-16.⁶ Paid sick leave has been increasing throughout the United States whether by state or local law mandates or decisions by employers. However, paid leave to care for others outside of paid vacation, PTO (generic paid time off), or paid sick leave is still not prevalent in the US.

Given that only a handful of states have enacted paid parental leave programs, research on their effectiveness is limited. However, what little research there is has demonstrated generally neutral to positive feedback from employers. In particular, BOT Report 9-I-17 noted California’s experience:

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. Similar outcomes have been reported for other cities and states.⁷⁻⁹

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 expansion of FMLA laws, through covering more eligible workers, replacing a larger percentage of usual earnings, and offering more weeks of paid leave would increase 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.¹⁰

Some employer groups claim paid leave policies or policies that provide coverage for more employees may burden and negatively impact employer operations.

When predicting employer reactions to programs, policies and benefits related to caregiving leaves and child and elder care, the NSE research articulated four primary factors: (1) the demographics of their workplace; (2) the demographics

of the workforce; (3) financial health of the employer; and (4) human resources issues such as the difficulty or ease of attracting and retaining employees as well as the costs of employee benefits.

The attitude and approach of employers is fundamental to progress on a broad national approach to paid parental leave. It is not atypical for employers to consider all four of these factors when considering what benefits to offer their employees. As it relates to paid time off, some employers are specific about how that time can be used (vacation, sick time). Other employers are more flexible (“paid time off”), wherein the employer provides a bank of paid time off that employees can use for any purpose. Employers typically review benefits offerings every year, with time off being only one of a myriad of benefits being evaluated.

As noted above, recent changes in the federal tax code increased the child care tax credit up to \$2000 per child. While it may be debatable whether the increase goes far enough, it is a positive step forward toward the intent of Resolution 416 and supporting the child care efforts of people with lower economic status.

While there has been recent publicity about proposals to have some type of child care financial assistance by allowing people to draw down future Social Security benefits, it does not seem at present that such proposals will receive meaningful consideration in Congress.

DISCUSSION

The Board’s review of existing research has demonstrated that despite positive health outcomes for children being cared for by their parents, meaningful progress on national policy mandating paid parental leave is unlikely in the near term. The necessary broad-based support of employers to support such policy is simply not present at this point in time. Additionally, the anti-regulatory views of the current Administration and political climate in Washington DC may not be ripe for federal policy or action on paid family leave.

The first resolve of Resolution 416-A-17 asked the AMA to advocate for improved social and economic support for paid family leave to care for newborns, infants and young children. The Board of Trustees believes that there would be considerable challenges to pursuing a public policy that would require employers to provide paid parental leave. Nevertheless, the Board believes that HOD policy supporting paid parental leave for the care of children is good public policy. Policy H-440.823 does support employer policies that allow employees to accrue paid time off and to use such time to care for themselves or a family member. As noted earlier in this report, approximately 38 percent of employers currently offer paid parental leave for employees who are new parents. Accordingly, the Board of Trustees also supports encouraging employers to offer and/or to expand these types of policies. The Board believes that state medical associations should also be encouraged to work with their state legislatures to establish and promote parental leave policies.

The second resolve of Resolution 416-A-17 asked the AMA to advocate for federal tax incentives to support early child care and unpaid child care by extended family members. As previously noted in this report, recent changes to Federal tax law have raised child care tax credits to a maximum of \$2000 per child, beginning in 2018. The expense of paying extended family members to perform child care can be considered in the calculation of this credit under certain circumstances.

As noted in prior Board reports on paid parental leave proposals, there are several primary sources that influence progress. The first is the general proposition that such policies are, in and of themselves, the right thing to do for the betterment of public health as noted in the original Resolution 416-A-17. The second and third would be governmental action at the state or federal level either requiring or encouraging via incentives compliance with potentially new law or regulations. The fourth is action by employers in making decisions on benefit offerings to their employees. It should be noted that there is little new additional research available to inform these issues beyond that articulated in Board Report 27-A-18. However, at the federal level several new bills have been introduced new Congress. The FAMILY Act, originally introduced in both the House and Senate in 2017 has been reintroduced, but as of yet has support only from Democrats. HR 1185 has been introduced in the House with 178 Democratic co-sponsors. S 463 has been introduced in the Senate with 34 Democratic cosponsors. No hearings have yet been scheduled on any of the bills and none of them yet seem to have traction with Republicans.

Given that testimony at Reference Committee D suggested the possibility of going back to the original language of Resolution 416 A-17, and the fact that there are competing proposals in Congress the Board believes it prudent to

support the original resolutions but also restate portions of the Board's recommendations from BOT Report 27-A-18 and continue to study and monitor developments as more specifics be available.

RECOMMENDATIONS

Therefore, the Board of Trustees recommends that the following be adopted in lieu of Resolution 416-A-17 and the remainder of this report be filed.

1. That our AMA reaffirm Policy H-440.823, which recognizes the public health benefits of paid sick leave and other discretionary paid time off, and supports employer policies that allow employees to accrue paid time off and to use such time to care for themselves or a family member.
2. That our AMA encourage employers to offer and/or expand paid parental leave policies.
3. That our AMA encourage state medical associations to work with their state legislatures to establish and promote paid parental leave policies.
4. *That our AMA advocate for improved social and economic support for paid family leave to care for newborns, infants and young children.*
5. *That our AMA advocate for federal tax incentives to support early child care and unpaid child care by extended family members.*

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12. DATA USED TO APPORTION DELEGATES

Reference committee hearing: see report of Reference Committee F.

**HOUSE ACTION: RECOMMENDATIONS ADOPTED
REMAINDER OF REPORT FILED**
See Policy G-600.016

At the 2018 Interim Meeting, Policy G-600.016, "Data Used to Apportion Delegates," was adopted. It states that:

1. Our AMA shall issue an annual, mid-year report on or around June 30 to inform each national medical specialty and state medical society of its current AMA membership count status report.
2. "Pending members" will be added to the number of active AMA members in the December 31 count for the purposes of AMA delegate allocations to national medical specialty and state medical societies for the following year.

3. Our AMA Physician Engagement department will develop a mechanism to prevent a second counting of those previous “pending members” at the end of the following year until their membership has been renewed.

Reporting mid-year membership counts to state medical societies as called for in paragraph 1 of the policy is a straightforward process and will be implemented within one month following the conclusion of the 2019 Annual Meeting of the House of Delegates. Because current Policy G-600.027 links the total number of national medical specialty society delegates to the overall number of constituent (i.e., state) association delegates and because membership counts for most national medical specialty societies are based on their most recent five-year review, membership figures will be unchanged from the apportionment data for all national medical specialty societies other than those that undergo a five-year review at the just concluded Annual Meeting. Accordingly, your Board of Trustees offers an alternate recommendation to clarify mid-year reporting.

The remainder of this report deals primarily with implementation of the second and third paragraphs of Policy G-600.016.

APPORTIONMENT OF DELEGATES

Under current AMA Bylaws (2.1.1), constituent associations are apportioned delegates at the rate of one delegate for each 1000 (or fraction thereof) **active** AMA members within the jurisdiction of each constituent association, as recorded by the AMA as of December 31 of each year. Thus, for example, a constituent association with 1000 or fewer AMA members is apportioned one delegate and one alternate delegate, while a constituent association with from 1,001 to 2,000 AMA members will receive two delegates and two alternate delegate seats. (Some other bylaws provisions deal with special circumstances such as a loss of AMA members by the constituent association, but those are not relevant for purposes of this report.) For 2019, 281 delegates were apportioned to constituent associations, which in turn means that 281 delegates were apportioned to national medical specialty societies using methods specified in Policy G-600.027, “Designation of Specialty Societies for Representation in the House of Delegates.” For both constituent associations and national medical specialty societies membership figures are calculated as of December 31 and delegates are apportioned for the following year. While actual end-of-year counts are used for constituent associations, national medical specialty society data generally come from the most recent five-year review.

Apportionment Under Policy G-600.016

Although the plan described below was adopted by the House of Delegates at I-18, no changes in delegate apportionment are possible until the AMA Bylaws are amended. The figures in Appendix 1 for the (hypothetical) 2019 delegate apportionment to constituent associations are based on this plan. Because national specialty society delegate apportionment is hinged to constituent associations, national specialty societies are not included in the table.

The definition of “pending members” referenced in paragraph 2 of Policy G-600.016 is critical to understanding apportionment under the new policy. Board of Trustees Report I-I-18, which eventuated in Policy G-600.016, defined pending members as individuals who at the time they apply for membership are not current in their dues and who pay dues for the following calendar year. For example, a nonmember in 2018 who during calendar year 2018 completed an application and paid dues for the 2019 membership year would be a “pending member.” In practical terms, a pending member’s active membership is not in effect on December 31, only becoming active the next day. Under current rules, those members are not reported as members in any end-of-year statistics. Pending members typically acquire “pending” status in the fourth quarter of a given year. Under Policy G-600.016 “pending members” will be added to the active members as of December 31 to determine delegate allocation for the following year.

The figures in the two rightmost columns of Appendix 1 were calculated using this plan, which counts both active and pending members for purposes of delegate apportionment. This count will differ from the membership reported in the annual “Performance, Activities and Status” report (BOT Report 7 at this meeting).

As is apparent from Appendix 1, the inclusion of pending members will result in ten new delegates. Thereafter, the plan will have relatively few effects. This is so for two reasons. As noted, delegates are apportioned at the one per 1000 members rate, so for a constituent association to gain a delegate, the number of pending members must move its member count across a 1000 threshold. The likelihood of that for any given constituent society after the first year when a few societies that are close to the threshold see a positive effect is low. At the same time, the number of

pending members must more than offset the number of active members who do not renew their memberships for the succeeding year to have an ongoing positive effect.

It is critical to avoid any gaming of the system. Consider a nonmember who becomes a pending member late in the year. As a pending member, that individual enters into the apportionment calculations for the succeeding year, and as a then current member would also be included in the counts for the next year as well. The following chart shows how someone joining late in the year every other year would affect delegate apportionment.

<u>YEAR</u>	<u>MEMBERSHIP STATUS</u>	<u>DUES PAYMENT</u>	<u>COUNTED IN APPORTIONMENT</u>
Year 1	Pending	Pays for year 2	Counts for year 2
Year 2	Member	Does not renew	Counts for year 3
Year 3	Pending	Pays for year 4	Counts for year 4
Year 4	Member	Does not renew	Counts for year 5
Year 5	Pending	Pays for year 6	Counts for year 6

Insofar as AMA membership benefits ought to accrue to members, and our members report that representation and advocacy on their behalf are highly valued, it is critical that apportionment be based on members, not individuals seeking to game the system. Paragraph 3 of Policy G-600.016 attempts to resolve the issue by calling for the development of a mechanism to prevent a second counting of these members the following year until they have renewed their membership. To ensure that a “pending member” who only pays membership for a single year is not counted for apportionment for two years, our AMA will track each “pending member” (who will be added to the membership count for purposes of delegate apportionment in the year in which they paid membership dues for the following year, as per paragraph 2) and, as specified in paragraph 3, they will not be counted in the subsequent year’s apportionment unless they renew their membership before the end of the following year. Once a “pending member” has renewed their membership for the following year, going forward they will be counted like all other active members and will no longer be tracked. While your Board of Trustees recognizes that it is still possible to “game” this system, continued tracking of an increasing cohort of “pending members” presents an ever-increasing data burden.

Our AMA currently reports active membership for any given year and over the course of the calendar year for a variety of reasons. We do not currently track “pending members” and certainly do not follow these members prospectively. Implementation of Policy G-600.016 will require an internal process to perform tracking of these individual members. Because the impact upon our AMA and the constituent societies of the House of Delegates of this new apportionment methodology beyond the first year is unknown and the data challenges to track pending members as they renew for subsequent years are difficult to determine prospectively, your Board of Trustees recommends that Policy G-600.016 be amended to reflect a trial period with a report back on the impact and recommendations for the future be submitted to the House of Delegates at the 2022 Annual Meeting.

CONCLUSION

Your Board of Trustees has prepared this report to ensure clarity with respect to the yet to be implemented plan for delegate apportionment outlined in Policy G-600.016 and to afford members of the House of Delegates an opportunity to provide additional input via the reference committee process. Moreover, because apportionment is effective for a calendar year, Bylaws amendments at the upcoming Interim Meeting will allow timely execution of the policy.

RECOMMENDATIONS

The Board of Trustees recommends that the following recommendations be adopted and the remainder of the report be filed:

- A. That Policy G-600.016, “Data Used to Apportion Delegates,” be amended to read as follows:
 1. Our AMA shall issue an annual, mid-year report on or around June 30 to inform each state medical society and each national medical specialty society that is in the process of its 5-year review and ~~state medical society~~ of its current AMA membership count ~~status report~~.

2. “Pending members” will be added to the number of active AMA members in the December 31 count for the purposes of AMA delegate allocations to national medical specialty and state medical societies for the following year and this total will be used to determine the number of national medical specialty delegates to maintain parity.
 - ~~3. Our AMA Physician Engagement department will develop a mechanism to prevent a second counting of those previous “pending members” at the end of the following year until their membership has been renewed.~~
 3. Our AMA will track “pending members” from a given year who are counted towards delegate allocation for the following year and these members will not be counted again for delegate allocation unless they renew their membership before the end of the following year.
 4. Our AMA Board of Trustees will issue a report to the House of Delegates at the 2022 Annual Meeting on the impact of Policy G-600.016 and recommendations regarding continuation of this policy.
- B. That the Council on Constitution and Bylaws prepare a report for the 2019 Interim Meeting that will allow the implementation of Policy G-600.016, as amended herein.

APPENDIX 1 - Constituent Association Delegate Apportionment: 2019 Actual and 2019 Hypothetical

Constituent Association	AMA members as of 31 Dec 2018	Apportionment 2019	AMA members including pending members	2019 hypothetical apportionment
Total	250,253	280 ²	263,061	290
Alabama	3,062	4	3,206	4
Alaska	352	1	367	1
Arizona	4,271	5	4,424	5
Arkansas	2,021	3	2,090	3
California	22,429	23	23,548	24
Colorado	4,096	5	4,206	5
Connecticut	3,413	4	3,601	4
Delaware	668	1	690	1
District of Columbia	1,981	2	2,085	3
Florida	13,489	14	14,142	15
Georgia	4,874	5	5,170	6
Guam	25	1	28	1
Hawaii	1,078	2	1,119	2
Idaho	563	1	595	1
Illinois	11,069	12	11,580	12
Indiana	4,439	5	4,924	5
Iowa	2,151	3	2,212	3
Kansas ¹	1,903	2	1,990	2
Kentucky	3,228	4	3,376	4
Louisiana	4,024	5	5,571	6
Maine	1,337	2	1,367	2
Maryland	4,414	5	4,658	5
Massachusetts	12,321	13	12,546	13
Michigan	12,011	13	12,467	13
Minnesota	4,393	5	4,586	5
Mississippi	2,749	3	2,830	3
Missouri	4,846	5	5,123	6
Montana	679	1	704	1
Nebraska	1,640	2	1,727	2
Nevada	1,471	2	1,530	2
New Hampshire	877	1	918	1
New Jersey	7,074	8	7,455	8
New Mexico	1,285	2	1,345	2
New York	19,468	20	20,529	21
North Carolina	5,181	6	5,471	6
North Dakota	762	1	776	1
Ohio	10,593	11	11,066	12

Constituent Association	AMA members as of 31 Dec 2018	Apportionment 2019	AMA members including pending members	2019 hypothetical apportionment
Oklahoma	3,751	4	3,813	4
Oregon	1,902	2	2,015	3
Pennsylvania	13,213	14	13,886	14
Puerto Rico	1,399	2	1,495	2
Rhode Island	1,018	2	1,072	2
South Carolina	4,572	5	4,694	5
South Dakota	963	1	997	1
Tennessee	4,744	5	4,943	5
Texas	18,002	19	18,735	19
Utah	1,668	2	1,760	2
Vermont	416	1	444	1
Virgin Islands	37	1	40	1
Virginia	7,111	8	7,360	8
Washington	3,888	4	4,087	5
West Virginia	1,831	2	1,944	2
Wisconsin	4,556	5	4,800	5
Wyoming	202	1	205	1
APO/FPO	743	-	749	-

1. Kansas had three delegates in 2018 and can retain the third delegate by submitting a plan for intensified membership recruitment. See bylaw 2.1.1.1.1.

2. Figures do not include delegates awarded under special bylaws provisions (e.g., provisions for the speaker and vice speaker).

APPENDIX 2 - Current AMA Policy and Bylaws

Policy G-600.027, "Designation of Specialty Societies for Representation in the House of Delegates"

1. 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. 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.

Bylaw B-2.1, "Constituent Associations"

Each recognized constituent association granted representation in the House of Delegates is entitled to delegate representation based on the number of seats allocated to it by apportionment, and such additional delegate seats as may be provided under Bylaw 2.1.1.2. Only one constituent association from each U.S. state, commonwealth, territory, or possession shall be granted representation in the House of Delegates.

2.1.1 Apportionment. The apportionment of delegates from each constituent association is one delegate for each 1,000, or fraction thereof, active constituent and active direct members of the AMA within the jurisdiction of each constituent association, as recorded by the AMA as of December 31 of each year.

2.1.1.1 Effective Date. Such apportionment shall take effect on January 1 of the following year and shall remain effective for one year.

2.1.1.1.1 Retention of Delegate. If the membership information as recorded by the AMA as of December 31 warrants a decrease in the number of delegates representing a constituent association, the constituent association shall be permitted to retain the same number of delegates, without decrease, for one additional year, if it promptly files with the AMA a written plan of intensified AMA membership development activities among its members. At the end of the one year grace period, any applicable decrease will be implemented.

2.1.1.2 Unified Membership. A constituent association that adopts bylaw provisions requiring all members of the constituent association to be members of the AMA shall not suffer a reduction in the number of delegates allocated to it by apportionment during the first 2 years in which the unified membership bylaw provisions are implemented.

2.1.2 Additional Delegates. A constituent association meeting the following criteria shall be entitled to the specified number of additional delegates.

2.1.2.1 Unified Membership. A constituent association shall be entitled to 2 additional delegates if all of its members are also members of the AMA. If during any calendar year a constituent association adopts bylaw provisions requiring unified membership, and such unified membership is to be fully implemented within the following calendar year, the constituent association shall be entitled to the 2 additional delegates. The constituent association shall retain the 2 additional delegates only if the membership information as recorded by the AMA as of each subsequent December 31 confirms that all of the constituent association's members are members of the AMA.

2.1.2.2 Minimum 75% Membership. A constituent association shall be entitled to one additional delegate if 75% or more of its members, but not all of its members, are members of the AMA. The constituent association shall retain the additional delegate only if the membership information as recorded by the AMA as of each subsequent December 31 confirms that 75% or more of the constituent association's members are members of the AMA. If the membership information indicates that less than 75% of the constituent association's members are members of the AMA, the constituent association shall be permitted to retain the additional delegate for one additional year if it promptly files with the AMA a written plan of intensified AMA membership development activities among its members. If the membership information for the constituent association, as recorded by the AMA as of the following December 31 indicates that for the second successive year less than 75% of the constituent association's members are members of the AMA, the constituent association shall not be entitled to retain the additional delegate.

2.1.2.3 Maximum Additional Delegates. No constituent association shall be entitled to more than 2 additional delegates under Bylaw 2.1.2.

2.1.2.3.1 Effective Date. The additional delegates provided for under this bylaw shall be based upon membership information recorded by the AMA as of December 31 of each year. Allocation of these seats shall take effect on January 1 of the following year.

2.1.3 Selection. Each constituent association shall select and adjust the number of delegates to conform with the number of seats authorized under this bylaw.

2.1.4 Certification. The president or secretary of each constituent association shall certify to the AMA the delegates and alternate delegates from their respective associations. Certification must occur at least 30 days prior to the Annual or Interim Meeting of the House of Delegates.

2.1.5 Term. Delegates from constituent associations shall be selected for 2-year terms and assume office on the date set by the constituent association, provided that such seats are authorized pursuant to these Bylaws. Constituent associations entitled to more than one delegate shall select them so that half the number, as near as may be, are selected each year. One-year terms may be provided but only to the extent and for such time as is necessary to accomplish this proportion.

2.1.6 Vacancies. The delegate selected to fill a vacancy shall assume office immediately after selection and serve for the remainder of that term.

2.1.7 Resident/Fellow Physician and Medical Student Delegates. A constituent association may designate one or more of its delegate and alternate delegate seats to be filled by a resident/fellow physician member or a medical student member.

2.1.7.1 Term. Such resident/fellow physician or medical student delegate or alternate delegate shall serve for a one-year term beginning as of the date of certification of the delegate or alternate delegate by the constituent association to the AMA.

2.1.7.2 No Restriction on Selection. Nothing in this bylaw shall preclude a resident/fellow physician or medical student member from being selected to fill a full 2-year term as a delegate or alternate delegate from a constituent association as provided in Bylaw 2.1.5.

2.1.8 Application by a Constituent Association for Representation in the House of Delegates. A constituent association seeking representation in the House of Delegates shall submit an application to the AMA. The Board of Trustees shall make a recommendation to the House of Delegates as to the proposed constituent association's qualifications for representation, based on all the current guidelines for representation in the House of Delegates.

13. EMPLOYED PHYSICIAN BILL OF RIGHTS AND BASIC PRACTICE PROFESSIONAL STANDARDS (RESOLUTIONS 701-A-18 AND 702-A-18)

Reference committee hearing: see report of Reference Committee G.

**HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS
IN LIEU OF RESOLUTIONS 701-A-18 AND 702-A-18
REMAINDER OF REPORT FILED**

*See Policies H-225.942, H-225.950, H-225.955, H-225.997, H-300.982,
H-383.998 and D-225.973*

INTRODUCTION

At the 2018 Annual Meeting, the House of Delegates (HOD) referred Resolution 701, Employed Physician Bill of Rights. Resolution 701 was introduced by the Illinois Delegation and asked our AMA to adopt an extensive Employed Physician's Bill of Rights. The HOD also referred Resolution 702, Basic Practice Professional Standards of Physician Employment, which was introduced by the Indiana Delegation and asked our AMA to adopt a series of best practices for physician employment contracts. These resolutions are reproduced in full in the appendix.

Testimony on Resolutions 701 and 702-A-18 suggested that much of the content of the resolutions is already addressed by AMA policy, and that in some cases the proposed policy positions might be inconsistent with existing AMA policy. This report compares these resolutions to the existing body of AMA policy on physician employment and related matters and provides recommendations accordingly.

BACKGROUND

AMA policy on physician employment matters dates back more than two decades and covers an extensive range of issues. In 2012, recognizing the growing number of physicians becoming employed, the AMA consolidated and expanded this guidance in the form of the AMA Principles for Physician Employment (Policy H-225.950), which have since been updated a handful of times. As noted in the original preamble, the Principles "are intended to help physicians, those who employ physicians, and their respective advisors identify and address some of the unique challenges to professionalism and the practice of medicine arising in the face of physician employment." In addition to this body of policy, the AMA has developed a variety of resources to help physicians navigate physician-employer relations, most notably its model employment agreements.

RESOLUTION 701-A-18, EMPLOYED PHYSICIAN BILL OF RIGHTS

The first resolve of Resolution 701-A-18 asks the AMA to adopt an “Employed Physician Bill of Rights,” the provisions of which are delineated in resolves 2-11. We discuss below the asks of each resolve with respect to the AMA Principles for Physician Employment and other AMA policy.

Resolve 2 asks “That this bill of rights include the principle that compensation should be based on the totality of physician activities for the organization, including but not limited to educational endeavors and preparation, committee participation, student/resident activities and administrative responsibilities.”

Resolve 2 is addressed by Policy H-225.997, “Physician-Hospital Relationships,” which is also more nuanced than the proposed policy position:

(4) Hospital-associated medical specialists, as well as all members of the medical staff, are expected to contribute a reasonable amount of their time, without compensation, to participation in hospital staff committee activities for the purpose of improving patient care; providing continuing education for the benefit of the medical staff; and assisting in the training of physicians and allied health personnel. Physicians who provide teaching or other services in excess of those ordinarily expected of members of the attending staff are entitled to reasonable compensation therefore.

Resolve 3 asks “That this bill of rights include the principle that physicians have academic freedom, without censorship in clinical research or academic pursuits.”

While existing policy recognizes several areas in which employed physicians should have “freedom,” it does not explicitly address academic freedom. We therefore propose an amendment to Policy H-225.950, “AMA Principles for Physician Employment,” as follows:

(1)(b) Employed physicians should be free to exercise their personal and professional judgement in voting, speaking and advocating on any manner regarding patient care interests, the profession, health care in the community, and the independent exercise of medical judgment. Employed physicians should not be deemed in breach of their employment agreements, nor be retaliated against by their employers, for asserting these interests. Employed physicians also should enjoy academic freedom to pursue clinical research and other academic pursuits within the ethical principles of the medical profession and the guidelines of the organization.

Resolve 4 asks “That this bill of rights include the principle that physicians should not be solely responsible for data entry, coding and management of the use of electronic medical record systems.”

Current AMA policy does not explicitly address administrative burden on employed physicians. While physicians must ultimately take responsibility for the care of their patients, which includes documentation and other uses of the electronic medical record, they should not be burdened with such tasks to the detriment of patient care. We therefore recommend adoption of new AMA policy as follows:

Employed physicians should be provided sufficient administrative and clinical support to ensure that they can appropriately care for their patients.

Resolve 5 asks “That this bill of rights include the principle that clinical activity should be evaluated only through the peer review process and judged only by clinicians, not corporate executives.”

Resolve 5 is addressed by Policy H-225.950, “AMA Principles for Physician Employment,” and H-225.942, “Physician and Medical Staff Member Bill of Rights:”

H-225.905: “(5)(c) Peer review of employed physicians should be conducted independently of and without interference from any human resources activities of the employer. Physicians—not lay administrators—should be ultimately responsible for all peer review of medical services provided by employed physicians.”

H-225.942: “(IV)(d) “individual medical staff members have “the right to be evaluated fairly, without the use of economic criteria, by unbiased peers who are actively practicing physicians in the community and in the same specialty.”

Resolve 6 asks “That this bill of rights include the principle that physician activities performed outside of defined employed-time boundaries are the sole prerogative of the individual physician and not the employer organization unless it directly conflicts with or increases risk to the organization.”

AMA Policy H-225.950, “AMA Principles for Physician Employment,” recognizes two important points related to Resolve 6: First, that employed physicians do in fact owe a duty of loyalty to their employers, which may reasonably limit their rights to engage in activities that conflict with the financial or other interests of the employer—for example, moonlighting at a competing hospital:

(1)(a) A physician’s paramount responsibility is to his or her patients. Additionally, given that an employed physician occupies a position of significant trust, he or she owes a duty of loyalty to his or her employer. This divided loyalty can create conflicts of interest...which employed physicians should strive to recognize and address.

At the same time, the policy states that “employed physicians should be free to engage in volunteer work outside of, and which does not interfere with, their duties as employees.”

We believe that these two statements taken together appropriately addresses the matter of “physician activities performed outside of defined employed-time boundaries” and recommend no amendments to existing policy. Physicians are encouraged to carefully negotiate their contract to ensure their desired level of independence outside the context of employed time is protected.

Resolve 7 asks “That this bill of rights include the principle that conflict-of-interest disclosures should be limited to physician activities that directly affect the organization and should only be disclosed to entities that directly reimburse the physician during their employed time period.”

Resolve 7 is addressed by two provisions of Policy H-225.955, “Protection of Medical Staff Members' Personal Proprietary Financial Information,” to which we recommend a clarifying edit:

(1)(a) Physicians should be required to disclose personal financial information to the hospital/health system only if they are serving or being considered to serve as a member of the governing body, as a corporate officer, or as an employee/contractor of the hospital/health system; and such information should be used only so that other individuals understand what conflicts may exist when issues are discussed and when recusal from voting or discussion on an issue may be appropriate.

(2) Medical staff members' personal financial information shall remain confidential except for disclosure to those with a bona fide need for access to such information. The security and storage of such information, including electronic and paper-based, should be at the same level as that afforded to other data and files in the hospital, such as patient and peer review information that enjoy confidentiality and privacy protections, including restricted access, password protection and other protective mechanisms.

Resolve 8 asks “That this bill of rights include the principle that restrictive covenants should be limited only to physicians with partnership stakes in the organization and should not apply to salary-based physicians.”

Resolve 8 is addressed by Ethical Opinion 11.2.3.1, “Restrictive Covenants,” and Policy H-225.950, “AMA Principles for Physician Employment,” both of which discourage physicians from entering into employment contracts that contain restrictive covenants, regardless of status as a partner or salaried employee:

Code of Medical Ethics 11.2.3.1: “Competition among physicians is ethically justifiable when it is based on such factors as quality of services, skill, experience, conveniences offered to patients, fees, or credit terms. Covenants-not-to-compete restrict competition, can disrupt continuity of care, and may limit access to care. Physicians should not enter into covenants that: (a) Unreasonably restrict the right of a physician to practice medicine for a specified period of time or in a specified geographic area on termination of a contractual relationship; and (b) Do not make reasonable accommodation for patients’ choice of physician.”

H-225.950: “(g) Physicians are discouraged from entering into agreements that restrict the physician's right to practice medicine for a specified period of time or in a specified area upon termination of employment.”

Resolve 9 asks “That this bill of rights include the principle that resources should be appropriately allocated by the organization for continuing medical education as defined by state licensure guidelines.”

Resolve 9 is inconsistent with Policy H-300.982, “Maintaining Competence of Health Professionals,” which places on the physician the burden of the cost of completing continuing medical education:

(1) Health professionals are individually responsible for maintaining their competence and for participating in continuing education; all health professionals should be engaged in self-selected programs of continuing education. In the absence of other financial support, individual health professionals should be responsible for the cost of their own continuing education.

We note also that compensation or reimbursement for CME is a fairly common benefit of employment which physicians should consider carefully as they negotiate employment contracts. Refer to the AMA annotated model physician employment agreements for guidance.*

Resolve 10 asks “That this bill of rights include the principle that employed physicians have the right to the collective bargaining process as outlined in the National Labor Relations Act of 1935 (The Wagner Act).”

Given that collective bargaining is largely toothless without the specter of a strike, resolve 10 is arguably inconsistent with Ethical Opinion 1.2.10, “Political Action by Physicians,” and Policy H-383.998, “Resident Physicians, Unions and Organized Labor,” which discourage physicians from withholding essential medical services from patients or otherwise disrupting patient care as a bargaining tactic:

Code of Medical Ethics 1.2.10: “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.”

H-383.998: “Our AMA strongly advocates for the separation of academic issues from terms of employment in determining negotiable items for labor organizations representing resident physicians and that those organizations should adhere to the AMA's Principles of Medical Ethics which prohibits such organizations or any of its members from engaging in any strike by the withholding of essential medical services from patients.”

Resolve 11 asks “That this bill of rights include the principle that all physicians be empowered to first be the patient’s advocate and be allowed to adhere to the spirit of the Hippocratic Oath allowing patient privacy, confidentiality and continuity of a patient’s health care and dignity.”

Resolve 11 is addressed by Policy H-225.950, “AMA Principles for Physician Employment:”

H-225.950: “(2)(a) Patient advocacy is a fundamental element of the patient-physician relationship that should not be altered by the health care system or setting in which physicians practice, or the methods by which they are compensated.”

H-225.950: “(1)(b) Employed 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

* These and other resources on employment contracts are available at ama-assn.org/residents-students/career-planning-resource/understanding-employment-contracts.

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.”

Additionally, as noted in the AMA’s history of its Code of Medical Ethics, the Code “is rooted in an understanding of the goals of medicine as a profession, which dates back to the 5th century BCE and the Greek physician Hippocrates, to relieve suffering and promote well-being in a relationship of fidelity with the patient.”

RESOLUTION 702-A-18, BASIC PRACTICE PROFESSIONAL STANDARDS OF PHYSICIAN EMPLOYMENT

Resolution 702-A-18 identifies a set of “best practices” related broadly to physician employment and asks our AMA to support specific contract provisions that might improve the physician experience in the employed settings:

That our American Medical Association support best practice for physician employment that will promote improved work-life balance and maximum employment adaptability and professional treatment to maintain physicians in productive medical practice and minimize physician burnout. To achieve these goals, best practice efforts in physician employment contracts would include, among other options:

1. Establishing the degree of physician medical staff support as well as specifying how different medical staff costs will be covered.
2. Establishing a specific degree of clerical and administrative support. This would include access to an EMR (electronic health record) scribe, as well as specifying how different clerical or administrative support costs will be shared/covered.
3. Providing information regarding current EMR systems and their national ranking, including user ratings and plans to improve these systems.
4. Providing work flexibility with pay and benefit implications for reduced work hours, reduced call coverage, job sharing, child care support, use of locum tenens coverage, leave of absence for personal reasons or extended duty in the military, medical service organizations or other “greater societal good” organizations.
5. Establishing an expected workload that does not exceed the mean RVU production of the specialty in that state/county/region.

While none of these aims is objectionable on its face, the creation of such a list would seem to be inconsistent with an overarching theme of AMA employment-related policy: that physicians must be free to and should exercise self-determination in employment contracting. Specifically, Policy H-225.950, “AMA Principles for Physician Employment,” avers that “Physicians should be free to enter into *mutually satisfactory* contractual arrangements, including employment, with hospitals, health care systems, medical groups, insurance plans, and other entities as permitted by law and in accordance with the ethical principles of the medical profession” (emphasis added). Furthermore, “physicians should never be coerced into employment” and “employment agreements between physicians and their employers should be negotiated in good faith,” with “both parties [being] urged to obtain the advice of legal counsel experienced in physician employment matters....”

Individual physicians must determine for themselves what they seek in employment arrangements and how they weigh these various desires. For example, some physicians may choose to forego work flexibility or smaller workload in exchange for greater compensation; others may choose to forego additional compensation to work for an organization that provides a higher level of administrative support. So long as they balance these desires in a manner that does not compromise the ethical principles of the medical profession, physicians should be free to negotiate their contracts as they see fit. Physicians are encouraged to use AMA resources in this regard, such as the AMA’s model physician employment agreements. These valuable resources include a thorough description of basic contract terms typically found in an employment agreement, an in-depth explanation of the significance of such provisions and language that benefits the physician employee, and important examples of language that may be problematic to the physician employee.

Finally, we note that some sections of Resolution 702-A-18—in particular, items 1-3—raise an issue discussed earlier in this report: appropriate levels of support for employed physicians. While physicians should be free to negotiate for

their desired level of staffing, AMA should ensure that physicians are provided at least the level of staffing needed to ensure that they can deliver safe, high-quality care to their patients. We therefore recommend adoption of new AMA policy as follows (and as presented in the discussion on Resolve 4 of Resolution 701-A-18):

Employed physicians should be provided sufficient administrative and clinical support to ensure that they can appropriately care for their patients.

CONCLUSION

The concepts set forth in Resolution 701-A-18, “Employed Physician Bill of Rights,” and Resolution 702-A-18, “Basic Professional Standards of Physician Employment,” are for the most part addressed by a variety of existing AMA policies. We recommend reaffirmation of these policies. In a few instances, the concepts set forth in Resolutions 701 and 702-A-18 are inconsistent with current policy, in which case we recommend no change in policy. Finally, we have identified two themes not addressed by existing policy—academic freedom for employed physicians and appropriate levels of administrative and clinical support—and we recommend adoption of new policy in these areas.

RECOMMENDATIONS

The Board of Trustees recommends the following be adopted in lieu of Resolution 701-A-18 and Resolution 702-A-18, and the remainder of the report be filed:

1. That our AMA reaffirm the following policies:

- H-225.950, AMA Principles for Physician Employment,
- H-225.997, Physician-Hospital Relationships,
- H-225.942, Physician and Medical Staff Member Bill of Rights,
- H-225.955, Protection of Medical Staff Members' Personal Proprietary Financial Information,
- H-300.982, Maintaining Competence of Health Professionals, and
- H-383.998, Resident Physicians, Unions and Organized Labor.

2. That our AMA amend policy H-225.955, Protection of Medical Staff Members' Personal Proprietary Financial Information:

“(1)(a) Physicians should be required to disclose relevant personal financial information to the hospital/health system only if they are serving or being considered to serve as a member of the governing body, as a corporate officer, or as an employee/contractor of the hospital/health system; and such information should be used only so that other individuals understand what conflicts may exist when issues are discussed and when recusal from voting or discussion on an issue may be appropriate.”

3. That our AMA amend policy H-225.950, AMA Principles for Physician Employment:

“(1)(b) Employed physicians should be free to exercise their personal and professional judgement in voting, speaking and advocating on any manner regarding patient care interests, the profession, health care in the community, and the independent exercise of medical judgment. Employed physicians should not be deemed in breach of their employment agreements, nor be retaliated against by their employers, for asserting these interests. Employed physicians also should enjoy academic freedom to pursue clinical research and other academic pursuits within the ethical principles of the medical profession and the guidelines of the organization.”

4. That our AMA advocate that employed physicians should be provided sufficient administrative and clinical support to ensure that they can appropriately care for their patients.

APPENDIX - Resolution 701-A-18, “Employed Physician’s Bill of Rights”

RESOLVED, That our American Medical Association adopt an “Employed Physician’s Bill of Rights”; and be it further RESOLVED, That this bill of rights include the principle that compensation should be based on the totality of physician activities for the organization, including but not limited to educational endeavors and preparation, committee participation, student/resident activities and administrative responsibilities; and be it further

RESOLVED, That this bill of rights include the principle that physicians have academic freedom, without censorship in clinical research or academic pursuits; and be it further

RESOLVED, That this bill of rights include the principle that physicians should not be solely responsible for data entry, coding and management of the use of electronic medical record systems; and be it further

RESOLVED, That this bill of rights include the principle that clinical activity should be evaluated only through the peer review process and judged only by clinicians, not corporate executives; and be it further

RESOLVED, That this bill of rights include the principle that physician activities performed outside of defined employed-time boundaries are the sole prerogative of the individual physician and not the employer organization unless it directly conflicts with or increases risk to the organization; and be it further

RESOLVED, That this bill of rights include the principle that conflict-of-interest disclosures should be limited to physician activities that directly affect the organization and should only be disclosed to entities that directly reimburse the physician during their employed time period; and be it further

RESOLVED, That this bill of rights include the principle that restrictive covenants should be limited only to physicians with partnership stakes in the organization and should not apply to salary-based physicians; and be it further

RESOLVED, That this bill of rights include the principle that resources should be appropriately allocated by the organization for continuing medical education as defined by state licensure guidelines; and be it further

RESOLVED, That this bill of rights include the principle that employed physicians have the right to the collective bargaining process as outlined in the National Labor Relations Act of 1935 (The Wagner Act); and be it further

RESOLVED, That this bill of rights include the principle that all physicians be empowered to first be the patient's advocate and be allowed to adhere to the spirit of the Hippocratic Oath allowing patient privacy, confidentiality and continuity of a patient's health care and dignity.

Resolution 702-A-18, "Basic Practice Professional Standards of Physician Employment"

RESOLVED, That our American Medical Association support best practice for physician employment that will promote improved work-life balance and maximal employment adaptability and professional treatment to maintain physicians in productive medical practice and minimize physician burnout. To achieve these goals, best practice efforts in physician employment contracts would include, among other options:

Establishing the degree of physician medical staff support as well as specifying how different medical staff costs will be covered.

Establishing a specific degree of clerical and administrative support. This would include access to an EMR (electronic medical record) scribe, as well as specifying how different clerical or administrative support costs will be shared/covered.

Providing information regarding current EMR systems and their national ranking, including user ratings and plans to improve these systems.

Providing work flexibility with pay and benefit implications for reduced work hours, reduced call coverage, job sharing, child care support, use of locum tenens coverage, leave of absence for personal reasons or extended duty in the military, medical service organizations or other "greater societal good" organizations.

Establishing an expected workload that does not exceed the mean RVU production of the specialty in that state/county/region.

**14. REFORMING THE ORPHAN DRUG ACT (RESOLUTION 217-A-18)
AN OPTIONAL NATIONAL PRESCRIPTION DRUG FORMULARY (RESOLUTION 227-A-18)
REFORM OF PHARMACEUTICAL PRICING: NEGOTIATED PAYMENT SCHEDULES
(RESOLUTION 238-A-18)**

Reference committee hearing: see report of Reference Committee B.

**HOUSE ACTION: RECOMMENDATIONS ADOPTED
IN LIEU OF RESOLUTIONS 217-A-18, 227-A-18 AND 238-A-18
REMAINDER OF REPORT FILED
*See Policy H-110.987***

At the 2018 Annual Meeting, the American Medical Association's (AMA) House of Delegates (HOD) referred three resolutions for a combined Board of Trustees (BOT) Report (Report) at the 2019 Annual Meeting. The first resolution, Resolution 217-A-18, "Reforming the Orphan Drug Act," was introduced by the Medical Student Section and asks that:

Our AMA: (1) support efforts to reform the Orphan Drug Act (ODA) by closing loopholes identified by the Food and Drug Administration [(FDA)] in order to protect the Act's original intent of promoting therapies targeting rare diseases; (2) support increased transparency in development costs, post-approval regulation and overall earnings

for pharmaceuticals designated as “Orphan Drugs” and (3) support modifications to the exclusivity period of “Orphan Drugs” to increase access to these pharmaceutical drugs for patients with rare diseases.

The second resolution, Resolution 227-A-18, “An Optional National Prescription Drug Formulary,” was introduced by the Florida Delegation and asks that:

Our AMA: (1) develop a set of principles for a National Prescription Drug Formulary (NPD Formulary) that are designed to lower prescription drug prices to the patient, and be transparent, independent, non-profit, and fee-based, with a report back to the AMA HOD at the 2018 Interim Meeting; (2) produce model legislation for an NPD Formulary with input from appropriate stakeholders based on a set of principles for such a Formulary that the AMA will develop; and (3) that our AMA join with appropriate stakeholders to advocate that Congress authorize the establishment of this NPD Formulary that will be available to all Americans as an option to their healthcare insurance program in an actuarially appropriate manner.

The third resolution, Resolution 238-A-18, “Reform of Pharmaceutical Pricing: Negotiated Payment Schedules,” was introduced by the Illinois Delegation and asks that:

Our AMA: (1) support federal legislation that modifies the Hatch-Waxman Act and the Biologics Price Competition and Innovation Act (Biosimilars Act) to institute the replacement of time-specific patent protections with negotiated payment schedules and indefinite exclusivity for U.S. Food and Drug Administration-approved drugs in the Medicare Part D Program.

The reference committee heard varying testimony on Resolutions 217, 227, and 238. There was testimony providing strong support for the current strategic focus of AMA advocacy and initiatives to increase market competition as well as increased transparency of cost and price along the pharmaceutical supply chain. There was testimony in response to Resolution 217 noting that incentives are needed to support innovation in drug development for rare diseases and general support for the intent of the ODA, but there was concern that manufacturers are manipulating ODA exclusivities and may be driving higher drug costs to vulnerable patient populations. The reference committee heard testimony on Resolution 227 that a new national not-for-profit pharmaceutical benefit manager (which is referred to in the resolution as a national formulary) would not necessarily promote innovation and competition and could substantially limit patient access to medically necessary options. The reference committee heard testimony on Resolution 238 that it did not accurately identify the federal laws that would have to be amended in order to institute the replacement of time-specific patent protections with negotiated payment schedules and indefinite exclusivity for FDA-approved drugs in the Medicare Part D benefit prescription drug program. Testimony was offered noting it would require marked changes to the U.S. Patent Act, the U.S. Food, Drug, and Cosmetic Act (FDCA), and the Social Security Act (SSA). Furthermore, testimony was offered that such changes could limit patient access to clinically necessary alternative options and depress innovation while interjecting significant confusion and complexity in the patent system and the FDA regulatory regime. The reference committee found that all three resolutions are either a potentially complex solution to address the high cost of prescription drugs, or too narrowly crafted. Given these concerns, the reference committee recommended referral for a consolidated report.

AMA STRATEGIC FOCUS: INCREASING TRANSPARENCY AND COMPETITION

The varied contributing causes fueling the rise in prescription medication prices and the proliferation in barriers faced by patients who need medically necessary medication have resulted in the HOD adopting a wide-range of policies concerning prescription medication affordability and access. In order to prioritize impactful and viable policies that would enable the AMA to effectively advocate at the federal and state levels, Policy H-110.987, “Pharmaceutical Costs,” adopted in 2015 directed the AMA to 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. Accordingly, the AMA convened a Task Force on Pharmaceutical Costs, which met four times in the first six months of 2016 to develop principles to guide advocacy and grassroots efforts aimed at addressing pharmaceutical costs. The Task Force agreed that increasing transparency among pharmaceutical companies, health plans, and pharmacy benefit managers (PBMs) should be the initial focus of the campaign, which led to the launch of a grassroots campaign in the third quarter of 2016, and the launch of the TruthinRx website, TruthinRx.org, on November 1, 2016. The foregoing was done in concert with the AMA’s long-standing advocacy to increase competition. Based on the foregoing the AMA has vigorously supported the focus of policymakers at the federal and

state levels to address pharmaceutical supply chain transparency and accelerated and expanded legislative and regulatory action to increase pharmaceutical market competition by, among other things, combating anti-competitive practices.

Increase Pharmaceutical Market Competition and Combat Anticompetitive Practices

Policymakers have increased scrutiny of laws enacted to ensure drug safety and efficacy and to promote innovation that have been manipulated by pharmaceutical manufacturers to delay or block competition. Building off policy raising concerns with anti-competitive practices, the AMA has focused on increasing the authorities and resources of the Federal Trade Commission (FTC) to combat anti-competitive actions of manufacturers as well as changes to the FDA's oversight of the FDCA provisions that have been misused by manufacturers to delay the entry of more affordable generics as outlined below. In addition, the AMA has urged changes to the U.S. Patent Act that are inviting misuse for anti-competitive reasons by manufacturers.

Consistent with long-standing advocacy, the AMA continues to support the FTC's actions to stop pay-for-delay settlements, whereby a brand-name pharmaceutical manufacturer pays a potential generic competitor to abandon its challenge and delay offering a generic drug product for a number of years, for anti-competitive purposes. The AMA is also urging the FTC and Congress to evaluate certain uses of U.S. Patent Act and market exclusivities conferred under the FDCA by pharmaceutical companies that appear primarily designed to increase litigation costs for generic manufacturers and delay market competition. The AMA is also urging more rigorous FTC evaluation of mergers and consolidations among pharmaceutical companies and their impact on competition as well as consumer access by, among other things, expanding clinical expertise within the FTC and consulting with the relevant national medical specialty societies. The AMA is also expressing strong support of enforcement action referrals by the FTC against manufacturers that engage in anticompetitive actions to the U.S. Department of Justice.

In addition, the AMA continues to support measures to address the misuse of FDCA provisions for anti-competitive purposes. The AMA continues to urge Congress and federal agencies to take action to: (1) end the ability of generic manufacturers to indefinitely "park" the 180-day exclusivity period authorized by the FDCA by delaying final approval of their application by the FDA as part of a settlement agreement with a brand manufacturer; (2) further expand the ability of the FDA to address anticompetitive abuse of risk evaluation and mitigation strategies by brand manufacturers—particularly voluntary elements to assure safe use that involve proprietary measures that pose barriers to use by generic competitors; (3) make necessary amendments to the U.S. Patent Act and the FDCA to prevent the inappropriate extension of the exclusivity and patent life of pharmaceuticals. The AMA also strongly supports passage of legislation to increase competition and thus access to some of the most-costly prescription medications: biologicals. The AMA supported the original legislation establishing the follow-on biological pathway and it is now evident that there is a need to shorten the exclusivity period for biological products in order to spur competition which will not decrease the impetus to innovate.

Require Pharmaceutical Supply Chain Transparency

The second component of AMA advocacy has been to encourage transparency throughout the pharmaceutical supply chain. The ability of patients and physicians to have the information they need to make key decisions regarding medication, and of policymakers to craft viable solutions to high and escalating pharmaceutical costs, has been hampered by the often byzantine and confidential arrangements that are driving increased medication prices without a clear and justifiable reason. The practices and policies of pharmaceutical manufacturers, pharmacy benefit managers (PBMs), and health insurers warrant steps by Congress to interject much needed transparency. To that end the AMA strongly supports: (1) requiring pharmaceutical manufacturers to provide public notice before increasing the price of any drug by 10 percent or more each year or per course of treatment and provide justification for the price increase; (2) requiring pharmaceutical manufacturers to publicly disclose a variety of information, which could include research and development costs, expenditures on clinical trials, total costs incurred in production, and marketing and advertising costs; (3) requiring PBMs to apply manufacturer rebates and pharmacy price concessions to drug prices at the point-of-sale to ensure that patients benefit from discounts as well as eliminate some incentives for higher drug list prices; (4) requiring insurers to provide increased transparency in formularies, prescription drug cost-sharing, and utilization management requirements for patients and physicians at the point-of-prescribing as well as when beneficiaries make annual enrollment elections; and (5) prohibiting removal of drugs from a formulary or moving to a higher cost tier during the duration of the patient's plan year unless a change is made for safety reasons.

AMA POLICY

The AMA has extensive policy relevant to the issues raised in all three resolutions. In general, the AMA opposes the use of price controls in any segment of the health care industry, and continues to promote market-based strategies to achieve access to and affordability of health care goods and services (Policy H-155.962, “Maximum Allowable Cost of Prescription Medications”).¹ The AMA has adopted comprehensive policy to address anti-competitive measures by manufacturers and to promote increased cost and price transparency (Policy H-110.987, “Pharmaceutical Costs”). AMA policy provides support for action by federal agencies to address manufacturer price gouging. AMA policy also outlines support for the FTC in its efforts to stop “pay for delay” arrangements by pharmaceutical companies and federal legislation to expand the FTC’s existing authorities to stop such arrangements (Policy H-110.989, “Pay for Delay Arrangement by Pharmaceutical Companies”). The AMA also supports FDA implementation of the biosimilar pathway established under the Biologics Price Competition and Innovation Act of 2009 in order to ensure patient access, protect patient safety, and preserve market competition and innovation (Policy H-125.980, “Abbreviated Pathway for Biosimilar Approval”).

In support of driving increased competition, AMA policy provides for ongoing evaluation of strategies by manufacturers to extend the patent life of pharmaceuticals, and to work with Congress and the Administration where such actions are pursued for anti-competitive purposes (Policy D-110.994, “Inappropriate Extension of Patent Life of Pharmaceuticals”). The AMA also continues to advocate that the FDA and Congress ascertain the pervasiveness of brand manufacturers forcing switching from an established drug formulation about to lose market exclusivity and patent protection to another formulation that retains such protections. This practice is called evergreening and AMA policy provides that a balance must be struck between incentivizing innovation (superior formulations) versus anti-competitive practices designed to slow generic competition (Policy H-125.978, “Patient Protection from Forced Switching of Patent-Protected Drugs”). AMA policy also provides that physicians who develop medical innovations may ethically patent their discoveries or products but should uphold the following guidelines: (a) Not use patents (or other means, such as trade secrets or confidentiality agreements) to limit the availability of medical innovations and patent protection should not hinder the goal of achieving better medical treatments and technologies; and (b) Not allow patents to languish and physicians who hold patents should negotiate and structure licensing agreements in such a way as to encourage the development of better medical technology (Policy H-110.988, “7.2.3 Patents & Dissemination of Research Products”).

The AMA supports collaboration with federal and state agencies, policymakers and key stakeholders (e.g., the FTC, FDA, and the Generic Pharmaceutical Association) to identify and promote adoption of policies to address the already high and escalating costs of generic prescription drugs (Policy H-110.988, “Controlling the Skyrocketing Costs of Generic Prescription Drugs”). The same policy provides that the AMA will also seek to advance with interested parties legislation to ensure fair and appropriate pricing of generic medications. The policy also provides that the AMA encourages the development of methods that increase choice and competition in the development and pricing of generic prescription drugs and the AMA supports measures that increase price transparency for generic prescription drugs.

The AMA has policy to support programs that are designed to contain the rising costs of prescription drugs, provided that physicians have significant input into the development and maintenance of such programs and such programs must encourage optimum prescribing practices and quality of care (Policy H-110.997, “Cost of Prescription Drugs”). Furthermore, under this AMA policy all patients must have access to all prescription drugs necessary to treat their illnesses and physicians must have the freedom to prescribe the most appropriate drug(s) and method of delivery for the individual patient; and the freedom to use either generic or brand name pharmaceuticals in prescribing drugs for their patients. In addition, AMA policy provides support for consumer choice of at least two options for their pharmaceutical benefits program. This must include a fee-for-service option where restrictions on patient access and physician autonomy to prescribe any FDA-approved medication are prohibited and reaffirms support for physicians to use either generic or brand name pharmaceuticals in prescribing drugs for their patients. Finally, the AMA policy provides support for a managed pharmaceutical benefit option with market-driven mechanisms to control costs, provided cost control strategies satisfy AMA policies and standards defined in AMA Policy H-125.991 (Policy H-100.964, “Drug Issues in Health System Reform”).

The AMA also has a growing body of policy concerning PBMs given growing concerns with their role on patient costs. Policy adopted last year provides that the AMA will gather more data on the erosion of physician-led medication therapy management in order to assess the impact PBM tactics may have on patients’ timely access to medications,

patient outcomes, and the physician-patient relationship (Policy D-120.933, “Pharmacy Benefit Managers Impact on Patients”). In addition, the same AMA policy provides for an examination of PBM-related clawbacks and direct and indirect remuneration (DIR) fees to better inform existing advocacy efforts. AMA policy further provides that physicians should report to the FDA MedWatch reporting program any instances of adverse consequences (including therapeutic failures and adverse drug reactions) that have resulted from the switching of therapeutic alternates precipitated by PBM actions (Policy H-125.986, “Pharmaceutical Benefits Management Companies”). The policy provides support for increased oversight by the FTC to assess the relationships between pharmaceutical manufacturers and PBMs, especially with regard to manufacturers’ influences on PBM drug formularies and drug product switching programs, and to take enforcement actions as appropriate where there are indicia of anti-trust and anti-competitive practices. Further, AMA policy provides that certain actions/activities by PBMs and others constitute the practice of medicine without a license and interfere with appropriate medical care to patients. The policy also outlines support for effort to ensure that reimbursement policies established by PBMs are based on medical need; these policies include, but are not limited to, prior authorization, formularies, and tiers for compounded medication.

DISCUSSION

The AMA is engaged in a comprehensive advocacy campaign at the state and federal level to advance legislation and agency action to increase patient access to affordable prescription medication by increasing market competition and increasing price and cost transparency along the pharmaceutical supply chain. Two of the resolutions and associated resolves would materially depart from this strategy and existing policy. The two resolutions are Resolution 227-A-18, which would involve a major initiative to advance the creation of a not-for-profit PBM fashioned as a national formulary, and Resolution 238-A-18, which would require substantial changes to the U.S. Patent Act, the FDCA (to alter FDA conferred market exclusivities) and the Social Security Act (to alter relevant Medicare Part D drug benefit provisions). In the case of Resolution 227-A-18, the lack of transparency among the existing commercial PBMs hampers any effort to assess the true value of PBMs in driving affordable pricing and there are widespread concerns, as demonstrated by AMA policies summarized above, that PBM practices have negatively impacted medical practice and patient access to the most appropriate treatment options.

Continued efforts to increase transparency are gaining support from the Trump Administration and Congress. Diverting current AMA efforts to shine a light on PBM practices in order to instead advocate for the creation of a not-for-profit version would be hindered by a lack of information on the measures and mechanisms used by PBMs. Similarly, adoption of Resolution 238-A-18 would represent support for government-imposed price controls in the Medicare program and involve massive disruptions to established patent law and alterations to FDCA conferred exclusivities without addressing drug prices in the commercial market as the resolve calls for government negotiated prices for Medicare Part D drugs, but makes no mention of the commercial market. It would be expected many brand manufacturers would increase prices in the commercial market to offset lower payments in the Medicare program. This would be successful as under this proposed policy, brand manufacturers would not have generic competition as they would receive “indefinite” FDCA exclusivities per the resolve. Perversely, if adopted as policy Resolution 238-A-18 would drive rapid escalation of drug prices in all commercial markets.

Finally, for the most part, AMA policy already addresses Resolution 217-A-18. There are legitimate concerns that the ODA exclusivities² have been misused by manufacturers.³ In November 2018, the Government Accountability Office (GAO) issued a report, [Orphan Drugs: FDA Could Improve Designation Review Consistency; Rare Disease Drug Development Challenges Continue](#). The GAO found that FDA reviewers evaluating a manufacturer’s application seeking orphan drug status were not consistently recording or evaluating the required background information needed to assess the appropriateness of the designation. For example, 48 of 148 cases reviewed by the GAO were missing information on the drug’s U.S. marketing history. The GAO concluded that the FDA could not be sure that reviewers are conducting complete evaluations that include all critical information needed for assessing its criteria. The FDA has indicated that steps will be taken to ensure such information is included and evaluated. While such steps are meaningful, reportedly, by 2024, orphan drugs are projected to capture a fifth of worldwide prescription drug sales (\$262 billion) and the compound annual growth rate is forecasted to grow by 11.3 percent, which is double the rate forecast for the non-orphan drug market. Thus, continued scrutiny is warranted of how ODA exclusivities are conferred and careful consideration to the impact on market competition will remain essential.

RECOMMENDATIONS

In light of these considerations, your Board of Trustees recommends that the following be adopted in lieu of Resolutions 217-A-18, 227-A-18, and 238-A-18, and the remainder of this report be filed.

1. That our AMA reaffirm Policy H-110.987, “Pharmaceutical Costs,” which outlines a series of measures to address anti-competitive actions by pharmaceutical manufacturers as well as policies to promote increased transparency along the pharmaceutical supply chain including among PBMs.
2. That our AMA support legislation to shorten the exclusivity period for FDA pharmaceutical products where manufacturers engage in anti-competitive behaviors or unwarranted price escalations.

NOTES

1. While the AMA has policy that provides support for federal legislation which would confer the Secretary of the Department of Health and Human Services (HHS) with the authority to negotiate contracts with manufacturers for covered Medicare Part D prescription drugs, and provides that the AMA will work toward eliminating Medicare prohibition on drug price negotiation (Policy D-330.954), the taskforce prioritized strategies to increase transparency and to combat the pervasive anti-competitive practices by pharmaceutical manufacturers that are blocking or delaying lower cost, affordable alternative options.
2. An orphan drug is a prescription medication that treats a rare condition or disease affecting fewer than 200,000 nationwide. The development of orphan drugs has been financially incentivized by the market exclusivities provided under FDCA as amended by the ODA as well as tax credits on research and development, grants for phase I and II clinical trials, and, in some cases, waiver of FDA user fees.
3. In 2017, it was reported that 70, out of 450, prescription medications with orphan drug status were first approved by the FDA for mass-market use. Early in 2017, Senators Orrin Hatch (R-UT), Charles Grassley (R-IA) and Tom Cotton (R-AR) requested that the U.S. Government Accountability Office (GAO) evaluate the performance of the FDA’s Office of Orphan Products Development (OOPD) and to identify “any regulatory or legislative changes may be needed in order to preserve the intent of this vital law.” Later in 2017, the new FDA Commissioner urged Congress to implement two new ODA requirements in order to curb abuses of the ODA. Tribble S.J., Lupkin S., Drugmakers Manipulate Orphan Drug Rule to Create Prized Monopolies, Kaiser Health New, January 17, 2017.

**15. PHYSICIAN BURNOUT AND WELLNESS CHALLENGES (RESOLUTION 601-I-17)
PHYSICIAN AND PHYSICIAN ASSISTANT SAFETY NET (RESOLUTION 604-I-17)
IDENTIFICATION AND REDUCTION OF PHYSICIAN DEMORALIZATION (RESOLUTION 605-I-17)**

Reference committee hearing: see report of Reference Committee G.

**HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS
IN LIEU OF RESOLUTIONS 601-I-17, 604-I-17 AND 605-I-17
REMAINDER OF REPORT FILED**

*See Policies H-95.955, H-170.986, H-295.858, H-405.957, H-405.961,
D-310.968 and D-405.990*

INTRODUCTION

At the 2017 Interim Meeting, three resolutions (601-I-17, “Physician Burnout and Wellness Challenges,” 604-I-17, “Physician and Physician Assistant Safety Net,” and 605-I-17, “Identification and Reduction of Physician Demoralization”) with shared components of a central issue were referred for report back together at the 2018 Annual Meeting and presented in BOT Report 31-A-18. Based on testimony in Reference Committee G asking for further clarifications, BOT 31-A-18 was referred back for a report at the 2019 Annual Meeting. This report addresses the overarching topic, each resolution as it relates to the issue, and the concerns raised at the 2018 Annual Meeting, and presents recommendations accordingly.

Resolution 601-I-17, “Physician Burnout and Wellness Challenges,” was introduced by the International Medical Graduates Section and the American Association of Physicians of Indian Origin. Resolution 601-I-17 asks the American Medical Association (AMA) to advocate for health care organizations to develop a wellness plan to prevent and combat physician burnout and improve physician wellness, and for state and county medical societies to implement wellness programs to prevent and combat physician burnout and improve physician wellness.

Resolution 604-I-17, “Physician and Physician Assistant Safety Net,” was introduced by the Oregon Delegation and asks the AMA to study a safety net, such as a national hotline, that all United States physicians and physician assistants can call when in a suicidal crisis. Such safety net services would be provided by doctorate level mental health clinicians experienced in treating physicians. Resolution 604-I-17 also directs the AMA to advocate that funding for such safety net programs be sought from such entities as foundations, hospital systems, medical clinics, and donations from physicians and physician assistants.

Resolution 605-I-17, “Identification and Reduction of Physician Demoralization,” was introduced by the Organized Medical Staff Section and asks that the AMA: (1) recognize that physician demoralization, defined as a consequence of externally imposed occupational stresses, including but not limited to electronic health record (EHR)-related and administrative burdens imposed by health systems or by regulatory agencies, is a problem among medical staffs; (2) advocate that hospitals be required by accrediting organizations to confidentially survey physicians to identify factors that may lead to physician demoralization; and (3) develop guidance to help hospitals and medical staffs implement organizational strategies that will help reduce the sources of physician demoralization and promote overall medical staff wellness.

BACKGROUND

Today’s physicians are experiencing burnout at increasing rates, expressing feelings of professional demoralization, and feeling professionally under-valued and overburdened by an ever-changing health care system.¹⁻³ Forty-four percent of practicing physicians report experiencing at least one symptom of burnout, compared to 54 percent in 2014 and 45 percent in 2011.⁴ Practicing physicians are not alone in reported symptoms of burnout; resident and medical student burnout is also on the rise. It is recognized that with growing numbers of physicians, residents and medical students experiencing burnout, health care quality will decline and patient safety will suffer.⁵ Physician suicide rates have been found to be historically higher than the general population.⁶ Stress, depression and burnout can lead to suicidal ideation and sometimes suicide. Resources such as safety nets and hotlines are available for individuals experiencing suicidal ideation and are available from a number of national and reputable sources.

AMA POLICY

The AMA recognizes the importance of addressing and supporting physician satisfaction as well as the impact physician burnout may have on patient safety, health outcomes and overall costs of health care. This commitment to physician satisfaction and well-being is evidenced by AMA’s ongoing development of targeted policies and tools to help physicians, residents and medical students, and its recognition of professional satisfaction and practice sustainability as one of its three strategic pillars.

The AMA supports programs to assist physicians in early identification and management of stress. The programs supported by the AMA concentrate on the physical, emotional and psychological aspects of responding to and handling stress in physicians’ professional and personal lives, as well as when to seek professional assistance for stress-related difficulties (Policy H-405.957, “Programs on Managing Physician Stress and Burnout”). AMA policy and the Code of Ethics acknowledge that when physician health or wellness is compromised, so may the safety and effectiveness of the medical care provided (Code of Ethics 9.3.1, “Physician Health & Wellness”). In recognizing the importance of access to health and wellness-focused resources, AMA policy encourages employers to provide, and employees to participate in, programs on health awareness, safety and the use of health care benefit packages (Policy H-170.986, “Health Information and Education”). The AMA affirms the importance of physician health and the need for ongoing education of all physicians and medical students regarding physician health and wellness (Policy H-405.961, “Physician Health Programs”).

Educating physicians about physician health programs is greatly important to the AMA. The AMA will continue to work closely with the Federation of State Physician Health Programs (FSPHP) to educate its members about the availability of services provided by state physician health programs to ensure physicians and medical students are fully knowledgeable about the purpose of physician health programs and the relationship that exists between the physician health program and the licensing authority in their state or territory. The AMA, in collaboration with the FSPHP, develops state legislative guidelines to address the design and implementation of physician health programs, as well as messaging for all Federation members to consider regarding elimination of stigmatization of mental illness and illness in general in physicians and physicians in training (Policy D-405.990, “Educating Physicians About

Physician Health Programs”). The AMA will continue to collaborate with other relevant organizations on activities that address physician health and wellness.

The AMA recognizes physical or mental health conditions that interfere with a physician’s ability to engage safely in professional activities can put patients at risk, compromise professional relationships and undermine trust in medicine. While protecting patients’ well-being must always be the primary consideration, physicians who are impaired are deserving of thoughtful, compassionate care (Code of Ethics 9.3.2, “Physician Responsibilities to Impaired Colleagues”). AMA policy defines physician impairment as any physical, mental or behavioral disorder that interferes with ability to engage safely in professional activities. In the same policy, the AMA encourages state medical society-sponsored physician health and assistance programs to take appropriate steps to address the entire range of impairment problems that affect physicians and to develop case finding mechanisms for all types of physicians (Policy H-95.955, “Physician Impairment”).

Access to confidential health services for medical students and physicians is encouraged by the AMA to provide or facilitate the immediate availability of urgent and emergent access to low-cost, confidential health care, including mental health and substance use disorder counseling services. The AMA will continue to urge state medical boards to refrain from asking applicants about past history of mental health or substance use disorder diagnosis or treatment, only focus on current impairment by mental illness or addiction, and to accept “safe haven” non-reporting for physicians seeking licensure or re-licensure who are undergoing treatment for mental health or addiction issues to help ensure confidentiality of such treatment for the individual physician while providing assurance of patient safety. The AMA encourages medical schools to create mental health and substance abuse awareness and suicide prevention screening programs that would: (a) be available to all medical students on an opt-out basis; (b) ensure anonymity, confidentiality, and protection from administrative action; (c) provide proactive intervention for identified at-risk students by mental health and addiction professionals; and (d) inform students and faculty about personal mental health, substance use and addiction, and other risk factors that may contribute to suicidal ideation. The AMA: (a) encourages state medical boards to consider physical and mental conditions similarly; (b) encourages state medical boards to recognize that the presence of a mental health condition does not necessarily equate with an impaired ability to practice medicine; and, (c) encourages state medical societies to advocate that state medical boards not sanction physicians based solely on the presence of a psychiatric disease, irrespective of treatment or behavior. The AMA: (a) encourages study of medical student mental health, including but not limited to rates and risk factors of depression and suicide; (b) encourages medical schools to confidentially gather and release information regarding reporting rates of depression/suicide on an opt-out basis from its students; and (c) will work with other interested parties to encourage research into identifying and addressing modifiable risk factors for burnout, depression and suicide across the continuum of medical education (Policy H-295.858, “Access to Confidential Health Services for Medical Students and Physicians”).

The AMA recognizes that burnout, defined as emotional exhaustion, depersonalization, and a reduced sense of personal accomplishment or effectiveness, is a problem not only with practicing physicians, but among residents, fellows, and medical students. The AMA will work with other interested groups to regularly inform the appropriate designated institutional officials, program directors, resident physicians, and attending faculty about resident, fellow, and medical student burnout (including recognition, treatment and prevention of burnout) through appropriate media outlets. In addition, the AMA will encourage the Accreditation Council for Graduate Medical Education and the Association of American Medical Colleges to address the recognition, treatment, and prevention of burnout among residents, fellows, and medical students. The AMA will encourage further studies and disseminate the results of studies on physician and medical student burnout to the medical education and physician community. Finally, the AMA will continue to monitor this issue and track its progress, including publication of peer-reviewed research and changes in accreditation requirements (Policy D-310.968, “Physician and Medical Student Burnout”).

DISCUSSION

The AMA is committed to upholding the tenets of the Quadruple Aim: Better Patient Experience, Better Population Health, Lower Overall Costs of Health Care, and Improved Professional Satisfaction.⁷ This is evidenced by AMA policy supporting the Triple Aim and requesting that it be expanded to the Quadruple Aim, adding the goal of improving the work-life balance of physicians and other health care providers (Policy H-405.955, “Support for the Quadruple Aim”). In order to achieve the fourth aim, the AMA acknowledges that interventions at both system and individual levels are necessary for enhancing physician satisfaction and reducing burnout.

The AMA partnered with the RAND Corporation in 2013 to identify and study the factors that influence physician professional satisfaction, as well as understand the implications of these factors for patient care, health systems, and health policy.⁸ This seminal work informed subsequent initiatives and a long-term strategy for AMA's Professional Satisfaction and Practice Sustainability (PS2) unit. This dedicated AMA unit is focused on institutional and system-level solutions that aim to resolve root causes of burnout and demoralization, rather than solely focusing on improving individual resilience to alleviate symptoms experienced by dealing with a dysfunctional health system.

Through the PS2 unit, the AMA supports and carries out research efforts aimed at understanding and identifying solutions to the system-level issues that lead to physician demoralization and burnout. In 2017 and 2018 the AMA partnered with leading academic institutions to conduct follow-up research to its 2011 and 2014 national studies on physician burnout and satisfaction, seeking to learn if the rates of burnout have changed over the past 7 years.⁹ The AMA has studied how physicians spend their time to quantify the administrative burdens during and after a physicians' workday.¹⁰ The AMA has also completed significant research on the burdens of EHRs, including the time to complete tasks, the usability of products, and the process of EHR development.^{11, 12} Furthermore, the AMA has researched the impacts of physician burnout, including the effects on a physician's innate sense of calling¹³ and implications for the physician workforce.¹⁴ All of this research has been published in leading peer-reviewed journals to build the evidence base for the factors that cause physician dissatisfaction and burnout and their impacts. This body of knowledge has been a powerful tool for advocating to legislators, regulators, and industry executives to make improvements to address the issues that cause physician dissatisfaction.

The AMA continues to convene members of the research community at the bi-annual American Conference on Physician Health and International Conference on Physician Health. To provide hands-on, real-world demonstration of practice-level solutions, the AMA hosts boot camps that help physicians learn how to plan and implement effective strategies to improve their practice to reduce the amount of time they spend on administrative and clerical work, ultimately improving physician satisfaction and reducing reports of burnout.

A number of key accomplishments and offerings have been realized through AMA's launch of the free, online STEPS Forward™ practice transformation platform. This online resource offers over 50 modules of content developed by subject matter experts and is specifically designed for physicians, practices, and health systems. The STEPS Forward platform has been openly shared with leadership of many state and specialty societies, as well as presented to their memberships in various forums. In addition, the AMA has partnered with health systems, large practices, state medical societies, state hospital associations and graduate medical education programs to deploy and assess physician burnout utilizing the Mini-Z Burnout Assessment. The assessment offers organizations a validated instrument that provides an organizational score for burnout, along with two subscale measures for "Supportive Work Environment" and "Work Pace and EMR Frustration." In addition to the organizational dashboard, the assessment is able to provide a comprehensive data analysis complete with medical specialty and clinic level benchmarking. The trends and findings from the assessment are shared and targeted interventions are recommended to the surveying organization. The interventions and suggested solutions are curated from existing STEPS Forward content and through specific best practices identified through AMA collaborators.

The AMA is also developing the AMA Practice Transformation Initiative: Solutions to Increase Joy in Medicine. This initiative will support research to advance evidence-based solutions and engage health care leaders to improve joy in medicine through the use of validated assessment tools, a centralized, integrated data lab, grant-funded practice science research, and field-tested information dissemination and implementation support. It will build the evidence base for private and public investment in clinician well-being as a means of achieving the Quadruple Aim. The focus of the AMA Practice Transformation Initiative is distinct from and complementary to other national initiatives addressing clinician well-being. For example, the work of the National Academy of Medicine's Action Collaborative on Clinician Well-Being and Resilience is focused on building awareness. This AMA initiative will move beyond awareness to filling the knowledge gaps that exist regarding effective systemic interventions to reduce burnout. In a similar manner, the 1999 Institute of Medicine (now renamed the National Academy of Medicine) report "To Err is Human" raised awareness of patient safety issues. It was then up to other organizations to build further evidence and disseminate effective interventions. In this vein, the AMA Practice Transformation Initiative will be positioned to lead the medical community in building momentum and disseminating evidence-based solutions to reduce burnout and improve satisfaction. This effort is currently in the pilot phase with broader expansion planned for mid- to late-2019.

Resolution 601-I-17 asks the AMA to advocate for health care organizations to develop a wellness plan to prevent and combat physician burnout and improve physician wellness, and for state and county medical societies to implement

wellness programs to prevent and combat physician burnout and improve physician wellness. In addition to HOD policy that affirms the importance of physician health and education about wellness, the AMA has been actively and directly engaged with health care organizations, including state and county medical societies, to build awareness and support for addressing physician burnout. The Physicians Foundation funded an effort to develop a manual on how to create a Physician Wellness Program (PWP) for medical societies called LifeBridge. In addition to a toolkit, the manual includes research and background supporting the need for such a program. Having medical societies provide local, onsite counseling is the cornerstone of the program, in addition to including other aspects of physician wellness resources such as professional coaching, educational topics, resource centers, and ways to address health system barriers and advocate for employer change. With this resource, numerous state and county medical societies are developing and launching physician wellness programs with in-person support. Hundreds of physicians have accessed these resources to date.

The mission of the Federation of State Physician Health Programs (FSPHP) is to support physician health programs in improving the health of medical professionals, thereby contributing to quality patient care. One of FSPHP's top priorities is the development of a Performance Enhancement and Effectiveness Review program called PEER™. The goal of PEER is to empower physician health programs (PHPs) to optimize effectiveness. At the same time, they are developing a Provider Accreditation program that will accredit specialized treatment centers and other providers in the care of physicians and other safety-sensitive professionals. These programs will ensure quality care and ensure PHPs select providers that have proven compliance with objective standards. The AMA has provided grant funding toward this new effort and has provided a designee to serve on FSPHP's Accreditation Review Council (ARC) that will oversee the strategy and policies of the developing PEER program.

Concerns have been raised that physicians who access wellness programs may be stigmatized if they report feelings of demoralization or burnout. This could subject a physician to loss of employment or to state medical licensing board actions, including loss of license. It is imperative that strategies be developed by state medical associations to encourage physicians to participate in health programs without fear of loss of license or employment. Assuring that de-stigmatization of physician burnout is addressed at the local, state and national levels is an important first step in ensuring those who need support can receive it without fear of adverse consequences.

Resolution 604-I-17 asks the AMA to study a safety net, such as a national hotline, that all United States physicians and physician assistants can call when in a suicidal crisis. Testimony heard in the reference committee hearing further clarified the request for a task force to research, collect, publish and administer a repository of information about programs and strategies that optimize physician wellness. The AMA, through its ongoing work in the Professional Satisfaction and Practice Sustainability (PS2) strategy unit, acknowledges the importance of addressing and supporting physician mental health and has developed and published numerous resources to help physicians manage stress and prevent and reduce burnout. Since its inception in 2011, the activities have been aided by a PS2 Advisory Committee composed of a diverse membership representing the AMA physician membership as well as the business of medicine. Meeting quarterly, the PS2 Advisory Committee provides strategic insight and direct feedback to the PS2 staff on activities ranging from practice transformation and burnout to digital health, payment and quality. The composition of the PS2 Advisory Committee ensures the committee provides content expertise in the subject matter areas on which the PS2 group focuses.

While an online search indicates there is no current, easily identifiable suicide prevention line exclusively for physicians or health care workers, there are many national, state and locally operated hotlines available that are open to all individuals regardless of profession. A list of many of these resources is available in the STEPS Forward module "Preventing Physician Distress and Suicide." The AMA is evaluating Employee Assistance Program (EAP) service providers to explore the option of piloting a service to AMA members as a membership benefit. Some EAP services provide participants with 24/7 telephone or video access to qualified and trained counselors, wellness services, and critical incident support. This evaluation is in early stages and a decision to pursue various options will be considered. In addition, the AMA will continue to update the list of available suicide prevention resources in its related STEPS Forward module.

The AMA is also developing a dynamic education module that will help physicians, physicians in training, and medical students learn about the risks of suicide for physicians, identify characteristics to look for in patients who may be at risk of harming themselves, and recognize the warning signs of potential suicide risk in colleagues. The module, to be offered with continuing medical education credit on the AMA's Education Center, will also provide tools and resources to guide learners in supporting patients and colleagues at risk for suicide.

In addition, the AMA regularly reviews and updates relevant modules of the STEPS Forward program and identifies validated student-focused, high-quality resources for professional well-being, and will encourage the Medical Student Section and Academic Physicians Section to promote these resources to medical students. In addition to the “Preventing Physician Distress and Suicide” module, the STEPS Forward platform provides other relevant modules to address physician well-being, specifically “Improving Physician Resiliency” and “Physician Wellness: Preventing Resident and Fellow Burnout.” In conjunction with STEPS Forward modules, the Mini-Z Burnout Assessments provide organizations the option to embed the PHQ-2 Depression Screening Tool. This allows organizations to gain a deeper understanding of those physicians experiencing more severe levels of depression and disinterest and correlate those responses to burnout. The survey also offers a free text section for physicians in need of services to self-identify and receive direct outreach and support. Additionally, the Mini-Z tool provides information on the National Suicide Prevention Lifeline for organizations to utilize in their physician wellness and burnout efforts.

Current efforts and strategic priorities demonstrate that the AMA recognizes the importance of assessment and attention to depression in physicians, residents and medical students, as well as the relationship that depression can have with suicidal ideation. Current AMA research and strategic initiatives are focused on enhancing workflows within the system and clinical setting with the intent to increase efficiency and reduce feelings of burnout among physicians. The AMA’s role in sharing burnout and depression screening data is to assist physician employers in understanding individual physician burnout and connecting physicians with employee assistance resources. Considering the AMA’s current efforts and ongoing commitment to providing resources on the topics of burnout, distress and suicide prevention, stress reduction, and wellness, convening an exclusive task force separate from the AMA staff already dedicated to this work would be duplicative. Making existing relevant AMA resources available to physicians seeking help can be accomplished and is part of current AMA practices. The AMA will continue to direct physicians to its current resources and those that are being developed by state and county medical associations to learn about strategies, programs and tools related to this topic, and will further explore options for providing more direct assistance for physicians in need.

Feedback from the reference committee at A-18 expressed concern about the earlier report’s lack of proposals for prevention and treatment programs to address physician burnout. By its current policies, through the work of AMA business units, and in the Code of Medical Ethics, the AMA recognizes the importance of programs that prevent and treat stress, depression and other conditions that can lead to burnout. We also realize that the AMA is not a direct provider of health care services; however, the AMA supports and will continue to encourage the development of and participation in programs to assist physicians in early identification and management of stress, burnout and demoralization.

Resolution 605-I-17 asks the AMA to (1) recognize that physician demoralization is a problem among medical staffs; (2) advocate that hospitals be required by accrediting organizations to confidentially survey physicians to identify factors that may lead to physician demoralization; and (3) develop guidance to help hospitals and medical staffs implement organizational strategies that will help reduce the sources of physician demoralization and promote overall medical staff wellness. Testimony in the reference committee hearing recognized that “burnout” is a commonly used term favored by many physicians, and while there is some preference for the use of another term instead of “burnout,” there was no consensus on what that term should be. The AMA recognizes that burnout is characterized by emotional exhaustion, depersonalization, and a reduced sense of personal accomplishment or effectiveness. These feelings can result from a multitude of driving factors, such as administrative burden, excessive EHR documentation and systemic cultural deficiencies. The term “burnout” is often used to encompass the multiple driving factors of physician dissatisfaction as well as the resultant feelings and behaviors associated with being overworked, excessively scrutinized and overburdened with unnecessary tasks. As the term “burnout” is used broadly, this allows for many variations in the interpretation of its meaning. The AMA does not define the term “burnout” as an individual “resilience deficiency” or character flaw. The AMA supports and voices a position that burnout is derived from system and environmental issues, not from the individual physician. In other words, physician burnout is a symptom of system dysfunction. This position is evidenced by AMA resources and services targeted at system-level approaches to intervention.

The AMA has numerous efforts underway to address the system-driven sources of physician demoralization and burnout, such as the increasing volume of administrative requirements like quality reporting and prior authorization, the lack of transparency and interoperability with EHRs, and the complex and ever-changing payment environment. The AMA, as part of its prior authorization reform initiatives, convened a workgroup of 17 state and specialty medical societies, national provider associations and patient representatives to develop a set of Prior Authorization Principles.

The AMA has used these principles to spur conversations with health plans about “right-sizing” prior authorization programs. One outcome of these discussions was the January 2018 release of the Consensus Statement on Improving the Prior Authorization Process by the AMA, American Hospital Association, America’s Health Insurance Plans, American Pharmacists Association, Blue Cross Blue Shield Association, and Medical Group Management Association. The consensus document reflects an agreement between national associations representing both providers and health plans on the need to reform prior authorization programs in multiple ways, including advancing automation to improve transparency and efficiency. The AMA, in addition to providing an evidence-base demonstrating the need for prior authorization reform, offers multiple resources to help physicians understand prior authorization laws and improve processes within the practice.

It is well-documented that the use of EHRs is a source of dissatisfaction for physicians. The AMA’s research includes multiple time-motion studies to determine how much and in what ways physicians spend time completing tasks in their EHRs. This research demonstrates evidence highlighting the need for system-level changes in the demands placed on the EHR as a tool for reporting and patient care. The AMA has also published eight EHR usability priorities, which outline and support the need for better usability, interoperability, and access to data for both physicians and patients. If followed, these priorities will enable the development of higher-functioning, more efficient EHRs, contributing to a reduction in the burden that EHR use places on patient care. Multiple collaborations are in place to help foster better EHR design and innovative HIT solutions to help make the EHR user experience better and more efficient. The AMA has established partnerships with the SMART Initiative, AmericanEHR Partners and Medstar Health’s National Center for Human Factors in Healthcare to help foster innovative HIT design and transparent testing solutions which will ensure EHRs are designed and implemented with physicians and patients in mind. In addition, the AMA actively participates in The Sequoia Project, Carequality, and the CARIN Alliance, all aimed at enhancing interoperability in health care. The AMA is also working to address specific cost drivers, such as connecting to clinical data registries and prohibitive fees that amount to data blocking. The AMA’s Physician Innovation Network is connecting physicians and health care technology entrepreneurs to ensure that the physician voice is integrated into health care technology solutions coming to market. Finally, the AMA is working with other high-profile stakeholders, including five EHR vendors, to develop a Voluntary EHR Certification framework which will help catalyze an industry wide shift to higher-quality EHR systems that enable better, more efficient use.

Another source of discontent for physicians are the myriad changes in payment models and quality reporting requirements facing practices. The AMA recently published a follow-up study to its 2014-2015 RAND research on the effects of payment models on physician practices in the U.S. The findings of the 2017-2018 study help the AMA, other industry stakeholders, and policymakers understand that the challenges experienced in practice due system complexity continue, and much improvement is still needed. To help physicians and practices navigate these challenges, particularly those spurred by the MACRA Quality Payment Program, the AMA offers a variety of educational resources and practical tools, including step-by-step tutorials on QPP reporting, a MIPS Action Plan, and several others. Additional resources are in development to help physicians navigate the changing payment system that is increasingly putting an emphasis on cost and quality measurement.

Physicians who work irregular or long hours, or physicians in certain specialties, may experience a lack of work-life balance, which can further exacerbate burnout and professional dissatisfaction.¹⁵ Forty percent of physicians report not feeling that their work schedule leaves enough time for personal and/or family life.⁹ Furthermore, female physicians are more likely to be dissatisfied with work-life balance.¹⁵ To help physicians improve work-life balance, the AMA Women Physicians Section is working together with the American Academy of Pediatrics to explore the workforce issues and help physicians find practice options that work best for them and their families. For example, a physician may consider reducing work hours to accommodate their schedule. The AMA provides a self-assessment tool that helps physicians explore work/practice options and address career goals. The AMA hosts a series of educational resources that offer strategies on how to increase practice efficiency, understand physician burnout and how to address it, as well as develop a culture that supports physician well-being. Examples of education include online CME modules: “Creating the Organizational Foundation for Joy in Medicine™: Organizational changes lead to physician satisfaction,” “Creating Strong Team Culture: Evaluate and improve team culture in your practice,” “Physician Wellness: Preventing Resident and Fellow Burnout,” “Preventing Physician Burnout: Improve patient satisfaction, quality outcomes and provider recruitment and retention,” and “Improving Physician Resiliency: Foster self-care and protect against burnout.”

In addition, the AMA will continue to advocate for organizations to confidentially survey physicians to understand local levels of burnout and opportunities for strategic improvement. It should be noted that the AMA’s Mini-Z Burnout

Assessment is deployed confidentially and takes protective safeguards very seriously to ensure accurate and safe reporting of results. To date, numerous health systems, physician practices, and residency programs have completed AMA's burnout measurement program. This program will continue to be marketed and scaled to expand the use of measuring physician dissatisfaction and burnout. Through leveraging ongoing AMA media channels, hosting educational webinars, live speaking engagements, and the Transforming Clinical Practices Initiative (TCPI) grant through the Centers for Medicare and Medicaid Services (CMS), the AMA is striving to scale awareness and intervention to advance physician satisfaction and help address the burnout epidemic.

CONCLUSION

The AMA is committed to addressing the issue of burnout and enhancing joy in practice for physicians, residents and medical students. The AMA will continue its focus on research, advocacy and activation to address the issues presented in each of the resolutions discussed herein. The AMA will continue to work diligently to address the issues through its existing work, partnerships, resource development and policies. We present the following recommendation to not only emphasize the work already being done, but also to further address the issues brought forth in these three resolutions.

RECOMMENDATIONS

The AMA Board of Trustees recommends that the following recommendations be adopted in lieu of Resolutions 601-I-17, 604-I-17 and 605-I-17, and that the remainder of the report be filed:

1. That our American Medical Association reaffirm the following policies:
 1. H-170.986, "Health Information and Education"
 2. H-405.957, "Programs on Managing Physician Stress and Burnout;"
 3. H-405.961, "Physician Health Programs;"
 4. D-405.990, "Educating Physicians About Physician Health Programs;"
 5. H-95.955, "Physician Impairment;" and
 6. H-295.858, "Access to Confidential Health Services for Medical Students and Physicians."
2. That our American Medical Association amend existing Policy H-405.961, "Physician Health Programs," to add the following directive:
 1. Our AMA affirms the importance of physician health and the need for ongoing education of all physicians and medical students regarding physician health and wellness.
 2. Our AMA encourages state medical societies to collaborate with the state medical boards to a) develop strategies to destigmatize physician burnout, and b) encourage physicians to participate in the state's physician health program without fear of loss of license or employment.
3. That our AMA amend existing Policy D-310.968, "Physician and Medical Student Burnout," to add the following directives:
 1. Our AMA recognizes that burnout, defined as emotional exhaustion, depersonalization, and a reduced sense of personal accomplishment or effectiveness, is a problem among residents, fellows, and medical students.
 2. Our AMA will work with other interested groups to regularly inform the appropriate designated institutional officials, program directors, resident physicians, and attending faculty about resident, fellow, and medical student burnout (including recognition, treatment, and prevention of burnout) through appropriate media outlets.
 3. Our AMA will encourage partnerships and collaborations with accrediting bodies (e.g., the Accreditation Council for Graduate Medical Education and the Liaison Committee on Medical Education) and other major medical organizations to address the recognition, treatment, and prevention of burnout among residents, fellows, and medical students and faculty.
 4. Our AMA will encourage further studies and disseminate the results of studies on physician and medical student burnout to the medical education and physician community.

5. Our AMA will continue to monitor this issue and track its progress, including publication of peer-reviewed research and changes in accreditation requirements.
6. Our AMA encourages the utilization of mindfulness education as an effective intervention to address the problem of medical student and physician burnout.
7. Our AMA will encourage medical staffs and/or organizational leadership to anonymously survey physicians to identify local factors that may lead to physician demoralization.
8. Our AMA will continue to offer burnout assessment resources and develop guidance to help organizations and medical staffs implement organizational strategies that will help reduce the sources of physician demoralization and promote overall medical staff well-being.
9. Our AMA will continue to (1) address the institutional causes of physician demoralization and burnout, such as the burden of documentation requirements, inefficient work flows and regulatory oversight; and (2) develop and promote mechanisms by which physicians in all practices settings can reduce the risk and effects of demoralization and burnout, including implementing targeted practice transformation interventions, validated assessment tools and promoting a culture of well-being.

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**16. DEVELOPING SUSTAINABLE SOLUTIONS TO DISCHARGE
OF CHRONICALLY-HOMELESS PATIENTS
(RESOLUTION 826-I-18)**

Reference committee hearing: see report of Reference Committee D.

**HOUSE ACTION: RECOMMENDATIONS ADOPTED
IN LIEU OF RESOLUTION 826-I-18
REMAINDER OF REPORT FILED**

See Policies H-130.940, H-160.903, H-160.942, H-160.978 and H-270.962

At the 2018 Interim Meeting, the House of Delegates referred Resolution 826, Developing Sustainable Solutions to Discharge of Chronically-Homeless Patients, which was introduced by the Resident and Fellow Section. Resolution 826 asked that our AMA “work with relevant stakeholders in developing sustainable plans for the appropriate discharge of chronically-homeless patients from hospitals.” The resolution further asked that our AMA reaffirm Policy H-270.962, Unfunded Mandates, and Policy H-130.940, Emergency Department Boarding and Crowding.

This report (1) explores how homelessness contributes to emergency department (ED) overuse and hospitalization, (2) outlines current regulatory requirements related to homelessness and discharge planning, and (3) describes the need for broader efforts to address the unique healthcare and social needs of homeless patients.

BACKGROUND

Homeless individuals are more likely than the general population to experience behavioral health disorders, acute and chronic conditions, and injuries resulting from assaults and accidents. This increased prevalence, in concert with lack of insurance or access to a usual source of medical care, leads homeless individuals to seek care at EDs at a high rate and increases their rates of hospitalization. Indeed, as many as two-thirds of homeless individuals visit an ED each year, as compared to just one-fifth of the general population, and the hospitalization rate for homeless individuals is as much as four times higher than that for non-homeless individuals.¹⁻⁶

Not only are homeless patients more likely to visit an ED, but they are also more likely to re-visit an ED. Indeed, an analysis of national ED utilization rates found that homeless patients were more than three times as likely as non-homeless patients to have been evaluated in the same ED within the previous three days, and were more than twice as likely to visit an ED within a week of discharge from the hospital.⁷

ED utilization is not uniform across the homeless population, with one study representative of the literature on the topic finding that a small proportion of frequent users (7.9%) account for an outsized proportion of total use (54.5%).⁵ Anecdotal accounts, which are not uncommon, cite cases of individual homeless patients with more than 100 ED visits in a year and total costs topping \$1 million.^{8,9}

DISCUSSION

Discharge planning and ED overuse

As suggested by Resolution 826-I-18, hospital and ED discharge planning plays a key role in ending the revolving door of ED visits, hospitalizations, and readmissions, especially among homeless frequent users. Specifically, evidence shows that well-coordinated case management (the development and initiation of which is a key outcome of discharge planning) may reduce ED use and costs, and improve both clinical and social outcomes for homeless patients.¹⁰⁻¹² Despite these findings, discharge planning for homeless patients remains rare: one analysis found that 64% of ED visits resulted in homeless patients being discharged back to the street, with only 4% having a discharge plan addressing their housing status.¹³

Current approaches to discharge planning also overlook important opportunities to improve the health of homeless patients in areas unrelated to their ED visits. For example, given that the CDC Advisory Committee on Immunization Practices now recognizes “homelessness” as an indication for hepatitis A vaccination,¹⁴ patient encounters in the ED present an excellent opportunity to assess immunization status and need for vaccination, and to administer vaccines

or refer patients for vaccination.¹⁵ As an added bonus, this holistic approach ensures that homeless patients are immunized, which helps keep them well and out of the ED.

Hospital requirements for discharge planning

Recognizing the value of discharge planning in preventing hospital readmissions, the Centers for Medicare and Medicaid Services (CMS) Conditions of Participation (CoPs) include comprehensive discharge planning requirements for hospitals participating in the Medicare or Medicaid programs. These requirements include:

- (1) Identifying inpatients for whom discharge planning is necessary;²
- (2) Providing a discharge plan evaluation to each identified patient, which “must include an evaluation of the likelihood of a patient’s capacity for selfcare or of the possibility of the patient being cared for in the environment from which he or she entered the hospital;”
- (3) Developing and “[arranging] for the initial implementation of the patient’s discharge plan;”
- (4) Transferring or referring the patient, “along with necessary medical information, to appropriate facilities, agencies, or outpatient services, as needed, for follow-up or ancillary care;” and
- (5) Reassessing the discharge planning process “on an on-going basis;” which must include “a review of discharge plans to ensure that they are responsive to discharge needs.”¹⁶

The CoPs do not require discharge planning for ED visits without hospital admission, which are categorized as outpatient visits. However, in recent revisions to its interpretive guidelines for discharge planning, CMS observes that “many of the same concerns for effective posthospital care coordination arise [for outpatients] as for inpatients” and therefore recommends that “hospitals might consider utilizing, on a voluntary basis, an abbreviated post-hospital planning process for certain categories of outpatients...and for certain categories of emergency department discharges.”¹⁷

At the state level, in 2018 California adopted regulations requiring more stringent discharge planning requirements and services for homeless patients. Set to take effect July 1, 2019, these new regulations require California hospitals to “include a written homeless patient discharge planning policy and process within the hospital discharge policy.”¹⁸ The law further requires hospitals to perform a variety of specific tasks and in a specific manner, including but not limited to:

- logging all discharges of homeless patients;
- providing a meal, clothing, medication, and transportation upon discharge;
- coordinating with social service agencies; and
- discharging homeless patients only during the daytime.^{19,20}

The California law was met with concern by many in the healthcare community, including the California chapter of the American College of Emergency Physicians and the California Hospital Association.^{20,21} While recognizing the importance of and supporting appropriate discharge planning and protocols, critics questioned the feasibility of many aspects of the law—for example, how exactly would a hospital go about maintaining a supply of clothing for homeless patients? They also pointed to severe unintended consequences of the law—for example, that prohibiting overnight discharges would further exacerbate ED overcrowding and constrain hospitals’ capacity to provide timely, lifesaving care to those patients who need it most. And, at the broadest level, they questioned why the societal costs of homelessness should be borne by hospitals, especially safety net hospitals that treat a disproportionately large share of homeless patients and are least able to comply with unfunded mandates.

² Note that “in the absence of a finding by the hospital that a patient needs a discharge plan, the patient’s physician may request a discharge plan...[and] the hospital must develop a discharge plan for the patient.”

Moving beyond discharge planning

Effective ED and hospital discharge planning constitutes just one component of what ought to be a more comprehensive approach to addressing the unique healthcare needs of homeless patients—one which, as stated by CMS in its interpretive guidelines for discharge planning, “moves away from a focus primarily on a patient’s hospital stay to consideration of transitions among the multiple types of patient care settings that may be involved at various points in the treatment of a given patient.”¹⁷

Central to these more comprehensive efforts is housing security, an area in which, in the absence of comprehensive state and local homelessness strategies, hospitals and health systems have been obligated to take action in recent years. In 2017, for example, the American Hospital Association published a guidebook, *Housing and the Role of Hospitals*, identifying how hospitals can address this particular social determinant of health. This resource outlines strategies and provides case studies on:

- neighborhood revitalization;
- home assessment and repair programs;
- medical care for the homeless;
- medical respite care; and
- transitional or permanent supportive housing.²²

The last of these strategies has received considerable attention, with hospitals and health systems investing an estimated \$75 to \$100 million in housing for homeless patients.²³ Insurers and local units of government also have contributed to these efforts, typically in partnership with hospitals and health systems.²⁴⁻²⁶ Initial outcomes data on these endeavors suggest that providing housing for homeless patients can decrease ED use and hospitalizations while yielding net savings on combined expenditures for healthcare and social services.²⁷ Despite these outcomes, the long-term desirability and feasibility of this approach is uncertain, as questions of appropriate resource allocation (is there a better way to spend these monies?), cost-sharing (is it appropriate to ask hospitals to cover the cost of social services for homeless patients?), and society’s overall approach to eliminating homelessness remain unresolved.

AMA policy on discharge planning and care for homeless patients

AMA policy recognizes the link between housing security and health outcomes, and supports a coordinated, collaborative approach to care for homeless patients that combines clinical and social services. For example, Policy H-160.903, *Eradicating Homelessness*, “supports improving the health outcomes and decreasing the health care costs of treating the chronically homeless through clinically proven, high quality, and cost-effective approaches which recognize the positive impact of stable and affordable housing coupled with social services.”

Furthermore, Policy H-160.978, *The Mentally Ill Homeless*, avers that “public policy initiatives directed to the homeless, including the homeless mentally ill population, should...[promote] care that is sensitive to the overriding needs of this population for food, clothing, and residential facilities.”

Finally, the AMA’s comprehensive Evidence-Based Principles of Discharge and Discharge Criteria (Policy H-160.942), while not explicitly addressing homelessness, “calls on physicians, specialty societies, insurers, and other involved parties to join in developing, promoting, and using evidence-based discharge criteria that are sensitive to the physiological, psychological, social, and functional needs of patients.”

CONCLUSION

Homelessness is an exacerbating factor in ED overuse, excess hospitalization, and preventable readmissions. Hospital discharge planning for homeless patients, with a holistic focus on case management that coordinates clinical and social services, has been shown to alleviate some of these problems. Despite this evidence, focused discharge planning remains rare for homeless ED patients. Our AMA should educate physicians about the importance of discharge planning for homeless patients, and encourage the development of holistic, cost-effective, evidence-based discharge plans for homeless patients who present to the emergency department but are not admitted to the hospital.

While critical, discharge planning alone will not prevent unnecessary ED visits and hospitalizations for homeless individuals. Instead, a more comprehensive approach to addressing the unique healthcare and social needs of homeless

patients is required, with efforts reaching beyond the hospital and into the community. Our AMA should encourage collaborative efforts to address homelessness that do not leave hospitals and physicians alone to bear their costs.

RECOMMENDATIONS

The Board of Trustees recommends that the following be adopted in lieu of Resolution 826-I-18 and that the remainder of the report be filed:

1. That our American Medical Association partner with relevant stakeholders to educate physicians about the unique healthcare and social needs of homeless patients and the importance of holistic, cost-effective, evidence-based discharge planning, and physicians' role therein, in addressing these needs.
2. That our AMA encourage the development of holistic, cost-effective, evidence-based discharge plans for homeless patients who present to the emergency department but are not admitted to the hospital.
3. That our AMA encourage the collaborative efforts of communities, physicians, hospitals, health systems, insurers, social service organizations, government, and other stakeholders to develop comprehensive homelessness policies and plans that address the healthcare and social needs of homeless patients.
4. That our AMA reaffirm Policy H-160.903, *Eradicating Homelessness*, which supports improving the health outcomes and decreasing the health care costs of treating the chronically homeless through clinically proven, high quality, and cost-effective approaches which recognize the positive impact of stable and affordable housing coupled with social services.
5. That our AMA reaffirm Policy H-160.978, *The Mentally Ill Homeless*, which states that public policy initiatives directed to the homeless, including the homeless mentally ill population, should...[promote] care that is sensitive to the overriding needs of this population for food, clothing, and residential facilities.
6. That our AMA reaffirm Policy H-160.942, *Evidence-Based Principles of Discharge and Discharge Criteria*, which calls on physicians, specialty societies, insurers, and other involved parties to join in developing, promoting, and using evidence-based discharge criteria that are sensitive to the physiological, psychological, social, and functional needs of patients.
7. That our AMA reaffirm Policy H-130.940, *Emergency Department Boarding and Crowding*, which supports dissemination of best practices in reducing emergency department boarding and crowding.
8. That our AMA reaffirm Policy H-270.962, *Unfunded Mandates*, which vigorously opposes any unfunded mandates on physicians.

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AMA POLICIES RECOMMENDED FOR REAFFIRMATION

H-160.942 Evidence-Based Principles of Discharge and Discharge Criteria

The AMA defines discharge criteria as organized, evidence-based guidelines that protect patients' interests in the discharge process by following the principle that the needs of patients must be matched to settings with the ability to meet those needs.

The AMA calls on physicians, specialty societies, insurers, and other involved parties to join in developing, promoting, and using evidence-based discharge criteria that are sensitive to the physiological, psychological, social, and functional needs of patients and

that are flexible to meet advances in medical and surgical therapies and adapt to local and regional variations in health care settings and services.

The AMA encourages incorporation of discharge criteria into practice parameters, clinical guidelines, and critical pathways that involve hospitalization.

The AMA promotes the local development, adaptation and implementation of discharge criteria.

The AMA promotes training in the use of discharge criteria to assist in planning for patient care at all levels of medical education. Use of discharge criteria will improve understanding of the pathophysiology of disease processes, the continuum of care and therapeutic interventions, the use of health care resources and alternative sites of care, the importance of patient education, safety, outcomes measurements, and collaboration with allied health professionals.

The AMA encourages research in the following areas: clinical outcomes after care in different health care settings; the utilization of resources in different care settings; the actual costs of care from onset of illness to recovery; and reliable and valid ways of assessing the discharge needs of patients.

The AMA endorses the following principles in the development of evidence-based discharge criteria and an organized discharge process:

As tools for planning patients' transition from one care setting to another and for determining whether patients are ready for the transition, discharge criteria are intended to match patients' care needs to the setting in which their needs can best be met. Discharge criteria consist of, but are not limited to: (i) Objective and subjective assessments of physiologic and symptomatic stability that are matched to the ability of the discharge setting to monitor and provide care. (ii) The patient's care needs that are matched with the patient's, family's, or caregiving staff's independent understanding, willingness, and demonstrated performance prior to discharge of processes and procedures of self care, patient care, or care of dependents. (iii) The patient's functional status and impairments that are matched with the ability of the care givers and setting to adequately supplement the patients' function. (iv) The needs for medical follow-up that are matched with the likelihood that the patient will participate in the follow-up. Follow-up is time-, setting-, and service-dependent. Special considerations must be taken to ensure follow-up in vulnerable populations whose access to health care is limited.

The discharge process includes, but is not limited to: (i) Planning: Planning for transition/discharge must be based on a comprehensive assessment of the patient's physiological, psychological, social, and functional needs. The discharge planning process should begin early in the course of treatment for illness or injury (prehospitalization for elective cases) with involvement of patient, family and physician from the beginning. (ii) Teamwork: Discharge planning can best be done with a team consisting of the patient, the family, the physician with primary responsibility for continuing care of the patient, and other appropriate health care professionals as needed. (iii) Contingency Plans/Access to Medical Care: Contingency plans for unexpected adverse events must be in place before transition to settings with more limited resources. Patients and caregivers must be aware of signs and symptoms to report and have a clearly defined pathway to get information directly to the physician, and to receive instructions from the physician in a timely fashion. (iv) Responsibility/Accountability: Responsibility/accountability for an appropriate transition from one setting to another rests with the attending physician. If that physician will not be following the patient in the new setting, he or she is responsible for contacting the physician who will be accepting the care of the patient before transfer and ensuring that the new physician is fully informed about the patient's illness, course, prognosis, and needs for continuing care. If there is no physician able and willing to care for the patient in the new setting, the patient should not be discharged. Notwithstanding the attending physician's responsibility for continuity of patient care, the health care setting in which the patient is receiving care is also responsible for evaluating the patient's needs and assuring that those needs can be met in the setting to which the patient is to be transferred. (v) Communication: Transfer of all pertinent information about the patient (such as the history and physical, record of course of treatment in hospital, laboratory tests, medication lists, advanced directives, functional, psychological, social, and other assessments), and the discharge summary should be completed before or at the time of transfer of the patient to another setting. Patients should not be accepted by the new setting without a copy of this patient information and complete instructions for continued care.

The AMA supports the position that the care of the patient treated and discharged from a treating facility is done through mutual consent of the patient and the physician; and

Policy programs by Congress regarding patient discharge timing for specific types of treatment or procedures be discouraged.

H-160.978 The Mentally Ill Homeless

The AMA believes that public policy initiatives directed to the homeless, including the homeless mentally ill population, should include the following components:

access to care (e.g., integrated, comprehensive services that permit flexible, individualized treatment; more humane commitment laws that ensure active inpatient treatment; and revisions in government funding laws to ensure eligibility for homeless persons); clinical concerns (e.g., promoting diagnostic and treatment programs that address common health problems of the homeless population and promoting care that is sensitive to the overriding needs of this population for food, clothing, and residential facilities);

program development (e.g., advocating emergency shelters for the homeless; supporting a full range of supervised residential placements; developing specific programs for multiproblem patients, women, children, and adolescents; supporting the development of a clearinghouse; and promoting coalition development);

educational needs;

housing needs; and

research needs.

The AMA encourages medical schools and residency training programs to develop model curricula and to incorporate in teaching programs content on health problems of the homeless population, including experiential community-based learning experiences.

The AMA urges specialty societies to design interdisciplinary continuing medical education training programs that include the special treatment needs of the homeless population.

H-160.903 Eradicating Homelessness

Our American Medical Association:

supports improving the health outcomes and decreasing the health care costs of treating the chronically homeless through clinically proven, high quality, and cost effective approaches which recognize the positive impact of stable and affordable housing coupled with social services;

recognizes that stable, affordable housing as a first priority, without mandated therapy or services compliance, is effective in improving housing stability and quality of life among individuals who are chronically-homeless;

recognizes adaptive strategies based on regional variations, community characteristics and state and local resources are necessary to address this societal problem on a long-term basis;

recognizes the need for an effective, evidence-based national plan to eradicate homelessness; and

encourages the National Health Care for the Homeless Council to study the funding, implementation, and standardized evaluation of Medical Respite Care for homeless persons.

17. BAN ON MEDICARE ADVANTAGE “NO CAUSE” NETWORK TERMINATIONS

Reference committee hearing: see report of Reference Committee B.

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS REMAINDER OF REPORT FILED

See Policy H-285.902

INTRODUCTION

At the 2018 Annual Meeting, the House of Delegates (HOD) adopted Policy D-285.961, “Ban on Medicare Advantage ‘No Cause’ Network Terminations,” with a progress report back at the 2019 Annual Meeting. This policy asks that:

Our American Medical Association (AMA) develop a set of reform proposals addressing the way that Medicare Advantage plans develop and modify their physician networks with the aim of improving the stability of networks, the ability of patients to obtain needed primary and specialty care from in-network physicians, physician satisfaction, and communication with patients about network access with report back to the House of Delegates at the 2019 Annual Meeting.

This report provides background on the issues involved in Medicare Advantage (MA) physician networks and concerns that physicians have raised about the ways that plans form and manage these networks, as well as their communications with patients about their networks. The report recommends that the AMA adopt a set of reform proposals and advocate their adoption. The HOD also reaffirmed existing AMA Policies D-285.998, “Creation of Joint AMA Committee with Representatives from the America’s Health Insurance Plans,” which it further strengthened, Policy H-285.908, “Network Adequacy,” and Policy H-285.991, “Qualifications and Credentialing of Physicians Involved in Managed Care,” which directly dealt with termination issues as part of the overall action and consideration of this whole issue.

BACKGROUND

MA plans are health insurance plans offered to people with Medicare by private companies that contract with the Medicare program. MA plans must provide all Medicare Parts A and B benefits, they may provide Part D prescription drug coverage, and they often offer extra benefits that traditional Medicare does not cover, such as vision, hearing and dental care coverage. In 2018, over 20 million Medicare beneficiaries, or 34 percent, were enrolled in MA. The Congressional Budget Office estimates that MA enrollment will continue expanding its market share with MA plans projected to include about 42 percent of beneficiaries by 2028.¹

There are relatively few insurers in the MA market, with most MA enrollees in plans operated by UnitedHealthcare, Humana, or BCBS affiliates.² On average, seniors have a choice of 21 plans,³ with up to 40 in some large metropolitan areas and fewer in rural areas.

Narrow Networks

Narrow network plans have become increasingly common in private health insurance markets, including MA. Generally, such plans offer enrollees a narrow set of physicians and hospitals in a geographic area in exchange for lower premiums.⁴ Traditional Medicare allows seniors to access any physician or hospital that accepts Medicare patients, but MA access is limited to physicians and hospitals within plan networks. More than one in three MA enrollees are in a narrow physician network, which is defined as less than 30 percent of physicians in the county participating in the plan. Another 43 percent of enrollees are in medium networks, defined as 30 to 69 percent of physicians in the county participating.⁵ On average, MA networks include less than half of all physicians in a given county.

Narrow networks give insurers greater leverage to negotiate physician payment rates and to select those providers that the insurer believes deliver high quality of care.⁶ However, MA plans state that, because they already pay providers at or near Medicare fee schedule rates, negotiating lower payment rates is not a significant consideration.⁷ Instead, they achieve lower total costs by focusing on utilization.

The AMA and other physician groups have raised concerns that narrow physician networks create challenges for patients seeking care and pose potential patient protection issues. Specifically, a narrow network might have shortages of specific specialties, and plans may purposefully understaff specialties to avoid attracting enrollees with expensive pre-existing conditions like cancer and mental illness.⁸ Access to psychiatrists is more restricted than other specialties. On average, only 23 percent of psychiatrists in a county participate in MA plans, and 36 percent of plans include less than 10 percent of psychiatrists in their county.⁹ Limited access to specialists extends beyond psychiatry to cardiothoracic surgeons, neurosurgeons, radiation oncologists, and others.

Star Ratings

[Star ratings](#) are a key reason for forming narrow networks. MA plans' star ratings affect payment and enrollment, and higher star ratings help increase plan revenues.¹⁰ Plans with high star ratings receive bonuses to their benchmarks and payments from the Centers for Medicare & Medicaid Services (CMS). Total bonuses paid to MA plans have more than doubled over the last four years from \$3 billion to \$6.3 billion,¹¹ due to increases in MA enrollment and in the number of plans receiving bonuses. Importantly, MA plans with five-star ratings can enroll beneficiaries at any time throughout the year, not simply during open enrollment or initial eligibility, which is a competitive advantage.¹²

MA plans rely on physicians to achieve their high star ratings by delivering services such as screening tests and vaccines, managing chronic conditions, and cooperating with the plan. Because plans have broad authority to exclude physicians as long as they meet CMS network adequacy requirements, insurers may form narrow networks around already high-performing physicians that have proven track records of quality and utilization management. CMS data show that five-star ratings have been achieved only by vertically integrated and provider-led narrow networks.¹³

Insurers recognize that risk adjustment is another critical component of star ratings. Narrow networks can limit the number of physicians that plans need to coordinate with and educate about diagnosis coding for risk adjustment, which increases plan revenues by increasing the apparent severity of patient conditions compared to traditional Medicare.¹⁴

DISCUSSION

To improve the way that MA plans develop and modify their physician networks, the Board offers several policy proposals focused on network directory accuracy, network adequacy, network stability, communications with patients, and establishment of an external advisory group to better inform CMS regarding MA network issues.

Enhance CMS Efforts to Ensure Directory Accuracy

MA plans are required to maintain accurate provider directories on a real-time basis, but they are currently only required to submit provider directories to CMS when the plan first begins operations in an area, and then every three years unless CMS requests a review based on significant terminations of contracts or complaints. Since CMS has begun conducting triennial reviews of directories, it has found significant inaccuracies, which justifies more frequent reviews and more significant penalties. MA plans could reduce the administrative burden on themselves and on

physicians if they would use a common system for updating provider directory information, such as the AMA/Lexis-Nexis VerifyHCP system.¹⁵

The AMA could urge CMS to enhance its efforts to ensure directory accuracy by:

- Requiring MA plans to submit provider directories to CMS every year prior to the Medicare open enrollment period and whenever there is a significant change in the physicians included in the network;
- Auditing directory accuracy more frequently for plans that have had deficiencies;
- Publicly reporting accuracy scores on [Medicare Plan Finder](#);
- Taking enforcement action against plans that fail to maintain complete and accurate directories, or to have a sufficient number of physician practices open and accepting new patients; and
- Offering plans the option of using [AMA/Lexis-Nexis VerifyHCP](#) system to update provider directory information.

Ensure That CMS Network Adequacy Standards Provide Adequate Access for Beneficiaries and Support Coordinated Care Delivery

Current standards do not assess the extent to which physicians in the network are willing and able to see new patients or the extent to which patients want to use the physicians in the network. If most plan members are receiving services only from a subset of physicians in the network, that subset may not represent the “true” network that is available to patients. Additionally, CMS has not released or sought public comments on the standards for the Minimum Provider Ratios and Maximum Time/Distance. In addition, current adequacy standards are established separately for each specialty and there is no requirement that physicians who work together must all be included. For example, there is a requirement to include at least one hospital which offers cardiac catheterization services and at least one cardiologist, but there is no requirement that the network cardiologist be able to perform cardiac catheterizations or that the network cardiologist has privileges at the network hospital.

Ensure Lists of Contracted Physicians Are Made More Easily Accessible

Finding out whether a patient’s physicians are in each plan’s network requires going separately to each health plan’s website, finding the directory, and searching it. If a patient receives care from multiple physicians, this requires considerable time and effort. The plans are already required to submit their initial list to CMS in an electronic form that includes the physician’s National Provider Identifier (NPI), so it should be feasible to not only make the lists downloadable, but also to link the information in the lists to [Physician Compare](#). There is also currently no simple way for a physician to determine whether they are being accurately reported as in-network by the plans with which they currently contract and as out-of-network by other plans. A physician could use a Physician Compare linkage to find which plans say they have contracts with the physician.

Simplify the Process for Beneficiaries to Compare Network Size and Accessibility

It is difficult for patients to determine which plans will have physicians available nearby if new conditions arise or their existing conditions worsen. It is very difficult to compare plans based on the relative size and specialty structure of their networks.

Measure the Stability of Networks

Patients need to know whether they are likely to need to keep changing physicians if they choose a particular plan. There is currently no way to determine if MA plans tend to have the same physicians in-network each year or their networks change significantly from year-to-year.

Physicians have outlined many concerns with the processes that MA plans use to narrow their networks. Plans often send notices to physicians terminating their participation in the network with no explanation, and they do not take steps to ensure that patients can complete their treatment plan and/or find an in-network physician who can take over their care. The lack of explanation for the change, often referred to as “no cause terminations,” also makes it impossible for physicians to successfully challenge plans’ decisions. As transitions in care are where many adverse events occur, a more cautious approach with more active management of the transition process and more emphasis on supporting established physician-patient relationships would be a major improvement.

There is another side to this story, though, and there are also medical practices who see great benefit in the move to narrower networks. Participants in accountable care organizations (ACOs), for example, may find that they have better opportunities to appropriately manage care for patients assigned to the ACO if the network is largely comprised of other ACO-participating practices. Other practices may benefit from having a higher volume of patients insured by a particular MA plan, and may find that they have more leverage to negotiate better terms and conditions with the plan because the plan’s subscribers cannot easily move to a different, out-of-network practice.

The AMA could urge CMS to ensure that network adequacy standards provide adequate access for beneficiaries and support coordinated care delivery by: Requiring plans to report the percentage of the physicians in the network who actually provided services to plan members during the prior year:

- Publishing the research supporting the adequacy of the ratios and distance requirements CMS currently uses to determine network adequacy;

- Conducting a study of the extent to which networks maintain or disrupt teams of physicians and hospitals that work together; and
- Evaluating alternative/additional measures of adequacy.

CMS Needs to Develop an Effective Communication Plan

CMS should create a plan to effectively communicate with patients about network access and any changes to the network that may directly or indirectly impact patients. Additionally, CMS should update the Medicare Plan Finder Website to ensure the website is user-centered.

[Oscar Health Care](#) is a New York-based health insurance company focused on delivering care through telemedicine, health care focused technological interfaces, and transparent claims pricing systems.¹⁶ Recently, the America's Health Insurance Plans (AHIP) highlighted "[How Oscar Guides Its Members Through the Health System](#)," noting the ease with which users can enroll. Members can sign-up for health insurance in under 10 minutes using the Oscar-created platform (as opposed to brokers or exchanges), which showed a 30 percent increased probability of matching with a plan that optimizes for expected behavior. In an [interview](#) with the Oscar Health Care *Head of Product*, Eddie Segal noted that in building the online platform the company prioritized simplicity, incremental navigation, information reduction, and informed, data-driven design.

User-centered design is an iterative process in which architects of said technology or platform focus on the users and their needs, in each phase of the design process. User-centered design requires the involvement of applicable users throughout this process via a variety of research and design techniques in order to create highly usable and accessible products.

The need for user-centered design has become increasingly important, as more health care professionals and patients are exposed to, rely on, and operate within electronic platforms for information related to treatment and diagnosis, disease management, prescription drug coverage, health insurance, and general health care delivery. In 2006, 80 percent of internet users, or approximately 93 million Americans, searched for a health-related topic online, with 25 percent of that population seeking information regarding health insurance – although that number has likely increased significantly during the past 13 years.¹⁷ Of note, between 2000 and 2013, internet and technology usage among seniors rose from 14 to nearly 60 percent.¹⁸

Medicare patients continue to report frustration and difficulty comparing plans (both fee-for-service and MA) using the "Medicare Compare" tool. They avoid switching plans due to the complexity surrounding initial set-up and voice concern in accessing their preferred physicians and providers.¹⁹ Further interrogation of the Medicare Plan Finder by the National Council on Aging found that poor plan selection and patient confusion often flows from poorly presented information and outdated, misleading user design.²⁰ Improved and intuitive user-centered design application can enable and empower patients to successfully shop for Medicare plans that meet both clinical need and financial reality.

The AMA could recommend several policy changes to improve communications with patients about MA plan networks. These could include:

- Requiring that MA plans submit their contracted provider list to CMS annually and whenever changes occur;
- Post the lists on the Medicare Plan Finder website;
- Linking the provider lists to Physician Compare so that a patient can first find a physician and then find which health plans contract with that physician;
- Expanding the information for each MA plan on Medicare Plan Finder to include number of contracted physicians in each specialty and county, extent to which networks exceed minimum standards in each specialty and county, and percent of physicians in each specialty and county who participate in Medicare that are included in the plan's network;
- Measuring and reporting on the stability of networks; and
- Urging CMS to develop a plan to effectively communicate with patients about network access and any changes to MA networks that may directly or indirectly impact patients.

Process Improvements for Recurring Physician Input Regarding Network Policies

Finally, CMS should initiate a Network Adequacy Task Force to meet twice a year with relevant stakeholders, including practicing physicians, trade associations and specialty societies, to both review current policy and develop new policies to address network adequacy issues.

- The American Medical Association could urge Centers for Medicare & Medicaid Services to create a network adequacy task force in order to obtain ongoing input from physicians on needed improvements.

RECOMMENDATIONS

The Board of Trustees recommends that the following recommendations be adopted and that the remainder of the report be filed:

1. That our American Medical Association (AMA) urge Centers for Medicare & Medicaid Services (CMS) to further enhance the agency's efforts to ensure directory accuracy by:
 - a. Requiring Medicare Advantage (MA) plans to submit accurate provider directories to CMS every year prior to the Medicare open enrollment period and whenever there is a significant change in the physicians included in the network.
 - b. Conducting accuracy reviews on provider directories more frequently for plans that have had deficiencies.
 - c. Publicly reporting the most recent accuracy score for each plan on [Medicare Plan Finder](#).
 - d. Indicating to plans that failure to maintain complete and accurate directories, as well as failure to have a sufficient number of physician practices open and accepting new patients, may subject the MA plans to one of the following: 1. civil monetary penalties; 2. enrollment sanctions; or 3. incorporating the accuracy score into the Stars rating for each plan.
 - e. Offering plans the option of using [AMA/Lexis-Nexis VerifyHCP](#) system to update provider directory information.
 - f. Requiring MA plans immediately remove from provider directories providers who no longer participate in their network.
2. That our AMA urge CMS to ensure that network adequacy standards provide adequate access for beneficiaries and support coordinated care delivery by:
 - a. Requiring plans to report the percentage of the physicians, broken down by specialty and subspecialty, in the network who actually provided services to plan members during the prior year.
 - b. Publishing the research supporting the adequacy of the ratios and distance requirements CMS currently uses to determine network adequacy.
 - c. Conducting a study of the extent to which networks maintain or disrupt teams of physicians and hospitals that work together.
 - d. Evaluating alternative/additional measures of adequacy.
3. That our AMA urge CMS to ensure lists of contracted physicians are made more easily accessible by:
 - a. Requiring that MA plans submit their contracted provider list to CMS annually and whenever changes occur, and post the lists on the Medicare Plan Finder website in both a web-friendly and downloadable spreadsheet form.
 - b. Linking the provider lists to [Physician Compare](#) so that a patient can first find a physician and then find which health plans contract with that physician. That our AMA urge CMS to simplify the process for beneficiaries to compare network size and accessibility by expanding the information for each MA plan on Medicare Plan Finder to include: A. the number of contracted physicians in each specialty and county; B. the extent to which a plan's network exceeds minimum standards in each specialty, subspecialty and county; and C. the percentage of the physicians in each specialty and county participating in Medicare who are included in the plan's network.

4. That our AMA urge CMS to measure the stability of networks by calculating the percentage change in the physicians in each specialty and subspecialty in an MA plan's network compared to the previous year and over several years and post that information on Plan Finder.
5. That our AMA urge CMS to develop a marketing/communication plan to effectively communicate with patients about network access and any changes to the network that may directly or indirectly impact patients; including updating the Medicare Plan Finder website.
6. That our AMA urge CMS to develop process improvements for recurring input from in-network physicians regarding network policies by creating a network adequacy task force that includes multiple stakeholders, including patients.
7. That our AMA urge CMS to ban "no cause" terminations of MA network physicians during the initial term or any subsequent renewal term of a physician's participation contract with a Medicare Advantage plan.
8. That our AMA rescind Policy D-285.961, which directed the AMA to conduct the study herein.

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18. INCREASED USE OF BODY-WORN CAMERAS BY LAW ENFORCEMENT OFFICERS (RESOLUTION 208-I-17)

Reference committee hearing: see report of Reference Committee B.

**HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS
IN LIEU OF RESOLUTION 208-I-17
REMAINDER OF REPORT FILED
See Policy D-160.919**

INTRODUCTION

At the 2018 Interim Meeting, the American Medical Association (AMA) House of Delegates (HOD) referred Board of Trustees (BOT) Report 4-I-18, "Increased Use of Body-Worn Cameras by Law Enforcement Officers." The BOT Report 4-I-18 followed referral of Resolution 208-I-17, "Increased Use of Body-Worn Cameras by Law Enforcement Officers," introduced by the Medical Student Section, which asked:

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

The reference committee heard supportive testimony of BOT Report 4-I-18, though many requested further study into issues of confidentiality and privacy when body-worn cameras are taken into patient care areas in health care settings.

This Board report provides background, discussion of body-worn cameras by law enforcement officers, including a discussion of body-worn cameras in health care settings, and a recommendation.

BACKGROUND

Following a number of high-profile incidents involving deadly force used against minorities, law enforcement agencies have increasingly adopted body-worn cameras for their officers. Often affixed to the torso, body-worn cameras are small, wearable audio, video or photographic recording systems that record events in which law enforcement officers are involved. The recordings can be used to demonstrate transparency to the community, to document events and to deter inappropriate, illegal or unethical behavior by both the wearer of the camera and the public.

To date, 34 states and the District of Columbia have enacted laws governing the use of body-worn cameras by law enforcement, though not all law enforcement departments utilize cameras in the same manner.¹ For example, some permit officers to turn off the devices under certain circumstances; others do not. In addition, a 2016 survey of large police departments nationwide found that 95 percent intended to implement or had already implemented a body camera program. According to the survey, 18 percent had fully operational programs.²

The cost to law enforcement entities to implement and maintain a body camera program can be ongoing. Implementing a program requires an initial capital outlay to purchase the technology and ancillary equipment; law enforcement agencies must account for continuing operational costs, such as training on use, data storage, software and staff and operational costs required for reviewing the recordings, redacting as necessary, and providing recordings to courts and the public as appropriate. In Washington, DC, for example, the city spent over \$1 million outfitting 2,800 officers and expects operating costs to top \$2 million per year.³

In 2015, the U.S. Department of Justice (DOJ) Bureau of Justice Assistance (BJA) awarded \$22.5 million in grant assistance to state and local law enforcement departments as part of the Body-Worn Camera Pilot Implementation Program. The Consolidated Appropriations Act, 2018 appropriated \$22.5 million for a competitive matching grant program for purchases of body-worn cameras for state, local and tribal law enforcement. The BJA expects to make up to 28 awards for a three-year period, which began on October 1, 2018. State and local funding is also available for body-worn cameras.

DISCUSSION

Predicated on whether the AMA ought to support funding of body camera programs is the question of whether the AMA ought to support the expanded use of body cameras and whether the devices achieve their intended outcomes.

Policing Activity

The underlying theory in support of body-worn cameras is that both officers and members of the community will change their behaviors for the better if their actions are being recorded. Indeed, a large body of research suggests that people act differently when they believe they are being watched. In the context of law enforcement, body-worn cameras are expected to increase self-awareness and thus deter unprofessional, inappropriate and illegal behavior by officers and civilians alike. As law enforcement officers are more likely to use force against minority community members, many hope body-worn cameras will improve policing behavior toward minorities, using force only when warranted and de-escalation tactics have failed.^{4,5} In cases where law enforcement officers do use force, body-worn cameras offer contemporaneous evidence of the officers' actions so that improper behavior can be disciplined. Evidence about the impact of cameras on policing activity generally, though not universally, supports this theory.

An early study conducted in the Rialto, California police department found use-of-force incidents declined 58.3 percent over a three-year period after a body camera program was implemented.⁶ Importantly, researchers later found that use of force rates were higher in the same Rialto, California police force despite the presence of a camera when officers were allowed discretion to turn off cameras.⁷ Another randomized controlled trial conducted between 2014 and 2015 in the Las Vegas Metropolitan Police Department found that officers wearing body cameras were 12.5 percent less likely to be involved in a use of force incident.⁸ Similar results were found in Orlando, Florida.⁹ In contrast, the largest randomized controlled study to date, conducted in 2015 with the Metropolitan Police Department of the District of Columbia, found no statistically significant difference in the rates of police use of force.¹⁰

Research has found mixed results about other forms of police activity. In the study conducted in Las Vegas, body camera use was not associated with a change in the number of police-community interactions, but body cameras were associated with a 6.8 percent increase in the number of citations issued and a 5.2 percent increase in the number of events that resulted in an arrest. A 2015 study conducted in Mesa, Arizona found officers wearing a camera were less likely to perform stop-and-frisks and make arrests, but were more likely to give citations and initiate encounters.¹¹ In Phoenix, Arizona use of body-worn cameras were associated with a 17 percent increase in arrests.¹² However, other studies have found body-worn cameras are associated with slightly lower incidents of arrest.¹³

Community Relations

Changing policing behaviors is not the only way body-worn cameras could provide benefits. Many communities and law enforcement agencies see body cameras as a valuable way to improve policing transparency and community relations. Indeed, in 2015 when DOJ grants were announced, then-US Attorney General Loretta Lynch stated that body-worn cameras hold "tremendous promise for enhancing transparency, promoting accountability, and advancing public safety for law enforcement officers and the communities they serve."¹⁴ Body cameras are lauded as a way for the public to better understand what transpires between law enforcement officers and civilians. Officers may also view body cameras positively, as recordings demonstrate to the community the difficult and dangerous job required of them.

Few studies have taken a comprehensive look at community attitudes toward police after the introduction of body-worn cameras.¹⁵ One such study conducted by the Urban Institute found that body-worn cameras do improve community members' satisfaction with police encounters.¹³ Another study found that individuals viewed officers as having greater legitimacy, professionalism and satisfaction, but did not find significant differences between citizens' perceptions of officers depending on whether the officer was wearing a camera.¹⁶

The evidence is clearer, however, that body-worn cameras are associated with decreased rates of complaints filed against law enforcement officers. For example, one early study found complaints against officers dropped 88 percent following implementation of a body cameras program.⁶ In Rialto, California, citizen complaints declined by 60 percent. In the Las Vegas Metropolitan Police, officers wearing body cameras were 14 percent less likely to be the subject of a citizen complaint.⁸ In Phoenix, complaints against officers who wore the cameras declined by 23 percent, compared to a 10.6 percent increase among comparison officers.¹² In contrast, research in the District of Columbia found no statistically significant difference in the rates of civilian complaints.

The available evidence does not identify the underlying behavioral changes responsible for the decline in complaint rates, however. It may be that body-worn cameras have the intended effect of changing officer behavior for the better, thus reducing circumstances that warrant citizen complaints. It may be that cameras have a “civilizing” effect on members of the public as well. Some evidence also suggests that frivolous complaints are less likely to be filed when recordings are available.¹⁵

It is important to note, however, that use of body cameras will not automatically foster greater trust between law enforcement and members of the community and should not be viewed, as one evaluation noted, as a “plug-and-play” solution.¹⁰ Notably, the Urban Institute found body-worn cameras improved community satisfaction to a lesser extent than did procedurally just practices, defined in that study as behaving fairly and acting with empathy.¹³

Privacy Considerations

Though the use of body cameras promises greater transparency of law enforcement behavior and actions, they also present new problems, namely intrusion into the privacy of victims, witnesses and bystanders. For instance, law enforcement officers frequently enter individuals’ homes and in-home recordings would become part of the public record. Similarly, interactions and conversations with victims and witnesses could make those individuals uncomfortable or put those individuals in danger. Heavily policed communities—often minority communities—will be more heavily recorded.

These privacy concerns could be addressed with policies to limit recording during such encounters and by limiting the circumstances under which recordings are made available to the public. The American Civil Liberties Union (ACLU) recommends use of body cameras with significant privacy protections. Officer privacy may also be a concern. Some law enforcement unions have opposed body-worn cameras, arguing that adoption of the technology must be negotiated as part of the collective bargaining agreement.

This report acknowledges the significant privacy concerns raised by the ubiquitous use of body-worn cameras, but notes that questions about when cameras need to be turned on and off, how long to keep footage, when recordings will be made publicly available and other policy details are beyond the expertise of the AMA.

Privacy considerations in the health care setting

Body-worn cameras present a unique threat to privacy in a health care setting when, for example, law enforcement officers enter facilities to interview victims and witnesses or retrieve evidence. Law enforcement agencies are not covered entities under the Health Information Portability and Accountability Act (HIPAA) and do not have the same obligation to prevent the disclosure of patient health information as do health care providers and facilities. Providers and facilities, on the other hand, do have a legal obligation under HIPAA to prevent against third-party recording of individually identifiable health information (e.g., patients’ faces).

Few states regulate body-worn camera recordings of medical treatment and the preservation of privacy depends instead on cooperation between law enforcement and health care providers. According to the Leadership Conference on Civil and Human Rights, which created a scorecard of body-worn camera policies across the country, many law enforcement agencies have developed policies and procedures which generally prohibit recordings in health care settings except under certain circumstances. Such policies vary considerably in scope and specificity.

Even when privacy laws and regulations are not implicated, the patient-physician relationship is foremost based on trust and the presence of cameras may interfere with honest communication between a physician and patient, particularly when treatment involves sensitive matters such as sexual activity, substance use and mental health. Policies must ensure that recordings are not permitted when they may interfere in the patient-physician relationship, including during clinical interviews, evaluations and treatments.

Nexus with the AMA’s Mission

The AMA does not have policy specifically addressing the use of body-worn cameras among law enforcement. During the debate over Resolution 208 during the 2017 Interim Meeting, the reference committee heard testimony questioning whether this topic is within the scope of the AMA’s expertise. This concern is reasonable, as AMA has not historically delved into issues of policing and significant resources would be required to bring the AMA into the public policy

debates surrounding community policing efforts. Further, while there are dozens of organizations (the Police Executive Research Forum, Leadership Conference on Civil and Human Rights, ACLU, etc.) that are actively engaged on this issue, it does not appear that any other major medical associations have emerged as significant stakeholders.

Nevertheless, there is a connection between health and police activity, particularly in terms of minority fatality rates. Research has demonstrated that minority communities are disproportionately subject to police force. Specifically, according to an analysis of FBI statistics, African-Americans account for 31 percent of police-involved shootings, but comprise 13 percent of the U.S. population.⁴ African-American males are particularly at risk. According to another analysis, African-American males are three times more likely to be killed by police than non-Hispanic white males.⁵

Research has also shown a correlation between policing and other health outcomes. In particular, a recent study found that police killings of unarmed African-Americans were associated with 1.7 days of poor mental health annually among African-Americans. The findings were seen regardless of whether the individual affected had a personal relationship with the victim or whether the incident was experienced vicariously. In addition, the numbers of police stops, coupled with the level of invasiveness during police encounters, is associated with increased levels of stress and anxiety.^{17, 18} African-American men report more anxiety and post-traumatic stress disorder and more morbidity from these psychiatric conditions than Caucasian men.⁵ In addition, research of data from the New York Police Department revealed that residents in neighborhoods with higher rates of stop-and-frisks were more likely to be in poor health, measured in terms of high blood pressure, diabetes, asthma and self-rated health.¹⁸ Research on the correlation between health and policing, however, remains sparse and warrants further research.

RELEVANT AMA POLICIES

Existing AMA policy does not address the use or funding of body-worn cameras. However, AMA policy does state that physical or verbal violence between law enforcement officers and the public, particularly within ethnic and racial minority communities, is a social determinant of health and supports research into the public health effects of violent interactions (Policy H-515.955). In addition, Policy H-350.971 instructs the AMA to establish a mechanism to facilitate the development and implementation of a comprehensive, long-range, coordinated strategy to address issues and concerns affecting minorities, including minority health.

Policy adopted during the 2018 Annual Meeting encourages states to require the reporting of legal intervention deaths and law enforcement officer homicides to public health agencies. New policy also encourages appropriate stakeholders, including law enforcement and public health communities, to define “serious injuries” for the purpose of systematically collecting data on law enforcement-related non-fatal injuries among civilians and officers.

Additionally, Policy H-145.977 cautions against excessive use of conducted electrical devices (often called Tasers) and recommends that law enforcement departments and agencies should have in place specific guidelines, rigorous training and an accountability system for the use of conducted electrical devices. AMA policy recommends research into the health impacts of conducted electrical device use and development of a standardized protocol developed with the input of the medical community for the evaluation, management and post-exposure monitoring of subjects exposed to conducted electrical devices.

RECOMMENDATIONS

The Board recommends that the following be adopted in lieu of Resolution 208-I-17, and that the remainder of the report be filed.

1. That our American Medical Association (AMA) work with interested state and national medical specialty societies to support state legislation and/or regulation addressing implementation of body-worn camera programs for law enforcement officers, including funding for the purchase body-worn cameras, training for officers and technical assistance for law enforcement agencies.;
2. That our AMA continue to monitor privacy issues raised by body-worn cameras in health care settings; and
3. That our AMA recommend that law enforcement policies governing the use of body-worn cameras in health care settings be developed and evaluated with input from physicians and others in the medical community and not interfere with the patient-physician relationship.

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19. FDA CONFLICT OF INTEREST (RESOLUTION 216-A-18)

Reference committee hearing: see report of Reference Committee B.

HOUSE ACTION: REFERRED

At the 2018 Annual Meeting of the House of Delegates (HOD), Resolution 216-A-18, “[Food and Drug Administration] FDA Conflict of Interest,” was referred for report back at the 2019 Annual Meeting. Resolution 216-A-18, sponsored by the Medical Student Section, asked that:

Our American Medical Association (AMA) advocate (1) that the Food and Drug Administration [(FDA)] place a greater emphasis on a candidate’s conflict of interest when selecting members for advisory committees; and (2) for a reduction in conflict of interest waivers granted to Advisory Committee candidates.

There was mixed testimony on Resolution 216 during the reference committee. Testimony was offered that disclosure and transparency into conflicts of interest (COI) are important, but on the other hand challenges may exist to find qualified individuals without COIs. Others offered that the FDA should utilize generally accepted COI policies and should limit waivers of such policies for advisory committees.

FDA AND THE ROLE OF ADVISORY COMMITTEES

The FDA utilizes advisory committees to obtain independent expert advice and recommendations on scientific, technical, and policy matters related to FDA-regulated products. There are 50 advisory committees and panels.¹ The recommendations of advisory committees do not bind the FDA. Although the advisory committees include permanent non-voting members who are FDA employees (typically responsible for administering the meetings), the majority are external experts who are considered special government employees (SGEs) while performing their advisory committee duties. The advisory committees cover a range of products.²

The FDA’s advisory committees are governed by several federal laws and regulations that: (1) establish standards for convening advisory committees; (2) specify criteria for what constitutes a COI; and (3) outline the requirements for disclosing, assessing, and managing COIs. In addition, the FDA has issued guidance documents interpreting government-wide regulations pertaining to the appearance of COIs as well as guidance related to the public availability of advisor COI disclosures and associated FDA waivers. For the most part, the federal laws, regulations, and guidance are generally the same whether a committee advisor is a permanent federal employee or SGE with some exceptions as outlined below. For over a decade, the FDA and Congress have implemented reforms to the FDA’s process for assessing COIs, managing COIs including waivers, and public disclosure.³ Members of the FDA’s advisory committees are subject to Federal COI laws (18 USC section 208) as well as government-wide standards of ethical conduct regulations (5 CFR section 2635.502). Even where a member has no financial interests that would require the member to refrain from participating in an advisory committee meeting (“recuse”) under Federal COI laws, the member may be disqualified from participation under the government-wide Federal regulation at 5 CFR section 2635.502 if the member has interests or relationships that may create the appearance that the member lacks impartiality on the issue before the advisory committee.

As specified in federal law, the FDA has a process for determining whether to grant a waiver for an advisory committee member with an actual financial COI. The FDA also has guidance outlining how the Agency evaluates whether an advisory committee member has potentially disqualifying interests or relationships that fall into the second category of interests: appearance of a COI. (In this latter case, the regulations provide that an authorization to participate would be issued as opposed to issuance of a waiver.) In both cases, the decision to permit voting, permit participation, or recusal will be made by the FDA.

PROHIBITION AGAINST FINANCIAL COI

Unless granted a waiver, a federal employee may not “personally and substantially participate” in an official capacity in any particular matter which, to the employee’s knowledge, the employee or a related person or organization (whose interests are imputed to the employee under 18 U.S.C. section 208) has a “financial interest” if the particular matter will have a “direct and predictable effect” on that interest (5 CFR section 2640.103(a)). In this analysis, federal

employees includes FDA advisory committee members who are considered SGEs. A financial interest is defined as the potential for gain or loss as a result of governmental action on the particular matter which includes stock options, a salary, job offer, indebtedness, and similar interests (5 CFR section 2640.103(b)). Under this law, the financial interests of other, related persons and organizations (as defined in law and statute)⁴ are imputed to the employee and may disqualify an employee to the same extent as the employee's own interests. Under the law, a COI arises when the employee participates in an official matter and there is a direct and predictable link between the matters in which the federal employee participates and the employee's financial interests. The link cannot be contingent and dependent on other events.

Process for Reviewing Financial COIs and Granting Waivers

The FDA reviews financial COI disclosures made by potential advisory committee members and the member's expertise with respect to the specific product or policy to be evaluated at a particular meeting. Each adviser is required to certify to the truth and completeness of any information provided.⁵ The Agency can issue a waiver to permit participation despite a current conflict or one that ended during the 12 months preceding a meeting consistent with applicable law. The FDA is required by law to apply different standards to SGEs (who constitute the majority of advisory committee members) and permanent government employees in order to determine if an applicable standard for granting a waiver pursuant to 18 USC section 208 is met.

If the individual is a SGE, the FDA's "determination must be based on a certification that the need for the [SGE's] ... services outweighs the potential for a conflict of interest created by the financial interest involved," (5 CFR section 2640.302). The FDA considers a number of factors, including the type of interest that is creating the disqualification, the relationship of the person whose financial interest is involved to the SGE, the uniqueness of the SGE's qualifications, the difficulty of locating a similarly qualified individual without a disqualifying financial interest, the dollar value of the disqualifying financial interest, and the extent to which the disqualifying financial interest could be affected by the actions of the advisory committee.⁶ If the individual is a permanent government employee, the FDA determines whether the member's financial interest is not so substantial as to be deemed likely to affect the integrity of the services provided by that individual. In making this determination, the FDA considers a number of factors, including the type of financial interest that is creating the disqualification, the relationship of the person whose financial interest is involved to the member, the dollar value of the disqualifying financial interest, the nature and importance of the employee's role in the matter, and the need for the employee's services in the particular matter.⁷ FDA guidance provides that a common factor to be considered for both categories of advisory committee members is the "need" for the individual's services. In deciding whether there is a need, the FDA will consider: (1) the uniqueness of the member's qualifications; (2) the difficulty locating similarly qualified individuals without a disqualifying financial interest; (3) the value and utility of the member's expertise to the matter being addressed by the committee; and, (4) the nature and extent of the disqualifying financial interest.

In addition, the FDA must apply one more standard to members serving on drug or biologic advisory committees that provide scientific advice and recommendations regarding a clinical investigation or marketing approval. For these members, the standard for a waiver to permit voting is whether a waiver is "necessary" to afford the committee "essential expertise."⁸ Where a financial COI exists, the FDA determines whether the member may: (1) participate as a non-voting member, or (2) not participate in the advisory committee.⁹ Individuals with financial COIs are not permitted to vote as a matter of FDA policy. A waiver may not be granted when the member's own scientific work is involved.¹⁰

The Food and Drug Administration Amendments Act of 2007 included a provision capping the number of COI waivers the FDA could grant in any given year. Subsequently, this cap was rescinded in the Food and Drug Administration Safety and Innovation Act of 2012.¹¹ A recent analysis of FDA COI waivers found that in fiscal year (FY) 2012, the waiver rate did not exceed one percent and this was less than in earlier years.¹² Additionally, the FDA reports COI waiver rates of less than one percent for FYs 2013, 2014, 2015, and 2016 on its online [FDA-TRACK Advisory Committees Dashboard](#).¹³

Public Disclosure

The FDA publicly discloses¹⁴ on the Agency's website the type, nature, and magnitude of the financial interests of each advisory committee member who has received a waiver under 18 U.S.C. section 208. The FDA also provides the

reasons for granting each waiver prior to the advisory committee meeting,¹⁵ including, as appropriate, the public health interest in having the expertise of the member with respect to the particular matter.¹⁶

APPEARANCE OF A CONFLICT OF INTEREST – PERSONAL AND BUSINESS RELATIONSHIPS

Federal law also contains provisions to help ensure that an employee takes appropriate steps to avoid an appearance of loss of impartiality in the performance of his or her official duties. Under 5 CFR section 2635.502 where an agency employee (including FDA advisory committee members), “knows that a particular matter involving specific parties is likely to have a direct and predictable effect on the financial interest of a member” of the employee’s household, or knows that a person with whom the employee has a “covered relationship is or represents a party to such matter,” and “where the employee determines that the circumstances would cause a reasonable person with knowledge of the relevant facts” to question the employee’s impartiality in the matter, the employee should not participate in the matter unless the employee has informed the agency designee of the appearance problem and received authorization from the agency designee. An employee has a “covered relationship” with:

- a person other than a prospective employer with whom the employee has or seeks a business, contractual or other financial relationship that involves other than a routine consumer transaction;
- a person who is a member of the employee’s household, or who is a relative with whom the employee has a close personal relationship;
- a person for whom the employee’s spouse, parent or dependent child is, to the employee’s knowledge, serving or seeking to serve as an officer, director, trustee, general partner, agent, attorney, consultant, contractor or employee; any person for whom the employee has, within the last year, served as officer, director, trustee, general partner, agent, attorney, consultant, contractor or employee; or
- an organization, other than a political party,¹⁷ in which the employee is an “active participant.”¹⁸

Granting a Section 502 Authorization

If the FDA concludes that an appearance issue exists, a determination is made whether the Agency’s interest in the member’s participation outweighs the concern that a reasonable person may question the integrity of the Agency’s programs and operations. If so, the FDA may grant an authorization (i.e., a waiver) before the meeting to allow the member to participate. The FDA may limit authorization or deny authorization. The Agency takes into consideration a number of factors including, but not limited to: (1) the nature of the relationship involved; (2) the effect that resolution of the matter would have upon the financial interests of the person involved in the relationship; (3) the nature and importance of the member’s role in the matter, including the extent to which the member is called upon to exercise discretion in the matter; (4) the sensitivity of the matter; (5) the difficulty of reassigning the matter to another expert; and (6) adjustments that may be made in the member’s duties that would reduce or eliminate the likelihood that a reasonable person would question her impartiality.

RESEARCH ON COI AND FDA ADVISORY COMMITTEE RECOMMENDATIONS

Despite long-standing federal laws governing COIs and waivers applicable to FDA advisory committee members, there have remained persistent concerns in the general public that waivers of COIs negatively impact the trustworthiness and independence of advisory committee recommendations. However, the research and investigations into this matter have produced mixed results. In a 2014 study of FDA advisory committee member COIs, a researcher found that, where an advisory committee member had an exclusive financial relationship with the manufacturer (referred to as a sponsor) of the product under review, the member appeared to be biased in support of the product sponsor.¹⁹ No similar bias was found where members had financial ties to both a sponsor and its competitors.²⁰ The study author noted that “[t]hese findings point to important heterogeneities in financial ties and suggest that policymakers will need to be nuanced in their management of financial relationships of FDA advisory committee members.”²¹ In another study, the researchers found little significant evidence that advisory committee members vote in their financial interests.²² The authors also found that the perverse exclusion of “financially-conflicted members resulted in a sharp drop in average member expertise, and an unintended increase in approval voting.” The study authors concluded that “[e]liminating conflicts could sharply reduce the level of expertise of the decision makers and lead to unexpected voting tendencies.”²³ More recently, an investigation of FDA advisory committee members COIs has called into question: (1) the completeness of COI disclosures submitted by members; (2) whether the FDA does enough to verify the completeness and accuracy of such disclosures; and (3) whether past or current COI assessments are inadequate as pay-later COIs may play a more significant role in influencing a member’s deliberations and vote.

Specifically, a 2018 investigation found that, at the time of or in the year leading up to the advisory committee meetings under scrutiny, many of the members received payments or other financial support from the sponsoring drug firm or key competitors for consulting, travel, lectures, or research.²⁴ The investigators concluded that the FDA did not publicly disclose those ties even though this information was disclosed in scholarly journals.²⁵ In the same investigation, a review was undertaken of compensation records from drug sponsors to advisory committee members who advised the FDA on whether to approve 28 psychopharmacologic, arthritis, and cardiac or renal drugs between 2008 and 2014.²⁶ The investigators concluded that there were “widespread after-the-fact payments or research support to panel members.”²⁷ As correctly noted by the investigators: “[t]he agency’s safeguards against potential conflicts of interest are not designed to prevent such future financial ties.”

AMA POLICY

The AMA has policy addressing COIs applicable to FDA advisory committees (Policy H-100.992, “FDA”) as well as ethics policy concerning COIs in the areas of research (Ethics Opinion 7.1.4/ AMA Principles of Medical Ethics: II, IV,V, “Conflicts of Interest in Research”) and clinical practice guidelines (Policy H-410.953, “Ethical Considerations in the Development of Clinical Practice Guidelines”).

DISCUSSION

The resolved clauses in Resolution 216 would have the AMA adopt policy that specifies that the FDA should place a greater emphasis on advisory committee member COIs and seek a further reduction in the number of COI waivers granted by the FDA. While there is widespread consensus that COI policies are appropriate and necessary along with a measured approach to granting COI waivers for FDA advisory committee members, there is also concern that an overzealous approach to waivers will undermine the actual or perceived quality of advisory committee recommendations. The FDA has reduced the number of waivers granted, but there are conflicting reports with regard to the magnitude of the challenge the Agency faces filling advisory committee vacancies. For example, one article reported that in FY 2017, “218 advisory committee positions of the 600-plus on the FDA’s 49 advisory committees had not been filled.”²⁸ Yet, data disclosed by FDA indicates that in FY 2017 there were 64 vacancies out of 564²⁹ and in FY 2018 there were 57 total vacancies out of 547 members.³⁰ A 10 percent vacancy is substantially lower than a nearly 50 percent vacancy. Nonetheless, the COI waiver rate has remained consistently below one percent. Lowering this percentage further is reasonably likely to increase vacancies which are hovering at 10 percent.

Existing AMA ethics policy provides a clear set of parameters concerning COIs and waivers regarding clinical practice guidelines development and clinical research that should be utilized to expand upon AMA policy concerning FDA advisory committee member COIs and waivers. Our current AMA policy related to advisory committee members provides that a FDA decision to approve a new drug, to withdraw a drug’s approval, or to change the indications for use of a drug must be based on sound scientific and medical evidence derived from controlled trials and/or postmarket incident reports as provided by statute and evidence of such should be evaluated by the FDA, in consultation with its advisory committees (Policy H-100.992, “FDA”). The policy also provides that the FDA should not let COIs overrule scientific evidence in making policy decisions. Building on the above policy, our AMA has ethics policy noting how minimizing and mitigating COIs in clinical research is imperative to justify and maintain trust in the medical research community (7.1.4, “Conflicts of Interest in Research”). This is equally true for FDA advisory committee member recommendations. This same policy provides that physicians who engage in research should disclose material ties to companies whose products they are investigating or other ties that create real or perceived COIs. Similarly, AMA ethics policy concerning clinical practice guidelines provides that patients, the public, physicians, and other stakeholders must have confidence that published guidelines are the ethically and scientifically credible product of development processes that are rigorous, independent, transparent, and accountable (Policy H-410.953, “Ethical Considerations in the Development of Clinical Practice Guidelines”). Notably, while Policy H-410.953 specifies that published guidelines/updates are to be developed independent of direct financial support from entities that have an interest in the recommendations, it does specify consideration for COIs (actual and perceived) for individuals associated in the development of the guidelines. The policy states: “ideally, all individuals associated with guideline development will be free of conflicts of interest during the development process and will remain so for a defined period following the publication of the guideline.” In order to ensure credibility, our AMA policy provides that:

formal procedures would be adopted to minimize the potential for financial or other interests to influence the process at all key steps (selection of topic, review of evidence, panel deliberations, development and approval of specific recommendations, and dissemination of final product). These should include: a) required disclosure of

all potential conflicts of interest by panel members, consultants, staff, and other participants; b) clearly defined criteria for identifying and assessing the seriousness of conflicts of interest; and c) clearly defined strategies for eliminating or mitigating the influence of identified conflicts of interest (such as prohibiting individuals from participating in deliberations, drafting, or voting on recommendations on which they have conflicts) in those limited circumstances when participation by an individual with a conflicting interest cannot be avoided.

Finally, the policy provides for a clear statement of methodology, COI policy and procedures, and disclosures of panel members' COIs. Extending the foregoing policies to FDA advisory committee member COIs and waivers will underscore the importance of existing FDA laws, regulations, and policies. However, the policy does not address concerns that advisory committee members may not be fully disclosing conflicts and independent targeted auditing for sufficiency may be warranted. In addition, existing policy does not address the impact of pay-later COIs (e.g., where a FDA advisory committee member develops a financial COI only after his or her initial appointment on the advisory committee has expired). Since there is limited research on the topic, this is important area for the FDA and researchers to more fully evaluate and craft appropriate policy.

RECOMMENDATION

In light of these considerations, your Board of Trustees recommends that the following be adopted in lieu of Resolution 216-A-18 and the remainder of this report be filed:

1. That our AMA reaffirm Policy H-100.992, "FDA," which supports that FDA conflicts of interest should not overrule scientific evidence in making policy decisions and the FDA should include clinical experts on advisory committees.
2. That our AMA adopt the following new policy:

It is the position of the American Medical Association that decisions of the Food and Drug Administration (FDA) must be trustworthy. Patients, the public, physicians, other health care professionals and health administrators, and policymakers must have confidence that FDA decisions and the recommendations of FDA advisory committees are ethically and scientifically credible and derived through a process that is rigorous, independent, transparent, and accountable. Rigorous policies and procedures should be in place to minimize the potential for financial or other interests to influence the process at all key steps. These should include, but not necessarily be limited to: a) required disclosure of all relevant actual or potential conflicts of interest, both financial and personal; b) a mechanism to independently audit disclosures when warranted; c) clearly defined criteria for identifying and assessing the magnitude and materiality of conflicts of interest; and d) clearly defined processes for preventing or terminating the participation of a conflicted member, and mitigating the influence of identified conflicts of interest (such as prohibiting individuals from participating in deliberations, drafting, or voting on recommendations on which they have conflicts) in those limited circumstances when an individual's participation cannot be terminated due to the individual's unique or rare skillset or background that is deemed highly valuable to the process. Further, clear statements of COI policy and procedures, and disclosures of FDA advisory committee members' conflicts of interest relating to specific recommendations, should be published or otherwise made public. Finally, it is recognized that, to the extent feasible in accordance with the principles stated above, participation on advisory committees should be facilitated through appropriate balancing of the relative scarcity or uniqueness of an individual's expertise and ability to contribute to the process, on the one hand, as compared to the feasibility and effectiveness of mitigation measures including those noted above.

3. That our AMA adopt the following new policy:

It is the position of the American Medical Association that the FDA should undertake an evaluation of pay-later conflicts of interest (e.g., where a FDA advisory committee member develops a financial conflict of interest only after his or her initial appointment on the advisory committee has expired) to assess whether these undermine the independence of advisory committee member recommendations and whether policies should be adopted to address this issue.

REFERENCES

1. [FDA Advisory Committees](#). Accessed on February 25, 2019
2. Id. Products include blood, vaccines and other biologics; human drugs; food; medical devices; patient engagement; pediatric; radiation-emitting products; risk communication; science board; toxicological research; veterinary; and tobacco.
3. See, for example, the FDA Amendments Act (FDAA) of 2007 which mandated that by 2012 no more than thirteen percent of committee advisors per year could receive COI waivers. The FDA reduced the maximum size of financial interests eligible for waivers from a combined financial interest of up to \$100,000, to a maximum of \$50,000. See also [Draft Guidance for the Public, FDA Advisory Committee Members, and FDA Staff on Procedures for Determining COI and Eligibility for Participation in FDA Advisory Committees](#) (March 2007); [Public Availability of Advisory Committee Members' Financial Interest Information and Waivers-Final Guidance](#) (2014); and, [Procedures for Evaluating Appearance Issues and Granting Authorizations for Participation in FDA Advisory Committees](#) (2016).
4. Related persons and organizations include: the employee's spouse, minor child, or general partner; an organization or entity for which the employee serves as officer, director, trustee, general partner, or employee; and a person with whom the employee is negotiating for, or has an arrangement concerning, prospective employment.
5. In preparation for advisory committee meetings involving particular matters, SGEs invited to participate in the meetings are required to report to FDA any financial interests related to the subject matter of the advisory committee meeting. 5 CFR § 2634.904(a)(2). Permanent government employees also report financial interests on a yearly basis and/or just prior to the advisory committee meeting they are planning to attend. 5 CFR §§ 2634.202 and 2634.904(a)(1). The FDA reviews not only the financial interests of a potential advisory committee participant and the individual's immediate family, but also the financial interests, of which the individual has knowledge, of the participant's business partners, organizations for which the individual serves as officer, director, trustee, general partner, or employee, and any prospective employer of the member (if there are ongoing employment negotiations or an agreement regarding future employment). See 18 U.S.C. § 208(a).
6. 5 CFR 2640.302(b)
7. 5 CFR 2640.301(b)
8. [Food, Drug, and Cosmetic Act section 505 \(n\)\(4\)](#) "Each member of a panel shall publicly disclose all conflicts of interest that member may have with the work to be undertaken by the panel. No member of a panel may vote on any matter where the member or the immediate family of such member could gain financially from the advice given to the Secretary. The Secretary may grant a waiver of any conflict of interest requirement upon public disclosure of such conflict of interest if such waiver is necessary to afford the panel essential expertise, except that the Secretary may not grant a waiver for a member of a panel when the member's own scientific work is involved."
9. Draft Guidance for the Public, FDA Advisory Committee Members, and FDA Staff on Procedures for Determining COI and Eligibility for Participation in FDA Advisory Committees March 2007
10. Id.
11. Wood SF, Mador JK. *Science and regulation. Uncapping conflict of interest?* Science (2013)
12. Lurie P. *Suggestions for Improving Conflict of Interest Processes in the US Food and Drug Administration Advisory Committees—Past Imperfect*. JAMA Intern Med. 2018;178(7):997–998. doi:10.1001/jamainternmed.2018.1324
13. Report to Congress Food and Drug Administration Safety and Innovation Act, Section 712 (e) of the Federal Food, Drug, and Cosmetic Act, [Fiscal Year 2016 Annual Report on FDA Advisory Committee Vacancies and Public Disclosures](#) Accessed on February 27, 2019
14. The FDA does not publicly disclose financial interest information if it is exempt from disclosure under the Freedom of Information Act or otherwise protected from disclosure by statute or regulation, except if necessary to describe the type, nature, and magnitude of the financial conflict being waived.
15. This information must be published within specified time frames before advisory committee meetings. Food, Drug, and Cosmetic Act section 712(c).
16. [FDA Guidance on Publication of Financial COI waivers](#).
https://www.fda.gov/RegulatoryInformation/Guidances/ucm391034.htm#_ftn11
17. Political party as described in 26 U.S.C. 527(e)
18. Participation is active if, for example, it involves service as an official of the organization or in a capacity similar to that of a committee or subcommittee chairperson or spokesperson, or participation in directing the activities of the organization. In other cases, significant time devoted to promoting specific programs of the organization, including coordination of fundraising efforts, is an indication of active participation. Payment of dues or the donation or solicitation of financial support does not, in itself, constitute active participation.
19. Pham-Kanter G., *Revisiting Financial Conflicts of Interest in FDA Advisory Committees*, Milbank Quarterly, September 2014 Volume 92, Issue 3 (pages 446–470), DOI: 10.1111/1468-0009.12073
20. Id.
21. Id.
22. Cooper J., Golec J. [Conflicts of Interest on Expert Committees: The Case of FDA Drug Advisory Committees](#), University of Connecticut School of Business Research Paper No. 17-02, April 2018 Accessed February 24, 2019
23. Id.
24. Piller C., You J. [Hidden conflicts? Pharma payments to FDA advisers after drug approvals spark ethical concerns](#), Science Magazine, July 5, 2018 Accessed February 24, 2019
25. Id.

26. Id.
27. Pillar C., You J. [Hidden conflicts? Pharma payments to FDA advisers after drug approvals spark ethical concerns](#), Science Magazine, July 5, 2018 Accessed February 24, 2019
28. Sullivan, T., FDA Conflicts of Interest Rules Means Fewer Experts on Advisory Panels, Policy and Medicine Blog, May 5, 2018 Accessed on February 24, 2019.
29. FDA website – online [Percent of FDA advisory committee member positions vacant at the end of the month](#) Accessed February 27, 2019
30. FDA website – online [Percent of FDA advisory committee member positions vacant at the end of the month](#) Accessed February 27, 2019

APPENDIX: RELEVANT AMA POLICY

Policy H-100.992, “FDA”

- (1) Our AMA reaffirms its support for the principles that: (a) an FDA decision to approve a new drug, to withdraw a drug’s approval, or to change the indications for use of a drug must be based on sound scientific and medical evidence derived from controlled trials and/or postmarket incident reports as provided by statute; (b) this evidence should be evaluated by the FDA, in consultation with its Advisory Committees and expert extramural advisory bodies; and (c) any risk/benefit analysis or relative safety or efficacy judgments should not be grounds for limiting access to or indications for use of a drug unless the weight of the evidence from clinical trials and postmarket reports shows that the drug is unsafe and/or ineffective for its labeled indications.
- (2) The AMA believes that social and economic concerns and disputes per se should not be permitted to play a significant part in the FDA’s decision-making process in the course of FDA devising either general or product specific drug regulation.
- (3) It is the position of our AMA that the Food and Drug Administration should not permit political considerations or conflicts of interest to overrule scientific evidence in making policy decisions; and our AMA urges the current administration and all future administrations to consider our best and brightest scientists for positions on advisory committees and councils regardless of their political affiliation and voting history.

7.1.4 Conflicts of Interest in Research

Increasing numbers of physicians, both within and outside academic health centers, are becoming involved in partnerships with industry to conduct biomedical and health research. As they do so, physicians must be mindful of the conflicts such engagement poses to the integrity of the research and the welfare of human participants. In addition to financial conflicts of interest created by incentives to conduct trials and recruit subjects, physicians must be sensitive to the differing roles of clinician and investigator, which may require them to balance dual commitments to participants and science. This conflict of commitment is particularly acute when a physician-investigator has treated or continues to treat a patient who is eligible to enroll as a participant in a clinical trial the physician is conducting.

Minimizing and mitigating conflicts of interest in clinical research is imperative if the medical community is to justify and maintain trust in the medical research community.

Physicians who engage in research should:

- (a) Decline financial compensation that awards in excess of the physician’s research efforts and does not reflect fair market value. Physicians should not accept payment solely for referring patients to research studies.
- (b) Ensure that the research protocol includes provision for funding participants’ medical care in the event of complications associated with the research. A physician should not double-bill a third-party payer for additional expenses related to conducting the trial if he or she has already received funds from a sponsor for those expenses.
- (c) As part of the informed consent process, disclose to prospective participants the nature and source of funding and financial incentives offered to the investigators. This disclosure should be included in any written consent materials.
- (d) Avoid engaging in any research where there is an understanding that limitations can be placed on the presentation or publication of results by the research sponsor.
- (e) Refrain from knowingly participating in a financial relationship with a commercial entity with whom they have a research relationship until the research relationship ends and the research results have been published or otherwise disseminated to the public.
- (f) Disclose material ties to companies whose products they are investigating or other ties that create real or perceived conflicts of interest to:
 - (i) institutions where the research will be carried out;
 - (ii) organizations that are funding the research;
 - (iii) any journal or publication where the research results are being submitted.
- (g) Physicians who have leadership roles in institutions that conduct biomedical and health research as well as the entities that fund research with human participants should promote the development of guidelines on conflicts of interest that clarify physician-investigators responsibilities.

AMA Principles of Medical Ethics: II,IV,V; The Opinions in this chapter are offered as ethics guidance for physicians and are not intended to establish standards of clinical practice or rules of law. Issued: 2016

Policy H-410.953, “Ethical Considerations in the Development of Clinical Practice Guidelines”

Clinical practice guidelines are statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options. Clinical practice guidelines help inform physician judgment and decision making by physicians and patients. Clinical practice guidelines also have significant potential to meaningfully inform efforts to provide care of consistently high quality for all patients and to help shape development of sound public policy in health care. To achieve those ends, clinical practice guidelines must be trustworthy. Patients, the public, physicians, other health care professionals and health administrators, and policymakers must have confidence that published guidelines are the ethically and scientifically credible product of development processes that are rigorous, independent, transparent, and accountable.

To that end, the development or updating of clinical practice guidelines should meet the following expectations:

1. Guidelines/updates are developed independent of direct financial support from entities that have an interest in the recommendations to be developed.
2. Formal, scientifically rigorous methods and explicit standards are adopted for the review and weighting of evidence, the integration of expert judgment, and the strength of clinical recommendations.
3. Guideline panels have access to appropriate expertise among members or consultants, including not only relevantly qualified clinical experts but also appropriately qualified methodologists, representatives of key stakeholders, and, ideally, one or more individuals skilled in facilitating groups.
4. Ideally, all individuals associated with guideline development will be free of conflicts of interest during the development process and will remain so for a defined period following the publication of the guideline.
5. Formal procedures are adopted to minimize the potential for financial or other interests to influence the process at all key steps (selection of topic, review of evidence, panel deliberations, development and approval of specific recommendations, and dissemination of final product). These should include: a) required disclosure of all potential conflicts of interest by panel members, consultants, staff, and other participants; b) clearly defined criteria for identifying and assessing the seriousness of conflicts of interest; and c) clearly defined strategies for eliminating or mitigating the influence of identified conflicts of interest (such as prohibiting individuals from participating in deliberations, drafting, or voting on recommendations on which they have conflicts) in those limited circumstances when participation by an individual with a conflicting interest cannot be avoided.
6. Guidelines are subject to rigorous, independent peer review.
7. Clear statements of methodology, COI policy and procedures, and disclosures of panel members’ conflicts of interest relating to specific recommendations are published with any guideline or otherwise made public.
8. Guidelines are in the first instance disseminated independent of support from or participation by individuals or entities that have a direct interest in the recommendations.

20. SAFE AND EFFICIENT E-PRESCRIBING

Reference committee hearing: see report of Reference Committee B.

**HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS
REMAINDER OF REPORT FILED**

*See Policies H-120.921, H-120.941, H-125.979, H-478.983, D-120.945, D-120.956,
D-120.958 and D-120.972*

INTRODUCTION

At the 2018 Annual Meeting Policy D-120.972, “Electronic Prescribing,” was amended by the House of Delegates (HOD) with additional directives from Resolution 237-A-18. The policy asks the American Medical Association (AMA) to study current electronic prescribing (e-prescribing) processes and make recommendations to improve these processes to make them as safe as possible for patients and as efficient as possible for prescribers.

This report provides the requested study of current e-prescribing processes, including benefits and challenges, examples of interventional case studies, and opportunities for improvement.

BACKGROUND

The electronic exchange of prescription and medication history information between prescribers, pharmacies, and payers/pharmacy benefit managers, referred to as e-prescribing, has been shown to improve efficiency, patient safety, and cost savings. E-prescribing has also been shown to reduce medication errors and increase efficiencies in patient care.¹ In 2017 almost 70% of prescribers and 98% of pharmacies were utilizing e-prescribing.² Despite vast increases in adoption of e-prescribing and the improvements realized thus far, there are still areas for improvement in e-

prescribing. For example, functions of the electronic systems, such as excessive or unnecessary alerts,^{1, 3} and the processes required for prescribing controlled substances, are perceived as remaining barriers to the optimal use of e-prescribing.¹ The authors of Resolution 237-A-18 expressed concern that some steps required to order an e-prescription, such as selecting a pharmacy to which the prescription should be filled, are error-prone and not efficient use of physician time. The current two-factor authentication process required to electronically prescribe controlled substances (EPCS) has also been noted as a cumbersome requirement lacking efficiency and contributing to the slower adoption of EPCS compared to non-controlled substances. In 2017 21% of controlled substances were prescribed electronically compared to 90% of non-controlled substances.⁴ Despite the numerous advantages of e-prescribing over the former paper prescription systems, the systems and processes still have opportunities for improvement to maximize efficiency and safety.⁵

AMA POLICY

The AMA supports e-prescribing for both controlled and non-controlled substances and has numerous policies expressing its commitment to advocating for better regulations and better systems that enable more efficient, safe, and less burdensome use of e-prescribing. The AMA supports programs that incentivize adoption of e-prescribing systems, but opposes a funding structure that financially penalizes physicians that have not adopted such technology (Policy H-478.991, “Federal EMR and Electronic Prescribing Incentive Program”). The AMA continues to work with the Centers for Medicare and Medicaid Services (CMS) to ensure that the e-prescribing policies and reporting procedures provide the greatest flexibility to physicians who participate in the program (Policy D-120.957, “Electronic Prescribing Incentive Program”). The AMA encourages states to implement modernized PDMPs that are seamlessly integrated into the physician's normal workflow, and provide clinically relevant, reliable information at the point of care (Policy H-95.939, “Development and Promotion of Single National Prescription Drug Monitoring Program”).

Recognizing that EPCS continues to pose administrative burdens for physicians, in 2017 the AMA modified existing policy to continue to advocate before federal and state agencies and legislative bodies for elimination of cumbersome, confusing and burdensome requirements relating to electronic transmission of physicians’ controlled substance prescriptions to pharmacies,” (Policy D-120.956, “Electronic Prescribing and Conflicting Federal Guidelines”). The AMA also supports action requiring that the U.S. Drug Enforcement Administration (DEA) establish reasonable requirements enabling the use of e-prescribing for controlled substances (Policy H-120.941, “e-Prescribing of Scheduled Medications”). In addition, the AMA is committed to reducing federal roadblocks to e-prescribing and is working with the CMS and states to remove or reduce barriers to electronic prescribing of both controlled substances and non-scheduled prescription drugs. Through this work the AMA will reduce regulatory burdens to facilitate further adoption of e-prescribing, including for controlled substances (Policy D-120.958, “Federal Roadblocks to E-Prescribing”).

The AMA advocates for changing the national standards for controlled substance prescriptions so that prescriptions for controlled substances can be transmitted electronically directly to the pharmacy in a secure manner and is committed to working with stakeholders to encourage the use of standards that allow direct physician/pharmacist communication within existing electronic health record (EHR) or e-prescribing systems (Policy D-120.944, “Improvement of Electronic Prescription Software”). The AMA sought from CMS and the DEA a requirement that all pharmacies and Pharmacy Benefits Managers (PBMs) acquire and implement the appropriate electronic prescribing of controlled substances software to accept electronically transmitted controlled substance prescriptions from prescriber systems that comply with CMS and DEA certification requirements (Policy D-120.945, “Completing the Electronic Prescription Loop for Controlled Substances”). The AMA also works with pharmacy benefit managers, payers and pharmacists to make accurate, real-time formulary information available at the point of care. It is AMA’s priority to promote procedural policies that ensure changes in formulary information are communicated promptly to prescribers so alternative medication can be provided to patients in a timely manner (Policy H-125.979, “Private Health Insurance Formulary Transparency”).

The AMA recognizes the importance of patient safety in the e-prescribing process, and is committed to working with pharmaceutical, e-prescribing and point of care resource stakeholders to increase physician awareness of risk evaluation and mitigation strategies to improve patient safety in the e-prescription process (Policy D-100.971, “Physician Awareness and Education About Pharmaceutical and Biological Risk Evaluation and Mitigation”). In addition, the AMA urges Congress to unify state prescription standards to facilitate further adoption of e-prescribing, and supports efforts to amend federal law to allow for the e-prescribing of a medication needed by a patient with a mental health or behavioral health diagnosis when a valid patient-physician relationship has been established through

telemedicine (Policy D-120.972, “Electronic Prescribing”). Last, in support of efforts to reduce medication errors by increasing efficiency and safety in the process of cancelling electronic prescriptions, the AMA supports the creation, standardization, and implementation of electronic prescription cancellation from all electronic medical records vendors and that these orders be accepted by pharmacies and pharmacy benefit managers (Policy H-478.983, “Electronic Prescription Cancellation”).

DISCUSSION

E-prescribing overview

E-prescribing is the computer-based electronic generation, transmission, and filling of a prescription, that replaces the need for paper and faxed prescriptions. CMS describes e-prescribing as “the ability for a prescriber to electronically send an accurate, error-free and understandable prescription directly to a pharmacy from the point-of-care.”⁶

E-prescribing eliminates the need for paper prescriptions, which can create hazards and increase risk of medical errors. E-prescribing systems can reduce medical errors, decrease pharmacy costs, improve both prescriber and pharmacy efficiency, eliminate handwriting interpretation errors, reduce phone calls between pharmacists and physicians, reduce data entry, and expedite prescription refill requests.⁷ In addition, e-prescribing can improve efficiencies by introducing an automatic process to reconcile drug-drug interactions and patient allergies at the point of prescribing. E-prescribing platforms also facilitate the ability to monitor prescribing patterns, which can help organizations ensure high-quality and cost-effective care.⁸

Although e-prescribing was not new and many practices had already transitioned from paper to electronic systems, in 2012 CMS implemented the Medicare eRx Incentive Program to encourage electronic prescribing by eligible professionals. The eRx program provided an incentive payment to eligible professionals who successfully e-prescribed for covered Medicare Part B services, and applied payment adjustments to those who did not. The eRx program ended in 2013 and was replaced with the Meaningful Use Incentive Program, which ended in 2017. E-prescribing measurement continues within the Merit Based Incentive Payment System track of the Medicare Quality Payment Program. In addition, CMS requires Medicare Part D sponsors, prescribers, and drug dispensers that transmit prescriptions and prescription-related information electronically to support and comply with the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard when filing prescriptions electronically. CMS will adopt a revised SCRIPT standard on January 1, 2020.⁹ The new standard will include support for several functions that aim to improve efficiency, clinical decision-making and patient safety. New functionalities will include support for grouping of multiple prescriptions and the reporting of allergies and adverse events, enhancements to digital signatures, and the choice of whether or not to receive RxFill notifications.¹⁰

Improvements gained from e-prescribing

With the introduction of EHRs and industry movement to leverage more technology solutions in patient care, e-prescribing has become a key component of the daily clinical workflow. E-prescribing has been shown to provide many benefits in comparison to traditional paper prescribing

A principal benefit of e-prescribing is the improvement in quality of care and patient outcomes. Through e-prescribing, prescription accuracy, standardization and safety have improved.¹¹ Prescribing through specialized pharmacy software and/or an EHR provides clinical decision support (CDS) tools and screening capabilities that alert prescribers to potential adverse drug interactions or over-prescribing. These improvements have led to a reduction in medical errors, resulting in better patient outcomes and improved quality of care. One study found error rates decreased from 42.5 per 100 prescriptions to 6.6 per 200 prescriptions.¹¹ It is estimated that medication errors have been reduced to as little as one-seventh of their previous level as a result of e-prescribing.¹

The reduction in medical errors and improved quality outcomes have led to significant cost savings to the overall healthcare system. It is estimated that improved patient outcomes and decreased patient visits may result in between \$140 billion and \$240 billion in cost avoidance over 10 years for practices that implement e-prescribing.¹ E-prescribing also assists with cost savings by reducing fraud, abuse and drug diversion. Through e-prescribing, prescriptions and usage are more effectively tracked, and the elimination of a paper script reduces the risk of fraud and illegal prescription sales. The secure and safe transfer of data and prescriptions to a pharmacy also serves as another protective safe guard in preventing drug diversion, as well as enhanced safety.

In addition, increased efficiency at the practice level has been reported. E-prescribing assists by reducing challenges with legibility problems from handwritten prescriptions.¹² It also saves time for the physician and team by reducing the number of calls received from the pharmacy to clarify prescriptions.⁵ Although one study estimated it takes a prescriber 20 seconds longer per patient to complete an e-prescription versus paper, the long-term benefits to the prescriber and patient are overall time savings, costs savings and reduced prescription errors.^{11, 13, 14}

E-prescribing has also been shown to improve patient satisfaction. Many patients prefer the ease and quick transmission of prescriptions to their pharmacy as well as the convenience of eliminating paper prescriptions and reduced wait time at the pharmacy. Many platforms are also providing more information on cost-effective medication options based on a patient's particular health plan, leading to cost-savings for the patient and health system.¹⁵

Despite the potential additional time and steps required for e-prescribing, the impacts to workflow should be minimal if systems are implemented effectively.¹ Most prescribers feel the benefits of e-prescribing outweigh the burdens created by additional steps, and that the extra time spent in the e-prescribing system is offset by the efficiencies gained in the overall process.^{1, 5}

The patient safety benefits and efficiencies of e-prescribing can be further enhanced through the use of Structured and Codified Sig (short for Signatura). Structured and Codified Sig is designed to communicate prescription dosing instructions in a codified way to the pharmacy that can then be conveyed to the patient, thus reducing the opportunity for transcription errors and improving efficiencies and work flows for prescribers and pharmacists. Unfortunately, despite its potential benefits, Structured and Codified Sig has neither been widely utilized by prescribers nor supported by EHRs that allow e-prescribing. NCPDP, which develops and maintains the SCRIPT standard, convened a task group to review these utilization and support issues and developed a Structured and Codified Sig Format Implementation Guide to support Structured and Codified Sig. Greater utilization of Structured and Codified Sig will present prescribers, pharmacists, and patients with an opportunity to improve safety and enhance workflow efficiency.

Barriers to adoption and use

Studies show unintended consequences of e-prescribing systems include changes in communication patterns, generation of new kinds of errors, more and new work for clinicians, unfavorable workflow issues, overdependence on technology, continuous demands for system upgrades, persistence of paper, negative emotions toward the technology, and changes in power structure and work roles.^{16, 17}

A principal barrier and challenge to e-prescription adoption is implementation. The cost of implementing e-prescribing technology can be the primary limiting factor. According to the Health Resources and Services Administration, the total cost of implementing an e-prescribing system was found to be \$42,332, with annual costs after implementation of about \$14,725 per year for a practice of 10 full-time equivalent psychiatrists.¹ A 2007 study by Scalise and colleagues revealed that the cost to implement a basic e-prescribing program ranges from \$1,500 to \$4,000 per physician and the price for an advanced system with alerts, reminders and system integration is \$29,000 per physician in the first year and \$4,000 per physician every year thereafter.¹⁸ The DEA in 2010 estimated the costs to implement the appropriate systems for EPCS, across pharmacies, hospitals and practitioners, to be between \$43 million and \$1.54 billion, annualized over 15 years.¹⁹ In addition to the cost of implementing e-prescribing technology, the time investment and training required can also present barriers to adoption.

Another challenge associated with e-prescribing is related to system errors and network challenges. A key concern for system errors in e-prescribing is related to the impact on quality and the potential to cause medical errors. Many systems have CDS tools, but there are considerable variances of capabilities across platforms. Design issues with CDS tools can present serious risks, for example in the programming of too few or too many alerts. A lack of alert specificity can result in missing an adverse drug reaction, while an overload of alerts can produce the phenomenon known as alert fatigue, which can result in providers overlooking and ignoring important alerts.²⁰ In addition, many physicians report technical problems and poor network connectivity as a key barrier in e-prescribing adoption. In some instances, pharmacies are not reliably receiving and processing prescriptions sent electronically due to poor connectivity or network issues. This also has a negative downstream effect on patients due to delays in filling medications.

Privacy and security issues also present concerns with e-prescribing processes. It is important for prescribers to have appropriate security parameters in place to safeguard protected health information (PHI). Protecting data securely is an ongoing and constant requirement and challenge for providers, especially with many web-based tools and multiple

opportunities for information to be stolen or compromised. In addition, many information breaches often originate from internal employee actions, which can be costly and require additional and ongoing training and security.²¹

Other barriers to efficient e-prescribing result from regulations of EPCS, enforced by the DEA. In 2010, the DEA legalized e-prescribing for Schedule II to Schedule V controlled substances. A dozen states have passed laws mandating the use of e-prescribing for controlled substances, some of which will be effective in 2020. The DEA ruling enforces strict standards for implementation and utilization, including identity proofing, two-factor authentication, digital certificates, monthly logs, third-party audits of software, and a requirement to keep two years of records.¹⁹ The SUPPORT for Patients and Communities Act, enacted in 2018, further requires that all providers use EPCS by January 1, 2021.²²

Two-factor authentication adds multiple additional steps to a prescriber's process.⁵ Board of Trustees Report 6-I-17 described in detail the barriers associated with 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 (HIT) 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 HIT vendors utilize for EPCS are not well-aligned with normal e-prescribing 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.²³ The SUPPORT for Patients and Communities Act requires the DEA to update its regulations pertaining to how prescribers authenticate prescriptions using biometric devices.²²

In addition to the requirements and time to e-prescribe controlled substances, providers also cite general clinic operational inefficiencies. Commonly cited challenges are time pressure on busy clinic days and frustration with time devoted to administrative portions of the e-prescription process, such as pharmacy selection and populating e-prescribing systems with patients' identifying information.¹⁵ Real-time benefit check applications integrated into the EHR can help gain efficiencies, but are not yet a universally utilized tool. Cancelling an electronic prescription often involves multiple steps and phone calls to the pharmacy, which can be burdensome and time-consuming, and can add to the risk of medication errors. Integration of state prescription drug monitoring program (PDMP) data into the e-prescribing software could also help reduce workflow burdens. CMS in 2018 encouraged states to improve their PDMP systems to enable integration of PDMP data with EHRs.²⁴

Another documented barrier is the excessive cost of complying with EPCS requirements. As reported in BOT 6-I-17, 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 HIT vendors. These fees and costs pose a significant barrier to EPCS adoption. The DEA registration fee for EPCS is \$731 for three years and covers the costs of its diversion control program.

Finally, some prescribers perceive the process of searching and selecting a pharmacy each time a prescription is ordered electronically to be time-consuming and error-prone. Challenges can occur when prescriptions need to be transferred from one pharmacy to another, sometimes a result of patients relocating or changing health plans. Disruption in adherence can occur if pharmacies don't stock particular medications and it becomes difficult for patients to fill their prescriptions. Health plan changes also sometimes result in changes in pharmacy network status, which can lead to unexpected coverage gaps. Additional costs to obtain a non-preferred pharmacy prescription may only be

realized when the patient picks up the prescription, resulting in phone calls from the patient back to the prescriber for help. Most commercial e-prescription systems offer a function to select a preferred pharmacy for patients. Other systems may also feature a “previously used pharmacy” option, which keeps a list of pharmacies at which the patient has historically filled prescriptions. Use of either of these functions, and regular verification of the indicated pharmacy, saves time and reduces the risk of selecting an erroneous pharmacy.²⁵

Interventional case studies

Given the amount of time and resources dedicated to ensuring prescriptions are authorized, filled and renewed safely and efficiently, and in light of government focus on improving care quality, many practices have implemented changes to improve their e-prescribing processes and outcomes.

For example, researchers at Texas Children’s Hospital implemented quality improvement interventions to improve e-prescribing.²⁶ Surveys and focus groups were conducted with patient families and pediatric residents to identify barriers and propose solutions to support efficient e-prescribing. These data were used to generate a series of interventions: (1) provider education; (2) changes in patient registration workflow; and (3) electronic health record changes to improve the frequency of e-prescribing on the pediatric hospital medicine (PHM) service.

One intervention was identified through the resident surveys which noted the absence of a preferred pharmacy in the patient’s EHR as a barrier to e-prescribing. Following this observation, registration personnel were trained on entering preferred pharmacy information, and it was added to their EHR workflow. Because personnel already input patients’ pediatrician information and other demographic data in the EHR, it was deemed an appropriate intervention to address this gap. Another intervention included an EHR build that required residents to assign an authorizing attending provider for discharge prescriptions, whether printed or e-prescribed. This enhancement ensured that attending information would be linked to all prescriptions for appropriate insurance processing and follow-up, whereas prior to that, residents were limited to manually writing in the attending name on printed prescriptions only, since the functionality was not allowed in the e-prescribing system. Texas Children’s Hospital also designated e-prescribing as the default method of prescription for all providers system-wide, and forcing providers to actively opt out of e-prescribing. The build included an in-line validation to ensure that prescription orders were eligible for e-prescribing and that all necessary information was present.

This onsite research resulted in an increase in e-prescribing frequency on the PHM service from a median of 7.4% to 48.9%, which was sustained for an additional six months. The frequency of PHM prescription errors was unchanged.²⁶

Marceglia et al identified six main phases of the e-prescribing process and proposed an updated comprehensive model for the e-prescribing process able to represent, analyze, and compare current systems and to support the design of new, more general, systems. Researchers identified six key phases of the e-prescribing process: Assign, Transmit, Dispense, Administer, Monitor, and Analysis Decision. The evaluation of systems completed in developing this model identified efficiency benefits primarily in the drug management controls within the e-prescribing systems. This model-based implementation of each phase is shown to have an impact on the quality of care, access to care, and the effectiveness of care delivery.²⁷

A 2011 case study tested the effects on prescribing errors of transitioning from a local EHR with minimal CDS to a new EHR with robust CDS for e-prescribing. Overall prescribing error rates declined significantly one year after implementation, the main improvement being a reduction in inappropriate abbreviation errors. At 12 weeks post-implementation, however, rates of non-abbreviation errors peaked and there was no significant improvement after one year, suggesting that there are still safety risks in transitioning to an e-prescribing system that features more robust CDS.¹⁴ Prescribers in this intervention, who were experienced e-prescribers, were surveyed for a parallel qualitative study. The participants found the transition to be extremely difficult and the EHR was not perceived to improve safety.²⁸

Another case study identified an approach to simplifying the overall prescription renewal process. Synchronized, bundled prescription renewal, a systematic approach to prescription management, can decrease patient inconvenience, support medication adherence, and save one to two hours of physician and staff time each day.²⁹ In this system, the prescriber renews all chronic medications (except narcotics and benzodiazepines) at the annual comprehensive care visit, allowing for sufficient refills to last until the next annual visit. This eliminates the need for the physician and

staff members to repeat the work of renewing each medication at interval visits. The AMA offers a STEPS Forward module on synchronized prescription renewal that is available with CME through the AMA Education Center.³⁰

AMA efforts

In addition to comprehensive policy on e-prescribing and educational content on synchronized prescription renewal, ongoing AMA advocacy has succeeded in addressing a number of concerns about e-prescribing practices and regulations. The AMA continues concerted engagement to address specific barriers to e-prescribing of controlled substances due to overly burdensome DEA regulations. In the past, the AMA provided comments as part of the DEA's rulemaking process, raising concerns with a number of regulations and requirements. 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 prescription system adds value to their practice of medicine and supports better patient care.²³

Recommendations for improvements to e-prescribing practices

Surescripts published "E-Prescribing Quality Guidelines" which offers e-prescribing clinicians and EHR vendors comprehensive guidance on key principles and best practices to consider when initiating and transmitting electronic prescription orders.² Based on these best practices, and the literature and case studies reviewed, several recommendations for improving e-prescribing processes can be offered.

Some improvement efforts are already part of AMA's ongoing commitment to optimizing the use of e-prescribing in medical practice, as outlined in the AMA policies previously discussed. For example, the AMA advocates for:

- States to work toward unifying prescription standards and standard vocabularies
- The DEA to ease authentication requirements for prescribing controlled substances, including the scope of technology that is compliant with EPCS requirements
- HIT developers to improve interoperability between prescriber interfaces and mail-order prescription services and pharmacies

Other opportunities for improvements in e-prescribing processes are possible for a number of stakeholders.

- Implementation teams can conduct an annual audit to evaluate the number, frequency and user acknowledgment/dismissal patterns of e-prescribing system alerts and provide an audit report to the software vendors for their consideration in future releases.
- Health care organizations and implementation teams can improve prescriber end-user training and on-going education.
- Implementation teams can prioritize the adoption of features like Structured and Codified Sig formats that can help address quality issues.
- Implementation teams can enable functionality of pharmacy directories and preferred pharmacy options. Leadership can encourage the practice of inputting a patient's preferred pharmacy at registration, and re-confirming it upon check-in at all subsequent visits.
- Implementation teams can enhance EHR function to require residents assign an authorizing attending physician.
- Organizational leadership can implement e-prescribing systems that feature more robust clinical decision support, but ensure prescriber preferences are tested and seriously considered in implementation decisions.
- Organizational leadership can assign e-prescribing as the default prescription method.
- The DEA can 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.
- Health insurers, pharmacies and e-prescribing software vendors should enable real-time benefit check applications that enable more up to date prescription coverage information and allow notification when a patient changes health plans or a health insurer has changed a pharmacy's network status.
- States can allow PDMP/EHR integration to reduce workflow burden and increase efficiency.

CONCLUSION

The increase in use of e-prescribing and the incentive programs aimed at encouraging its adoption have invigorated progress in improving the safety and efficiency of prescribing medications, but there is still much room for

improvement. While errors related to legibility issues or misinterpretation of handwriting have been reduced, rates of medication errors have declined, and organizations have experienced better patient satisfaction and cost savings, the trade-off is the additional time prescribers spend maneuvering multiple platforms and completing data entry tasks required to order prescriptions. Many physicians appreciate the benefits that e-prescribing has provided, but recognize that improvements can still be realized to make them as safe as possible for patients and efficient as possible for prescribers. These improvements may be possible through the recommendations outlined in this report.

RECOMMENDATIONS

The Board of Trustees recommends that the following be adopted in lieu of Resolution 237-A-18 and that the remainder of this report be filed:

1. That our American Medical Association (AMA) reaffirm the following policies:
 - a. H-125.979, “Private Health Insurance Formulary Transparency”
 - b. D-120.956, “Electronic Prescribing and Conflicting Federal Guidelines”
 - c. H-120.941, “e-Prescribing of Scheduled Medications”
 - d. D-120.958, “Federal Roadblocks to E-Prescribing”
 - e. D-120.945, “Completing the Electronic Prescription Loop for Controlled Substances”
 - f. H-478.983, “Electronic Prescription Cancellation”
2. That the second paragraph of AMA Policy D-120.972, “Electronic Prescribing,” be rescinded as having been fulfilled by this report.
3. That our AMA encourage health care stakeholders to improve electronic prescribing practices in meaningful ways that will result in increased patient safety, reduced medication error, improved care quality, and reduced administrative burden associated with e-prescribing processes and requirements. Specifically, the AMA encourages:
 - a. E-prescribing system implementation teams to conduct an annual audit to evaluate the number, frequency and user acknowledgment/dismissal patterns of e-prescribing system alerts and provide an audit report to the software vendors for their consideration in future releases.
 - b. Health care organizations and implementation teams to improve prescriber end-user training and on-going education.
 - c. Implementation teams to prioritize the adoption of features like structured and codified Sig formats that can help address quality issues, allowing for free text when necessary.
 - d. Implementation teams to enable functionality of pharmacy directories and preferred pharmacy options.
 - e. Organizational leadership to encourage the practice of inputting a patient’s preferred pharmacy at registration, and re-confirming it upon check-in at all subsequent visits.
 - f. Implementation teams to establish interoperability between the e-prescribing system and the EHR to allow prescribers to easily confirm continued need for e-prescription refills and to allow for ready access to pharmacy choice and selection during the refill process.
 - g. Implementation teams to enhance EHR and e-prescribing system functions to require residents assign an authorizing attending physician when required by state law.
 - h. Organizational leadership to implement e-prescribing systems that feature more robust clinical decision support, and ensure prescriber preferences are tested and seriously considered in implementation decisions.
 - i. Organizational leadership to designate e-prescribing as the default prescription method.
 - j. The DEA to 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.
 - k. States to allow integration of PDMP data into EHR systems.
 - l. Health insurers, pharmacies and e-prescribing software vendors to enable real-time benefit check applications that enable more up to date prescription coverage information and allow notification when a patient changes health plans or a health insurer has changed a pharmacy’s network status.
 - m. Functionality supporting the electronic transfer and cancellation of prescriptions.

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21. AUGMENTED INTELLIGENCE (AI) IN HEALTH CARE

Reference committee hearing: see report of Reference Committee B.

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS REMAINDER OF REPORT FILED

See Policy H-480.939

At the 2018 Annual Meeting, our American Medical Association's (AMA) House of Delegates (HOD) adopted Board of Trustees (BOT) Report (Report) 41-A-18, "Augmented Intelligence (AI) in Health Care" policy recommendations as amended in lieu of Resolution 205-A-18, "Augmented Intelligence," introduced by the American Academy of Pediatrics. However, the HOD referred the following proposed additional recommendation to the report for a BOT Report at the 2019 Annual Meeting.

AI should be funded as an enhancement of the primary care medical home so that patients who really need AI can benefit from the technology and such that AI does not become a requirement that must be incorporated into the care of every patient.

The reference committee heard overwhelmingly supportive testimony on BOT Report 41-A-18 and mixed testimony on Resolution 205. The reference committee heard testimony that physicians must provide a clear set of policy positions on health care AI to ensure the best interests of patients are served. The reference committee noted that Resolution 205 intends to advance important goals of health care AI such as ensuring it is part of workflow, that it is not mandated for use, and it strengthens the medical home. The reference committee noted that BOT Report 41 captures those goals and establishes policy that addresses additional important issues such as guarding against bias, application to specialty care, and the legal implications of health care AI.

The reference committee heard further testimony that federal and state legislators and policymakers are already developing laws and regulations on health care AI. The reference committee agreed with testimony that physicians have a critical perspective and must engage now to ensure this technology is developed in a way that improves patient outcomes, reduces administrative and technological burdens, and contributes to physician professional satisfaction. The reference committee heard testimony offering an amendment to safeguard patients' and individuals' privacy interests. Finally, the reference committee recommended adoption of BOT Report 41 with amendment in lieu of Resolution 205.

TERMINOLOGY¹

The AMA's BOT Report 41-A-18 and the AMA's Council on Long Range Planning and Development's (CLRPD) Primer on Artificial and Augmented Intelligence establish definitions related to key AI systems, methods, and techniques. In this report on payment, it is essential to specify systems that augment the work of clinicians do so by assisting the decision making or by offering fully automated (autonomous) assistance. Furthermore, it is necessary to define and differentiate between AI systems that utilize machine learning (ML) where there is either (1) a continuous learner algorithm or (2) a locked learner algorithm. The foregoing approaches have critical implications for risk, safety, regulation, liability, and, as a result, cost of integration into clinical practice (whether in a health system or a physician practice).

Augmented Intelligence and the Human – Machine Dyad

Although AMA physician leaders considered using the term "artificial intelligence," ultimately through the HOD process it was determined that the term augmented intelligence more accurately reflects the purpose of such systems, whether assistive or fully autonomous, because they are intended to coexist with human decision-making.² As we enter what many experts view as the fourth industrial revolution, it is important to update terms to explicitly articulate the expectation that rapidly evolving technologies should complement and extend the work of humans. And, the AMA is not alone in this measured view of what current AI systems in health care are able to do and what the expectations should be for the future development of such systems. The term "augmented" intelligence has become the preferred term among key technology companies,³ other innovators, and physician AI experts. While one leading expert has advocated the use of the term "dyadarity" to underscore the human-machine dyad, the rationale for the use of the term dyadarity also points to the appropriateness of the use of the term "augmented intelligence:"

As we embed more and more machine learning in our clinical decision support and in our clinical workflows (face to face [and] virtual care), we will discover far more interaction and meshing between human and machine, physician and computer. The notion that the machine will acquire absolute superiority over the human in decision-making implies that the output of the machine will be strictly deterministic, as if it were just like the result of a serum sodium level. ... Incorporating [...] highly variable and contextual human considerations into the treatment plan really requires thoughtful and empathic discussion between doctor and patient. The literature is now replete with references to various types of bias associated with how machine learning is applied to different people in different contexts. Similarly, there are over 100 cognitive biases that have been well documented in human decision-making. What we will really need as physicians is assistance in how to more systematically surface and expose the biases of both the machine, also known as “thinking in silico” and the human “thinking in carbon,” in ways that allow the individual physician to manage, reconcile when possible, and mitigate those biases. This will become more of a collaborative exercise and the notion of a machine-superiority emerging after the “singularity is here” will begin to fade into a more realistic “dyadarity” where all potential bias and ethical issues are made more transparent, but ultimately the human will be responsible for making the decision.⁴

As noted in BOT Report 41-A-18, “combining machine learning software with the best human clinician ‘hardware’ will permit delivery of care that outperforms what either can do alone.”⁵ Other physicians have noted that “the applications of AI to ‘augment’ physicians is more realistic and broader reaching than those that portend to replace existing health care services.”⁶ Other early adopters of such systems note that “[t]he difference between artificial intelligence and augmented intelligence may seem inconsequential to some; it could quite literally make a world of difference when it comes to how we approach robotics in the decades to come ... [and] [i]t’s businesses using the technology to supplement rather than replace their employees that stand to benefit most from the further development and refinement of this technology.”⁷ In sum, whether AI systems are assistive (such as clinical decision support programs) or fully autonomous (such as software programs that provide a definitive diagnostic decision), these rapidly evolving systems should augment and scale the capabilities of physicians, the broader health care team, and patients in achieving the quadruple aim in health care.⁸

Machine Learning (ML): Continuous Learning System and “Locked” Model

The term AI covers a range of methods, techniques, and systems. Common examples of AI systems include, but are not limited to, natural language processing, computer vision, and ML. In health care, as in other sectors, AI solutions may include a combination of these systems and methods. ML presents some of the thornier regulatory and oversight challenges that implicate cost and payment.

An AI system utilizing ML employs an algorithm programmed to learn from data referred to as “training data.”⁹ The learner algorithm will then automatically adjust the ML model based on the training data. In health care, it is important to know whether the learner algorithm is eventually locked or whether the learner algorithm continues to learn once deployed into clinical practice. A “continuous learning system” continues to update the model without human oversight as new data is presented to the learner algorithm, whereas “locked learners” will not automatically update the model with new data. There are both benefits and risks to continuous learning systems which may:

... more precisely calibrate suggestions to specific demographic or geographic areas over time, taking into account [for example] that certain diagnoses are more common in that setting and/or adjusting for local norms in the input data formatting or presentation. However, as software changes, the rate and distribution of false-positives and false-negatives may also change, potentially in ways that no longer have an acceptable benefit-risk profile. As such, there are serious concerns about the risks and ethics of deploying a continuously learning software system in the clinical setting.¹⁰

Current AI systems developed utilizing ML for clinical applications that have been authorized by the U.S. Food and Drug Administration (FDA) involve a two-step process. First, the learner algorithm remains “on” until the model, a software tool, has been developed with enough “training data.” The learner algorithm is then “locked” and model is not updated in real time. In short, “once an AI system is developed utilizing a learning algorithm, it can be ‘locked’ and used without automatic updates.”¹¹ Why lock the learner algorithm? When AI systems are applied to patient clinical care, it is necessary to allow developers (and regulators where the system is considered a medical device) to undertake safety and clinical efficacy testing. However, reportedly, developers may run a parallel AI system with a learner algorithm still “on” in order to assess quality and identify enhancements. The developer will update the AI system which has a locked learner on a periodic basis after validation for clinical efficacy and safety. This has been

characterized by certain innovators as “discontinuous learning.”¹² In addition, it has been noted that if these regular updates are not done, “locked models have the potential to degrade over time if inputs change significantly.”¹³

While there are significant benefits and needed health care transformations that AI systems using ML promise to produce, careful consideration should be given to clinical applications of such systems and the attendant quality and safety challenges. A group of British and U.S. experts has proposed a general framework for identifying and addressing short-, medium-, and long-term quality and safety issues vis-à-vis AI systems utilizing ML for clinical applications including distributional shift, insensitivity to impact, black box decision-making, unsafe failure mode, automation complacency, reinforcement of outmoded practice, self-fulfilling prediction, negative side effects, reward hacking, unsafe exploration, and unscalable oversight.¹⁴

Furthermore, all AI systems are reliant upon data, but ML amplifies the risks associated with an incomplete understanding or disclosure of data origin (often called provenance) and bias. Data often can be incomplete and contain erroneous information¹⁵ and all data is biased in some manner.¹⁶ It is imperative to disclose and provide means to address AI system bias in order to avoid, among other unintended outcomes, exacerbating health disparities and other inequities. Developers of AI systems used for clinical care should—as soon as there is a preliminary validation of a clinically relevant bias or potential patient safety risk associated with any of the recommendations emerging from an AI system—report the bias to the users of that software (appropriate institutional notification should suffice for institutions with many users). Developers of AI systems used in clinical care should be required to maintain an active intake process for reports of such issues from end-users, and there should be transparency into those reporting and quality assurance processes. Developers must have a process for continuous efficacy monitoring. In addition, there should be transparency into key attributes of the population that was the source of training data set while ensuring the protection of individual patient data and privacy interests. The purpose of this transparency is to enhance the understanding of risk associated with applying an AI system to individuals whose personal characteristics may diverge in significant ways from the population in the training data set. Finally, there should be transparency and “traceability” of training data.

USES AND APPLICATIONS OF AI SYSTEMS IN HEALTH CARE

A prerequisite to payment for AI systems involves identifying, at minimum, the intended use of the AI system, whether it is assistive or fully autonomous, conditions required for successful deployment, and the level of regulatory oversight required to ensure patient safety and the clinical efficacy of the system. These factors, along with associated liability risk, impact costs and sustainability. Broadly speaking, AI systems can be used in many areas of health care, including, but not limited to: (1) research; (2) education and workforce professional development; (3) finance, business processes, and health administration; (4) tools and services that improve medical practice, e.g., cybersecurity; (5) population health and public health; (6) patient and caregiver engagement and prevention; and (7) clinical care, e.g., clinical decision support or autonomous diagnostic system. Furthermore, when used in the foregoing areas, AI systems can function to automate repetitive and time-intensive tasks, improve communication and interactions, and enhance decision-making which improve efficiency and accuracy.

Key AI System Considerations, Standards Development and Ongoing Research

While overall research on clinical applications of AI systems continues to grow rapidly, there is a paucity of peer-reviewed publications of the results of head-to-head comparisons between physicians and AI systems. The specialty areas where such research exists include: radiology, neurology, pathology, dermatology, ophthalmology, gastroenterology, and cardiology.¹⁷ There is growing research in other areas such as oncology, but not necessarily comparative. Increased funding and support for research into AI system applications in health care, particularly for specific clinical applications, will remain a critical priority. However, research on AI system applications in the areas of population health, patient engagement, and health administration will also produce important findings of benefits and possible unintended consequences (such as inequitable impact). Experts have also noted that the following areas of research remain a priority:

- **Verification.** Research into methods of guaranteeing that the AI systems meet established specifications.
- **Validation.** Research into ensuring that the specifications, even if met, do not result in unwanted behaviors and consequences.
- **Security.** Research on how to build systems that are increasingly difficult to tamper with – internally or externally.

- Control. Research to ensure that AI systems can be interrupted (even with other AIs) if and when something goes wrong, and restore normal function.¹⁸

Other priority areas include research into explicability (which is also referred to as explainability) which is receiving significant focus by U.S. federal agencies and Congress. Widespread deployment and scaling of advanced AI systems utilizing, for example, ML in health care has not yet occurred. Conditions of deployment will require continued attention to assess safety, efficacy, and fairness. And, while existing standards must be met, additional ones are needed to address specific issues raised by AI and ML. For example, in February 2019, the British Standards Institution (BSI) and the Association for the Advancement of Medical Instrumentation issued a position paper with recommendations to support governance and regulation of AI and ML in health care to specifically address: (1) level of autonomy; (2) changing outputs of algorithms; (3) explicability; (4) transparency; and (5) quality of data outputs.¹⁹ Federal agencies and Congress are also prioritizing research and standards developments (as discussed below).

Legal Requirements

Depending on the intended use of an AI system, there are several legal requirements that developers must adhere to when marketing AI-enabled software if commercializing for mass distribution or when a health system designs, develops, and implements AI-enabled software within their own health system.²⁰ AI systems with clinical applications that meet the existing definition of medical device under the Food, Drug, and Cosmetic Act (FDCA) must comply with the FDA requirements related to safety and efficacy. Some of these AI systems may be subject to enforcement discretion because the FDA considers the risk of harm as it relates to a host of factors including intended use and conditions of deployment for example, sufficiently low.

Even where AI systems are not subject to the FDCA, the development, marketing, and deployment can be subject to a host of other federal and state laws. Some of the key laws include the:

- Health Insurance Portability and Accountability Act (HIPAA). HIPAA is meant to protect the privacy and security of protected health information. Certain entities are required to provide notifications of health information breaches. There are state laws that provide enhanced protections. In addition, there are newly emerging international standards such as Europe's General Data Protection Regulation (GDPR) that impact developers that reach global markets.
- Common Rule (Protection for Human Subject Research). Each federal agency that follows the Common Rule has guidance on federally funded research involving human subjects.
- Federal Trade Commission Act (FTCA). The Federal Trade Commission (FTC) has the authority to take action against developers of AI systems that engage in deceptive and unfair trade practices. This is most relevant where the developer makes false and misleading health claims, representations regarding the performance of an AI system, or claims that impact consumer data security and privacy. The FTC also provides enforcement of the Health Breach Notification Rule which applies to certain businesses that are required to provide notifications to consumers after a breach of personal health record information.

The above laws apply to AI systems with clinical uses (though the Common Rule will not always be applicable). Developers, regulators, and standards setting bodies must identify dynamic and useful mediums and methods to ensure physicians, medical staff, third-party payers, and patients who rely on AI-enabled systems understand whether (or not) the developer has complied with the relevant federal and state laws.

HEALTH CARE AI INVESTMENTS, ACQUISITIONS, AND PATENTS

The rapid growth in health care AI investments, acquisitions, and patents is expected to continue on a steep upward trajectory. Analysts report that the AI health market investment is expected to reach \$6.6 billion by 2021, a 40 percent compound annual growth rate.²¹ In addition, health care AI startups have raised billions since 2013, which exceeds all other industries in AI deal activity.²² A harbinger of this interest involves one of the largest merger and acquisitions deals in health care AI. Specifically, Flatiron Health was acquired by Roche Holdings for \$1.9 billion largely due to the curation of patient data by clinical experts that can be mined using AI systems employing ML.²³ The rapid rise in patent applications involving AI in the health care field is also significant. There were 79,936 patents filed in the United States between 2010 and 2018, with the plurality being in the health field (32.6 percent).²⁴ Some of the patents are very broad or seek to patent the obvious and, thus, may not ultimately be enforceable. However, such patents could create barriers to other innovators and increase costs due to litigation. While support for AI in health care is based on

the promise of advancing the quadruple aim including lowering health care costs, manipulations of the patent system may result in higher health care costs and perversely chill innovation.

CONGRESS, FEDERAL AGENCIES, WHITE HOUSE AND FEDERATION OF STATE MEDICAL BOARDS (FSMB)

Since the HOD adopted the recommendation of BOT Report 41-A-18, federal and state government activity has intensified rapidly. At the federal level, Congress and the Administration are taking steps to advance the use of AI systems for national security purposes and to ensure U.S. global economic competitiveness. The following summarizes the wide-range of actions from the various congressional committees, federal agencies, the White House, and FSMB. However, this BOT Report does not detail government activities²⁵ focused on data issues, which are broader—although germane—in scope than AI. These issues could be addressed in a future board report.

Congress

Congressional interest in AI continues to grow, although both chambers are primarily in the fact gathering and member education stages. In 2018, Representatives John Delaney (D-MD) and Pete Olson (R-TX) launched the AI Caucus to “inform policymakers of the technological, economic and social impacts of advances in AI and to ensure that rapid innovation in AI and related fields benefits Americans as fully as possible.” A number of congressional hearings concerning AI have taken place.²⁶

While a number of bills covering AI were introduced but not passed in the 115th Congress,²⁷ the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (H.R. 5515) became law and had a provision regarding AI. Section 1051 of the law requires the establishment of the National Security Commission on AI to provide recommendations to Congress and the President via an annual report on AI. The law directs the Secretary of the U.S. Department of Defense (DOD), no later than one year after the date of the enactment of law, to delineate a definition of the term “artificial intelligence” for use within the DOD. However, the law provides that AI should include:

- Any artificial system that performs tasks under varying and unpredictable circumstances without significant human oversight, or that can learn from experience and improve performance when exposed to data sets.
- An artificial system developed in computer software, physical hardware, or other context that solves tasks requiring human-like perception, cognition, planning, learning, communication, or physical action.
- An artificial system designed to think or act like a human, including cognitive architectures and neural networks.
- A set of techniques, including machine learning, that is designed to approximate a cognitive task.
- An artificial system designed to act rationally, including an intelligent software agent or embodied robot that achieves goals using perception, planning, reasoning, learning, communicating, decision making, and acting.²⁸

In September 2018, the U.S. House of Representatives Oversight and Government Reform Subcommittee on Information Technology former Chairman Will Hurd (R-TX) and former Ranking Member Robin Kelly (D-IL) released a white paper, titled “Rise of the Machines: Artificial Intelligence and its Growing Impact on U.S. Policy.” The white paper outlines three areas of concern including: public safety, innovation, and investment in research and development. Notably, the report contains a recommendation that the federal government should review existing oversight of AI systems in order to assess whether it is sufficient to ensure public safety. Where oversight is not adequate, the subcommittee recommended that Congress and the Administration modernize oversight while not overregulating.

In February 2019, the House Energy and Commerce Committee Subcommittee on Consumer Protection and Commerce scheduled a hearing on diversity in the technology industry. Though it had to be rescheduled, the Committee Chairman Frank Pallone (D-NJ) and subcommittee Chairwoman Jan Schakowsky (D-IL) issued a joint statement concerning AI systems and bias. Specifically, they noted that a lack of diversity can affect the design of AI. And, the foregoing could compound the risks of AI systems as the data used to train certain AI systems may amplify bias and lead to discriminatory outcomes.

White House

In May 2018, the White House hosted a [summit](#) with business leaders, government officials, and academics to identify how the U.S. government could increase AI research and prepare the U.S. workforce for the disruptions that AI will

bring. Officials from most cabinet-level agencies participated including the HHS Deputy Secretary as well as the HHS Chief Technology Officer. The health care AI panelists included representatives from CVS, Johnson & Johnson, Medtronic, Quest Diagnostics, Google, IBM, and Verily, a subsidiary of Google. At the conclusion, the Administration announced the establishment of an [advisory committee](#) comprised of federal agencies and issued a [report and memorandum](#).²⁹

In February 2019, a Presidential Executive Order was issued launching the American AI Initiative. The Initiative encompasses five key areas: (1) prioritization of investment by all federal agencies in AI research and development (R&D); (2) requiring federal agencies to make federal data, models, and computing resources more available to U.S.-based AI R&D experts, researchers, while maintaining the safety, security, civil liberties, privacy, and confidentiality protections of Americans; (3) establishing guidance for AI development and use across different types of technology and industrial sectors and directing the National Institute of Standards and Technology (NIST) to lead the development of appropriate technical standards for reliable, robust, trustworthy, secure, portable, and interoperable AI systems; (4) requiring federal agencies to prioritize fellowship and training programs to help U.S. workers gain AI-relevant skills through apprenticeships, skills programs, fellowships, and education in computer science and other growing Science, Technology, Engineering, and Math (STEM) fields; and (5) requiring federal agencies to develop and implement an action plan to protect the advantage of the U.S. in AI and technology critical to U.S. national and economic security interests against strategic competitors and foreign adversaries.³⁰

Food and Drug Administration (FDA)

In April 2018, the FDA authorized for market an “autonomous” AI system, IDx-DR, that detects more than mild diabetic retinopathy. IDx-DR was not the first AI-enabled software that the FDA has cleared or authorized for market under the existing FDA legal authorities designed to ensure safety and efficacy; however, it is the first designated as fully autonomous, meaning that it provides a diagnostic output and management recommendations without medical specialist interpretation. IDx-DR is intended for use by primary care providers who may not have expertise of diabetic retinopathy. A clinical staff member is able to upload the digital images of the patient’s retinas to the IDx-DR AI system. If the images are of sufficient quality, the system provides the medical practice with one of two diagnostic results: (1) “more than mild diabetic retinopathy detected: refer to an eye care professional” or (2) “negative for more than mild diabetic retinopathy; re-test in 12 months.” If a positive result is detected, patients should be referred to a specialist for further diagnostic and treatment evaluation.

The issue of levels of automation in the context of clinical care has become a central question from both a regulatory perspective and for purposes of payment and coverage because a clinically validated autonomous system is labeled by the FDA to perform a service without medical specialist interpretation. The FDA did not identify specific criteria it used to designate the IDx-DR system as autonomous; however, it did set precedent for autonomous AI by requiring a preregistered clinical trial to establish safety, efficacy, and equity, as reflected by the three corresponding trial endpoints. Narrowly defined, equity means that the AI is accurate and effective for all subgroups of the intended population, including age groups, races and ethnicities, not just for one or a few. It requires both design and validation of the AI to address potential bias and sources of bias. Thus, equity is a component of both safety and efficacy. The FDA also established special controls for the autonomous IDx-DR device including software documentation requirements, the requirement for clinical data to evaluate image acquisition as part of the system, the requirement for human factors validation, and the requirement for labeling to include instructions for obtaining quality images and how performance is affected by users interacting with the system.

Also last year, the FDA permitted marketing of clinical decision support software that alerts providers of a potential stroke in patients. The Viz.AI Contact application is intended for use by neurovascular specialists and other professionals with similar training. The Viz.AI Contact application analyzes CT images of the brain and sends a text notification to a neurovascular specialist if a suspected large vessel blockage has been identified. The AI system automatically notifies the specialist during the same time that the first-line provider is conducting a standard review of the images, thereby involving the specialist sooner than the usual workflow in which a radiologist reviews CT images and then notifies a neurovascular specialist. The specialist still reviews the images on a clinical workstation. The application is limited to analysis of imaging data and has not been authorized by the FDA as a replacement of a full patient evaluation or to be relied upon solely to make or confirm a diagnosis.

Although AI system developers are able to utilize existing FDA regulatory pathways to secure approval, or *de novo* authorization for AI systems, the FDA has indicated that the Agency’s alternative framework for oversight of software

as a medical device (SaMD) could also serve as potential pathway to market AI systems considered medical devices. Software that is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in humans meets the definition of medical device and is FDA regulated. However, certain software that would have met this definition of medical device is no longer subject to FDA oversight due to passage of the [21st Century Cures Act of 2016](#).

The FDA has two categories for software that qualifies as a medical device: SaMD and software in a medical devices (SiMD). The FDA is dedicating a substantial amount of time to develop a new voluntary SaMD oversight pathway for developers called the Precertification Program. The pre-certification designation would be analogous to the Pre-Check program used by airline travelers. Once initially vetted, a developer would go through a streamlined process. Simply stated, given the rate of modifications to software and with the advent of software based on continuous learning algorithms powered by deep learning and neural networks, the current oversight framework may be strained by the volume of software and entrance of new software developers.

Early in 2019, the FDA issued an updated version of the proposed Precertification Program. The FDA states that it contemplates that AI systems would be able to use the Precertification Program. Throughout 2019, the FDA intends to pilot the Precertification Program in order to assess how the program could maintain FDA standards for assuring safe and effective products, while still achieving its aim of modernizing and streamlining the FDA's review of novel digital health products. The FDA will test how the Precertification Program approach utilizing the streamlined *de novo* authorization pathway compares to the traditional FDA submission pathway. The AMA continues to provide comments and evaluate carefully the Precertification Program to assess whether it will ensure the safety and efficacy of software, particularly AI-enabled software that would be cleared, authorized, or approved through this pathway.

Centers for Medicare & Medicaid Services (CMS)

In November 2018, the CMS Center for Medicare & Medicaid Innovation (CMMI) announced a cross-industry challenge competition to innovate how AI can be implemented in current and future health care models dubbed the [AI Health Outcomes Challenge](#). CMS noted it would seek applications for AI and analytics that can boost clinical care and improve overall patient health. The competition is open to technology vendors, clinicians, scientists, academics and patients who are innovating their uses of AI for quality improvement. In February 2019, it was announced that the challenge was being launched in partnership with the American Academy of Family Physicians. Reportedly, CMS is “brainstorming how [the Agency] can incorporate AI in the implementation of both our current and new payment and service delivery models.”³¹

National Institutes of Health (NIH)

In July 2018, the NIH hosted a full-day public workshop titled [Harnessing Artificial Intelligence and Machine Learning to Advance Biomedical Research](#). Subsequently, the NIH established an AI Working Group comprised of twelve members—drawn primarily from industry and universities. The AI Work Group is co-chaired by an engineering director at Verily, and the NIH's Principal Deputy Director. In December 2018 the AI Work Group provided an [update](#) as part of the Meeting of the Advisory Committee to the NIH Director. The charge of the AI Work Group includes making recommendations to address the following questions: (1) Are there opportunities for cross-NIH effort in AI? How could these efforts reach broadly across biomedical topics and have positive effects across many diverse fields? (2) How can NIH help build a bridge between the computer science community and the biomedical community? (3) What can NIH do to facilitate training that marries biomedical research with computer science? and (4) Identify the major ethical considerations as they relate to biomedical research and using AI/ML/deep learning for health-related research and care, and suggest ways that NIH can build these considerations into its AI-related programs and activities.

The AI Work Group will offer interim recommendations in June 2019 and final recommendations will be issued in December 2019. There are a range of additional NIH activities such as the NIH AI Interest Group (AIIG) that is charged with facilitating communication among the scientists of NIH, FDA, universities and industries with interest in the development of AI systems to improve medical treatments. In August 2018, the NIH's National Institute of Biomedical Imaging and Bioengineering (NIBIB) hosted an Artificial Intelligence and Medical Imaging Workshop to discuss AI systems used for medical imaging and the challenges with regard to quality, reproducibility, and reliability of AI in medical imaging for clinical use. The meeting also sought to address how AI systems might improve the value of medical imaging and health care overall. In addition to ongoing NIH research, peer publications, and meetings, the

Director of NIH also blogs concerning the research and evidence related to AI system applications to clinical care. In January 2019, for example, the Director posted a blog on [Using Artificial Intelligence to Detect Cervical Cancer](#).

Federal Trade Commission (FTC)

In November 2018, the FTC held a two-day hearing on [Algorithms, Artificial Intelligence, and Predictive Analytics](#). The hearing focused on: (1) the current and potential uses of these technologies; (2) the ethical and consumer protection issues that are associated with the use of these technologies; (3) how the competitive dynamics of firm and industry conduct are affected by the use of these technologies; and, (4) policy, innovation, and market considerations associated with the use of these technologies.

The developer of the IDx-DR program, a practicing physician, was invited by the FTC to provide testimony on the panel titled [Understanding Algorithms, Artificial Intelligence, and Predictive Analytics Through Real World Applications](#). While he remarked that FDA has not set specific criteria for autonomous AI, the developer described proposed minimum criteria for autonomous AI and emphasized the need for rigorous FDA processes before deployment into clinical practice, including the three principles of safety, efficacy and equity. He also noted that AI developers with autonomous AI systems used for clinical applications must assume medical liability. The IDx-DR developer emphasized the importance of transparency; agreement on enforceable definitions; the minimum requirements for AI system validation, including human factors validation; requirements for addressing age, racial, and ethnic bias in the design; and validation of the AI system. He discussed the need for the highest-level reference standard based on patient outcomes, and aligned to the specialty preferred practice pattern, the importance of a pre-registered clinical trial reflecting the intended use, cybersecurity, training data stewardship, and other aspects unique to autonomous AI. The AMA filed comments which included the AMA policy on health care AI and expressing agreement that there is a need for: (1) clinical validation by regulators, (2) appropriate assignment of legal liability to developers for autonomous AI systems; and (3) transparency to support clinical decision-making.

Defense Advanced Research Projects Agency (DARPA)

In August 2016, DARPA launched the Explainable Artificial Intelligence (XAI) program. The program focuses on ML systems in order to: (1) produce more explainable models, while maintaining a high level of learning performance (prediction accuracy); and (2) enable human users to understand, appropriately trust, and effectively manage the emerging generation of artificially intelligent partners. In July 2018, DARPA launched the [Artificial Intelligence Exploration \(AIE\) Program](#). And, then, in September 2018 the Agency announced a multi-year investment of more than \$2 billion in new and existing programs called the “[AI Next](#)” campaign. Key areas of the campaign include automating critical DOD business processes, such as security clearance vetting or accrediting software systems for operational deployment; improving the robustness and reliability of AI systems; enhancing the security and resiliency of ML and AI technologies; reducing power, data, and performance inefficiencies; and pioneering the next generation of AI algorithms and applications, such as “explainability” and common sense reasoning.

Federation of State Medical Boards

In April 2018, the FSMB House of Delegates resolved to convene relevant stakeholders, subject matter experts, including representatives from state medical boards, the AMA, and the American Osteopathic Association to discuss AI and its potential impact on patient safety, decision-making and regulation.³² In November 2018, FSMB hosted AI in Health Care: The Role of Medical Boards. The Summit was comprised of a cross-section of stakeholders including representatives from the AMA and various state medical boards, FSMB leadership, staff, and industry. The discussion centered on the regulatory environment in which health related AI technology is deployed, the mission of state medical boards and approaches to AI regulation taken in other jurisdictions, and the appropriate role and function of medical boards in the deployment of health AI technology.

POLICY

The AMA’s foundational Policy H-480.940, “Augmented Intelligence in Health Care,” provides that the perspective of practicing physicians should be included in the development, design, validation, and implementation of health care AI. Furthermore, the policy provides that thoughtfully designed, high-quality, clinically validated health care AI must be designed and evaluated in keeping with best practices in user-centered design, particularly for physicians and other members of the health care team; be transparent; conform to leading standards for reproducibility; identify and take

steps to address bias and avoid introducing or exacerbating health care disparities including when testing or deploying new AI tools on vulnerable populations; and safeguard patients' and other individuals' privacy interests and preserves the security and integrity of personal information. The policy also provides that our AMA will address the legal implications of health care AI, such as issues of liability or intellectual property, and advocate for appropriate professional and governmental oversight for safe, effective, and equitable use of and access to health care AI.

In addition, AMA policy concerning payment for digital medicine and integration of health information technology are related to payment and use of AI systems in health care as the latter are a subset of the former.

AMA Policy H-480.946, "Coverage of and Payment for Telemedicine," provides that payment and coverage should only occur when delivered consistent with applicable regulatory and oversight requirements designed to ensure patient safety and consistent with clinical practice guidelines developed by national medical specialty societies and other evidence-based practice guidelines, to ensure patient safety, quality of care and positive health outcomes. Furthermore, the policy specifies appropriate disclosure, informed consent, and care coordination must be in place. The policy also provides that digital modalities should comply with laws addressing privacy and security of patients' medical information and urges physicians to verify that their medical liability insurance policy covers use of such technologies. In this latter regard, it will be important that physicians verify that AI system developers have taken steps to be legally responsible and accountable for the AI system where there is a lack of transparency or the developer is providing or marketing a fully autonomous AI system.

AMA policies (H-480.946 and H-480.940) outline the importance of: research to build the evidence base for digital medicine; federally funded pilots to assess new delivery models, scaling, quality, and payment; and physician organizations and national medical specialty societies in particular in developing standards and clinical practice guidelines. The policies provide that physician organizations should collaborate with other key stakeholders in the development of technical standards for digital medicine, to the extent practicable, and to take the lead in the development of clinical practice guidelines. AMA policy also provides support for research to develop appropriate practice parameters to address the various applications of digital medicine modalities and to guide quality assessment and liability issues.

In addition to outlining essential prerequisites to payment such as evidence of clinical usefulness, compliance with state and federal legal requirements to ensure patient safety, and adherence to clinical practice guidelines, AMA Policy H-480.974, "Evolving Impact of Telemedicine," provides support for pathways to payment under existing payment and delivery models while also specifying that the AMA will work with CMS and other payers to develop and test through demonstration projects appropriate reimbursement mechanisms.

AMA also has policy concerning the acquisition and cost of health information technology. AMA Policy D-478.990, "Clinical Information Technology Assistance," provides that the AMA will seek a full refundable federal tax credit or equivalent financial mechanism to indemnify physician practices for the cost of purchasing and implementing clinical information technology, including electronic medical record systems, e-prescribing and other clinical information technology tools, in compliance with applicable safe harbors. And, a related Policy D-478.996, "Information Technology Standards and Cost," provides that our AMA will 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 and to take into account the cost to physicians at the office-based level; and to continue to advocate for and support initiatives that minimize the financial burden to physician practices of adopting and maintaining electronic medical records. Finally, the policy provides that our AMA will advocate that physicians not be financially penalized for certified EHR technology not meeting current standards.

DISCUSSION

The recommendation referred for report raises many of the same questions and concerns that physicians across medical specialty and practice sites have expressed when adopting new digital medicine modalities or when acquiring, implementing, and maintaining health information technology, as discussed below. In addition, since the referral, payment and use of AI systems in health care has rapidly taken on relevance as the FDA has authorized or cleared for use AI-enabled systems for clinical practice, including, as detailed above, the first autonomous AI-system. And, CMS in collaboration with the American Academy of Family Physicians has launched a challenge competition to innovate how AI can be implemented in current and future health care payment and delivery models.

AMA policies related to payment and coverage of digital medicine and acquisition of health information technology are directly applicable to funding, payment, and access to AI systems for health administration, population health, practice management, clinical care, and related use. However, AI systems do raise additional issues. Also, these challenges (and potential benefits) may impact physicians and their patients differently depending on the practice size, setting, and specialty and these are germane.

Advancing the Quadruple Aim for All Patients, Medical Specialties and Care Setting

The referred recommendation would establish AMA policy to support funding for AI systems as an “enhancement of the primary care medical home so that patients who really need AI can benefit from the technology.” While this should be one of the outcomes of payment and funding policy for AI systems, it is not the only one. Instead, our AMA should support payment and funding for the range of practice types and specialties where different AI system uses will advance the quadruple aim. The quadruple aim seeks to advance simultaneously the improvement of the health of populations, the enhancement of the patient experience of care, the reduction of the per capita cost of health care, and the improvement the work life of health care clinicians and staff.³³

In 2016, the AMA commissioned a survey of physicians from varied medical specialties and practice settings in order to investigate their motivations, current usage, and expectations for integrating digital medicine tools into their practice ([Digital Health Study](#)). The surveyed physicians were optimistic that digital medicine tools would improve medical practice and patient care. Surveyed physicians in larger practices tended to use digital medicine tools more. Key factors relevant to increased adoption included practice size and setting which suggests economies of scale and the ability of relatively larger practices to scale infrastructure may play a role in adoption. More physicians reported adoption of telehealth visits than use of remote patient monitoring. Physicians, however, have greater enthusiasm for the clinical benefit and work efficiencies of remote patient monitoring and management systems. It is anticipated that this latter modality will utilize increasingly advanced AI systems and methods. In addition, utilization of remote patient monitoring is expected to increase as a result of Medicare expanded coverage of remote patient monitoring for chronic conditions as of January 1, 2019.

In addition to needing credible evidence that a digital modality is clinically effective, surveyed physicians ranked in order of importance the key issues that must be addressed to support their adoption of these technologies including: (1) appropriate measures to address liability; (2) data privacy/security assured by experts; (3) workflow integration with electronic health record systems; and then, (4) coverage and payment. Similarly, our AMA policies specify that digital medicine payment and integration are subject to: (1) appropriate regulatory oversight; (2) accountability by technology developers for adverse events caused by such technologies; and (3) patient privacy and security protections.

The foregoing underscores that AMA policy should address payment for AI systems without limits on medical specialty, practice setting, or payment model. Furthermore, payment for such systems should ensure key issues and considerations are addressed as with all digital medicine modalities when incorporating these systems into practice, while also accounting for the additional risks that AI systems may pose.

Mandates, Penalties, Interference with Medical Practice, and Liability

The referred also would have established AMA policy that AI systems should not be “a requirement that must be incorporated into the care of every patient.” If adopted, it would have only partially addressed a range of long-standing physician concerns related to technology mandates, penalties, and other similar requirements that interfere with the patient-physician relationship and medical practice while exposing physicians to increased liability. When technologies are well-designed and clinically validated and useful, mandates are not needed. Where technologies are poorly designed, mandates and penalties have been used to drive adoption. However, the approach to include mandates and penalties has stymied innovation and fueled physician burnout. As a result, it is important that payment policies incentivize development of AI systems that: (1) are informed by real-world workflow and human-centered design principles; (2) enable physicians and other health care stakeholders to prepare for and transition to changes in care delivery; (3) support effective communication and engagement among patients, physicians, and the health care team; (4) seamlessly integrate into the clinical and administrative workflow; and (5) enable frictionless end-user feedback to support iterative product improvement.

Furthermore, mandated use of AI systems for specific clinical uses or health administration raise concerns as to the validation and scaling of AI systems for a range of applications that remain a work in progress. As detailed in this report, there is an ongoing need for standards development and wide-spread adoption of such standards, regulatory modernization, research, and experience with varied deployment models. There are significant risks associated with AI systems that are not properly designed, developed, validated and deployed as previously detailed in BOT Report 41-A-18. In brief, AI systems utilizing ML present pronounced risk of bias. Physicians, health systems, developers, or regulators may not be in a position to understand the risks due to black-box systems due to design or for proprietary reasons. Thus, mandated or required uses of such systems should be disfavored and liability should be borne by the developer and/or the entity mandating use of such systems whether fully autonomous or assistive.

Building Evidence Base

The foregoing underscores that there is the need to build the evidence base for health care AI. Research should prioritize evaluation of AI systems that utilize ML in clinical practice to assess safety, efficacy, performance, equity, privacy, and security under varied conditions of deployment. Public and private funding and other resources should be prioritized to support research that expands the evidence base for applications of health care AI systems.

RECOMMENDATION

In light of these considerations, your Board of Trustees recommends that the following be adopted in lieu of the recommendation and the remainder of this report be filed:

Our AMA supports the use and payment of augmented intelligence (AI) systems that advance the quadruple aim. AI systems should enhance the patient experience of care and outcomes, improve population health, reduce overall costs for the health care system while increasing value, and support the professional satisfaction of physicians and the health care team. To that end our AMA will advocate that:

1. Oversight and regulation of health care AI systems must be based on risk of harm and benefit accounting for a host of factors, including but not limited to: intended and reasonably expected use(s); evidence of safety, efficacy, and equity including addressing bias; AI system methods; level of automation; transparency; and, conditions of deployment.
2. Payment and coverage for all health care AI systems must be conditioned on complying with all appropriate federal and state laws and regulations, including, but not limited to those governing patient safety, efficacy, equity, truthful claims, privacy, and security as well as state medical practice and licensure laws.
3. Payment and coverage for health care AI systems intended for clinical care must be conditioned on (a) clinical validation; (b) alignment with clinical decision-making that is familiar to physicians; and (c) high quality clinical evidence.
4. Payment and coverage for health care AI systems must (a) be informed by real world workflow and human-centered design principles; (b) enable physicians to prepare for and transition to new care delivery models; (c) support effective communication and engagement between patients, physicians, and the health care team; (d) seamlessly integrate clinical, administrative, and population health management functions into workflow; and (e) seek end-user feedback to support iterative product improvement.
5. Payment and coverage policies must advance affordability and access to AI systems that are designed for small physician practices and patients and not limited to large practices and institutions. Government-conferred exclusivities and intellectual property laws are meant to foster innovation, but constitute interventions into the free market, and therefore, should be appropriately balanced with the need for competition, access, and affordability.
6. Physicians should not be penalized if they do not use AI systems while regulatory oversight, standards, clinical validation, clinical usefulness, and standards of care are in flux. Furthermore, our AMA opposes:
 - a. Policies by payers, hospitals, health systems, or governmental entities that mandate use of health care AI systems as a condition of licensure, participation, payment, or coverage.

- b. The imposition of costs associated with acquisition, implementation, and maintenance of healthcare AI systems on physicians without sufficient payment.
7. Liability and incentives should be aligned so that the individual(s) or entity(ies) best positioned to know the AI system risks and best positioned to avert or mitigate harm do so through design, development, validation, and implementation. Our AMA will further advocate:
 - a. Where a mandated use of AI systems prevents mitigation of risk and harm, the individual or entity issuing the mandate must be assigned all applicable liability.
 - b. Developers of autonomous AI systems with clinical applications (screening, diagnosis, treatment) are in the best position to manage issues of liability arising directly from system failure or misdiagnosis and must accept this liability with measures such as maintaining appropriate medical liability insurance and in their agreements with users.
 - c. Health care AI systems that are subject to non-disclosure agreements concerning flaws, malfunctions, or patient harm (referred to as gag clauses) must not be covered or paid and the party initiating or enforcing the gag clause assumes liability for any harm.
 8. Our AMA, national medical specialty societies, and state medical associations—
 - a. Identify areas of medical practice where AI systems would advance the quadruple aim;
 - b. Leverage existing expertise to ensure clinical validation and clinical assessment of clinical applications of AI systems by medical experts;
 - c. Outline new professional roles and capacities required to aid and guide health care AI systems; and
 - d. Develop practice guidelines for clinical applications of AI systems.
 9. There should be federal and state interagency collaboration with participation of the physician community and other stakeholders in order to advance the broader infrastructural capabilities and requirements necessary for AI solutions in health care to be sufficiently inclusive to benefit all patients, physicians, and other health care stakeholders.
 10. AI is designed to enhance human intelligence and the patient-physician relationship rather than replace it.

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26. The U.S. House of Representatives, Oversight and Government Reform Committee Subcommittee on Information Technology has held a series of hearings captioned: Game Changer: Artificial Intelligence; Artificial Intelligence and Public Policy; and Artificial Intelligence and the Federal Government. The U.S. Senate Commerce Committee’s Subcommittee on Space, Science and Competitiveness has also held a series of hearings including The Dawn of Artificial Intelligence (a broad overview of the state of AI and the policy implications and the effects on commerce), The Promise and Perils of Emerging Technologies for Cybersecurity (an exploration of the impact of emerging technologies, including AI, the internet of things, blockchain, and quantum computing on the future of cybersecurity), and The Digital Decision Making: The Building Blocks of Machine Learning and Artificial Intelligence (a review of the new and emerging role of AI in the nation’s growing digital environment). Both the U.S. House of Representatives Energy and Commerce Committee and the U.S. Senate Committee on the Judiciary held hearings Facebook: Transparency and Use of Consumer Data and Facebook, Social Media Privacy, and Use and Abuse of Data, respectively. Facebook CEO and Chairman Mark Zuckerberg mentioned AI tools more than 30 times as a way to monitor and ban hate speech on the platform in the future. However, the Co-Chairs of the congressional AI Caucus subsequently released a statement that in part provided: “While AI can be utilized to help Facebook and other entities tackle problems on a massive scale, we also need to make sure that AI is implemented in an unbiased way. As the Co-Chairs of the AI Caucus, we believe that Facebook should provide more information to Congress on how they plan to use AI and what steps they are taking to make sure that AI is being used in an unbiased manner that also respects users’ privacy.” AI Caucus Co-Chairs: Facebook Should Clarify Plans to Use AI, Address Bias and Privacy Concerns, Congressional Artificial Intelligence Caucus Press Release, April 13, 2018 Accessed February 20, 2019.
27. Other bills that were introduced, but not passed in the 115th Congress include: (1) H.R. 4829, the Artificial Intelligence Job Opportunities and Background Summary Act of 2018 (AI JOBS) Act of 2018 introduced by Rep. Darren Soto (D-FL) would direct Department of Labor to prepare report on Congress on AI and its impact on the workforce. Rep. Soto has reintroduced the AI JOBS Act of 2019 which is now H.R. 827 in the 116th Congress (2019-2020); (2) S. 2217/H.R. 4625, the Fundamentally Understanding the Usability and Realistic Evolution of Artificial Intelligence Act of 2017 (FUTURE of AI Act) introduced by Senators Maria Cantwell (D-WA) and Todd Young (R-IN) and Representative John Delaney, respectively, would have established the Federal Advisory Committee on the development and implementation of AI; (3) S. 3502, the Artificial Intelligence in Government Act introduced by Senators Gardner (R-CO), Schatz (D-HI), Portman (R-OH), and Harris (D- CA) would have promoted the use of AI by the federal government through increased executive agency coordination through an advisory board and development of a strategy for investing and deploying AI as part of the federal government.
28. H.R. 5515, the John S. McCain National Defense Authorization Act for Fiscal Year 2019
29. The advisory committee is the Select Committee under National Science and Technology Council’s (“NSTC”) and is tasked with “improv[ing] the coordination of federal efforts related to AI and ensur[ing] continued U.S. leadership in AI.” As part

of this effort, the Networking and Information Technology Research and Development Subcommittee (NITRD) and the new Select Committee were charged with updating “The National Artificial Intelligence Research and Development Strategic Plan” (the “Strategic Plan”) that was created in 2016 in order to establish a set of objectives for federally-funded AI research. The ultimate goal of this federally-funded research is to “produce new AI knowledge and technologies that provide a range of positive benefits to society, while minimizing the negative impacts.” The plan identifies seven priorities to achieve this goal: (1) Make long-term investments in AI research; (2) Develop effective methods for human-AI collaboration; (3) Understand and address the ethical, legal, and societal implications of AI; (4) Ensure the safety and security of AI systems; (5) Develop shared public datasets and environments for AI training and testing; (6) Measure and evaluate AI technologies through standards and benchmarks; and, (7) Better understand the national AI research and development workforce needs.

30. [Executive Order on Maintaining American Leadership in Artificial Intelligence](#), February 11, 2019 Accessed February 20, 2019.
31. Landi, H. [HIMSS19: CMMI launching challenge competition to drive AI innovation](#), FierceHealthcare, February 14, 2019, Accessed February 20, 2019
32. [Actions by the FSMB House of Delegates](#), April 28, 2018 Accessed February 20, 2019
33. Bodenheimer, T. Sinsky, C. [From Triple to Quadruple Aim: Care of the Patient Requires Care of the Provider](#), Ann Fam Med November/December 2014 vol. 12 no. 6 573-576 Accessed February 20, 2019.

APPENDIX - Relevant AMA Policy

Policy H-480.940, “Augmented Intelligence in Health Care”

As a leader in American medicine, our AMA has a unique opportunity to ensure that the evolution of augmented intelligence (AI) in medicine benefits patients, physicians, and the health care community.

To that end our AMA will seek to:

1. Leverage its ongoing engagement in digital health and other priority areas for improving patient outcomes and physicians’ professional satisfaction to help set priorities for health care AI.
2. Identify opportunities to integrate the perspective of practicing physicians into the development, design, validation, and implementation of health care AI.
3. Promote development of thoughtfully designed, high-quality, clinically validated health care AI that:
 - a. is designed and evaluated in keeping with best practices in user-centered design, particularly for physicians and other members of the health care team;
 - b. is transparent;
 - c. conforms to leading standards for reproducibility;
 - d. identifies and takes steps to address bias and avoids introducing or exacerbating health care disparities including when testing or deploying new AI tools on vulnerable populations; and
 - e. safeguards patients’ and other individuals’ privacy interests and preserves the security and integrity of personal information.
4. Encourage education for patients, physicians, medical students, other health care professionals, and health administrators to promote greater understanding of the promise and limitations of health care AI.
5. Explore the legal implications of health care AI, such as issues of liability or intellectual property, and advocate for appropriate professional and governmental oversight for safe, effective, and equitable use of and access to health care AI.

Policy H-480.946, “Coverage of and Payment for Telemedicine”

1. Our AMA believes that telemedicine services should be covered and paid for if they abide by the following principles:
 - a. A valid patient-physician relationship must be established before the provision of telemedicine services, through:
 - A face-to-face examination, if a face-to-face encounter would otherwise be required in the provision of the same service not delivered via telemedicine; or
 - A consultation with another physician who has an ongoing patient-physician relationship with the patient. The physician who has established a valid physician-patient relationship must agree to supervise the patient’s care; or
 - Meeting standards of establishing a patient-physician relationship included as part of evidence-based clinical practice guidelines on telemedicine developed by major medical specialty societies, such as those of radiology and pathology. Exceptions to the foregoing include on-call, cross coverage situations; emergency medical treatment; and other exceptions that become recognized as meeting or improving the standard of care. If a medical home does not exist, telemedicine providers should facilitate the identification of medical homes and treating physicians where in-person services can be delivered in coordination with the telemedicine services.
 - b. Physicians and other health practitioners delivering telemedicine services must abide by state licensure laws and state medical practice laws and requirements in the state in which the patient receives services.
 - c. Physicians and other health practitioners delivering telemedicine services must be licensed in the state where the patient receives services, or be providing these services as otherwise authorized by that state’s medical board.
 - d. Patients seeking care delivered via telemedicine must have a choice of provider, as required for all medical services.
 - e. The delivery of telemedicine services must be consistent with state scope of practice laws.
 - f. Patients receiving telemedicine services must have access to the licensure and board certification qualifications of the health care practitioners who are providing the care in advance of their visit.

- g. The standards and scope of telemedicine services should be consistent with related in-person services.
 - h. The delivery of telemedicine services must follow evidence-based practice guidelines, to the degree they are available, to ensure patient safety, quality of care and positive health outcomes.
 - i. The telemedicine service must be delivered in a transparent manner, to include but not be limited to, the identification of the patient and physician in advance of the delivery of the service, as well as patient cost-sharing responsibilities and any limitations in drugs that can be prescribed via telemedicine.
 - j. The patient's medical history must be collected as part of the provision of any telemedicine service.
 - k. The provision of telemedicine services must be properly documented and should include providing a visit summary to the patient.
 - l. The provision of telemedicine services must include care coordination with the patient's medical home and/or existing treating physicians, which includes at a minimum identifying the patient's existing medical home and treating physicians and providing to the latter a copy of the medical record.
 - m. Physicians, health professionals and entities that deliver telemedicine services must establish protocols for referrals for emergency services.
2. Our AMA believes that delivery of telemedicine services must abide by laws addressing the privacy and security of patients' medical information.
 3. Our AMA encourages additional research to develop a stronger evidence base for telemedicine.
 4. Our AMA supports additional pilot programs in the Medicare program to enable coverage of telemedicine services, including, but not limited to store-and-forward telemedicine.
 5. Our AMA supports demonstration projects under the auspices of the Center for Medicare and Medicaid Innovation to address how telemedicine can be integrated into new payment and delivery models.
 6. Our AMA encourages physicians to verify that their medical liability insurance policy covers telemedicine services, including telemedicine services provided across state lines if applicable, prior to the delivery of any telemedicine service.
 7. Our AMA encourages national medical specialty societies to leverage and potentially collaborate in the work of national telemedicine organizations, such as the American Telemedicine Association, in the area of telemedicine technical standards, to the extent practicable, and to take the lead in the development of telemedicine clinical practice guidelines.

Policy H-480.974, "Evolving Impact of Telemedicine"

Our AMA:

1. will evaluate relevant federal legislation related to telemedicine;
2. urges CMS, AHRQ, and other concerned entities involved in telemedicine to fund demonstration projects to evaluate the effect of care delivered by physicians using telemedicine-related technology on costs, quality, and the physician-patient relationship;
3. urges professional organizations that serve medical specialties involved in telemedicine to develop appropriate practice parameters to address the various applications of telemedicine and to guide quality assessment and liability issues related to telemedicine;
4. encourages professional organizations that serve medical specialties involved in telemedicine to develop appropriate educational resources for physicians for telemedicine practice;
5. encourages development of a code change application for CPT codes or modifiers for telemedical services, to be submitted pursuant to CPT processes;
6. will work with CMS and other payers to develop and test, through these demonstration projects, appropriate reimbursement mechanisms;
7. will develop a means of providing appropriate continuing medical education credit, acceptable toward the Physician's Recognition Award, for educational consultations using telemedicine;
8. will work with the Federation of State Medical Boards and the state and territorial licensing boards to develop licensure guidelines for telemedicine practiced across state boundaries; and
9. will leverage existing expert guidance on telemedicine by collaborating with the American Telemedicine Association (www.americantelemed.org) to develop physician and patient specific content on the use of telemedicine services-- encrypted and unencrypted.

Policy D-478.990, "Clinical Information Technology Assistance"

Our AMA will seek a full refundable federal tax credit or equivalent financial mechanism to indemnify physician practices for the cost of purchasing and implementing clinical information technology, including electronic medical record systems, e-prescribing and other clinical information technology tools, in compliance with applicable safe harbors.

Policy D-478.996, "Information Technology Standards and Costs"

1. Our AMA will:

- (a) 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;

- (b) 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;
 - (c) review the following issues when participating in or commenting on initiatives to create a NHII:
 - (i) cost to physicians at the office-based level;
 - (ii) security of electronic records; and
 - (iii) the standardization of electronic systems;
 - (d) continue to advocate for and support initiatives that minimize the financial burden to physician practices of adopting and maintaining electronic medical records; and
 - (e) continue its active involvement in efforts to define and promote standards that will facilitate the interoperability of health information technology systems.
2. Our AMA advocates that physicians:
- (a) are offered flexibility related to the adoption and use of new certified Electronic Health Records (EHRs) versions or editions when there is not a sufficient choice of EHR products that meet the specified certification standards; and
 - (b) not be financially penalized for certified EHR technology not meeting current standards.

Policy D-480.970, “Access and Equity in Telemedicine Payments”

Our AMA will advocate that the Centers for Medicare & Medicaid Services pay for telemedicine services for patients who have problems accessing physician specialties that are in short supply in areas that are not federally determined shortage areas, if that area can show a shortage of those physician specialists.

22. INAPPROPRIATE USE OF CDC GUIDELINES FOR PRESCRIBING OPIOIDS (RESOLUTION 235-I-18)

Reference committee hearing: see report of Reference Committee B.

**HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS
IN LIEU OF RESOLUTION 235-I-18 AND RESOLUTION 229
REMAINDER OF REPORT FILED
*See Policy D-120.932***

INTRODUCTION

At the 2018 Annual Meeting, the House of Delegates (HOD) referred the second resolve of alternate Resolution 235, “Inappropriate Use of CDC Guidelines for Prescribing Opioids.” The second resolve in the alternate resolution asked:

[T]hat our AMA actively continue to communicate and engage with the nation’s largest pharmacy chains, pharmacy benefit managers, National Association of Insurance Commissioners, Federation of State Medical Boards, and National Association of Boards of Pharmacy in opposition to communications being sent to physicians that include a blanket proscription against filing prescriptions for opioids that exceed numerical thresholds without taking into account the diagnosis and previous response to treatment for a patient and any clinical nuances that would support such prescribing as falling within standards of good quality patient care.

This report provides an update on those communications, highlights complementary AMA advocacy and provides recommendations.

DISCUSSION

The nation’s opioid epidemic has led to extensive policy development in multiple areas—from several hundred new state laws and regulations to hundreds of millions of dollars earmarked by federal legislation for treatment of opioid use disorder, harm reduction efforts and other initiatives. Debating the merits of the new laws and regulations would go beyond the scope of this report, but it should be noted that each new law or regulation occurred within a notice and comment period as well as extensive public debate informed by stakeholder advocacy that underpins the lawmaking process. Medical societies may not have supported each piece of legislation or agreed with the regulatory agencies charged with rulemaking, but organized medicine has been an active participant in every state, in Congress and with the relevant federal agencies.

That is not, however, the only type of policymaking that has occurred. Health insurance companies, national pharmacy chains and pharmacy benefit management companies (PBMs) all have—to varying degrees—implemented their own policies governing physician prescribing of controlled substances as well as patients' abilities to have a controlled substance prescription dispensed to them. The result of this type of quasi-regulation is incredibly difficult to quantify on a large scale basis due to the lack of transparency in the public sphere, but the AMA and many medical societies continue to receive concerns from physicians and patients as to the disruptive nature of health plan, pharmacy chain or PBM interference in the patient-physician relationship. The concern and/or perceived interference has included pharmacists calling to ask about a patient's diagnosis or request patient records, a pharmacist asking for clarification about a prescription or alerting the physician to red flags, a pharmacist recommending a different medication strategy, and in some cases, a pharmacist informing the physician that the prescription will not be filled. This concern and/or interference has even gone so far as a pharmacist demanding patients taper their opioid prescriptions, telling them that the U.S. Drug Enforcement Administration (DEA) identified the patient's prescription as "exceeding the maximum Morphine Milligram Equivalents (MME) as defined by the Centers for Disease Control and Prevention (CDC)."¹ In response to this last incident, the DEA and CDC, among others, stated to the AMA (and the Medical Association of Georgia) that the pharmacist's actions and interpretation of CDC and DEA rules and guidelines were incorrect and inappropriate. MAG informed the AMA of this situation, and the AMA, in turn, reached out to the DEA, CDC, National Association of Boards of Pharmacy and others—all of whom quickly engaged with the AMA to register their disapproval of the pharmacy action and state that they would take all relevant actions in Georgia. Your Board appreciates the fact that DEA, CDC, NABP and others took action to support the concerns of MAG and the AMA.

These different physician-pharmacist interactions, however, are often the inevitable result of policies mainly focused on the dose and/or number of days for a prescription for opioid analgesics. It should be noted at the outset that the AMA strongly supports physicians' efforts to ensure that if a prescription for an opioid analgesic is warranted to help treat a patient's pain, physicians should prescribe the lowest effective dose only for the shortest duration of time. The AMA also supports pharmacists as key partners in helping ensure medication safety and as part of the patient-physician-pharmacist therapeutic triad. The Board and the AMA Opioid Task Force point out that physicians' efforts to make more judicious prescribing decisions have led to a more than 22 percent reduction in retail opioid prescriptions dispensed between 2013-2017, and that these reductions began prior to nearly all legislative, regulatory and other efforts focused on reducing opioid supply.

Concurrent with and despite this progress, national pharmacy chains, health insurance companies and PBMs have implemented their own restrictive opioid prescribing policies. This report will not detail every iteration and difference between the policies except to say that most of the policies are some variation of the "CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016" (the CDC Guideline).² In the CDC Guideline's introduction, CDC stated:

[T]he recommendations in the guideline are voluntary, rather than prescriptive standards. They are based on emerging evidence, including observational studies or randomized clinical trials with notable limitations. Clinicians should consider the circumstances and unique needs of each patient when providing care.

Yet, the CDC Guideline goes on to make two recommendations that appear in nearly all the pharmacy, payer and PBM policies:

[Recommendation] 5. When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to ≥ 50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥ 90 MME/day or carefully justify a decision to titrate dosage to ≥ 90 MME/day.

[Recommendation] 6. Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed.

The AMA is concerned by the fact that policymakers, health plans, corporate pharmacy chains and PBMs have used these recommendations to restrict or refuse patients (with few exceptions) to receive a prescription greater than 90 MME or for more than seven days. It is important to note that CDC Guideline Recommendations 5 and 6 were intended

guidelines for acute pain episodes, not a hard threshold, and not intended for chronic pain patients. The U.S. Department of Health and Human Services Interagency Pain Care Task Force draft report commented:

[A]t least 28 states have enacted legislation related to opioid prescription limits, and many states and organizations **have** implemented the guideline without recognizing that the intended audience was [primary care providers]; have used legislation for what should be medical decision making by healthcare professionals; and have applied them to all physicians, dentists, NPs, and PAs, including pain specialists. Some stakeholders have interpreted the guideline as intended to broadly reduce the amounts of opioids prescribed for treating pain; some experts have noted that the guideline emphasizes the risk of opioids while minimizing the benefit of this medication class when properly managed. The CDC guideline was not intended to be model legislation for state legislators to enact.³

Many of the state legislative and other policies enacted and/or implemented since then, however, justify the dosage limit for acute pain based on the CDC Guideline. The HOD addressed this in Policy D-120.932, “Inappropriate Use of CDC Guidelines for Prescribing Opioids.” While it is common for state opioid prescribing restriction policies to allow for exceptions for patients with cancer, in hospice or who require palliative care, to name a few, exceptions are highly variable regarding post-operative surgical care, chronic pain, cancer remission-related pain, sickle cell or other conditions for which a patient might require a prescription for a greater dosage than a state law might allow.

AMA has consistently stated its opposition to these hard thresholds because of the potential danger they pose if a patient does not neatly fit into an exception category (e.g., hospice, cancer, palliative care). At the same time, multiple national pharmacy chains implemented some variation⁴ of the CDC Guideline as their policy—a move the AMA warned would occur.⁵ AMA President Barbara L. McAneny, MD, shared with the HOD at the 2018 Interim Meeting that a pharmacy denied an opioid prescription to one of her prostate cancer patients—claiming he was a drug seeker.⁶ Additionally, the AMA “FixPriorAuth” campaign⁷ heard from a patient’s wife that:

[T]his happened to my sweetheart, changing insurance companies. He was on pain meds for an extended period and they wouldn’t authorize his meds in time so his current prescription ran out and we had to go to the hospital for pain control. They are heartless!!

The AMA’s first engagement with this issue dates to discussions that occurred in 2013-2014 with the National Association of Boards of Pharmacy (NABP), the Federation of State Medical Boards (FSMB) and many other stakeholders. Those discussions were born from concerns physicians and others raised with respect to early precursors of opioid prescription restriction policies. The result of those discussions was not only a consensus statement highlighting the legal and professional obligations of physicians, but also the corresponding responsibility of pharmacists.⁸

The AMA’s work with the FSMB, moreover, also pre-dated the issuance of the CDC Guideline. One prominent outcome from the FSMB was adoption, in 2017, of an updated “Guidelines for the Chronic Use of Opioid Analgesics.”⁹ The AMA was a member of the workgroup that provided input to the FSMB during its deliberations and strongly voiced its concern about “one-size-fits-all” thresholds. The FSMB, to its great credit, supported those concerns and the resulting policy reflects support for ensuring patient-focused care. For example, the FSMB states:

[T]he “focus of the [FSMB] Guidelines that follow is on the general overall safe and evidence-based prescribing of opioids and treatment of chronic, non-cancer pain with the specific limitation and restriction that these Guidelines do not operate to create any specific standard of care, which standard must depend upon fact-specific totality of circumstances surrounding specific quality-of-care events.”

In addition to the FSMB’s ongoing support for patient-focused care, the development of the NABP consensus statement also resulted in the development of close relationships with pharmacy counterparts at several national chain pharmacies. When issues have arisen in select states where a physician reports a concern with the dispensing decision of a pharmacy, these relationships have enabled AMA to work directly with the national chain and the state medical society to resolve the issue—a resolution based on specific facts rather than a one-size-fits-all approach. The AMA also has remained in close contact with the NABP to share information and work collaboratively where interests align, including efforts to bolster constructive relationships between physicians and pharmacists. It also is worth highlighting that some pharmacy boards are taking steps to remind their licensees about the need to ensure dispensing determinations are made on an individualized patient basis.¹⁰

Despite continued efforts by AMA to constructively engage Walmart, Inc. (Walmart), however, the national pharmacy chain has taken a markedly different course. Specifically, Walmart has sent an unknown number of what can be considered “blacklist” letters to physicians. These unsigned letters from Walmart’s corporate headquarters have been sent in multiple states and only include a generic email address for the physician to respond to if the letter was believed to be sent in error. The letter typically states that the physician in question had his or her “prescribing patterns and practices” reviewed and as a result, “[Walmart] determined that we will not be able to continue filling your controlled substance prescriptions.” AMA has sent multiple letters, email and voice messages to Walmart opposing its policy and seeking explanation—all without meaningful response.¹¹ Others, including the Texas Medical Association, also have not received a meaningful response from Walmart.¹² In one instance, the overly broad and vague Walmart policy targeted a rural Idaho addiction medicine physician who prescribed buprenorphine, but did not prescribe opioid analgesics. As CDC has stated, buprenorphine for the treatment of opioid use disorder should not be used in an MME calculation,¹³ but resolution of this matter required extensive commitment from the Idaho Medical Association and Idaho Board of Pharmacy—and resulted in patients being forced to find alternate pharmacies to continue their care.

With respect to health insurance companies, the AMA has made inquiries but is not aware of any widespread action by payers to send physicians letters or other communication “that include a blanket proscription against filing prescriptions for opioids that exceed numerical thresholds without taking into account the diagnosis and previous response to treatment for a patient and any clinical nuances would support such prescribing as falling within standards of good quality patient care.” Rather, AMA is acutely aware of health insurance companies implementing hard-threshold guidelines based on the CDC guideline.

AMA President-elect and Chair of the AMA Opioid Task Force, Patrice A. Harris, MD, MA, raised concerns about these payer policies directly to the National Association of Insurance Commissioners (NAIC) at its Regulatory Framework Task Force hearing on Saturday, March 24, 2018. AMA Chair Jack Resneck, Jr., MD, raised similar concerns about patients facing restrictions on receiving opioid analgesics without payers removing prior authorization and other restrictions on non-opioid behavioral, restorative, surgical and other non-opioid modalities at the November 16, 2018 hearing of the NAIC Health Insurance and Managed Care Committee. Both Drs. Harris and Resneck highlighted patients’ need for greater access to comprehensive, multidisciplinary, multimodal pain care. The AMA has continued this advocacy directly to state regulators—a primary feature of new, spotlight analyses of state responses to the opioid epidemic.¹⁴

AMA POLICY

The AMA has extensive and wide-ranging policy in support of ensuring patients receive optimal pain care and removal of arbitrary restrictions on the provision of that care. This includes having AMA “oppose legislative or other policies that arbitrarily restrict a patient’s ability to receive effective, patient-specific, evidence-based, comprehensive pain care. (Policy H-95.930, “Legislative Pain Care Restrictions”). It also includes AMA’s “strong commitment to better access and delivery of quality pain care through the promotion of enhanced research, education and clinical practice in the field of pain medicine,” as well as the AMA’s “commitment to delivering compassionate and ethical pain management, promoting safe opioid prescribing, reducing opioid-related harm and the diversion of controlled substances, improving access to treatment for substance use disorders, and fostering a public health based-approach to addressing opioid-related morbidity and mortality.” (Policy D-160.981, “Promotion of Better Pain Care”). AMA policy also supports “the position that physicians who appropriately prescribe and/or administer controlled substances to relieve intractable pain should not be subject to the burdens of excessive regulatory scrutiny, inappropriate disciplinary action, or criminal prosecution.” (Policy H-120.960, “Protection for Physicians Who Prescribe Pain Medication”). As noted above, AMA policy supports ensuring that patients are not harmed by the “misapplication of the CDC Guideline for Prescribing Opioids for Chronic Pain by pharmacists, health insurers, pharmacy benefit managers, legislatures, and governmental and private regulatory bodies in ways that prevent or limit patients’ medical access to opioid analgesia.” (Policy D-120.932, “Inappropriate Use of CDC Guidelines for Prescribing Opioids”).

RECOMMENDATIONS

The Board recommends that the following recommendations be adopted in lieu of the second resolve of alternate Resolution 235-I-18, and that the remainder of the report be filed.

1. That our American Medical Association (AMA) support balanced opioid-sparing policies that are not based on hard thresholds, but on patient individuality, and help ensure safe prescribing practices, minimize workflow

disruption, and ensure patients have access to their medications in a timely manner, without additional, cumbersome documentation requirements.

2. That our AMA oppose the use of “high prescriber” lists used by national pharmacy chains, pharmacy benefit management companies or health insurance companies when those lists do not provide due process and are used to blacklist physicians from writing prescriptions for controlled substances and preventing patients from having the prescription filled at their pharmacy of choice.
3. That our AMA incorporate into its advocacy that clinical practice guidelines specific to cancer treatment, palliative care, and end of life be utilized in lieu of the CDC’s Guideline for Prescribing Opioids for Chronic Pain as per the CDC’s clarifying recommendation.
4. That our AMA reaffirm Policy D-120.932, “Inappropriate Use of Centers for Disease Control and Prevention Guidelines for Prescribing Opioids.”

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4. See, for example, CVS Caremark® Opioid Quantity Limits Pharmacy Reference Guide. Available at https://www.caremark.com/portal/asset/Opioid_Reference_Guide.pdf
5. See also AMA January 12, 2016 letter to then-CDC Director Thomas Frieden, MD. Available at <https://searchlf.ama-assn.org/letter/documentDownload?uri=/unstructured/binary/letter/LETTERS/cdc-opioid-guidelines-12jan2016.pdf>
6. Attacking the Dysfunction in Health Care. Barbara L. McAneny, MD, President, American Medical Association. AMA Interim Meeting, National Harbor, MD, November 10, 2018. Available at <https://www.ama-assn.org/system/files/2018-11/i18-mcaneny-speech.pdf>
7. Physicians and patients can learn more about American Medical Association advocacy to broadly address prior authorization issues at www.FixPriorAuth.org
8. See “NABP Collaborates with Health Care Stakeholders on Ensuring Delivery of Responsible and Effective Patient Care,” February 4, 2014. Available at <https://nabp.pharmacy/nabp-collaborates-with-health-care-stakeholders-on-ensuring-delivery-of-responsible-and-effective-patient-care/>
9. Guidelines for the Chronic Use of Opioid Analgesics Adopted as policy by the Federation of State Medical Boards April 2017. Available at https://www.fsmb.org/siteassets/advocacy/policies/opioid_guidelines_as_adopted_april-2017_final.pdf
10. See, for example, a January 23, 2019 letter from the Alaska Board of Pharmacy stressing, among other things, that “Simply refusing to fill a prescription without trying to resolve the concern may call into question the knowledge, skill or judgment of the pharmacist and may be deemed unprofessional conduct.” The full letter is available at https://www.commerce.alaska.gov/web/portals/5/pub/pha_ControlledSubstanceDispensing_2019.01.pdf
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**23. PRIOR AUTHORIZATION REQUIREMENTS FOR POST-OPERATIVE OPIOIDS
(RESOLUTION 208-A-18)**

Reference committee hearing: see report of Reference Committee B.

**HOUSE ACTION: RECOMMENDATIONS ADOPTED
IN LIEU OF RESOLUTION 208-A-18
REMAINDER OF REPORT FILED**
See Policy H-95.919

INTRODUCTION

At the 2018 Annual Meeting, the American Medical Association (AMA) House of Delegates (HOD) referred Resolution 208-A-18, “Prior Authorization Requirements for Post-Operative Analgesia,” introduced by the Pennsylvania Delegation, which asked:

That our American Medical Association strongly oppose prior authorization requirements for postoperative analgesia equivalent to five days or less so as to prevent patient suffering.

Reference committee testimony generally was supportive of the original resolution given physicians’ and patients’ experiences with legislative and other policies focused on hard thresholds for opioid prescribing post-surgery and other acute care settings. Yet, there was concern raised regarding taking a position to oppose all prior authorization or other utilization management protocols. The AMA Council on Medical Service and Council on Legislation were among those who asked that our Board take this resolution back for consideration, discussion and present clear recommendations to further the intent of the original resolution.

DISCUSSION

There are multiple, competing and often contradictory trends that define the nation’s opioid epidemic. Opioid-related mortality continues to increase, but data from the Centers for Disease Control and Prevention (CDC)¹ show that the nation’s opioid overdose and death epidemic continues to be driven by increases in death due to illicit fentanyl. Deaths due to prescription opioid- and heroin-related causes appear to have plateaued but remain at historic highs. In 2017:

- 28,466 died from illicit fentanyl-related overdose (19,413 in 2016).
- 15,482 died from heroin-related overdose (15,469 in 2016).
- 14,495 died from prescription opioid-related overdose (14,487 in 2016). (More than 60 percent of people who misused prescription opioids steal them or obtain them from a family member or friend.²)
- 3,194 died from methadone-related causes—the lowest number since 2003. (The data does not distinguish whether methadone was used for pain or for the treatment of opioid use disorder.³)

At the same time, opioid prescribing in the United States continues to decrease. Between 2013-2017, retail filled opioid prescriptions decreased by 22.2 percent with a total of 196 million opioid prescriptions filled in 2017.⁴ Decreases occurred in every state. The most common opioid prescription was for less than 30 days and less than 50 morphine milligram equivalents (MME). From 2014 to 2016, opioid prescriptions written for fewer than 30 days decreased from 150.4 million to 126.5 million; and opioid prescriptions of less than 50 MME decreased from 175.6 million in 2014 to 158.0 million in 2016.⁵

Policymakers for the past several years have focused almost entirely on mandating a few specific policies or approaches that they believe would help end the epidemic. These include enacting legislation in nearly four out of five states to require physicians to use a state prescription drug program (PDMP); mandating content-specific continuing medical education (CME) in more than half of the states; and prohibiting a prescription for an opioid analgesic if it is greater than a certain number of days or for a greater than a certain MME.

Restrictions on opioid prescribing also have been implemented by health plans, national pharmacy chains and pharmacy benefit management companies.⁶ Many of these policies follow the publication from the CDC entitled, “CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016 (the Guideline).”⁷ In the Guideline’s introduction, CDC stated:

The recommendations in the guideline are voluntary, rather than prescriptive standards. They are based on emerging evidence, including observational studies or randomized clinical trials with notable limitations. Clinicians should consider the circumstances and unique needs of each patient when providing care.

Many of the state legislative and other policies enacted and/or implemented since then, however, justify the day/dose limit for acute pain based on the CDC Guideline. The HOD addressed this in Policy D-120.932, “Inappropriate Use of CDC Guidelines for Prescribing Opioids.” And while it is common for state opioid restriction policies to allow for exceptions for patients with cancer, in hospice or who require palliative care, to name a few, there generally is no exception for when post-operative surgical care might require a prescription for a greater number of days or dose strength than a particular state might allow.

State policymaking also has resulted in no consistency between opioid restriction or other laws. For example, some states require checking the PDMP prior to prescribing any controlled substance or limited to only opioid analgesics. Other states require a PDMP check every 90 days (or another interval) for repeated prescriptions, and other states require a check only once per year. With respect to CME mandates, the number of hours and specific nature of the CME vary by state. The Board notes that the AMA Opioid Task Force has gathered more than 400 state- and specialty-specific resources to help promote the availability of education and training that is relevant and meaningful to a physician’s specific practice and patient population.⁸ The Board thanks all those Federation partners who have contributed to this effort.

With respect to opioid prescribing, physicians and other prescribers of controlled substances have borne a considerable amount of blame. The AMA and countless physician organizations have accepted responsibility for both working to reduce patients’ pain and the medical community acknowledges its role in having in the past increased opioid prescribing as one way to help alleviate patients’ pain. The AMA also has supported efforts by law enforcement and others to stop illegal activities such as pill mills and the AMA and countless physician organizations have made considerable progress in urging physicians to be more judicious in their prescribing decisions as the above data show. The Board knows, however, that there is much more work to do before the epidemic will end.

The AMA continues to stress the need for evidence-based decision making on the part of policymakers with respect to restrictions on opioid prescribing. Given that state policies have been the result of political negotiations rather than scientific evidence, it is possible that a course correction could be made. One such direction could be to follow the patient-centric recommendations of the U.S. Department of Health and Human Services, “Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations,”⁹ which includes among its many positive recommendations, support for:

- Individualized treatment as the primary goal of acute pain management, accounting for patient variability with regard to factors such as comorbidities, severity of conditions, surgical variability, geographic considerations, and community/hospital resources.
- Improved pain control, faster recovery, improved rehabilitation with earlier mobilization, less risk for blood clots and pulmonary embolus, and mitigation of excess opioid exposure.

Similarly, as physicians continue to play a leading role in reducing opioid prescriptions and advocating for patients’ access to opioid analgesics when appropriate, there is a great need to remove prior authorization for multidisciplinary and multimodal pain care, including non-opioid alternatives. This has been one of the central findings of AMA spotlight analyses of efforts in the Medicaid agencies of several states,¹⁰ but the AMA also continues to hear regularly from physicians about commercial health insurance companies who resist removing prior authorization hurdles as well as their limited efforts to increase access to non-opioid alternatives. The Board strongly recommends that health insurance companies work with physicians and the nation’s medical societies to remove barriers to non-opioid pain care.

There are good examples in the pain stewardship and other comprehensive pain care programs that have been implemented in many areas of the country. This includes programs at Kaiser Permanente, Geisinger Health System, Intermountain Health Care and the University of Chicago, to name a few. There also continues to be emerging research focusing on the most appropriate length and dose of an opioid prescription post-operatively. This includes for procedures ranging from rhinoplasty,¹¹ gynecologic and abdominal surgery,¹² care delivered in the emergency department,¹³ as well as mastectomy, general surgery and musculoskeletal procedures.¹⁴

There generally are three common elements to these efforts by systems and researchers. First, they all have engaged in extensive data review to determine what baseline of opioid prescribing was taking place in the system and for the specific procedures. Second, they all discovered that while opioid prescribing overall could be reduced, none put a hard threshold on the amount given post-operatively or following an acute care episode. And third, even when guidelines were established for physicians, those guidelines provided a range rather than a single number. In the systems, furthermore, and as noted above in Medicaid, there is increasing realization that while opioid sparing protocols may be beneficial, patients must not be left without sufficient forms of pain care. That is, opioid reductions may have occurred, but the focus for these physicians has been on improving patient outcomes.

AMA POLICY

AMA has extensive policy supporting the principle that utilization management policies, clinical practice guidelines and clinical quality improvement activities must be based on sound clinical evidence, data and allow for variation based on individual patient needs (e.g., Policy H-320.949, Clinical Practice Guidelines and Clinical Quality Improvement Activities). AMA policy also promotes patient access to comprehensive, multidisciplinary, multimodal pain care, including working with all stakeholders to promote research and develop evidence to support quality pain care. This includes promoting safe opioid prescribing and promoting a public health approach to ending the nation's opioid epidemic (e.g., Policy D-160.981, Policy H-95.990, "Promotion of Better Pain Care and Drug Abuse Related to Prescribing Practices"). And, it includes AMA strong support for "timely and appropriate access to non-opioid and non-pharmacologic treatments for pain, including removing barriers to such treatments when they inhibit a patient's access to care." (Policy D-450.956, "Pain as the Fifth Vital Sign.") It should also be stressed that AMA's efforts to reduce prior authorization burdens and protect patients' access to medically necessary therapy extend far beyond only post-operative pain care (e.g., Policy H-320.939, "Prior Authorization and Utilization Management Reform" and the grassroots advocacy campaign based on the online hub, FixPriorAuth.org).

RECOMMENDATIONS

The Board recommends that the following recommendation be adopted in lieu of Resolution 208-A-18, and that the remainder of the report be filed.

1. That our American Medical Association (AMA) advocate for state legislatures and other policymakers, health insurance companies and pharmaceutical benefit management companies to remove barriers, including prior authorization, to non-opioid pain care.
2. That our AMA support amendments to opioid restriction policies to allow for exceptions that enable physicians, when medically necessary in the physician's judgment, to exceed statutory, regulatory or other thresholds for post-operative care and other medical procedures or conditions.
3. That our AMA oppose health insurance company and pharmacy benefit management company utilization management policies, including prior authorization, that restrict access to post-operative pain care, including opioid analgesics, if those policies are not based upon sound clinical evidence, data and emerging research.

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**24. DISCOUNTED/WAIVED CPT FEES AS AN AMA MEMBER BENEFIT AND
FOR MEMBERSHIP PROMOTION
(RESOLUTION 607-A-18)**

Reference committee hearing: see report of Reference Committee F.

**HOUSE ACTION: RECOMMENDATIONS ADOPTED
RESOLUTION 607-A-18 NOT ADOPTED
REMAINDER OF REPORT FILED**

At the 2018 Annual Meeting, the House of Delegates referred Resolution 607, “Discounted/ Waived CPT Fees as an AMA Member Benefit and for Membership Promotion,” to the Board of Trustees. Resolution 607, introduced by New York Delegate, Dr. Gregory L. Pinto, asked:

That our American Medical Association (AMA) investigate mechanisms by which Members may receive a discount or waiver on CPT-related fees, specifically the fees associated with using CPT codes within electronic medical billing systems.

BACKGROUND ON AMA MEMBERSHIP DUES AND BENEFITS

As the largest association of physicians and medical students in the United States, the AMA provides a wide range of benefits and services to its members. In turn, members pay annual dues in accordance with their career progression, from medical students to residents and fellows to physicians. For example, dues applicable to first year medical school students are less than those applicable to physicians. Membership dues applicable to physicians are graduated over their first five years in practice, such that physicians pay full regular practice dues (i.e. \$420) only after four years of medical practice. The AMA seeks to support physicians in the most prudent and direct ways possible. The AMA typically offers its physician members discounts on AMA-developed products sold directly to those members, such as published books, journals and newsletters.

EXPLANATION OF CPT LICENSING AND ROYALTIES

The Current Procedural Terminology (CPT) code set user-base is diverse and varied, and the AMA does not distinguish different types of users from one another, e.g., a nurse and a medical claims specialist both use CPT. In fact, approximately two-thirds of CPT users are not eligible for AMA membership because they are not physicians or medical students. CPT is typically licensed by organizations for all users of CPT – irrespective of user type – and the AMA does not receive information identifying the individuals covered under an organization’s license.

Additionally, the majority of CPT licensing is completed by third party distributors such as software vendors (e.g., vendors of electronic medical billing systems) that embed CPT in their products to enable critical healthcare functions. Hundreds of such organizations contract with the AMA to distribute CPT domestically and globally. Distributor agreements specify a method of calculating a royalty due to the AMA from the distributor, but do not dictate the amount of CPT royalties (if any) to be charged by the distributors to their client, i.e. the end users of CPT. The AMA also does not dictate how distributors contract with their end user customers and these practices vary widely. Some distributors elect to absorb the cost of CPT royalties paid to the AMA, or embed the cost into the cost of their product(s), while others choose to directly pass the cost through to their customers. Some distributors license their software (and in turn CPT) based on aggregate user counts, do not track the identities of specific users, and as a result, are unaware of an individual physician’s usage of their product or that physician’s membership status with the AMA.

As for CPT licensees who contract directly with the AMA (rather than through a distributor), most are large or mid-sized health systems, hospitals or practices. As mentioned above, the AMA does not receive information identifying specific users covered under the CPT license and thus is not able to confirm which users are physicians and whether any such physician user is an AMA member. We note that small practices with 25 or fewer CPT users are currently eligible for CPT royalty discounts between 13 and 22% when an AMA physician member purchases the license directly from the AMA, as AMA physician membership can be confirmed in this limited situation. The discount is applied to the entire license, not just the pro rata portion related to the individual physician member.

DISCUSSION

The CPT code set is a mission-driven product, which means that its royalties, like those from JAMA and other AMA assets, are used to carry out the mission to promote the art and science of medicine and the betterment of public health, to the benefit of all physicians and patients.

Development of a new CPT licensing and distribution process to administer a membership-based discount is at best impractical, requiring a complete reinvention of the AMA’s licensing and distribution model, renegotiation of hundreds of contracts, and the introduction of cumbersome business processes that AMA’s distributors are unlikely to accept. It would also require high volume and high frequency exchange of sensitive data and a large data reconciliation process. This approach would be inefficient, burdensome and costly for the AMA, the AMA’s distributors and the distributors’ licensees. Even if these significant changes were undertaken, it is unclear that savings would be delivered to AMA members, as distributors (often commercial companies) have different interests than membership organizations.

CONCLUSION

The AMA enhances its ability to achieve its mission by managing its assets in a fiscally prudent manner. Expanding CPT discounts beyond direct licensees would present significant policy, operational and contractual challenges that would divert resources from other important endeavors and result in unnecessary cost to the AMA. It is also very likely that the benefits of these discounts would accrue to distributors or licensee organizations rather than to AMA member physicians.

RECOMMENDATION

Through the analysis that led to this report, an opportunity was identified to improve AMA member benefits for direct licensees with 25 or fewer users by increasing their discount to 30%. This change will go into effect for the 2020 CPT data file. The increased discount will enable the AMA to continue to support its mission, while having a positive impact on AMA members in small practices. This is also consistent with other AMA Membership discount programs.

Consequently, the Board of Trustees recommends that Resolution 607-A-18 not be adopted and that the remainder of this report be filed.

25. ALL PAYER GRADUATE MEDICAL EDUCATION FUNDING

Reference committee hearing: see report of Reference Committee C.

HOUSE ACTION: RECOMMENDATIONS ADOPTED REMAINDER OF REPORT FILED

See Policy D-305.967

INTRODUCTION

At the 2018 Annual Meeting, the House of Delegates adopted Policy D-305.967, “The Preservation, Stability and Expansion of Full Funding for Graduate Medical Education,” which asks that our AMA:

...investigate the status of implementation of AMA Policies [D-305.973](#), “Proposed Revisions to AMA Policy on the Financing of Medical Education Programs” and [D-305.967](#), “The Preservation, Stability and Expansion of Full Funding for Graduate Medical Education” and report back to the House of Delegates with proposed measures to resolve the problems of underfunding, inadequate number of residencies and geographic maldistribution of residencies.

BACKGROUND

An Overview of Graduate Medical Education

Graduate medical education (GME) programs account for nearly three-quarters of the U.S. Department of Health & Human Services’ (HHS) health workforce expenditures, and may be a strong policy lever to impact patient access to care because the number of medical school graduates who obtain and complete a residency determines the size of the physician workforce and the types of residencies they complete determine its specialty composition.¹ Also, where physicians complete their residencies often affects where they establish their practices.² As a result, policies that alter federal funding for GME may impact future physician supply and could be used to address certain workforce concerns.

Although the federal government is not the sole contributor to GME funding, it is by far the largest single source, primarily through Medicare funding. Medicare funding to support GME programs comes from direct GME funding and indirect GME funding. Direct GME (DGME) funding represents approximately one-third of all Medicare support for GME. It supports the direct costs of running a residency program and covers salaries for residents and faculty as well as educational support. Indirect GME payments (IME), which represent the majority of Medicare GME funding, are calculated based on the size of a hospital, the number of residents supported, and the number of Medicare inpatients treated. IME payments are in addition to payments an institution receives from Medicare reimbursement and are meant to offset the costs of maintaining an educational program that are not captured by Medicare reimbursement. Both IME and DGME payments are derived by complex formulas and are not designed to account for differences in costs resulting from training residents of different specialties. The Department of Veterans Affairs, Medicaid, and the Children’s Health Insurance Program are other federal sources of GME funding of varying levels. In addition, the Army, Navy, and Air Force support their own in-house residencies and fellowships to provide for the future physician workforce needs of those services.

Federal Funding for Graduate Medical Education³

Program Name	Total Funding	Number of Trainees	Cost Per Trainee
<i>Control over trainees</i>			
MANDATORY FUNDING			
Medicare GME Payments <i>The number of Medicare-supported residents and per-resident payment amount is capped for each hospital, but hospitals determine staffing needs and types of residents with the exception of certain primary care residents.</i>	FY2015 (est.): \$10.3 - \$12.5 billion	FY2015 (est.): 85,712 - 87,980 FTE (DGME) slots 85,578 - 88,416 FTE (IME) slots	FY2015 (est. average): \$112,000 - 129,000 per FTE
Medicaid GME Payment <i>States are permitted to make these payments using their own criteria to determine which providers are eligible for payments.</i>	N/A.	N/A The Medicaid program does not require states to report these data.	N/A. The Medicaid program does not require states to report these data.
Teaching Health Centers GME Payment Program <i>Funding to applicant teaching health centers that meet the program's eligibility requirements.</i>	FY2018: \$126.5 million (est.)	AY2016-AY2017: 742 FTE slots 771 total residents trained	N/A.
DISCRETIONARY FUNDING			
Veterans Affairs GME Payments <i>VA facilities determine their staffing needs and the number and type of residents supported.</i>	FY2017: \$1.78 billion	AY2016-AY2017: 11,000 FTE slots and > 43,565 residents spent part of their training at a VA facility	FY2015 (est.): \$137,792/resident
Children's Hospital GME Payment Program <i>Grant funding awarded to applicant children's hospitals that meet the program's eligibility requirements.</i>	FY2019: \$325billion	FY2016-FY2017 58 hospitals received payments to support 7,164 FTE slots	N/A
Department of Defense GME Payments <i>Divisions of the armed forces determine their staffing needs and the number and type of residents supported.</i>	FY2012: \$16.5 million	FY2017: 3,983 FTE residents	N/A

Source: CRS analysis of agency data, including review of various agency budget justification and The Robert Graham Center program data sourced from CMS Medicare hospital cost report data, and GAO report, *Physician Workforce: HHS Needs Better Information to Comprehensively Evaluate Graduate Medical Education Funding* (GAO-18-240, 2018).

Notes: AY = Academic year; Academic year 2016-2017 began on July 1, 2016, and concluded on June 30, 2017. DGME = direct graduate medical education. est. = estimate. FTE = full time equivalent. FY = fiscal year. IME = Indirect Medical Education. N/A = not available. VA = the Department of Veterans Affairs.

Data on Medicaid GME funding are limited. The Centers for Medicare & Medicaid Services (CMS) began collecting information about Medicaid GME payments made through the fee-for-service delivery system in FY2010 through the CMS-64 data. Other information about Medicaid GME payments is available from the Association of American Medical Colleges (AAMC) and U.S. Government Accountability Office (GAO). AAMC conducts a 50-state survey about Medicaid GME payments every two to three years. According to AAMC's 2016 50-state survey, in 2015, the overall level of support for GME continued to grow, reaching \$4.26 billion. This represents a significant increase since 1998, when Medicaid GME support totaled \$2.3–\$2.4 billion. However, three states reported in 2015 that they explicitly reduced GME payments; another seven states reported their total 2015 GME payments decreased by 10 percent or more over 2012 levels.⁴

The Medicare GME Caps

Medicare's GME support was initially open-ended, where Medicare would pay for additional full time equivalent (FTE) residents that hospitals trained. In 1997, GME stakeholders released a consensus statement arguing that the United States was on the verge of a serious oversupply of physicians and recommending limiting federal funding of GME positions to more align with the number of graduates of accredited U.S. medical schools.⁵ Congress enacted the Balanced Budget Act of 1997, (P.L. 105-33), which limits Medicare's GME—most hospitals would receive DGME and IME support only for the number of allopathic and osteopathic FTE residents it had in training in 1996; in other words, the number of positions Medicare supported in each hospital in 1996 was established as the upper limit in terms of the number of positions or slots that Medicare would fund in those institutions thereafter. Slots, which may be occupied by residents or fellows, do not directly correspond to a specific individual, as residents or fellows may spend periods of a given year at different facilities, or doing research. Residents may not be counted simultaneously for payment by two government programs. Therefore, when residents are located at different facilities, they are not counted by the sponsoring hospital.

The Medicare cap is not absolute. Medicare provides GME funding to newly constructed hospitals that introduce residency programs and to existing hospitals that did not previously sponsor residency training. Furthermore, the GME cap is not calculated and implemented until new teaching programs' fifth year; this is meant to offer institutions time to build and scale their programs to appropriate levels.

Since the Medicare cap was enacted, hospitals have expanded the number of residents they are training by using non-Medicare sources of support (e.g., hospital, state, or local funds). Specifically, in the 20 years since the cap was enacted, the number of residency slots has increased by approximately 27 percent. Generally, these increases have been in subspecialties (i.e., for fellowship training); subspecialty services tend to generate higher revenue or impose lower cost burden on hospitals. In addition, Medicare GME slots have been redistributed since the cap was enacted. For example, the Affordable Care Act included two redistribution programs—the first redistributed unused slots, and the second continually redistributes slots from closed hospitals. However, caps on the number of resident trainees imposed by Medicare continue to further restrict the number of residency positions offered and provide teaching hospitals with little flexibility for expansion.

Source: <https://mk0nrmpcikgb8jxyd19h.kinstacdn.com/wp-content/uploads/2018/04/Main-Match-Result-and-Data-2018.pdf>

Furthermore, based on the projected physician shortfall that is expected by 2030, the cap established in 1997 is outdated and will continue to cause stress on a health care system already beginning to show signs of strain in communities lacking sufficient numbers of physicians to care for individuals living in these rural and underserved areas. It is projected that physician demand will grow faster than supply, leading to a projected total physician shortfall of between 42,600 and 121,300 physicians by 2030. A primary care shortage of between 14,800 and 49,300 physicians is projected by 2030. With regard to non-primary care specialties, a projected shortfall of between 33,800 and 72,700 physicians is expected, including a shortfall of between 20,700 and 30,500 physicians in 2030 for surgical specialties. Major drivers of these projected trends continue to be an aging population requiring increasingly complex care concomitant with an aging physician workforce.⁶

DISCUSSION

AMA Advocacy

For more than a decade, the AMA has advocated for the modernization of GME, calling for increased funding for medical residency slots, development of innovative practice models as well as residency positions that reflect societal needs. Below is an overview of recent advocacy efforts by the AMA in this area. The advocacy efforts detailed below were taken by the AMA in accordance to and in concert with the policy directives outlined in AMA Policy D-305.973, "Proposed Revisions to AMA Policy on the Financing of Medical Education Programs," and Policy D-305.967, "The Preservation, Stability and Expansion of Full Funding for Graduate Medical Education."

Congressional Advocacy

The AMA advocated in support of the following federal bills that were introduced during the 115th Congress (2017-2018):

- The Advancing Medical Resident Training in Community Hospitals Act of 2017 (S. 1291/H.R. 4552) – The bill would have closed a loophole in GME cap-setting criteria affecting hospitals who host small numbers of residents for temporary training assignments. The AMA submitted a [support letter](#) in June 2018.
- The Resident Physician Shortage Act of 2017 (S. 1301/H.R. 2267) – The bill would have provided 15,000 additional Medicare-supported GME positions over five years. The AMA submitted a [support letter](#) in June 2017.
- The Teaching Health Centers Graduate Medical Education (THCGME) Extension Act of 2017 (S. 1754/H.R. 3394) – The bill would have reauthorized the THCGME program for an additional three years and support program expansion to serve more rural and underserved communities. The AMA submitted a [support letter](#) in September 2017.
- The Conrad 30 and Physician Access Reauthorization Act (S.898/H.R.2141) – The bill would have reauthorized the J-1 visa waiver program for an additional three years, protecting patient access to care in medically underserved areas across the United States. The AMA submitted a [support letter](#) in May 2017. In [2013](#) and [2015](#), the AMA also actively supported legislation to reauthorize Conrad 30.
- Opioid Workforce Act of 2018 (S.2843/H.R. 5818) – The bill would have increased the number of residency positions eligible for GME under Medicare for hospitals that have addiction or pain management programs, with an aggregate increase of 1,000 positions over a five-year period. The AMA submitted a [support letter](#) in June 2018.

The AMA is advocating for the following federal bills that have been introduced during the 116th Congress (2019-2020):

- The Community and Public Health Programs Extensions Act ([S. 192](#)) – The bill would reauthorize \$310M for the National Health Service Corps, \$126M for THCGME programs, and \$4B for Community Health Centers for each fiscal year from 2019 to 2024. The AMA has submitted a [support letter](#).
- Rural Physician Workforce Production Act of 2019 ([S. 289](#)) – The bill would establish a national per resident payment amount in order to make accepting residents a financially viable option for rural hospitals.
- Training the Next Generation of Primary Care Doctors Act of 2019 ([S. 304](#)) – The bill provides funding for current THCGME programs and supports and funds the creation of new programs and/or centers, with a priority for those serving rural and medically underserved populations and areas.
- Resident Physician Shortage Reduction Act of 2019 ([S. 348](#)) – The bill would provide 15,000 additional Medicare-supported GME positions over five years. The AMA has submitted a [support letter](#).

The Compendium of GME Initiatives

- The AMA has long-focused on ways to improve GME to ensure medical students can fulfill training requirements and become practicing physicians. The “[Compendium of Graduate Medical Education Initiatives](#)” was created and distributed in 2016. It provides background regarding the challenges faced by the current GME system and GME initiatives, including those by the AMA, private, and state-based stakeholders. It also provides a snapshot of AMA’s advocacy efforts through 2016. The GME Compendium will be updated in 2019 to include relevant federal and state legislation, regulatory proposals, and state-based initiatives that have emerged since 2016. The updated version will also reflect any changes in AMA HOD policy.

Cap-Flexibility

- GME cap-flexibility is an emerging policy concept which calls for targeted policy efforts to provide new teaching hospitals in underserved areas flexibility and additional time in establishing Medicare-funded GME caps. In October 2017, in accordance with AMA policy

D-305.967 (31), the AMA advocated in a [letter](#) to CMS that the agency provide for more flexibility in the graduate medical education cap-setting deadline, particularly for new residency programs in underserved areas and/or economically-depressed areas.

Reimagining Residency

- In 2013, the AMA instituted the “Accelerating Change in Medical Education” initiative by making grants to medical schools to support undergraduate medical education innovation. “[Reimagining Residency](#)” is the next phase in this initiative. The aim of this five-year \$15-million grant program is to significantly improve GME through bold, rigorously evaluated innovations that align residency training with the needs of patients, communities and the rapidly changing health care environment. Funding will be provided to U.S. medical schools, GME programs, GME sponsoring institutions, health systems and other organizations associated with GME to support bold and innovative projects that promote systemic change in graduate medical education.

SaveGME.org

- The AMA created the [SaveGME.org webpage](#) in 2013 as a grassroots advocacy platform that medical students and residents could use to apply pressure to lawmakers in favor of preserving essential funding for GME. In 2017, the SaveGME.org website was updated to include public-facing messaging and educational materials. To date, more than 3,000 medical students and residents have taken action via SaveGME.org to urge their members of Congress not to make cuts to GME.

2019 Medical Student Advocacy & Region Conference (MARC)

- Each year, approximately 400 medical students participate in the [MARC](#) and advocate for increased GME funding. Medical students learn about relevant legislation and lobby their Members of Congress on Capitol Hill in Washington, DC.

Increased Accountability and Transparency to Support Increased GME Funding

The federal government supports workforce data collection and projections of future needs. In addition, researchers and advocates also collect and disseminate such data. Such data are necessary inputs for GME policy but are not sufficient to comprehensively determine whether the federal investment in GME training meets national physician workforce needs. The information agencies collect is not always complete or consistent within or across programs. For example, national data on GME training costs are not systematically collected, and some agencies lacked data to determine the total amount spent or the outcomes of their programs, such as where supported residents went on to practice. Furthermore, HHS currently cannot target Medicare GME funding to specific areas of workforce need because funds are disbursed based on a statutory formula that is unrelated to projected needs.⁷ The AMA agrees with the GAO that comprehensive information is needed to identify gaps between federal GME programs and national physician workforce needs—particularly the distribution of physicians geographically or across specialties—and to recommend to Congress and the Administration changes to improve the efficient and effective use of federal funds to meet those needs.^{8,9} Therefore, it is recommended that AMA Policy D-305.967, “The Preservation, Stability and Expansion of Full Funding for Graduate Medical Education,” be amended to call on the AMA to encourage HHS to coordinate with federal agencies that fund GME training to identify and collect information needed to effectively evaluate how hospitals, health systems, and health centers with residency programs are utilizing these financial resources to meet the nation’s health care workforce needs.

CONCLUSION

The AMA has extensive policy in support of a broad spectrum of GME-related issues and remains a strong advocate for the modernization and increased funding of GME. The AMA will continue to advocate for legislation that removes the caps on Medicare funding of GME positions for resident physicians that were imposed by the Balanced Budget Amendment of 1997 and increases support and funding for GME programs in the U.S. The AMA will also update the “Compendium of Graduate Medical Education Initiatives” to reflect current proposals related to GME. Furthermore, the Board recommends the adoption of additional policy to encourage the Secretary of the U.S. Department of Health and Human Services to coordinate with federal agencies that fund GME training to identify and collect information needed to effectively evaluate how hospitals, health systems, and health centers with residency programs are utilizing these financial resources to meet the nation’s health care workforce needs.

RECOMMENDATIONS

1. The Board recommends that our AMA amend Policy D-305.967, “The Preservation, Stability and Expansion of Full Funding for Graduate Medical Education,” with the addition of a new clause to read as follows, and that the remainder of the report be filed:

Our AMA encourages the Secretary of the U.S. Department of Health and Human Services to coordinate with federal agencies that fund GME training to identify and collect information needed to effectively evaluate how hospitals, health systems, and health centers with residency programs are utilizing these financial resources to meet the nation’s health care workforce needs. This includes information on payment amounts by the type of training programs supported, resident training costs and revenue generation, output or outcomes related to health workforce planning (i.e., percentage of primary care residents that went on to practice in rural or medically underserved areas), and measures related to resident competency and educational quality offered by GME training programs.

2. That our AMA rescind section 33 of Policy D-305.967, which directed the AMA to conduct the study herein.

REFERENCES

1. Congressional Research Service (CRS), Federal Support for Graduate Medical Education: An Overview, pg. 1, December 27, 2018, <https://fas.org/sgp/crs/misc/R44376.pdf>
2. Id.
3. Id.
4. Medicaid Graduate Medical Education Payments: A 50-State Survey (2016), https://members.aamc.org/eweb/upload/Medicaid_Graduate_Medical_Education_Payments--A_50_State_Survey.docx.pdf
5. Consensus Statement on the Physician Workforce. Paper issued at a joint press conference, February 28, 1997, Washington, D.C.; and Association of Academic Health Centers subsequently [testified](#) before Congress regarding the Consensus Statement.
6. AAMC, 2018 Update: The Complexities of Physician Supply and Demand: Projections from 2016 to 2030, https://aamc-black.global.ssl.fastly.net/production/media/filer_public/85/d7/85d7b689-f417-4ef0-97fb-ec129836829/aamc_2018_workforce_projections_update_april_11_2018.pdf.
7. GAO, Health Care Workforce: Comprehensive Planning by HHS Needed to Meet National Needs, December 11, 2015, <https://www.gao.gov/assets/680/674137.pdf>
8. GAO, Physician Workforce: HHS Needs Better Information to Comprehensively Evaluate Graduate Medical Education Funding, March 2018, <https://www.gao.gov/assets/700/690581.pdf>
9. A May 2017 GAO report, found that there is an uneven distribution of residents across the country, with most concentrating in certain urban centers and the northeast, where GME training programs have historically been located; See GAO, Physician Workforce: Locations and Types of Graduate Training Were Largely Unchanged, and Federal Efforts May Not Be Sufficient to Meet Needs, <https://www.gao.gov/assets/690/684946.pdf>

APPENDIX - AMA Policies

D-305.973, “Proposed Revisions to AMA Policy on the Financing of Medical Education Programs”

Our AMA will work with: (1) the federal government, including the Centers for Medicare and Medicaid Services, and the states, along with other interested parties, to bring about the following outcomes: (a) ensure adequate Medicaid and Medicare funding for graduate medical education; (b) ensure adequate Disproportionate Share Hospital funding; (c) make the Medicare direct medical education per-resident cost figure more equitable across teaching hospitals while assuring adequate funding of all residency positions; (d) revise the Medicare and Medicaid funding formulas for graduate medical education to recognize the resources utilized for training in non-hospital settings; (e) stabilize funding for pediatric residency training in children’s hospitals; (f) explore the possibility of extending full direct medical education per-resident payment beyond the time of first board eligibility for specialties/subspecialties in shortage/defined need; (g) identify funding sources to increase the number of graduate medical education positions, especially in or adjacent to physician shortage/underserved areas and in undersupplied specialties; and (h) act on existing policy by seeking federal legislation requiring all health insurers to support graduate medical education through an all-payer trust fund created for this purpose; and (2) other interested parties to ensure adequate funding to support medical school educational programs, including creating mechanisms to fund additional medical school positions.

CME Rep. 7, A-05 Reaffirmation I-06 Reaffirmation I-07 Reaffirmed: Res. 921, I-12 Reaffirmation A-13 Reaffirmed: CME Rep. 5, A-13

D-305.967, “The Preservation, Stability and Expansion of Full Funding for Graduate Medical Education”

1. Our AMA will actively collaborate with appropriate stakeholder organizations, (including Association of American Medical Colleges, American Hospital Association, state medical societies, medical specialty societies/associations) to advocate for the

preservation, stability and expansion of full funding for the direct and indirect costs of graduate medical education (GME) positions from all existing sources (e.g. Medicare, Medicaid, Veterans Administration, CDC and others). 2. Our AMA will actively advocate for the stable provision of matching federal funds for state Medicaid programs that fund GME positions. 3. Our AMA will actively seek congressional action to remove the caps on Medicare funding of GME positions for resident physicians that were imposed by the Balanced Budget Amendment of 1997 (BBA-1997). 4. Our AMA will strenuously advocate for increasing the number of GME positions to address the future physician workforce needs of the nation. 5. Our AMA will oppose efforts to move federal funding of GME positions to the annual appropriations process that is subject to instability and uncertainty. 6. Our AMA will oppose regulatory and legislative efforts that reduce funding for GME from the full scope of resident educational activities that are designated by residency programs for accreditation and the board certification of their graduates (e.g. didactic teaching, community service, off-site ambulatory rotations, etc.). 7. Our AMA will actively explore additional sources of GME funding and their potential impact on the quality of residency training and on patient care. 8. Our AMA will vigorously advocate for the continued and expanded contribution by all payers for health care (including the federal government, the states, and local and private sources) to fund both the direct and indirect costs of GME. 9. Our AMA will work, in collaboration with other stakeholders, to improve the awareness of the general public that GME is a public good that provides essential services as part of the training process and serves as a necessary component of physician preparation to provide patient care that is safe, effective and of high quality. 10. Our AMA staff and governance will continuously monitor federal, state and private proposals for health care reform for their potential impact on the preservation, stability and expansion of full funding for the direct and indirect costs of GME. 11. Our AMA: (a) recognizes that funding for and distribution of positions for GME are in crisis in the United States and that meaningful and comprehensive reform is urgently needed; (b) will immediately work with Congress to expand medical residencies in a balanced fashion based on expected specialty needs throughout our nation to produce a geographically distributed and appropriately sized physician workforce; and to make increasing support and funding for GME programs and residencies a top priority of the AMA in its national political agenda; and (c) will continue to work closely with the Accreditation Council for Graduate Medical Education, Association of American Medical Colleges, American Osteopathic Association, and other key stakeholders to raise awareness among policymakers and the public about the importance of expanded GME funding to meet the nation's current and anticipated medical workforce needs. 12. Our AMA will collaborate with other organizations to explore evidence-based approaches to quality and accountability in residency education to support enhanced funding of GME. 13. Our AMA will continue to strongly advocate that Congress fund additional graduate medical education (GME) positions for the most critical workforce needs, especially considering the current and worsening maldistribution of physicians. 14. Our AMA will advocate that the Centers for Medicare and Medicaid Services allow for rural and other underserved rotations in Accreditation Council for Graduate Medical Education (ACGME)-accredited residency programs, in disciplines of particular local/regional need, to occur in the offices of physicians who meet the qualifications for adjunct faculty of the residency program's sponsoring institution. 15. Our AMA encourages the ACGME to reduce barriers to rural and other underserved community experiences for graduate medical education programs that choose to provide such training, by adjusting as needed its program requirements, such as continuity requirements or limitations on time spent away from the primary residency site. 16. Our AMA encourages the ACGME and the American Osteopathic Association (AOA) to continue to develop and disseminate innovative methods of training physicians efficiently that foster the skills and inclinations to practice in a health care system that rewards team-based care and social accountability. 17. Our AMA will work with interested state and national medical specialty societies and other appropriate stakeholders to share and support legislation to increase GME funding, enabling a state to accomplish one or more of the following: (a) train more physicians to meet state and regional workforce needs; (b) train physicians who will practice in physician shortage/underserved areas; or (c) train physicians in undersupplied specialties and subspecialties in the state/region. 18. Our AMA supports the ongoing efforts by states to identify and address changing physician workforce needs within the GME landscape and continue to broadly advocate for innovative pilot programs that will increase the number of positions and create enhanced accountability of GME programs for quality outcomes. 19. Our AMA will continue to work with stakeholders such as Association of American Medical Colleges (AAMC), ACGME, AOA, American Academy of Family Physicians, American College of Physicians, and other specialty organizations to analyze the changing landscape of future physician workforce needs as well as the number and variety of GME positions necessary to provide that workforce. 20. Our AMA will explore innovative funding models for incremental increases in funded residency positions related to quality of resident education and provision of patient care as evaluated by appropriate medical education organizations such as the Accreditation Council for Graduate Medical Education. 21. Our AMA will utilize its resources to share its content expertise with policymakers and the public to ensure greater awareness of the significant societal value of graduate medical education (GME) in terms of patient care, particularly for underserved and at-risk populations, as well as global health, research and education. 22. Our AMA will advocate for the appropriation of Congressional funding in support of the National Healthcare Workforce Commission, established under section 5101 of the Affordable Care Act, to provide data and healthcare workforce policy and advice to the nation and provide data that support the value of GME to the nation. 23. Our AMA supports recommendations to increase the accountability for and transparency of GME funding and continue to monitor data and peer-reviewed studies that contribute to further assess the value of GME. 24. Our AMA will explore various models of all-payer funding for GME, especially as the Institute of Medicine (now a program unit of the National Academy of Medicine) did not examine those options in its 2014 report on GME governance and financing. 25. Our AMA encourages organizations with successful existing models to publicize and share strategies, outcomes and costs. 26. Our AMA encourages insurance payers and foundations to enter into partnerships with state and local agencies as well as academic medical centers and community hospitals seeking to expand GME. 27. Our AMA will develop, along with other interested stakeholders, a national campaign to educate the public on the definition and importance of graduate medical education, student debt and the state of the medical profession today and in the future. 28. Our AMA will collaborate with other stakeholder organizations to evaluate and work to establish consensus regarding

the appropriate economic value of resident and fellow services. 29. Our AMA will monitor ongoing pilots and demonstration projects, and explore the feasibility of broader implementation of proposals that show promise as alternative means for funding physician education and training while providing appropriate compensation for residents and fellows. 30. Our AMA will monitor the status of the House Energy and Commerce Committee's response to public comments solicited regarding the 2014 IOM report, Graduate Medical Education That Meets the Nation's Health Needs, as well as results of ongoing studies, including that requested of the GAO, in order to formulate new advocacy strategy for GME funding, and will report back to the House of Delegates regularly on important changes in the landscape of GME funding. 31. Our AMA will advocate to the Centers for Medicare & Medicaid Services for flexibility beyond the current maximum of five years for the Medicare graduate medical education cap-setting deadline for new residency programs in underserved areas and/or economically depressed areas. 32. Our AMA will: (a) encourage all existing and planned allopathic and osteopathic medical schools to thoroughly research match statistics and other career placement metrics when developing career guidance plans; (b) strongly advocate for and work with legislators, private sector partnerships, and existing and planned osteopathic and allopathic medical schools to create and fund graduate medical education (GME) programs that can accommodate the equivalent number of additional medical school graduates consistent with the workforce needs of our nation; and (c) encourage the Liaison Committee on Medical Education (LCME), the Commission on Osteopathic College Accreditation (COCA), and other accrediting bodies, as part of accreditation of allopathic and osteopathic medical schools, to prospectively and retrospectively monitor medical school graduates' rates of placement into GME as well as GME completion. 33. Our AMA will investigate the status of implementation of AMA Policies D-305.973, "Proposed Revisions to AMA Policy on the Financing of Medical Education Programs" and D-305.967, "The Preservation, Stability and Expansion of Full Funding for Graduate Medical Education" and report back to the House of Delegates with proposed measures to resolve the problems of underfunding, inadequate number of residencies and geographic maldistribution of residencies.

Sub. Res. 314, A-07 Reaffirmation I-07 Reaffirmed: CME Rep. 4, I-08 Reaffirmed: Sub. Res. 314, A-09 Reaffirmed: CME Rep. 3, I-09 Reaffirmation A-11 Appended: Res. 910, I-11 Reaffirmed in lieu of Res. 303, A-12 Reaffirmed in lieu of Res. 324, A-12 Reaffirmation: I-12 Reaffirmation A-13 Appended: Res. 320, A-13 Appended: CME Rep. 5, A-13 Appended: CME Rep. 7, A-14 Appended: Res. 304, A-14 Modified: CME Rep. 9, A-15 Appended: CME Rep. 1, I-15 Appended: Res. 902, I-15 Reaffirmed: CME Rep. 3, A-16 Appended: Res. 320, A-16 Appended: CME Rep. 04, A-16 Appended: CME Rep. 05, A-16 Reaffirmation A-16 Appended: Res. 323, A-17 Appended: CME Rep. 03, A-18 Appended: Res. 319, A-18 Reaffirmed in lieu of: Res. 960, I-18

D-305.958, "Increasing Graduate Medical Education Positions as a Component to any Federal Health Care Reform Policy"

1. Our AMA will ensure that actions to bolster the physician workforce must be part of any comprehensive federal health care reform. 2. Our AMA will work with the Centers for Medicare and Medicaid Services to explore ways to increase graduate medical education slots to accommodate the need for more physicians in the US. 3. Our AMA will work actively and in collaboration with the Association of American Medical Colleges and other interested stakeholders to rescind funding caps for GME imposed by the Balanced Budget Act of 1997. 4. Our AMA will actively advocate for expanded funding for entry and continued training positions in specialties and geographic regions with documented medical workforce shortages. 5. Our AMA will lobby Congress to find ways to increase graduate medical education funding to accommodate the projected need for more physicians. 6. Our AMA will work with key organizations, such as the US Health Resources and Services Administration, the Robert Graham Center, and the Cecil G. Sheps Center for Health Services Research, to: (A) support development of reports on the economic multiplier effect of each residency slot by geographic region and specialty; and (B) investigate the impact of GME funding on each state and its impact on that state's health care workforce and health outcomes.

Sub. Res. 314, A-09 Appended: Res. 316, A-12 Reaffirmed: Res. 921, I-12 Reaffirmation A-13 Reaffirmed: CME Rep. 5, A-13

H-310.917, "Securing Funding for Graduate Medical Education"

Our American Medical Association: (1) continues to be vigilant while monitoring pending legislation that may change the financing of medical services (health system reform) and advocate for expanded and broad-based funding for graduate medical education (from federal, state, and commercial entities); (2) continues to advocate for graduate medical education funding that reflects the physician workforce needs of the nation; (3) encourages all funders of GME to adhere to the Accreditation Council for Graduate Medical Education's requirements on restrictive covenants and its principles guiding the relationship between GME, industry and other funding sources, as well as the AMA's Opinion 8.061, and other AMA policy that protects residents and fellows from exploitation, including physicians training in non-ACGME-accredited programs; and (4) encourages entities planning to expand or start GME programs to develop a clear statement of the benefits of their GME activities to facilitate potential funding from appropriate sources given the goals of their programs.

CME Rep. 3, I-09 Modified: CME Rep. 15, A-10 Reaffirmed in lieu of Res. 324, A-12 Reaffirmed: CME Rep. 5, A-13 Appended: CME Rep. 1, I-15

H-305.988, "Cost and Financing of Medical Education and Availability of First-Year Residency Positions"

1. believes that medical schools should further develop an information system based on common definitions to display the costs associated with undergraduate medical education; 2. in studying the financing of medical schools, supports identification of those elements that have implications for the supply of physicians in the future; 3. believes that the primary goal of medical school is to educate students to become physicians and that despite the economies necessary to survive in an era of decreased funding, teaching functions must be maintained even if other commitments need to be reduced; 4. believes that a decrease in student enrollment in medical schools may not result in proportionate reduction of expenditures by the school if quality of education is to be maintained; 5. supports continued improvement of the AMA information system on expenditures of medical students to determine which items

are included, and what the ranges of costs are; 6. supports continued study of the relationship between medical student indebtedness and career choice; 7. believes medical schools should avoid counterbalancing reductions in revenues from other sources through tuition and student fee increases that compromise their ability to attract students from diverse backgrounds; 8. supports expansion of the number of affiliations with appropriate hospitals by institutions with accredited residency programs; 9. encourages for profit-hospitals to participate in medical education and training; 10. supports AMA monitoring of trends that may lead to a reduction in compensation and benefits provided to resident physicians; 11. encourages all sponsoring institutions to make financial information available to help residents manage their educational indebtedness; and 12. will advocate that resident and fellow trainees should not be financially responsible for their training.

CME Rep. A, I-83 Reaffirmed: CLRPD Rep. 1, I-93 Res. 313, I-95 Reaffirmed by CME Rep. 13, A-97 Modified: CME Rep. 7, A-05 Modified: CME Rep. 13, A-06 Appended: Res. 321, A-15 Reaffirmed: CME Rep. 05, A-16 Modified: CME Rep. 04, A-16

H-465.988, "Educational Strategies for Meeting Rural Health Physician Shortage"

1. In light of the data available from the current literature as well as ongoing studies being conducted by staff, the AMA recommends that: A. Our AMA encourage medical schools and residency programs to develop educationally sound rural clinical preceptorships and rotations consistent with educational and training requirements, and to provide early and continuing exposure to those programs for medical students and residents. B. Our AMA encourage medical schools to develop educationally sound primary care residencies in smaller communities with the goal of educating and recruiting more rural physicians. C. Our AMA encourage state and county medical societies to support state legislative efforts toward developing scholarship and loan programs for future rural physicians. D. Our AMA encourage state and county medical societies and local medical schools to develop outreach and recruitment programs in rural counties to attract promising high school and college students to medicine and the other health professions. E. Our AMA urge continued federal and state legislative support for funding of Area Health Education Centers (AHECs) for rural and other underserved areas. F. Our AMA continue to support full appropriation for the National Health Service Corps Scholarship Program, with the proviso that medical schools serving states with large rural underserved populations have a priority and significant voice in the selection of recipients for those scholarships. G. Our AMA support full funding of the new federal National Health Service Corps loan repayment program. H. Our AMA encourage continued legislative support of the research studies being conducted by the Rural Health Research Centers funded by the National Office of Rural Health in the Department of Health and Human Services. I. Our AMA continue its research investigation into the impact of educational programs on the supply of rural physicians. J. Our AMA continue to conduct research and monitor other progress in development of educational strategies for alleviating rural physician shortages. K. Our AMA reaffirm its support for legislation making interest payments on student debt tax deductible. L. Our AMA encourage state and county medical societies to develop programs to enhance work opportunities and social support systems for spouses of rural practitioners. 2. Our AMA will work with state and specialty societies, medical schools, teaching hospitals, the Accreditation Council for Graduate Medical Education (ACGME), the Centers for Medicare and Medicaid Services (CMS) and other interested stakeholders to identify, encourage and incentivize qualified rural physicians to serve as preceptors and volunteer faculty for rural rotations in residency. 3. Our AMA will: (a) work with interested stakeholders to identify strategies to increase residency training opportunities in rural areas with a report back to the House of Delegates; and (b) work with interested stakeholders to formulate an actionable plan of advocacy with the goal of increasing residency training in rural areas.

CME Rep. C, I-90 Reaffirmation A-00 Reaffirmation A-01 Reaffirmation I-01 Reaffirmed: CME Rep. 1, I-08 Reaffirmed: CEJA Rep. 06, A-18 Appended: Res. 956, I-18

H-200.954, "US Physician Shortage"

Our AMA: (1) explicitly recognizes the existing shortage of physicians in many specialties and areas of the US; (2) supports efforts to quantify the geographic maldistribution and physician shortage in many specialties; (3) supports current programs to alleviate the shortages in many specialties and the maldistribution of physicians in the US; (4) encourages medical schools and residency programs to consider developing admissions policies and practices and targeted educational efforts aimed at attracting physicians to practice in underserved areas and to provide care to underserved populations; (5) encourages medical schools and residency programs to continue to provide courses, clerkships, and longitudinal experiences in rural and other underserved areas as a means to support educational program objectives and to influence choice of graduates' practice locations; (6) encourages medical schools to include criteria and processes in admission of medical students that are predictive of graduates' eventual practice in underserved areas and with underserved populations; (7) will continue to advocate for funding from public and private payers for educational programs that provide experiences for medical students in rural and other underserved areas; (8) will continue to advocate for funding from all payers (public and private sector) to increase the number of graduate medical education positions in specialties leading to first certification; (9) will work with other groups to explore additional innovative strategies for funding graduate medical education positions, including positions tied to geographic or specialty need; (10) continues to work with the Association of American Medical Colleges (AAMC) and other relevant groups to monitor the outcomes of the National Resident Matching Program; and (11) continues to work with the AAMC and other relevant groups to develop strategies to address the current and potential shortages in clinical training sites for medical students.

Res. 807, I-03 Reaffirmation I-06 Reaffirmed: CME Rep. 7, A-08 Appended: CME Rep. 4, A-10 Appended: CME Rep. 16, A-10 Reaffirmation: I-12 Reaffirmation A-13 Appended: Res. 922, I-13 Modified: CME Rep. 7, A-14 Reaffirmed: CME Rep. 03, A-16

D-310.977, “National Resident Matching Program Reform”

Our AMA: (1) will work with the National Resident Matching Program to develop and distribute educational programs to better inform applicants about the NRMP matching process; (2) will actively participate in the evaluation of, and provide timely comments about, all proposals to modify the NRMP Match; (3) will request that the NRMP explore the possibility of including the Osteopathic Match in the NRMP Match; (4) will continue to review the NRMP's policies and procedures and make recommendations for improvements as the need arises; (5) will work with the Accreditation Council for Graduate Medical Education and other appropriate agencies to assure that the terms of employment for resident physicians are fair and equitable and reflect the unique and extensive amount of education and experience acquired by physicians; (6) does not support the current the "All-In" policy for the Main Residency Match to the extent that it eliminates flexibility within the match process; (7) will work with the NRMP, and other residency match programs, in revising Match policy, including the secondary match or scramble process to create more standardized rules for all candidates including application timelines and requirements; (8) will work with the NRMP and other external bodies to develop mechanisms that limit disparities within the residency application process and allow both flexibility and standard rules for applicant; (9) encourages the National Resident Matching Program to study and publish the effects of implementation of the Supplemental Offer and Acceptance Program on the number of residency spots not filled through the Main Residency Match and include stratified analysis by specialty and other relevant areas; (10) will work with the National Resident Matching Program (NRMP) and Accreditation Council for Graduate Medical Education (ACGME) to evaluate the challenges in moving from a time-based education framework toward a competency-based system, including: a) analysis of time-based implications of the ACGME milestones for residency programs; b) the impact on the NRMP and entry into residency programs if medical education programs offer variable time lengths based on acquisition of competencies; c) the impact on financial aid for medical students with variable time lengths of medical education programs; d) the implications for interprofessional education and rewarding teamwork; and e) the implications for residents and students who achieve milestones earlier or later than their peers; (11) will work with the Association of American Medical Colleges (AAMC), American Osteopathic Association (AOA), American Association of Colleges of Osteopathic Medicine (AACOM), and National Resident Matching Program (NRMP) to evaluate the current available data or propose new studies that would help us learn how many students graduating from US medical schools each year do not enter into a US residency program; how many never enter into a US residency program; whether there is disproportionate impact on individuals of minority racial and ethnic groups; and what careers are pursued by those with an MD or DO degree who do not enter residency programs; (12) will work with the AAMC, AOA, AACOM and appropriate licensing boards to study whether US medical school graduates and international medical graduates who do not enter residency programs may be able to serve unmet national health care needs; (13) will work with the AAMC, AOA, AACOM and the NRMP to evaluate the feasibility of a national tracking system for US medical students who do not initially match into a categorical residency program; (14) will discuss with the National Resident Matching Program, Association of American Medical Colleges, American Osteopathic Association, Liaison Committee on Medical Education, Accreditation Council for Graduate Medical Education, and other interested bodies potential pathways for reengagement in medicine following an unsuccessful match and report back on the results of those discussions; (15) encourages the Association of American Medical Colleges to work with U.S. medical schools to identify best practices, including career counseling, used by medical schools to facilitate successful matches for medical school seniors, and reduce the number who do not match; (16) supports the movement toward a unified and standardized residency application and match system for all non-military residencies; and (17) encourages the Educational Commission for Foreign Medical Graduates (ECFMG) and other interested stakeholders to study the personal and financial consequences of ECFMG-certified U.S. IMGs who do not match in the National Resident Matching Program and are therefore unable to get a residency or practice medicine.

CME Rep. 4, A-05 Appended: Res. 330, A-11 Appended: Res. 920, I-11 Appended: Res. 311, A-14 Appended: Res. 312, A-14 Appended: Res. 304, A-15 Appended: CME Rep. 03, A-16 Reaffirmation: A-16 Appended: CME Rep. 06, A-17 Appended: Res. 306, A-17 Modified: Speakers Rep. 01, A-17

26. RESEARCH HANDLING OF DE-IDENTIFIED PATIENT INFORMATION

Reference committee hearing: see report of Reference Committee on Amendments to Constitution and Bylaws.

HOUSE ACTION: REFERRED

INTRODUCTION

At the 2018 Annual Meeting, Policy D-315.975, “Research Handling of De-Identified Patient Information,” was adopted by the House of Delegates. This policy directs the American Medical Association (AMA) to study the handling of de-identified patient data and report the findings and recommendations to the House of Delegates at the 2019 Annual Meeting. This report outlines appropriate and inappropriate use of de-identified patient data, perspectives from stakeholders in organized medicine, potential ethical concerns of the commercial use of such data, regulatory implications, and recommendations for the future use of de-identified patient data.

BACKGROUND

Health-related information collected during the course of clinical care has always been of great interest for a number of secondary use cases, including scientific research in the academic and commercial settings, marketing for pharmaceutical and medical device companies, and a wide variety of other uses. More recently, a new and substantial interest has been raised from technology companies who seek to use patient data to build new clinical tools using machine learning and “big data.” Clinical data is the topic of significant ethical guidance and regulation at both the state and federal levels, focused primarily on the appropriate use and handling of identifiable patient information. Little guidance exists, however, on the use of de-identified patient data.

A variety of entities, including provider organizations, clinical laboratories, and commercial entities such as personal genomics companies, may collect patient data intended for clinical use or to deliver genetics information, and then resell de-identified data to other entities for other purposes. For example, 23andMe, a personal genomics and biotech service, sells de-identified user data to pharmaceutical companies that use it to conduct research on various diseases. Concerns arise in that when the data is de-identified, it is no longer considered PHI and therefore patient authorization or consent for use is not required and therefore not solicited—meaning that patients are not always aware how their data is being used.¹ For example, research using de-identified data such as biologic specimens may result in scientific knowledge that has commercial value. Proper consent for use and/or disclosure of commercial interest in this research is ideal but not always documented, sometimes resulting in legal action against physicians or researchers.²

In addition, there is a perceived lack of transparency and regulation in how patients’ data is being sold, distributed, or used outside of their direct health care. Risk of re-identification, which some studies have demonstrated to be possible through matching data to other publicly available data sources, is another issue related to the use of de-identified data. There are also concerns about access to such information that is sought for marketing purposes on behalf of commercial entities that have financial interests in physicians’ treatment and/or prescribing behavior. In addition, the sale of de-identified data by clinicians and provider organizations may create a real or perceived conflict of interest, which could lead to a loss of patient confidence.

What is Protected Health Information

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) provides extensive protections for patient data that is considered protected health information (PHI).³ PHI is information, including demographic information, which relates to an individual’s past, present, or future physical or mental health or condition; the provision of health care to the individual; or the past, present, or future payment for the provision of health care to the individual, and that identifies the individual or for which there is a reasonable basis to believe can be used to identify the individual.⁴ PHI includes many common identifiers (e.g., name, address, birth date, Social Security Number) when they can be associated with the health information listed above. The HIPAA Privacy Rule sets limits and conditions on the uses and disclosures that may be made of such information without patient authorization.⁵ Security of PHI safeguards patients from the risk of their data being released or used in manners that could result in discrimination, stigmatization, or embarrassment.^{6,7} Section 164.514(a) of the HIPAA Privacy Rule establishes standards for de-identifying PHI so individuals can no longer be identified by any portion of the data. The use, sale, or distribution of de-identified patient data is not prohibited under HIPAA, since once PHI is de-identified in accordance with the HIPAA Privacy Rule, it is no longer considered PHI and, thus, may be used and disclosed by a covered entity or health information organization (HIO) for any purpose.⁸

In addition to regulation at the federal level, state lawmakers have exhibited a general trend toward establishing stricter guards on the use of patient data and the requirement for patient consent, some of which reflect standards set forth in the European Union’s recent General Data Protection Regulation (GDPR).⁹ Some states are considering and passing laws to protect consumer privacy as it relates to the use of their personal information. For example, California in June 2018 passed the California Consumer Privacy Act of 2018 (effective January 1, 2020), which protects consumers’ right to: (1) know what personal information a for-profit business has collected about them, where it was sourced from, what it is being used for, whether it is being disclosed or sold, and to whom it is being disclosed or sold; (2) “opt out” of allowing a business to sell their personal information to third parties; (3) have a business delete their personal information, with some exceptions; and (4) receive equal service and pricing from a business, even if they exercise their privacy rights under the Act.¹⁰ California’s law does not apply to information covered by HIPAA, de-identified personal data, or aggregate consumer data, however, as long as the de-identification measures meet the Act’s strict standards.¹¹

What is de-identified patient data?

De-identified patient data is information about a patient or user of a health-related service that has been stripped of individually identifiable health information. Removing identifiers from PHI mitigates privacy risks to individuals and thereby supports the secondary use of data for comparative effectiveness studies, policy assessment, life sciences research, and other endeavors.⁴ Information can be de-identified by either of two means: (1) a formal determination by a qualified expert (expert determination); or (2) the removal of specified individual identifiers and an absence of actual knowledge by the covered entity that residual information could be used to identify the individual (safe harbor).

The identifiers removed from PHI in the safe harbor method include:⁴

- Names
- All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP code, and their equivalent geocodes, except for the initial three digits of the ZIP code if, according to the current publicly available data from the Bureau of the Census:
 - The geographic unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people; and
 - The initial three digits of a ZIP code for all such geographic units containing 20,000 or fewer people is changed to 000
- All elements of dates (except year) for dates that are directly related to an individual, including birth date, admission date, discharge date, death date, and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older
- Telephone numbers
- Vehicle identifiers and serial numbers, including license plate numbers
- Fax numbers
- Device identifiers and serial numbers
- Email addresses
- Web URLs
- Social security numbers
- Internet Protocol addresses
- Medical record numbers
- Biometric identifiers, including finger and voice prints
- Health plan beneficiary numbers
- Full-face photographs and any comparable images
- Account numbers
- Any other unique identifying number, characteristic, or code, except as permitted
- Certificate/license numbers

How is de-identified data used?

De-identified data is used for research to derive information and knowledge about treatment and outcomes, as well as other patient care-related purposes. Outside of health care organizations and researchers, de-identified patient data is used by a variety of organizations and industries for various purposes, including many not related to patient care. De-identified data is sourced, collected, and used by a variety of organizations, including health care provider organizations such as hospitals or academic medical centers, and commercial enterprises such as personal genomics and biotechnology companies. Pharmaceutical manufacturers and retail pharmacies may also find use in de-identified health data to target their advertising. Health care providers use this data typically in research or the direct care of patient populations. The data can also be used to help reduce costs of care, improve treatment options, and support public health initiatives.

Machine learning is a family of methods used by some health care and data solution organizations to help predict certain outcomes and better prepare for and treat patients identified to be at risk. Machine learning models establish predictive rules using vast amounts of computing power. The more data a machine learning model has, the more complex the rules and the more accurate the predictions.¹² However, machine learning models are vulnerable to biases induced by data that does not adequately represent the patient population, such as data collected from only one institution or one geographic region. In order to develop clinical decision support tools that can be effectively used to

treat the diverse patient populations in the United States, large amounts of data are required, and often data from many different providers across the country are required to avoid bias. This data is often sourced from de-identified or anonymized patient records. Allscripts, for example, used 50 million de-identified patient records, and the application of an advanced machine learning algorithm, to “train” its systems and further improve its clinical decision support tools.¹³ Organizations like Orion Health and Precision Driven Health are using datasets like these to generate machine learning aimed at improving health care decisions, and driving operational and cost efficiencies.^{12, 14} By combining multiple datasets, such as behavioral data, device use data, patient claim data and socioeconomic and geographic data, these organizations are developing advanced predictive analytics to further improve precision health care.¹⁴ The data used for the purposes of data mining and honing machine learning algorithms are either sourced and used at the organizational level, or de-identified or anonymized when used for external research, such as the analysis done by Allscripts. Data may be sourced via publicly available de-identified datasets, databases established through collaborative research agreements, or via the purchase of bulk de-identified data, on an exclusive or non-exclusive basis. Since this technology is relatively new in the health care space its implications for patient data are not well-studied. As artificial intelligence and advanced machine learning proliferate in the health care space, the value and number of potential uses of patient health data will inevitably increase. Stakeholders should be prepared for increasing concerns about related patient privacy and data security.

Commercial entities, such as personal genomics companies, may collect data to deliver genetics information to subscribers and then subsequently sell the de-identified data to another entity for another purpose. For example, 23andMe, a genomics and biotech service, sells de-identified user data to pharmaceutical companies that use it to conduct research on various diseases. Concerns arise in that when the data is de-identified, it is no longer considered PHI and therefore patient authorization or consent for use is not required and therefore not solicited—meaning that patients are not always aware how their data is being used.¹ For example, research using de-identified data such as biologic specimens may result in scientific knowledge that has commercial value. Proper consent for use and/or disclosure of commercial interest in this research is ideal but not always documented, sometimes resulting in legal action against physicians or researchers.²

In addition, there is a perceived lack of transparency and regulation in how patients’ data is being sold, distributed, or used outside of their direct health care. Risk of re-identification, which some studies have demonstrated to be possible through matching data to other publicly available data sources, is another issue related to the use of de-identified data. There are also concerns about access to such information that is sought for marketing purposes on behalf of commercial entities that have financial interests in physicians’ treatment and/or prescribing behavior.

AMA POLICY

The AMA has multiple policies expressing its recognition of the importance of data privacy and protection of PHI, as well as policies expressing commitment to ensuring safe and appropriate use of de-identified data.

Board of Trustees Report 21-A-18, “Ownership of Patient Data,” outlines federal and state laws that establish who owns a patient’s medical records. The report also highlights the importance of ensuring patients have appropriate access to their data and physicians have the tools and controls they need to be good stewards of their patients’ information while at the same time maintaining the ability to share information to seamlessly coordinate the best care. In support of these initiatives, the AMA has actively engaged with the U.S. Department of Health and Human Services (HHS), the Office of Inspector General, the Office of Civil Rights, and the Office of the National Coordinator for Health Information Technology (ONC), and has broad policy in place covering all aspects of patient record maintenance, access and control.

AMA Policy H-315.978, “Privacy and Confidentiality,” states that where possible, informed consent should be obtained before personally identifiable health information is used for any purpose. However, in those situations where specific informed consent is not practical or possible, either (1) the information should have identifying information stripped from it or (2) an objective, publicly accountable entity must determine that patient consent is not required after weighing the risks and benefits of the proposed use. Re-identification of personal health information should only occur with patient consent or with the approval of an objective, publicly accountable entity.

AMA Policy H-315.974, “Guiding Principles, Collection and Warehousing of Electronic Medical Record Information,” expresses the AMA’s commitment to advocating that physicians, as trusted stewards of PHI, should be the owners of all patient claims data and de-identified aggregate data that is established and maintained by the

physician practice, specifically including data stored in the electronic health record or practice management system. The policy establishes principles around the use of these data that include compliance with HIPAA, requires physician consent for analysis of the data, and requires data to remain accessible to authorized users for purposes of treatment, public health, patient safety, quality improvement, medical liability defense, and research.

AMA Policy H-315.983, "Patient Privacy and Confidentiality," states that whenever possible, medical records should be de-identified for purposes of use for utilization review, panel credentialing, quality assurance, and peer review. This policy also states our AMA will guard against the imposition of unduly restrictive barriers to patient records that would impede or prevent access to data needed for medical or public health research or quality improvement and accreditation activities, and that whenever possible, de-identified data should be used for these purposes. Policy H-315-983 posits that in the event of a sale or discontinuation of a medical practice, only de-identified and/or aggregate data should be used for "business decisions," including sales, mergers, and similar business transactions when ownership or control of medical records changes hands. This policy includes extensive language emphasizing the AMA's commitment to protecting PHI, and that it will continue its advocacy for privacy and confidentiality regulations, including: (a) The establishment of rules allocating liability for disclosure of identifiable patient medical information between physicians and the health plans of which they are a part, and securing appropriate physician control over the disposition of information from their patients' medical records; (b) The establishment of rules to prevent disclosure of identifiable patient medical information for commercial and marketing purposes; and (c) The establishment of penalties for negligent or deliberate breach of confidentiality or violation of patient privacy rights.

In Policy H-315.975, "Police, Payer, and Government Access to Patient Health Information," the AMA commits to advocating for narrow and clearly defined bounds for the appropriate use of patient information by law enforcement, payers and government entities, for operations that cannot be reasonably undertaken with de-identified data. AMA Policy H-315.987, "Limiting Access to Medical Records," further defines who should and should not have access to this information.

The AMA's Code of Medical Ethics includes an opinion on "Access to Medical Records by Data Collection Companies." Opinion E-3.2.4 asserts that disclosing information to third parties for commercial purposes without consent undermines trust, violates principles of informed consent and confidentiality, and may harm the integrity of the patient-physician relationship. The opinion further expresses that physicians who wish to permit third-party access to *specific patient information* for commercial purposes should: (a) only provide data that has been de-identified, and (b) fully inform each patient whose record would be involved about the purpose(s) for which access would be granted. This opinion, with respect to requests for permission to allow access to or disclose a *full medical record*, prohibits disclosing identifiable information for commercial purposes *without obtaining consent* from the patient to do so.

The authors of Resolution 3-A-18, which established policy D-315.975 and is the subject of this report, expressed particular concern that this Code of Medical Ethics Opinion may contradict itself in its emphasis on informing the patient of how their de-identified data will be used and the subsequent emphasis on the importance of obtaining consent. The key difference between the two elements of the opinion lies in the description of the patient information being requested (specific, de-identified patient information vs. full medical record), thus our AMA does not agree that these statements are contradictory.

The authors also expressed that this Opinion may be in disharmony with the rules set forth in the HIPAA Privacy Rule, specifically stating that authorization, rather than consent, is sometimes mandated for the release of PHI when being requested for purposes not related to treatment, payment, or health care operations (TPO). HIPAA defines three such uses or disclosures for which written authorization of the patient is required: (1) use and disclosure of psychotherapy notes; (2) use and disclosure of PHI for marketing; and (3) any sale of PHI.

Ethical Opinion E-3.2.4 was originally issued in 1994 and updated in 1998, prior to the enactment of the HIPAA Privacy Rule, yet provides an even higher standard than the Rule with respect to requirements for consent to disclose patient data, including data that has been de-identified. With respect to authorization requirements, Opinion E-3.2.4 does not include a statement about when authorization, rather than consent, is appropriate and/or required. Guidance provided in the Code of Ethics is provided by standards of conduct that define the essentials of honorable behavior for the physician. They cover broad ethical principles and are not intended to align with law or specific regulations that may be legally enforceable. During a comprehensive eight-year modernization process that ended in 2017, the AMA *Code of Medical Ethics* was reviewed for relevance/timeliness of guidance, clarity, and consistency of guidance. Opinion E-3.2.4 was reorganized in this process, taking the HIPAA provisions into consideration during the process.

Care was taken to ensure the Council on Ethical and Judicial Affairs was conservative in suggesting substantive change, doing so only where needed to ensure that guidance remains relevant in the face of changes in biomedical science and conditions of medical practice. No contradictions or points of discord with HIPAA were identified in that review.

DISCUSSION

Oversight of patient information

The use of de-identified patient data is not heavily regulated. The HIPAA Privacy Rule does not restrict the use or disclosure of de-identified health information, since it is not considered PHI.^{2, 5} HIPAA permits secondary uses of de-identified data for purposes such as public health initiatives, research, law enforcement, and other public interest endeavors.^{5, 15} In addition, commercial entities that sell or use de-identified data, such as biotech and pharmaceutical companies, are not considered covered entities under HIPAA. Through their interactions with pharmacy benefit managers, pharmacies, payers, physicians and patients, however, they are indirectly impacted by privacy rules and must structure their transactions, projects, and internal data programs such that their partners that are covered entities or business associates thereof meet data privacy requirements under HIPAA and any other applicable standards.

Studies that use de-identified data are exempt from regulations that govern human subject research.^{2, 16} Entities that collect and use consumer data, such as pharmaceutical companies or academic institutions conducting research, should employ privacy protections into their practices, such as data security, reasonable collection limits, sound retention and disposal practices, and data accuracy to protect privacy, as guided in recommendations from the Federal Trade Commission (FTC).¹⁷ For example, Harvard University, like many academic institutions receiving federal grants, implements strict policy to govern the collection, storage and use of research data, including PHI.¹⁸ In addition to the enforcement of strict policy, all human subjects research is subject to approval by the institution's Institutional Review Board (IRB). It is the responsibility of IRBs to specify the security level for research projects they review and approve, obtain confirmation that the relevant security controls are being implemented and decide if the human subject must give consent or in the case of de-identified information, approve the research under an exempt status from obtaining the consent.

Human subject research conducted or supported by certain federal departments or agencies is governed by the Federal Policy for the Protection of Human Subjects ("Common Rule"). Revisions to the Common Rule in 2017 were adopted in response to shifts in science, technology, public engagement, and public expectations that have raised concerns about the limitations of the existing ethical framework in research.¹⁹ The rapid pace of change in the availability, utility, and value of patient data, including PHI and de-identified data, will continue to necessitate regular reconsideration of the ethical oversight of patient data and how it is protected by researchers and other entities.

Risks and ethical concerns

There are ethical concerns about the disclosure and use of de-identified health data that are rooted in the risk of re-identification. Studies have shown that certain elements of patient records, although not exclusive or unique to individual patients, increase the risk of re-identification if not removed from individual-level data.^{20, 21} Elements such as gender, date of service, date of birth or zip code can potentially be linked back to other sources of data, such as voter registration lists, and could put the data at risk of re-identification.^{21, 22} Organizations that collect, store, transfer and distribute de-identified data should take steps to reduce this risk, such as replacing a specific date of birth or date of service with a year.

Studies have been undertaken to assess the risk of re-identification after steps have been taken to de-identify the data, and have found gaps that can put de-identified patient health data at risk of being re-identified.^{20, 23, 24} While these findings are significant and should not be ignored, one review of some of these studies concluded that many of them were small and did not use data that was de-identified according to existing standards (those set forth in the HIPAA Privacy Rule), so caution should be taken when making generalizations based on the few cases identified in the studies.²⁵

In addition to risk of re-identification, there are general ethical concerns with the availability and use of patient health data, even if it's de-identified, without explicit authorization from patients. For example, pharmaceutical companies may use de-identified data to target marketing or advertising efforts to specific physicians, therefore influencing

treatment plans for patient populations with specific diseases or conditions. Accountable Care Organizations (ACOs), as business associates of the ACO participants or a covered entity, may use de-identified data to analyze quality measures, population risk scores and patient behaviors.²⁶ Other for-profit entities may use de-identified data for the development of new technology or clinical innovations. These sales of patient records for profit by provider organizations may raise concerns from the public that providers have an ulterior motive for collecting their data during clinical encounters. In addition, patient record licensing contracts with exclusive rights may raise questions about the appropriate stewardship of patient data, as such exclusive contracts may be seen to benefit specific licensees at the expense of others, rather than enabling research and product development across the entire marketplace.

Consent and authorization

Issues that arise in the potential risks of patient data use can be mitigated by proactively obtaining appropriate authorization or consent from patients for the use of their data. These issues primarily apply to PHI covered under HIPAA, however, and not de-identified data. The HIPAA Privacy Rule permits, but does not require, a covered entity voluntarily to obtain patient consent for uses and disclosures of PHI for TPO. Covered entities that decide to obtain consent have complete discretion to design a process that best suits their needs. By contrast, an authorization is required by the Privacy Rule for most uses and disclosures of PHI not otherwise allowed by the Rule. Where the Privacy Rule requires patient authorization, voluntary consent is not sufficient to permit a use or disclosure of PHI. An authorization is a detailed document that gives covered entities permission to use PHI for specified purposes (e.g., sale or marketing of PHI) or to disclose PHI to a third party specified by the individual. An authorization must include a number of elements, including a description of the PHI to be used and disclosed, the person authorized to make the use or disclosure, the person to whom the covered entity may make the disclosure, an expiration date, and, in some cases, the purpose for which the information may be used or disclosed.²⁷

PHI may be used and disclosed for research without an authorization in limited circumstances: (1) Under a waiver of the authorization requirement; (2) as a limited data set with a data use agreement; (3) preparatory to research; and (4) for research on decedents' information. Limited data sets exclude 16 categories of direct identifiers, rather than the 18 identifiers removed in de-identified data. The information in a limited data set is considered PHI and its use or disclosure requires a data use agreement between the covered entity and the entity that will receive or use the data.

Non-covered entities that use de-identified health data for purposes such as genomics services or research are not regulated under HIPAA, but most have policies and procedures in place to protect the privacy of their subscribers or participants, and to ensure transparency in the use of the data. 23andMe, for example, obtains personal information from its subscribers and through its service identifies genetic information that is stored within its databases. According to its Privacy Policy, 23andMe “implements physical, technical, and administrative measures to prevent unauthorized access to or disclosure of your information, to maintain data accuracy, to ensure the appropriate use of information, and otherwise safeguard your Personal Information.”²⁸ Subscribers can voluntarily consent to allow their information to be used in research, and can also choose what level of de-identified data they consent for use. 23andMe stores and allows access to both aggregate and individual level data to third-party service providers such as marketing and analytics organizations and targeted advertising service providers that contribute to the service provided by 23andMe. It also sells de-identified user data to pharmaceutical companies for the purposes of research.

Other entities may use anonymous, de-identified data in manners that are legal but may be perceived as ethically questionable since they may not have obtained patient consent for the use of the data. For example, a startup artificial intelligence business, funded by executives at a cancer center, has received exclusive access to the cancer center's database of millions of tissue slides.²⁹ The cancer center holds an equity stake in the organization along with two of its top leaders, and other board members are initial investors in the new venture. The company's leadership indicated that some patients had provided consent for the use of their data, others did not and their data was subsequently stripped of its identifying factors. Still, pathologists at the cancer center, and their patients, have expressed concern about the potential conflict of interest in the cancer center leadership's relationship with the startup, as well as the use of patient data for a profit-driven venture. In this case, it was reported that the enterprise had been reviewed and approved by an IRB.²⁹

Standards and guidance

ONC publishes the “Guide to Privacy and Security of Electronic Health Information” to help physicians, other health care providers and practices work to comply with federal requirements in collecting, storing and using patients' data.³⁰

In addition to the policy set by the AMA and the guidance provided in the *AMA Code of Medical Ethics*, other physician and health care organizations provide guidelines and standards on the use of de-identified patient data. For example, the American Academy of Family Physicians published a “Data Stewardship” policy that facilitates the appropriate collection, storage, transmission, analysis, and reporting of de-identified patient data.³¹ This policy includes guidance on establishing and maintaining a proper patient and physician consent process, as well as the appropriate use of data by third parties and policies that establish requirements for third party use.

The American College of Physicians (ACP) policy encourages clinical entities and physicians to publish electronically their policies and procedures for sharing patient data and ensuring privacy. ACP’s policy also states that in keeping with HIPAA, patients should know what information exists about them, its purpose, who can access and use it, and where it resides. While ACP supports the use of appropriately de-identified patient data for socially important activities, such as population health efforts and retrospective research, it does recommend tighter controls on the risks of re-identification of de-identified data.³²

CONCLUSION

Access to de-identified patient data is important for the future of health care. Its benefits to the field of research have significant implications for our ability to make progress in refining the practice of medicine, reducing health care costs, reducing and preventing chronic disease, identifying cures for deadly conditions, and much more. In practice-level interventions, de-identified data can help practice administrators recognize patterns and gaps in processes and treatment plans across clinicians. In the genomics and biotechnology fields the study of patient data, stripped of identifying factors, can contribute to global innovation in medical technology and pharmaceutical solutions. There are numerous ways in which the use of de-identified patient data contributes to the continuum of improvement that is much needed across health care.

Its use does not come without risks, however. In 1951, the development of the HeLa cell line led to many significant research accomplishments in medicine. However, the lack of patient consent in the development of the cell line raises serious ethical concerns, which were further compounded by the commercial use of the cell line for profit, which was not shared with the patient or her family. Though in recent times, substantial effort has been made to correct this historical wrong by the National Institutes of Health and other organizations, much of the harm done to patients who’s clinically obtained samples were used without consent can never be undone. Today, a new revolution in health science powered by big data is in process, and there is little doubt that the research accomplishments derived from this data will transform the practice of medicine. However, all stakeholders involved now have an opportunity to ensure that there is not a repeat of the ethical mistakes of the past. Risk mitigation is the responsibility of all stakeholders, from the individual clinician and patient to the administrators and third-party data users. The privacy and security of the patient data must be protected at every point, and its use needs to be ethically conducted with the appropriate level of consent or authorization required. The HIPAA provisions, regulations enacted at the state level, and organizational policies and procedures, ensure compliance with standards developed to protect the patient. If followed appropriately, these measures can effectively protect patient data from misuse.

RECOMMENDATIONS

The Board of Trustees recommends that the following be adopted and the remainder of this report be filed:

1. That our American Medical Association (AMA) reaffirm Policies H-315.974, “Guiding Principles, Collection and Warehousing of Electronic Medical Record Information,” H-315.983, “Patient Privacy and Confidentiality,” H-315.975, “Police, Payer, and Government Access to Patient Health Information,” H-315.978, “Privacy and Confidentiality,” and H-315.987, “Limiting Access to Medical Records.”
2. That our AMA support state-based efforts to protect patient privacy including the patient’s right to know whether information is being disclosed or sold and to whom and the right to opt out of the sale of their data.
3. That our Council on Ethical and Judicial Affairs consider re-examining existing guidance relevant to the confidentiality of patient information in light of new practices regarding de-identified patient data, including the use of exclusive de-identified data licensing agreements in healthcare.

4. That Policy D-315.975, “Research Handling of De-Identified Patient Information,” be rescinded, as having been fulfilled by this report.

REFERENCES

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27. ADVANCING GENDER EQUITY IN MEDICINE

Reference committee hearing: see report of Reference Committee F.

**HOUSE ACTION: RECOMMENDATIONS ADOPTED
REMAINDER OF REPORT FILED**

See Policies H-65.961, D-65.989 and G-600.035

INTRODUCTION

American Medical Association (AMA) Policy D-65.989 (1), “Advancing Gender Equity in Medicine,” directs our AMA to “draft and disseminate a report detailing its positions and recommendations for gender equity in medicine, including clarifying principles for state and specialty societies, academic medical centers and other entities that employ physicians, to be submitted to the House for consideration at the 2019 Annual Meeting.” This report responds to this directive.

AMA Policy D-65.989 was created following the adoption of Substitute Resolution 10-A-18, which was adopted in lieu of Resolution 10-A-18, “Advancing Gender Equity in Medicine;” Resolution 11-A-18, “Women Physician Workforce and Gender Gap in Earnings – Measures to Improve Equality;” Resolution 20-A-18, “Advancing the Goal of Equal Pay for Women in Medicine;” and Resolution 21-A-18, “Taking Steps to Advance Gender Equity in Medicine.” Testimony in support of these items before the reference committee acknowledged the problem of gender disparities in medicine and noted a need for study. Testimony also reflected the need for our AMA to set an example on this issue, by committing to pay equity for its employees.

This report: 1) describes issues associated with gender bias; 2) summarizes AMA positions and recommendations to promote gender equity in medicine; and 3) provides clarifying principles for state and specialty societies, academic medical centers and other entities that employ physicians.

BACKGROUND

Gender disparities in advancement and income are pervasive in medical practice settings, specialties, and positions. Significant differences in salary exist after accounting for age, experience, specialty, faculty rank, and measures of research productivity and clinical revenue. Advancement for women physicians has been slower than would be anticipated despite the growing number of women in medicine.

According to the U.S. Bureau of Labor Statistics, women earned about 82 percent of what men earned among full-time workers in all industries.¹ The gender pay disparity is indicative of “how far our nation still has to go to ensure that women can participate fully and equally in our economy,” according to a report from the National Partnership for Women and Families.²

Gender-based disparities in income and advancement are also prevalent in medicine. The 2018 Medscape Physician Compensation Report noted considerable gaps in pay, with female physicians in primary care earning nearly 18 percent less (\$36,000) than their male counterparts. Among physicians the pay disparity was more pronounced with females earning 36.1 percent less (\$95,000) than their male counterparts. This income disparity was consistent across all medical specialties.³

Ly, Seabury, and Jena conducted an analysis on income disparities among physicians, stratified by race and gender. Study results identified a considerable pay gap among black and white male physicians. The study also found that the income of black and white female physicians is “similar, but significantly lower than the incomes of male physicians.”⁴

In the United States, women represent more than one third (35.2%) of the active physician workforce,⁵ nearly half (45.6%) of all physicians-in-training⁶ and more than half (50.7%)⁷ of all entering medical students in MD-granting medical schools. Although the number of women entering the medical field has steadily increased, their proportion of leadership positions continues to be small. In a 2015 survey, women physicians (n = 3,285) identified the leadership positions they held as: medical director (35%), practice owner (23%), practice partner (13%), CEO (3%), and CMO (3%).⁸

Gender Disparities in Academic Medicine

A study of 10,241 physicians in 24 U.S. public medical schools found the annual salaries of female physicians were lower than those of male physicians, even after adjusting for “age, experience, specialty, faculty rank, and measures of research productivity and clinical revenue.” This study noted that “sex differences in salary were present at all faculty ranks and were largest among full professors.” The average salary difference among male and female full professors was \$33,620. Further, the adjusted salaries of female full professors (averaging \$250,971) were comparable to those of male associate professors (averaging \$247,212).⁹

Another study compared faculty income at 24 medical schools over a 17-year period and found that female physicians in academic medicine earned on average \$20,000 less per year than their male counterparts. That is to say, female physicians earned 90 cents for every dollar made by male physicians.¹⁰ These findings adjusted for factors such as specialty, experience, and faculty rank.

In addition to salary disparities, leadership disparities exist as well, with female physicians underrepresented in the higher ranks of medical school faculty. Although women accounted for 41.3 percent of full-time medical school faculty in 2018, they made up only 25 percent of tenured faculty (of all ranks) and only 24.6 percent of full professors and 37.5 percent of associate professors.^{11, 12} Female physicians were also underrepresented in leadership positions at medical schools. Eighteen percent of department chairs (permanent and interim)¹³ and eighteen percent of deans (permanent and interim) were women.¹⁴

DISCUSSION

Despite the increasing number of women physicians, gender-based differences in compensation and advancement exist in the medical profession. Researchers have cited factors such as specialty, experience, productivity, and work status as the reasons for these disparities. However, study results indicate that gender disparities persist even when controlling for age, specialty and practice characteristics. The following issues, which are often associated with gender inequities in medicine, have been highlighted for discussion.

Gender Bias and Discrimination

Women in medicine frequently encounter implicit and overt forms of gender bias as well as discrimination throughout their training and careers. Gender bias and discrimination can have a harmful effect on the professional experiences of women and impact opportunities for advancement such as promotions, grant awards, and manuscript acceptance. The formation of productive relationships with colleagues and mentors is often hindered by gender bias and discrimination. Study findings and anecdotal accounts have cited that women physicians are more likely to be disrespected by colleagues, held to a higher standard than male peers, introduced by their first names instead of professional titles, and excluded from events such as grand rounds.¹⁵

Adesoye, Mangurian, Choo, et al. conducted a study of physician mothers to assess their experiences with work place discrimination. More than three quarters (77.9%) of the respondents stated that they experienced some form of discrimination. Of those respondents, 66.3 percent reported gender discrimination and 35.8 percent reported maternal discrimination, which is defined as self-reported discrimination based on pregnancy, maternity leave or breastfeeding. Almost ninety percent (89.6%) of respondents who reported maternal discrimination noted that it was based on pregnancy or maternity leave. Nearly 48.4 percent of these respondents believed the discrimination was tied to breastfeeding. Those reporting maternal discrimination cited they experienced disrespectful treatment by nursing or other support staff, exclusion from administrative decision making, and gender disparities in salary and benefits.¹⁶

Implicit bias, explicit bias, stereotype threat and unconscious self-bias have implications for women as they may influence decisions on hiring, promotion, and compensation. Women may experience higher social costs for engaging in job negotiations and are less likely to negotiate.¹⁷ Further, statistical discrimination is often associated with the stereotype that “women are less productive during childbearing years” and contributes to beliefs that women are less likely to aspire to leadership positions or assume roles with higher pay (e.g., undesirable call shifts).¹⁸

Mentorship and Sponsorship Opportunities

Women in medicine continue to be underrepresented in leadership positions. It has been noted that guidance and support from mentors and sponsors can positively impact career advancement. Mentorship and sponsorship can also mitigate the professional isolation that can undermine one's sense of confidence and belonging. However, there is a key distinction between mentorship and sponsorship. Mentors can work at any level in the organization and are selected based on expertise. Sponsors have a position of power that enables them to have significant influence on advancement decisions.

According to Ibarra et al., women tend to be “over-mentored but under-sponsored.”¹⁹ Although sponsorship has been positively associated with career advancement, women are typically sponsored less frequently than men. Hewlett et al. found that 13 percent of women had sponsors compared to 19 percent of men.²⁰ Similar to mentorship, there was a difference in outcomes for women and men. For example, an analysis of the National Institutes of Health (NIH) grant recipients found that sponsorship was correlated with success. Seventy-two percent of men and 59 percent of women who reported sponsorship were successful in obtaining an NIH grant compared to 57.7 percent of men and 44.8 percent of women who did not report sponsorship.²¹

Research findings have shown that mentorship and sponsorship outcomes vary for women and men, with women lagging on career advancement metrics. This may, in part, be attributed to men and women having different experiences with mentors. A study of graduates from top business schools found that men were more likely to be mentored by someone from senior executive level positions (62% of men compared to 52% of women). After a two-year follow-up, it was found that men earned \$9,260 more than women annually and were promoted 15 percent more often.²²

Work-Life Balance

Many female physicians report work-life balance as a significant concern that may influence their career choices. This may be reflected in the disproportionate number of women physicians who choose part-time or reduced work hours to balance professional and personal life. In a recent survey, 92 percent of young physicians noted that they believe it is important to have a balance between work and personal responsibilities. However, only 65 percent felt they have achieved work-life balance.²³

While male physicians are increasingly expressing interest in flexible family leave and work options, female physicians continue to bear primary responsibility for caregiving and may face more challenges in aligning their career goals with family needs. Nearly a quarter (22%) of female physicians reported working part-time compared to twelve percent of male physicians.²⁴ Further, a 2017 study found that hours worked by women physicians with children remained statistically lower when compared to women physicians without children.²⁵

When professionals reach their mid-40s, many of them assume responsibility for eldercare, or providing care for older relatives. According to a 2017 Bureau of Labor Statistics report, more than twenty percent (21.4%) of adults between the ages of 45-54 and nearly a quarter (24.3%) of adults between the ages of 55-64 provide care for an older relative. This same report notes that there are currently 41.3 million adults that provide unpaid eldercare and the majority are women (56%).²⁶ Although flexible work options (e.g., part-time work, re-entry, etc.) are intended to balance professional and personal responsibilities, there is also an impact on income and earning potential. Additional accommodations, such as flexible scheduling time and re-entry assistance programs, need to be offered beyond parental and family leave.

Increased Risk of Burnout

Burnout among physicians has been associated with adverse quality outcomes, diminished patient satisfaction, increased job dissatisfaction, and reduction of work effort. More than half of U.S. physicians are experiencing symptoms of burnout and the prevalence of burnout in physicians is nearly two times greater than other professions. Similarly, the prevalence of burnout and depression among medical students and residents is higher than individuals of similar age.²⁷

Findings from a survey of more than 15,000 physicians from 29 specialties noted that 50 percent of female physicians reported burnout, compared with 39 percent of their male peers.²⁸ Many factors contribute to burnout, including

administrative burdens, challenges in working with electronic health records, discrimination, lack of respect, and maintaining work-life balance.

In addition, the conflict between professional and personal responsibilities has been associated with increasing burnout odds by 200 to 250 percent.²⁹ Women are often disproportionately responsible for childcare and family responsibilities. Further, maternal discrimination was associated with higher self-reported burnout (45.9% burnout in those with maternal discrimination compared to 33.9% burnout in those without).³⁰ Ultimately, it has been noted that “less pay combined with physician burnout might lead to more female physicians leaving the profession.”³¹

CONCLUSION

The AMA recognizes that gender inequity in medicine is a complex issue that requires a detailed, multifaceted approach. Promoting gender equity in medicine requires an acknowledgement of the underlying causes of gender-based disparities, creation of policies and resources that will promote gender equity, and collaboration to improve the environment for women and the profession as a whole.

Factors such as specialty, experience, productivity, and work status have been attributed to gender-based disparities in compensation and professional advancement. However, researchers have found that these disparities persist even when studies control for age, specialty and practice characteristics. Remaining disparities are attributed to a degree of gender discrimination and gender bias that can have a deleterious effect on the professional experiences of women and impact opportunities for advancement.

The proposed AMA Principles for Advancing Gender Equity in Medicine were derived from a review of current AMA policies on gender disparities, women in medicine, and equal opportunity. These policies were consolidated to ensure that AMA policy on gender equity in medicine is consistent and accurate. The principles being proposed in recommendation 1 incorporate relevant portions of the three existing AMA policies that are recommended for rescission in recommendation 2. Appendix A provides a comparison of the proposed language and the original language that is being modified. Appendix B lists the full text of the policies recommended for rescission.

RECOMMENDATIONS

The AMA recognizes that gender inequity in medicine is a complex, pervasive issue that requires a multilayered approach. Accordingly, the Board recommends that the following be adopted and that the remainder of the report be filed.

1. That our American Medical Association adopt the following language as policy, “Principles for Advancing Gender Equity in Medicine”:

Our AMA:

1. declares it is opposed to any exploitation and discrimination in the workplace based on personal characteristics (i.e., gender);
2. affirms the concept of equal rights for all physicians and that the concept of equality of rights under the law shall not be denied or abridged by the U.S. Government or by any state on account of gender;
3. endorses the principle of equal opportunity of employment and practice in the medical field;
4. affirms its commitment to the full involvement of women in leadership roles throughout the federation, and encourages all components of the federation to vigorously continue their efforts to recruit women members into organized medicine;
5. acknowledges that mentorship and sponsorship are integral components of one’s career advancement, and encourages physicians to engage in such activities;
6. declares that compensation should be equitable and based on demonstrated competencies/expertise and not based on personal characteristics;

7. recognizes the importance of part-time work options, job sharing, flexible scheduling, re-entry, and contract negotiations as options for physicians to support work-life balance;
 8. affirms that transparency in pay scale and promotion criteria is necessary to promote gender equity, and as such academic medical centers, medical schools, hospitals, group practices and other physician employers should conduct periodic reviews of compensation and promotion rates by gender and evaluate protocols for advancement to determine whether the criteria are discriminatory; and
 9. affirms that medical schools, institutions and professional associations should provide training on leadership development, contract and salary negotiations and career advancement strategies that include an analysis of the influence of gender in these skill areas.
2. That our AMA rescind the following policies, as they have been incorporated into the “Principles for Advancing Gender Equity in Medicine”:
 - a. D-200.981, “Gender Disparities in Physician Income and Advancement”
 - b. H-525.992, “Women in Medicine”
 - c. H-65.968, “Equal Opportunity”
 3. That our AMA rescind AMA Policy D-65.989 (1), “Advancing Gender Equity in Medicine,” as this report has fulfilled the request for information on positions and recommendations regarding gender equity in medicine, including the development of clarifying principles.
 4. That our AMA encourage state and specialty societies, academic medical centers, medical schools, hospitals, group practices and other physician employers to adopt the AMA Principles for Advancing Gender Equity in Medicine.
 5. That our AMA encourage academic medical centers, medical schools, hospitals, group practices and other physician employers to: (a) adopt policies that prohibit harassment, discrimination and retaliation; (b) provide anti-harassment training; and (c) prescribe disciplinary and/or corrective action should violation of such policies occur.
 6. That our AMA, modify Policy D-65.989, “Advancing Gender Equity in Medicine,” and continue to: (a) advocate for institutional, departmental and practice policies that promote transparency in defining the criteria for initial and subsequent physician compensation; (b) advocate for pay structures based on objective, gender-neutral ~~objective~~ criteria; (c) encourage a specified approach, sufficient to identify gender disparity, to oversight of compensation models, metrics, and actual total compensation for all employed physicians; and (d) advocate for training to identify and mitigate implicit bias in compensation determination for those in positions to determine salary and bonuses, with a focus on how subtle differences in the further evaluation of physicians of different genders may impede compensation and career advancement.
 7. That our AMA amend AMA Policy G-600.035, “The Demographics of the House of Delegates,” to read as follows:
 - a. 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.
 - b. 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.
 - c. Future reports on the demographic characteristics of the House of Delegates should, whenever possible, will identify and include information on successful initiatives and best practices to promote diversity within, particularly by age, state and specialty society delegations.

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APPENDIX A - Proposed AMA Policy: "Principles for Advancing Gender Equity" (Worksheet Version)

Note: The left column shows the proposed language for adoption; the right column shows the original language that is being modified and its policy number, if any.

Proposed language for adoption	Original language
Our AMA: 1. declares it is opposed to any exploitation and discrimination in the workplace based on personal characteristics (i.e., gender)	Our AMA: (1) declares it is opposed to any exploitation and discrimination in the workplace based on gender; H-65.968
2. affirms the concept of equal rights for all physicians and that the concept of equality of rights under the law shall not be denied or abridged by the U.S. Government or by any state on account of gender;	(2) affirms the concept that equality of rights under the law shall not be denied or abridged by the U.S. Government or by any state on account of gender; H-65.968
	(3) affirms the concept of equal rights for men and women; H-65.968
3. endorses the principle of equal opportunity of employment and practice in the medical field;	(4) endorses the principle of equal opportunity of employment and practice in the medical field. H-65.968
4. affirms its commitment to the full involvement of women in leadership roles throughout the federation, and encourages all components of the federation to vigorously continue their efforts to recruit women members into organized medicine;	Our AMA reaffirms its policy of commitment to the full involvement of women in leadership roles throughout the federation, and encourages all components of the federation to vigorously continue their efforts to recruit women members into organized medicine. H-525.992
5. acknowledges that mentorship and sponsorship are integral components of one's career advancement and encourages physicians to engage in such activities;	--
6. declares that compensation should be equitable and based on comparable work at each career stage, demonstrated competencies/expertise and not based on personal characteristics;	--
	Our AMA: (1) encourages medical associations and other relevant organizations to study gender differences in income and advancement trends, by specialty, experience, work hours and other practice characteristics, and develop programs to address disparities where they exist; D-200.981
7. recognizes the importance of part-time work options, job sharing, flexible scheduling, re-entry, and contract negotiations as options for physicians to support work-life balance;	(2) supports physicians in making informed decisions on work-life balance issues through the continued development of informational resources on issues such as part-time work options, job sharing, flexible scheduling, reentry, and contract negotiations; D-200.981
8. affirms that transparency in pay scale and promotion criteria is necessary to promote gender equity, and as such academic medical centers, medical schools, hospitals, group practices and other physician employers should conduct periodic reviews of compensation and promotion rates by gender and evaluate protocols for advancement to determine whether the criteria are discriminatory; and	(3) urges medical schools, hospitals, group practices and other physician employers to institute and monitor transparency in pay levels in order to identify and eliminate gender bias and promote gender equity throughout the profession; D-200.981
	(4) will collect and publicize information on best practices in academic medicine and non-academic medicine that foster gender parity in the profession; D-200.981
9. affirms that medical schools, institutions and professional associations should provide training on leadership development, contract and salary negotiations and career advancement strategies that include an analysis of the influence of gender in these skill areas.	and (5) will provide training on leadership development, contract and salary negotiations and career advancement strategies, to combat gender disparities as a member benefit. D-200.981

APPENDIX B - AMA Policies and Directives Proposed for Rescission

Equal Opportunity H-65.968

Our AMA: (1) declares it is opposed to any exploitation and discrimination in the workplace based on gender; (2) affirms the concept that equality of rights under the law shall not be denied or abridged by the U.S. Government or by any state on account of gender; (3) affirms the concept of equal rights for men and women; and (4) endorses the principle of equal opportunity of employment and practice in the medical field.

Gender Disparities in Physician Income and Advancement D-200.981

Our AMA: (1) encourages medical associations and other relevant organizations to study gender differences in income and advancement trends, by specialty, experience, work hours and other practice characteristics, and develop programs to address disparities where they exist; (2) supports physicians in making informed decisions on work-life balance issues through the continued development of informational resources on issues such as part-time work options, job sharing, flexible scheduling, reentry, and contract negotiations; (3) urges medical schools, hospitals, group practices and other physician employers to institute and monitor transparency in pay levels in order to identify and eliminate gender bias and promote gender equity throughout the profession; (4) will collect and publicize information on best practices in academic medicine and non-academic medicine that foster gender parity in the profession; and (5) will provide training on leadership development, contract and salary negotiations and career advancement strategies, to combat gender disparities as a member benefit.

Women in Medicine H-525.992

Our AMA reaffirms its policy of commitment to the full involvement of women in leadership roles throughout the federation, and encourages all components of the federation to vigorously continue their efforts to recruit women members into organized medicine.

Advancing Gender Equity in Medicine D-65.989 (1)

Our AMA will draft and disseminate a report detailing its positions and recommendations for gender equity in medicine, including clarifying principles for state and specialty societies, academic medical centers and other entities that employ physicians, to be submitted to the House for consideration at the 2019 Annual Meeting.

APPENDIX C - Status of Directives Associated with AMA Policy Advancing Gender Equity in Medicine, D-65.989

Policy Language	Status
<p>2. Our AMA will: (a) advocate for institutional, departmental and practice policies that promote transparency in defining the criteria for initial and subsequent physician compensation; (b) advocate for pay structures based on objective, gender-neutral objective criteria; (c) encourage a specified approach, sufficient to identify gender disparity, to oversight of compensation models, metrics, and actual total compensation for all employed physicians; and (d) advocate for training to identify and mitigate implicit bias in compensation determination for those in positions to determine salary and bonuses, with a focus on how subtle differences in the further evaluation of physicians of different genders may impede compensation and career advancement.</p>	<p>AMA PolicyFinder was updated to include Advancing Gender Equity in Medicine D-65.989.</p>
<p>3. Our AMA will recommend as immediate actions to reduce gender bias: (a) elimination of the question of prior salary information from job applications for physician recruitment in academic and private practice; (b) create an awareness campaign to inform physicians about their rights under the Lilly Ledbetter Fair Pay Act and Equal Pay Act; (c) establish educational programs to help empower all genders to negotiate equitable compensation; (d) work with relevant stakeholders to host a workshop on the role of medical societies in advancing women in medicine, with co-development and broad dissemination of a report based on workshop findings; and (e) create guidance for medical schools and health care facilities for institutional transparency of compensation, and regular gender-based pay audits.</p>	<p>Programming will be developed for future AMA meetings.</p>
<p>4. Our AMA will collect and analyze comprehensive demographic data and produce a study on the inclusion of women members including, but not limited to, membership, representation in the House of Delegates, reference committee makeup, and leadership positions within our AMA, including the Board of Trustees, Councils and Section governance, plenary speaker invitations, recognition awards, and grant funding, and disseminate such</p>	<p>A report with recommendations will be provided to the AMA House of Delegates at the 2019 Interim Meeting. This report will be based on data from the 1) Demographic Characteristics of the House of Delegates and AMA Leadership (CLRPD Report 1-A-19) and 2) results from an AMA staff survey used to collect information on committee composition, plenary speaker invitations, recognition awards, and grant funding.</p>

findings in regular reports to the House of Delegates and making recommendations to support gender equity.	
5. Our AMA will commit to pay equity across the organization by asking our Board of Trustees to undertake routine assessments of salaries within and across the organization, while making the necessary adjustments to ensure equal pay for equal work.	An evaluation of gender/demographic equity for pay practices in AMA’s internal workforce is underway.

**28. OPPOSITION TO MEASURES THAT CRIMINALIZE HOMELESSNESS
(RESOLUTION 410-A-18)**

Reference committee hearing: see report of Reference Committee D.

**HOUSE ACTION: RECOMMENDATIONS ADOPTED
IN LIEU OF RESOLUTION 410-A-18
REMAINDER OF REPORT FILED**
See Policy H-160.903

INTRODUCTION

Resolution 410-A-18, “Opposition to Measures that Criminalize Homelessness,” introduced by the Medical Student Section and referred by the House of Delegates asks that:

Our American Medical Association oppose measures that criminalize necessary means of living among homeless persons, including but not limited to, sitting or sleeping in public spaces; and advocate for legislation that requires non-discrimination against homeless persons, such as homeless bills of rights.

CURRENT AMA POLICY

Existing AMA policy supports improving health outcomes and decreasing the health care costs of treating people who are chronically homeless through clinically proven, high quality, and cost-effective approaches, which recognize the positive impact of stable and affordable housing coupled with social services. The AMA recognizes that stable, affordable housing as a first priority, without mandated therapy or services compliance, is effective in improving housing stability and quality of life among individuals who are chronically-homeless. Furthermore, the AMA recognizes that lack of identification is a barrier to accessing medical care and fundamental services that support health; and supports policy changes that streamline, simplify, and reduce or eliminate the cost of obtaining identification cards for the homeless population. Current policy does not specifically address criminalizing homelessness.

BACKGROUND

Insufficient income and lack of affordable housing are leading causes of homelessness in the United States. The Great Recession contributed to a shortage of affordable housing. It is estimated that we currently have a shortage of 7.2 million rental homes affordable and available to extremely low-income renters (those whose income is at or below the poverty guideline or 30 percent of their area median income).¹ Extremely low-income households face a shortage of affordable housing in every state and major metropolitan area. In addition to the shortage of affordable housing, in many U.S. cities, there are fewer shelter beds than are needed, leaving people experiencing homelessness with no choice, but to live in public places.²

In January 2018, almost 553,000 people were homeless on a single night in the United States, with nearly two-thirds found in emergency shelters or transitional housing programs.³ While the number of people experiencing homelessness increased by less than one percent between 2017 and 2018, overall homelessness has declined by more than 84,000 people (13 percent) since 2010.⁴ In the United States, sixty percent of people experiencing homelessness in 2018 were men or boys, and 39 percent were women or girls.⁵ Less than one percent were transgender or gender nonconforming.⁶ Nearly half (49 percent) of all people experiencing homelessness self-identified as white and almost 40 percent identified as black or African American.⁷ People identifying as white were underrepresented compared to their share of the U.S. population (72 percent), while African Americans were considerably overrepresented compared

to their share of the U.S. population (13 percent).⁸ One in five people experiencing homelessness was Hispanic or Latino (22 percent), which is slightly higher than their share of the U.S. population (18 percent).⁹

Substance use disorders and mental health problems are more prevalent among people who are homeless than in the general population. According to the Office of National Drug Control Policy, approximately 30 percent of people experiencing chronic homelessness have a serious mental illness, and around two-thirds have a primary substance use disorder or other chronic health condition.¹⁰ Lack of stable housing leaves them vulnerable to substance use and/or relapse, exacerbation of mental health problems, and a return to homelessness.¹¹

Laws Criminalizing Homelessness

Criminalizing homelessness refers to laws enacted by municipalities to prohibit life-sustaining activities such as sitting, sleeping, loitering, panhandling, camping, eating, storing belongings, and urinating in public spaces. Laws criminalizing homelessness trap vulnerable populations in the criminal justice system.¹² The continuous threat of citations and possibility of arrest contributes to a pervasive sense of fear and insecurity among the homeless population. For individuals experiencing homelessness, fines typically cannot be paid, leaving individuals to contest citations in court.¹³ Without a reliable address or transportation, citations can result in not receiving a notice to appear in court or having no way to get there. Failure to appear in court can result in a warrant for arrest.¹⁴ Arrests and criminal records make housing, employment, and social services more difficult to access thereby perpetuating the cycle of homelessness and health inequity.¹⁵

Laws criminalizing homelessness have increased in cities across the United States over the past 10 years.¹⁶ Since 2006, citywide bans on loitering, loafing, and vagrancy increased by 88 percent, bans on camping increased by 69 percent, bans on sitting and lying down in certain public places increased by 52 percent, bans on panhandling grew by 43 percent, and bans on sleeping in public increased by 31 percent.¹⁷ These laws are designed to move visibly homeless people out of commercial and tourist districts and are often justified based on the government's responsibility to maintain orderly, aesthetically pleasing public parks and streets as well as the responsibility to protect public health and safety.

DISCUSSION

Laws criminalizing homelessness have been found to violate international and, in some instances, federal law. In 2014, the United Nation's (UN) Committee on the Elimination of Racial Discrimination, called on the United States to abolish laws and policies making homelessness a crime and ensure cooperation among stakeholders to find solutions for people experiencing homelessness in accordance with human rights standards.¹⁸ Furthermore, the UN encouraged the United States to provide incentives to decriminalize homelessness, including financial support to local authorities that implement alternatives to criminalization, and withdrawing funding from local authorities that criminalize homelessness.¹⁹

In 2017, the UN Special Rapporteur on extreme poverty and human rights visited the United States to report to the Human Rights Council on the extent to which the government's policies and programs relating to extreme poverty are consistent with its human rights obligations and to offer recommendations to the government and other stakeholders. The report stated that:

In many cities, homeless persons are effectively criminalized for the situation in which they find themselves. Sleeping rough [i.e., sleeping outside without shelter], sitting in public places, panhandling, public urination and myriad other offences have been devised to attack the 'blight' of homelessness... Ever more demanding and intrusive regulations lead to infraction notices for the homeless, which rapidly turn into misdemeanours, leading to warrants, incarceration, unpayable fines and the stigma of a criminal conviction that in turn virtually prevents subsequent employment and access to most housing.²⁰

Courts in the United States have come to differing conclusions on laws criminalizing homelessness, particularly anti-camping ordinances, due to differing interpretations of whether the Eighth Amendment's protection against cruel and unusual punishment prohibits only criminalization of status or also the criminalization of involuntary conduct.²¹ In 2015, the United States government issued a statement indicating its position on the issue in the case of *Bell et al v. City of Boise*:

If the Court finds that it is impossible for homeless individuals to secure shelter space on some nights because no beds are available, no shelter meets their disability needs, or they have exceeded the maximum stay limitations, then the Court should also find that enforcement of the ordinances under those circumstances criminalizes the status of being homeless and violates the Eighth Amendment to the Constitution.²²

In the case in question, the 9th Circuit Court of Appeals held that the Cruel and Unusual Punishments Clause of the Eighth Amendment precluded enforcement of a statute prohibiting sleeping outside against homeless individuals with no access to alternative shelter. The court held that as long as there is no option of sleeping indoors, the government cannot criminalize indigent, homeless people for sleeping outdoors, on public property, on the false premise that they had no choice in the matter.²³ The court further explained that “[e]ven where shelter is unavailable, an ordinance prohibiting sitting, lying, or sleeping outside at particular times or in particular locations might well be constitutionally permissible. So, too, might an ordinance barring the obstruction of public rights of way or the erection of certain structures.”²⁴

Homeless Bill of Rights

Rhode Island, Illinois, and Connecticut, and Puerto Rico have enacted laws that protect the civil rights of people experiencing homelessness, these laws are referred to as a Homeless Bill of Rights. While the laws vary by jurisdiction, they specify that a person who is homeless has the same rights and privileges as any other state resident. The laws each outline the rights of persons experiencing homelessness (i.e. move freely in public spaces, receive equal treatment by state and municipal authorities, not face discrimination while seeking or maintaining employment, access to emergency medical services, etc.).²⁵ The impact these laws have had is unclear.

Public Health Nuisance Laws

Actions by government officials aimed at individuals experiencing homelessness are often justified based on public health and safety concerns. While laws criminalizing homelessness are of concern, it should be clear that there are legitimate instances in addressing homeless populations where the government needs to act to protect the health of the public. For example, the environmental conditions associated with homelessness, which can include overcrowding in encampments and shelters, exposure to the elements, and poor hygiene, facilitate the transmission of infectious diseases.

The United States is currently experiencing the worst multi-state outbreak of hepatitis A virus (HAV) in over 20 years, due in part to the lack of access to proper sanitation and hygiene among persons experiencing homelessness.²⁶ In response to this multi-state HAV outbreak, the CDC’s Advisory Committee on Immunization Practices, voted in 2018 to add a new policy recommending that everyone ages 1 and older who is experiencing homelessness routinely be immunized against hepatitis.²⁷ In some jurisdictions, there have been campaigns to vaccinate and educate people at risk and to provide portable hygiene facilities in areas where people who are homeless congregate. To address public health risks, some jurisdictions have created sanctioned tent encampments where they provide essential public services to help ensure that residents are in a safe environment. It has been cautioned that while these measures may prevent immediate harm, they are not long-term solutions to the problem of homelessness in the United States.²⁸

CONCLUSION

Insufficient income and lack of affordable housing are leading causes of homelessness in the United States. Laws criminalizing homelessness, or laws prohibiting life-sustaining activities in public spaces when there are no sheltered alternatives, have increased in U.S. cities over the past 10 years. These laws trap vulnerable populations in the criminal justice system and raise both human rights and constitutional concerns. Actions by government officials aimed at individuals experiencing homelessness are often justified based on public health and safety concerns. While there are instances where the government needs to act to protect public health and safety, such as during an infectious disease outbreak, governments should work to mitigate hazards and direct individuals to resources and services outside of the criminal justice system. Criminal sanctions should be a last resort.

Current AMA policy recognizes that stable, affordable housing as a first priority, without mandated therapy or services compliance, is effective in improving housing stability and quality of life among individuals who are chronically-homeless. In addition, to reaffirming this policy, the AMA should recognize the lack of affordable housing as a leading

cause of homelessness and support measures to address this problem through policies that preserve and expand affordable housing across all neighborhoods.

RECOMMENDATIONS

The Board of Trustees recommends that the following statements be adopted in lieu of Resolution 410-A-18 and the remainder of the report be filed.

1. That our American Medical Association: (1) supports laws protecting the civil and human rights of individuals experiencing homelessness and (2) opposes laws and policies that criminalize individuals experiencing homelessness for carrying out life-sustaining activities conducted in public spaces that would otherwise be considered non-criminal activity (i.e., eating, sitting, or sleeping) when there is no alternative private space available.
2. That our AMA recognizes that stable, affordable housing is essential to the health of individuals, families, and communities, and supports policies that preserve and expand affordable housing across all neighborhoods.
3. That our AMA reaffirm Policy H-160.903, “Eradicating Homelessness”

Our American Medical Association: (1) supports improving the health outcomes and decreasing the health care costs of treating the chronically homeless through clinically proven, high quality, and cost effective approaches which recognize the positive impact of stable and affordable housing coupled with social services; (2) recognizes that stable, affordable housing as a first priority, without mandated therapy or services compliance, is effective in improving housing stability and quality of life among individuals who are chronically-homeless; (3) recognizes adaptive strategies based on regional variations, community characteristics and state and local resources are necessary to address this societal problem on a long-term basis; (4) recognizes the need for an effective, evidence-based national plan to eradicate homelessness; and (5) encourages the National Health Care for the Homeless Council to study the funding, implementation, and standardized evaluation of Medical Respite Care for homeless persons.

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29. IMPROVING SAFETY AND HEALTH CODE COMPLIANCE IN SCHOOL FACILITIES (RESOLUTION 413-A-18)

Reference committee hearing: see report of Reference Committee D.

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS IN LIEU OF RESOLUTION 413-A-18 REMAINDER OF REPORT FILED

See Policies H-135.918, H-125.928 and H-135.998

INTRODUCTION

Resolution 423-A-18, “Improving Safety and Health Code Compliance in School Facilities,” which was introduced by the Medical Student Section, and was referred by the House of Delegates, asked:

That our American Medical Association (1) support the development and implementation of standardized, comprehensive guidelines for school safety and health code compliance inspections; and (2) That our AMA support policies aiding schools in meeting said guidelines, including support for financial and personnel-based aid for schools based in vulnerable neighborhoods; and (3) That our AMA support creation of a streamlined reporting system for school facility health data potentially through application of current health infrastructure.

Testimony during reference committee noted that there are already extensive guidelines provided for schools by the Centers for Disease Control and Prevention, Environmental Protection Agency, and state departments of health, and that our American Medical Association should review guidelines from these sources. It was further noted that there is no governing body that enforces the compliance of safety standards in schools. This report addresses school environmental health and safety.

CURRENT AMA POLICY

Existing American Medical Association (AMA) policy addresses environmental health and safety, including drinking water and indoor air quality (see Appendix for full text). Relevant to this report is AMA Policy H-135.928, “Safe

Drinking Water,” that supports creating and implementing standardized protocols and regulations pertaining to water quality testing, and reporting and remediation to ensure the safety of water in schools. AMA Policy H-135.998, “AMA Position on Air Pollution,” also supports maximum feasible reduction of all forms of air pollution, including biologically and chemically active pollutants, by all responsible parties, as governmental control programs are implemented primarily by local, regional, or state jurisdictions which possess the resources to bring about equitable and effective control.

BACKGROUND

School Environmental Health and Safety

Children are a vulnerable population with smaller body size and higher metabolism, which may increase susceptibility to environmental contaminants.¹ Children may also be more likely to encounter contaminants, due to proximity to the ground, where they may ingest substances such as toxic dust by placing objects in their mouths, and where levels of airborne pollutants may also be higher. Regardless of route of administration, encounters with toxins such as heavy metals can lead to lifelong negative health and behavioral impacts,² including via altered brain development.³

Safety implies prevention of unintentional injuries, a leading cause of death and disability among children. Unsafe environments can lead to chronic health conditions, including asthma and allergies. As many as 25 percent of school-age children in the United States have a chronic health condition. Children spend large amounts of time in schools, where better management of their chronic health conditions may be associated with improved academic achievement.⁴

Budget shortfalls for school infrastructure impact school operating resources, negatively affecting routine and preventative maintenance, particularly in lower-income districts. Lack of well-maintained school environments can pose obstacles to student learning and well-being, negatively affect surrounding communities, and contribute to health inequities.⁵

Environmental health and safety laws and guidelines have been designed to protect private and public employees, students, the public, and the environment.⁶ A complex jurisdictional arrangement throughout federal, state, county, and municipal levels may create confusion for schools about which regulations apply. The following provides a broad overview of various agencies and entities with interests in school environmental health and safety.

FEDERAL AGENCIES

The federal government’s role in education has traditionally been limited, due to the Tenth Amendment of the U.S. Constitution, which reserves powers not assigned to the federal government for the states of the people. Rather than mandating direct federal oversight of schools, state and local districts have generally retained school regulatory authorities under existing law.

U.S. Environmental Protection Agency (EPA)

The EPA is responsible for protecting the environment and public through legislative mandates. These laws include air pollution, drinking water, pesticides, hazardous waste, and asbestos, among other topics. The Energy Independence and Security Act of 2007 added a requirement for the EPA to develop voluntary guidelines (together with other relevant federal agencies) for K-12 schools, and then assist states in establishing and implementing environmental health programs.⁷

Other recent EPA mandates address drinking water and aging infrastructure, including: the Drinking Water State Revolving Fund of 2013 that provides loans that support lead pipe replacement projects across the United States; the Water Infrastructure Improvements for the Nation Act of 2016 that supports grant programs⁸ (e.g., the State Lead Testing in School and Child Care Program Drinking Water Grant⁹); the Water Infrastructure Finance and Innovation Act of 2018 that leverages funding for water infrastructure projects to reduce exposure to lead and other contaminants; and the America’s Water Infrastructure Act of 2018 that offers programs and resources to help reduce lead in drinking water.

The EPA assists states and local school districts by providing grant support¹⁰ and capacity building, developing policy and data tools,¹¹ and offering guidance on compliance and monitoring. The EPA’s voluntary guidelines provide

examples of best practices from existing state environmental health programs for schools, recommend a six-step plan states can use to build or enhance a sustainable school environmental health program, and provide extensive resources for states to promote healthy learning environments for children and school staff.

In addition to the voluntary guidelines, in 2018 the EPA announced the Tools for Schools program to support schools in ensuring clean, healthy, and environmentally conscious school communities. The Tools for Schools approach provides strategies and a robust suite of tools to help schools identify, correct, and prevent a wide range of environmental health and safety risks, and to put in place a sustainable system to institutionalize a successful program at the school or school district level.¹³ The EPA also offers comprehensive Healthy Schools, Healthy Kids educational resources and tools to help maintain and enhance environmental health programs.¹² These resources include educating students and school staff about prevention and management, as well as hands-on resources such as inspection manuals for staff and pest management professionals.¹⁴

Centers for Disease Control and Prevention (CDC)

The CDC conducts critical science and provides health information that protects our nation against dangerous health threats, and responds when these arise. The CDC serves a key role in environmental health, as well as health promotion and education activities designed to improve health.

Various CDC centers and agencies address environmental health and safety, including the Agency for Toxic Substances and Disease Registry, which works towards minimizing risks associated with exposure to hazardous substances, and maintains toxicological profiles for substances; the Division of Adolescent and School Health, which collects data to monitor healthy and safe school environments such as School Health Policies and Practices Study¹⁵ and conducts surveys of schools including School Health Profiles¹⁶ covering asthma and other chronic conditions; and the National Center for Environmental Health which conducts research including the Environmental Public Health Tracking Program¹⁷ and collects state surveillance data¹⁸ on children affected by lead.

The National Institute for Occupational Safety and Health (NIOSH) has a Safety Checklist for Schools¹⁹ to help K-12 schools with health compliance, including with EPA regulations and Occupational Safety and Health Administration (OSHA) standards. NIOSH also responds to requests to investigate health and safety problems in the workplace, via the Division of Surveillance, Hazard Evaluations, and Field Studies, including in public schools²⁰. It also provides training in occupational safety and health, conducts occupational disease and injury research, and recommends standards to OSHA.

The School Health Index²¹ was developed by the CDC as a confidential online self-assessment and planning tool that schools can use to help improve health and safety policies and programs. The CDC also has additional resources for drinking water access²² through Healthy Schools,²³ which offers the Whole School, Whole Community, Whole Child (WSCC) model as a framework for addressing health in schools.²⁴ According to the WSCC model:

The physical school environment encompasses the school building and its contents, the land on which the school is located, and the area surrounding it. A healthy school environment will address a school's physical condition during normal operation as well as during renovation (e.g., ventilation, moisture, temperature, noise, and natural and artificial lighting), and protect occupants from physical threats (e.g., crime, violence, traffic, and injuries) and biological and chemical agents in the air, water, or soil as well as those purposefully brought into the school (e.g., pollution, mold, hazardous materials, pesticides, and cleaning agents).

A recent report²⁵ provided a comprehensive analysis of state policies for alignment with the CDC's WSCC model, and these findings are available by state and category,²⁶ including physical environment.

STATE AGENCIES

State agencies also play a role in school environmental health and safety, and these vary by jurisdiction. Those that may be relevant include the state departments of education, labor, environmental protection, community affairs, and health.¹⁹

Departments of Education

State departments of education issue regulations that deal with private and public schools, as well as regulations related to school construction. Besides regulations for environmental safety and health regulations, a state department of education or school district may also provide policies and/or guidelines related to environmental safety and health programs.

Departments of Labor

Although students are not generally covered by federal OSHA, state legislative mandates may “adopt by reference” the OSHA standards. “Adoption by reference” requires compliance in the state with federal OSHA requirements. State OSHA programs then assume responsibility for enforcing regulations through the state department of labor, including health and safety.

Departments of Environmental Protection

In most states, the state EPA covers the same areas addressed by federal EPA, such as air pollution, drinking water, hazardous waste, pesticides, and noise pollution. When incorporated into state regulations, state EPAs are authorized by the U.S. EPA to enforce almost all EPA regulations. States have typically assumed responsibility for enforcement of EPA mandates, following adoption of their own state regulations, including inspections and enforcing EPA regulations in schools. The U.S. EPA provides voluntary guidelines for states to follow, and encourages a leadership role from state agencies, such as more comprehensive strategies, including by using available resources such as model programs for indoor air quality.²⁷

Departments of Community Affairs

Agencies such as the Department of Community Affairs may enforce state fire safety and building regulations. In many states, cities and counties are free to adopt their own codes, in the absence of state codes.

Departments of Health

State departments of health enforce health regulations directed by legislative mandate. Health departments may also work with schools and local health departments to provide technical assistance on school environmental health and safety issues and promote best practices.

LOCAL GOVERNMENTS

Various codes and standards have been adopted by states, counties, cities/towns and districts to help ensure school safety. One example includes building codes, which may also regulate children’s play spaces and equipment. Another example is fire protection codes that address topics such as means of egress from buildings. Many safety codes apply to public schools via entities such as the local building or fire department,²⁸ and some cover environmental health areas such as radon testing and elimination. At state or city levels, additional public safety statutes may apply.²⁹

KEY AREAS OF SCHOOL ENVIRONMENTAL HEALTH AND SAFETY

Air Quality

Airborne contaminants including mold³⁰ and chemicals such as cleaning products and pesticides, can trigger a variety of health issues, including allergies and asthma. Various state indoor air quality statutes cover topics such as HVAC system inspection and inadequate ventilation, while others focus primarily on green cleaning. Nearly every state has a statute that heavily regulates smoking in schools and most prohibit smoking in schools completely. There is no state statute that encompasses all facets of indoor air quality safety in schools.

Chemical Hazards

Asbestos. Asbestos minerals are a group of silicate compounds that cause chronic lung disease and have been classified as a known human carcinogen.³¹ Asbestos statutes generally pertain to any public building and not just schools, and

require certification and licensure before any contracting can occur for an asbestos abatement program, and substantial monitoring before and during any programs. Most state statutes provide for state or federal money for abatement programs in public buildings, including schools.

Radon. Radon is a colorless, odorless radioactive gas that seeps into buildings from surroundings, and can become trapped inside. Some states have radon statutes that provide that schools must be checked for radon, but most states delegate authority to various departments in the state.

Lead. Lead is a neurotoxin for which young children are particularly susceptible. Lead exposure is linked to impaired brain and nervous system development during childhood and associated with adverse effects including behavioral problems and additional health conditions later in life. Nearly every state has a statute that mitigates lead risks, though most are focused on reducing the risks of lead-based paint. Of the states that specifically address children, many only address children up to age six. The EPA offers voluntary guidance¹³ for preventing and mitigating some lead hazards in schools, including drinking water.³²

Water Quality

Currently, no federal law requires testing for lead in school drinking water. Although public water systems are regulated by the EPA, this regulation does not apply to downstream users such as schools. To date, federal agencies including the EPA, Department of Education and CDC have had a limited role in monitoring school drinking water. Improved federal guidance has been called for by the Government Accountability Office.³³

In 2017, 41 percent of school districts nationwide had not tested their water for lead, and additional 16 percent reported that they did not know whether the water had been tested.³³ In 2016, New York became the first state to require lead testing in school drinking water and by 2018, 15 states had requirements for lead testing in school drinking water³⁴ but many jurisdictions do not have programs to test for lead in drinking water.

Recent findings have highlighted challenges due a lack of standardized practices in data collection, reporting, and decision making. When testing has been performed, elevated levels of lead have often been found, and many schools must decide the levels that trigger retesting, prevent continued use of the source, and eventually spur remediation efforts.

CONCLUSION

Children are a vulnerable population and are susceptible to environmental contaminants. Given the amount of time children spend in schools, promoting healthy school environments is of importance. Existing guidelines recommend steps towards sustainable school environmental health programs, and additional tools are available to help schools implement guidelines to promote children's health. While some state and local governments have adopted these guidelines into law, overall adoption and enforcement of such guidelines remains voluntary. Budgets and school operating expenses directly impact school building infrastructure and maintenance. Schools in lower-income districts may be particularly vulnerable to environmental health hazards, which can pose obstacles to student learning and well-being, and contribute to health inequities.

RECOMMENDATIONS

The Board of Trustees recommends that the following recommendations be adopted in lieu of Resolution 413-A-18 and that the remainder of this report be filed.

1. That our AMA adopt the following new policy:

“Environmental Health and Safety in Schools”

Our AMA supports 1. the adoption of standards in schools that limit harmful substances from school facility environments, ensure safe drinking water, and indoor air quality, and promote childhood environmental health and safety in an equitable manner; 2. encourages the establishment of a system of governmental oversight, charged with ensuring the regular inspection of schools and identifying shortcomings that might, if left untreated, negatively impact the health of those learning and working in school buildings; 3. supports policies that increase funding for such remediations to take place, especially in vulnerable, resource-limited neighborhoods; and

4. supports continued data collection and reporting on the negative health effects of substandard conditions in schools.
2. That the following policies be reaffirmed: H-135.928, “Safe Drinking Water,” and H-135.998, “AMA Position on Air Pollution.”

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APPENDIX - Current AMA Policy

H-135.928, “Safe Drinking Water”

Our AMA supports updates to the U.S. Environmental Protection Agency’s Lead and Copper Rule as well as other state and federal laws to eliminate exposure to lead through drinking water by:

- (1) Removing, in a timely manner, lead service lines and other leaded plumbing materials that come into contact with drinking water;
- (2) Requiring public water systems to establish a mechanism for consumers to access information on lead service line locations;
- (3) Informing consumers about the health-risks of partial lead service line replacement;
- (4) Requiring the inclusion of schools, licensed daycare, and health care settings among the sites routinely tested by municipal water quality assurance systems;
- (5) Creating and implementing standardized protocols and regulations pertaining to water quality testing, reporting and remediation to ensure the safety of water in schools and child care centers;
- (6) Improving public access to testing data on water lead levels by requiring testing results from public water systems to be posted on a publicly available website in a reasonable timeframe thereby allowing consumers to take precautions to protect their health;
- (7) Establishing more robust and frequent public education efforts and outreach to consumers that have lead service lines, including vulnerable populations;
- (8) Requiring public water systems to notify public health agencies and health care providers when local water samples test above the action level for lead;
- (9) Seeking to shorten and streamline the compliance deadline requirements in the Safe Drinking Water Act; and
- (10) Actively pursuing changes to the federal lead and copper rules consistent with this policy.

H-135.998, “AMA Position on Air Pollution”

Our AMA urges that: (1) Maximum feasible reduction of all forms of air pollution, including particulates, gases, toxicants, irritants, smog formers, and other biologically and chemically active pollutants, should be sought by all responsible parties. (2) Community control programs should be implemented wherever air pollution produces widespread environmental effects or physiological responses, particularly if these are accompanied by a significant incidence of chronic respiratory diseases in the affected community. (3) Prevention programs should be implemented in areas where the above conditions can be predicted from population and industrial trends. (4) Governmental control programs should be implemented primarily at those local, regional, or state levels which have jurisdiction over the respective sources of air pollution and the population and areas immediately affected, and which possess the resources to bring about equitable and effective control.

30. OPIOID TREATMENT PROGRAMS REPORTING TO PRESCRIPTION MONITORING PROGRAMS (RESOLUTION 507-A-18)

Reference committee hearing: see report of Reference Committee B.

**HOUSE ACTION: RECOMMENDATIONS ADOPTED
(RESOLUTION 507-A-18 NOT ADOPTED)
REMAINDER OF REPORT FILED**

INTRODUCTION

At the 2018 American Medical Association (AMA) House of Delegates (HOD) Annual Meeting, the Medical Student Section introduced Resolution 507-A-18, asking that our AMA amend Policy D-95.980, “Opioid Treatment and Prescription Drug Monitoring Programs,” by deletion as follows:

Our AMA will seek changes to ~~allow states the flexibility to~~ require opioid treatment programs to report to prescription monitoring programs.

The resolution was ultimately referred. There was considerable testimony at the reference committee identifying numerous issues to both support and oppose the resolution. This report provides a current update of prescription drug monitoring programs (PDMPs), the privacy protections patients are afforded with respect to PDMPs, relevant federal laws governing opioid treatment programs (OTPs), highlights relevant AMA policy, and presents a recommendation.

DISCUSSION

Prescription drug monitoring programs

PDMPs are generally described as electronic interfaces that allow physicians and other authorized users to view a patient's-controlled substance prescription history. Every state except Missouri has a PDMP, although some are more advanced than others. The AMA supports physicians registering for and using PDMPs as part of the clinical decision-making process.

At present, at least 44 states require physicians and other clinicians who prescribe controlled substances to query the PDMP under certain circumstances. These mandates range from requiring a query prior to prescribing any controlled substances every time a prescription for a controlled substance is issued to every six months or a year; to queries limited only to the prescribing of opioid analgesics and benzodiazepines.

Emerging data suggests that PDMPs have not led to reductions in opioid-related mortality as proponents have predicted. From 2014 and 2017, physicians' and other health care professionals' use of PDMPs increased from 61.4 million queries to more than 300.3 million queries; and registration to use a PDMP increased from 471,896 to more than 1.5 million registered users.¹ Opioid-related mortality, however, has increased considerably. From 2012 to 2017, prescription opioid-related mortality increased from 11,134 to 14,495; heroin-related mortality increased from 5,925 to 15,482; and illicit fentanyl-related mortality increased from 2,628 to 28,466. Meanwhile, there remains an unacceptable treatment gap for those with a substance use disorder (SUD) or co-occurring mental illness. According to the 2017 National Survey on Drug Use and Health (NSDUH) conducted by the U.S. Substance Abuse and Mental Health Services Administration, 92.3 percent of those age 12 and older received no treatment for an SUD; and 91.7 percent of those 18 and older received no treatment for a co-occurring mental illness and SUD.²

Evaluation of PDMPs before 2012 found mixed results with respect to PDMP effects on opioid prescribing, reductions in morphine milligram equivalents (MME), per-capita opioid prescribing, mortality rates, and opioid-related admissions to the emergency department.³ A more recent, comprehensive study found that "PDMPs were not associated with reductions in drug overdose mortality rates and may be related to increased mortality from illicit drugs and other, unspecified drugs."⁴ A prospective look at how PDMPs can impact the nation's opioid epidemic found that "interventions such as prescription drug monitoring programs are unlikely to lead to major decreases in the number of deaths from opioid overdose in the near future."⁵ These studies are not to suggest there is no role for PDMPs or that there is no other data showing positive effects of PDMPs—rather, that an overreliance on PDMPs to solve the nation's opioid epidemic will not likely lead to widespread, positive impacts.

PDMPs and privacy protections

The AMA *Code of Medical Ethics* (the Code) states that "Protecting information gathered in association with the care of the patient is a core value in health care." The Code further states that

Patients need to be able to trust that physicians will protect information shared in confidence. They should feel free to fully disclose sensitive personal information to enable their physician to most effectively provide needed services. Physicians in turn have an ethical obligation to preserve the confidentiality of information gathered in association with the care of the patient.

In a recent letter to the United States Office of Civil Rights,⁶ the AMA stated that

[t]he first step of any ultimately successful privacy framework, legislative or regulatory, places the patient first. Each entity seeking access to patients' most confidential medical information must pass the stringent test of

showing why its professed need should override individuals' most basic right in keeping their own information private—something that technology can help physicians accomplish in a minimally burdensome way. Moreover, citizens deserve a full and open discussion of exactly who wants their private medical information and for what purpose. Only then may the true balancing of interests take place. These are the ground rules of AMA policy and they should be the ground rules for the federal debate regarding data privacy.

With respect to PDMPs, the AMA has significant privacy concerns about law enforcement and other non-health care entities using a PDMP because of the personal health information (PHI) contained within a PDMP. PHI may include a patient's controlled substance prescription history, which can potentially cause someone to learn a patient is being treated for gender dysphoria, a substance use disorder, mental illness, HIV/AIDS or other medical condition that has historically been subject to stigmatization. The AMA believes that an appropriate balance between law enforcement access and a patient's right to privacy occurs when law enforcement obtains a court-issued warrant or other judicially authorized access. That occurs, however, in fewer than 20 states.⁷ Only four states have granted authority for third-party payers other than Medicaid access to PDMPs⁸ despite third-party payer state legislative efforts.

In the courts, the AMA and nine state medical societies argued to the Ninth Circuit Court of Appeals against the United States Drug Enforcement Administration efforts to access the Oregon PDMP with only an administrative warrant that "patients have a basic right to privacy of their medical information. That privacy should be honored unless there is meaningful waiver by the patient or a strong countervailing public health or safety interest, and then only with stringent safeguards."⁹ The AMA and California Medical Association also argued against unfettered access to patients' prescription information in *Lewis v. Medical Board of California*, where "a Medical Board of California investigator testified that the board routinely obtains confidential prescribing records from [the California PDMP] for all patients of physicians subject to medical board investigations, even where the complaint is unrelated to the patients or the physician's prescribing practices."¹⁰

Additionally, before enacting a law requiring that police and prosecutors obtain warrants before searching in sensitive patient information in the state's prescription monitoring database, Massachusetts allowed police and prosecutors to view patient medical records without warrants nearly 11,000 times—or about 20 times per day—between August 2016 and March 2018.¹¹

Unauthorized access also can occur when law enforcement inappropriately pressures pharmacists to query a PDMP without judicial oversight. The American Pharmacists Association counsels that:

The information in PDMP reports is personal and private. Patients expect that pharmacists will maintain the confidentiality of this information, and this is a key aspect of the professional relationship of trust between pharmacists and patients.¹²

Unauthorized access and inappropriate use of an individual's person health information can have devastating effects, such as occurred to a Utah firefighter whose PDMP information was accessed and misinterpreted at multiple steps during several year long legal battle. Ultimately, all charges were dismissed, but not before the damage had been done.¹³

Notwithstanding the legal requirements, case law and news items noted above, states generally have strong protections regarding the unauthorized use of information within a PDMP. While important work is being done to remove stigma and regard SUD as a medical condition like any other, the fact remains that illicit substance use is illegal, which is decidedly unlike any other medical issue.¹⁴ Inappropriate disclosure of SUD data can result in consequences exponentially more harmful to a patient than the improper disclosure of his or her hypertension (e.g., loss of housing,¹⁵ loss of child custody,¹⁶ discrimination from medical professionals,¹⁷ loss of benefits¹⁸ or loss of employment,¹⁹ among others).²⁰ Any discussion of increasing the exchange of SUD information must contemplate the potential for such outcomes.

The AMA supports the refinement of PDMPs and development and implementation of technology that assists physicians with sharing information on prescriptions for controlled substances among states. AMA also calls for appropriate balance when the information in question relates to patients who receive treatment in an OTP—patients who often experience a much higher degree of stigmatization and prejudice than other patients with a chronic medical disease.

Further, even if a patient receiving care in an OTP authorized the disclosure of prescription information to be entered into a PDMP, it is unclear how that authorization would protect the patient against further re-disclosure. That is, proponents of removing OTP privacy and disclosure protections suggest that the PDMP already has sufficient safeguards against unauthorized use, but as noted above, that is not actually the reality. In addition, the patient privacy and consent provisions of relevant federal law (often referred to as Part 2) allow for a case-by-case determination by the patient to whom disclosure may be made. Thus, while the patient may authorize and provide specific consent for disclosure to other health care professionals who treat the patient, *any* authorized user of a PDMP could view the OTP patient's prescription history once it is entered into the PDMP. Until a PDMP has much more advanced controls and sufficient privacy protections for OTP users, entering a patient's prescription history into the PDMP would almost certainly mean widespread disclosure well beyond those involved in the patient's care.

It should further be emphasized that Part 2 written consents prohibit the recipient from further disclosure of the information. In other words, it would be neither operationally feasible nor legally logical to send information to a PDMP—the PDMP would not be allowed to redisclose it to anyone, regardless of whether they are authorized to access the PDMP, absent additional written patient consent. That is key because PDMPs are not set up to prevent re-disclosure. As explained at the outset of this report, they are databases that contain considerable information and can be accessed by any authorized user.

OTPs and PDMPs

Part 2 does not permit information about a patient in an OTP to be entered into the PDMP without the patient's specific consent, even if the OTP dispenses medication. The rationale for this rule is that identifying individuals with an SUD could lead to discrimination against the individual, and part of the original purpose of Part 2 was a decision by lawmakers to promote and protect individuals seeking SUD treatment. The AMA supports this rationale and has heard from front line clinicians who agree that identifying patients who receive SUD treatment could have a chilling effect on patients seeking care.

Adopting policy that requires OTPs to report to PDMPs would necessitate a change to the statute underlying Part 2. Most stakeholders who support such a change want OTPs (and other practice settings to which Part 2 applies) to disclose information in accordance with the Health Insurance Portability and Accountability Act (HIPAA)—that is, in a less-restricted manner. HIPAA allows disclosure of a patient's health information without a patient's consent for treatment, payment and health care operations (TPO) purposes, as defined by HIPAA. Purportedly, to address concerns that patients will maintain control over how their information is shared, proponents of changing Part 2 to allow OTPs to enter information into PDMPs claim that patients diagnosed with an SUD will still have the "same consent requirements" when his or her information is disclosed for TPO purposes as any other patient does under HIPAA. However, while patients *may be asked* for consent to share their information for TPO purposes under HIPAA, *patient consent is not required*.²¹ This is a critical distinction, and if Part 2 is changed, would immediately change patients' privacy protections for the hundreds of thousands of patients currently receiving care in an OTP.

Changing Part 2 to require OTPs to report to PDMPs would effectively remove the very privacy protections that were created to encourage SUD treatment. Indeed, 113 patient advocacy groups have stated that such a change will discourage individuals struggling with addiction from seeking treatment if they know that their information will not be protected.²² The 2017 NSDUH reported that among the top reasons for those with an SUD not receiving treatment: "Might Cause Neighbors/Community to Have Negative Opinion;" "Might Have Negative Effect on Job;" and "Did Not Want Others to Find Out."²³ At a time when the nation's opioid epidemic is worse than ever, policymakers must balance greater access to information with potential effects of undermining patient privacy when attempting to increase access to care. Given the lack of data showing the benefits of additional information or use of the PDMP to mitigate the epidemic's harms, the AMA believes that the balance clearly edges toward patient privacy as opposed to opening the door to adverse effects on patients who receive—or might be deterred from seeking—care in an OTP.

AMA POLICY

AMA policy strongly supports patient privacy and confidentiality protections in all areas of health care. This includes calling for "safeguards and protections of state databases by limiting database access by non-health care individuals to only those instances in which probable cause exists that an unlawful act or breach of the standard of care may have occurred" (Policy H-95.946, "Prescription Drug Monitoring Program Confidentiality"). AMA policy also makes clear that the AMA "considers PDMP data to be protected health information, and thus protected from release outside the

healthcare system unless there is a HIPAA exception or specific authorization from the individual patient to release personal health information, and recommends that others recognize that PDMP data is health information” (Policy H-95.945, “Prescription Drug Diversion, Misuse and Addiction”). The AMA also “supports legislation and regulatory action that would authorize all prescribers of controlled substances, including residents, to have access to their state prescription drug monitoring program.” (Policy H-95.927, “Universal Prescriber Access to Prescription Drug Monitoring Programs”). Despite the impression given by the title of the policy, the AMA broadly supports physicians using PDMPs only “when clinically appropriate” as well as sharing information “within the safeguards applicable to protected health information.” AMA policy also calls for using PDMPs as part of the effort to identify and reduce “multiple provider events” that can occur when patients receive multiple controlled substance prescriptions from multiple pharmacies or other dispensers in a short time frame to help ensure continuity of care.” (Policy H-95.928, Model State Legislation “Promoting the Use of Electronic Tools to Mitigate Risk with Prescription Opioid Prescribing”).

Finally, as noted throughout this report, AMA policy regarding patients’ rights to privacy and confidentiality of their personal health information is robust. (Policy H-315.983, “Patient Privacy and Confidentiality”). A strong, representative sample includes provisions that state:

there exists a basic right of patients to privacy of their medical information and records, and that this right should be explicitly acknowledged; That patients’ privacy should be honored unless waived by the patient in a meaningful way or in rare instances when strong countervailing interests in public health or safety justify invasions of patient privacy or breaches of confidentiality, and then only when such invasions or breaches are subject to stringent safeguards enforced by appropriate standards of accountability.

It goes on to state that in such instances that “breaches of confidentiality are compelled by concerns for public health and safety, those breaches must be as narrow in scope and content as possible, must contain the least identifiable and sensitive information possible, and must be disclosed to the fewest possible to achieve the necessary end.” Finally, AMA Policy H-315.983, “Patient Privacy and Confidentiality,” states that:

Employers and insurers should be barred from unconsented access to identifiable medical information lest knowledge of sensitive facts form the basis of adverse decisions against individuals,” and that “[t]he fundamental values and duties that guide the safekeeping of medical information should remain constant in this era of computerization. Whether they are in computerized or paper form, it is critical that medical information be accurate, secure, and free from unauthorized access and improper use.

RECOMMENDATION

The Board of Trustees recommends that Resolution 507-A-18 not be adopted and the remainder of this report be filed.

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23. See Table 5.54B – Detailed Reasons for Not Receiving Substance Use Treatment in Past Year among Persons Aged 18 or Older Classified as Needing But Not Receiving Substance Use Treatment at a Specialty Facility and Who Felt a Need for Substance Use Treatment in Past Year: Percentages, 2017. National Survey on Drug Use and Health. Available at <https://www.samhsa.gov/data/sites/default/files/cbhsq-reports/NSDUHDetailedTabs2017/NSDUHDetailedTabs2017.htm#tab5-46A>

31. NON-PAYMENT AND AUDIT TAKEBACKS BY CMS (RESOLUTION 704-A-18)

Reference committee hearing: see report of Reference Committee G.

**HOUSE ACTION: RECOMMENDATIONS ADOPTED
IN LIEU OF RESOLUTION 704-A-18
REMAINDER OF REPORT FILED**
See Policy D-330.901

At the 2018 Annual Meeting, the House of Delegates referred Resolution 704-A-18, "Non-Payment and Audit Takebacks by CMS," for report back at the 2019 Annual Meeting. This resolution was introduced by the New York Delegation and asked that:

Our American Medical Association (AMA) seek through legislation and/or regulation policies opposing claim nonpayment due to minor wording or clinically insignificant documentation inconsistencies;

Our AMA seek through legislation and/or regulation policies opposing extrapolation of overpayments based on minor inconsistencies; and

Our AMA seek through legislation and/or regulation policies opposing bundled payment denial based on minor wording or clinically insignificant documentation inconsistencies.

This report discusses the broader concept of medical record documentation, the administrative burden of documentation, and related AMA policy.

BACKGROUND

Medical record documentation is required to record pertinent facts, findings, and observations about an individual's health history, including past and present illnesses, examinations, tests, treatments, and outcomes. The medical record is a chronological reflection of the care of the patient and is an important element contributing to the quality of care.¹ In addition, the medical record documentation serves as evidence of the provision of services, who provided the care, the medical necessity, and the quality of care. The original medical documentation must be filed in the patient's medical record at that facility. The documentation of medical record can also be used by payers and oversight entities to deny or recoup payment for inadvertent mistakes.

While Congress, federal agencies, and states have made unprecedented investments in improving oversight and program integrity, significant challenges remain. Efforts to fight health care fraud or identify areas of waste or abuse have a tangible impact on physician practices. To comply with the federal program integrity and documentation requirements, physicians proactively conduct internal audits and adopt compliance programs at their own cost.

Broad-brush requirements that impose burdens on all physicians, rather than focusing on those providers who have demonstrated a propensity to commit fraud or abuse, inequitably affect physicians and providers who are good actors, and result in unnecessary costs to the health care system. This fact is especially true in pre- and post-payment review. The number of reviews and types of reviewers are confusing, add unwarranted physician burden and unnecessary costs, and disrupt and distract from delivering patient-centered care.² Furthermore, some contractors audit and attempt to recoup against services that Medicare does not require, do not adhere to CMS requirements surrounding the approval of Local Coverage Determinations (LCD), or are for minor, clinically insignificant errors.

The regulatory burden placed on physicians is also a major component of physician burnout. Physicians often must spend too much of their time on administrative tasks rather than providing care to patients. The evolving health care system needs easier enrollment, more rational program integrity rules, and fewer reporting requirements.

RELATED POLICIES

Our AMA has extensive policy opposing the imposition of inappropriate actions for minor documentation errors by the federal government and private payers. Physicians must be protected from allegations of fraud, waste and abuse, and penalties and sanctions due to the differences in interpretation and or inadvertent errors in coding.³ Moreover, AMA policy directs our AMA to oppose efforts to punish or harass physicians for unintentional errors in Medicare claims submissions and the legitimate exercise of professional judgment in determining medically necessary services.⁴

AMA policy also already directs our AMA to pursue legislative, regulatory, or other avenues to eliminate fines for inadvertent Medicare billing errors⁵ and to remove a physician from a potential review if there is proof that the error is only related to a clerical mistake.⁶ It is also AMA policy that insufficient documentation or inadvertent errors in the patient record do not constitute fraud or abuse⁷ and that there should be no medical documentation requirements for the inclusion of any items unrelated to the care provided.⁸ Furthermore, our AMA policy supports the elimination or improvement on the use of extrapolation in Medicare post-payment audits⁹ including RAC audits.¹⁰

DISCUSSION

Our AMA has strong existing policy (see appendix) regarding the opposing of claim nonpayment for inadvertent, unintentional, or clerical errors. Our AMA is already working with the federal government to reduce administrative burden through regulatory relief efforts including areas involving inadvertent, unintentional, or clerical errors in documentation. Moreover, our AMA has stated multiple times that unnecessary administrative tasks undercut the patient-physician relationship.¹¹ For example, studies have documented lower patient satisfaction when physicians spend more time looking at the computer and performing clerical tasks.¹² Moreover, for every hour of face-to-face time with patients, physicians spend nearly two additional hours on administrative tasks throughout the day.¹³ The

increase in administrative tasks is unsustainable, diverts time and focus away from patient care, and leads to additional stress and burnout among physicians. Furthermore, our AMA has already stated that CMS should review sub-regulatory guidelines, which create additional burdens on physicians, and reduce the number of sub-regulatory guidance documents that are issued.

While our AMA has policies, and has taken action in regard to inadvertent errors, the Board of Trustees believes that AMA policy could be more specific in addressing the concerns surrounding minor wording errors or clinically insignificant inconsistencies and their relationship to potential nonpayment, extrapolation of overpayments, and bundled payment denials. Although the original resolves of Resolution 704-A-18 call for our AMA to “seek through legislation and/or regulation,” the Board of Trustees believes that our AMA should have flexibility in addressing this issue and not be required to only seek reform through legislation or regulation. Instead, in addition to these avenues, our AMA should also be seeking reform through sub-regulatory guidance and other payer policies.

Our AMA believes that eliminating and/or streamlining reporting, monitoring, and documentation requirements will improve the health care delivery system and make the health care system more effective, simple, and accessible. By reducing administrative burden, CMS can support the patient-physician relationship and allow physicians to focus on an individual patient’s welfare and, more broadly, on protecting public health.

RECOMMENDATION:

The Board of Trustees recommends that the following recommendation be adopted in lieu of Resolution 704-A-18 and the remainder of the report be filed:

That our American Medical Association advocate to oppose claim nonpayment, extrapolation of overpayments, and bundled payment denials based on minor wording or clinically insignificant documentation inconsistencies.

REFERENCES

1. E.g., CMS, *Medicare Learning Network Fact Sheet: Complying with Medical Record Documentation Requirements*, (2017), <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/CERTMedRecDoc-FactSheet-ICN909160.pdf>; MSSNY, *Basics of E/M Coding: A Handbook for Physician Offices* (2009), https://www.mssny.org/Documents/2016/Practice%20Resources/Coding_Handbook.doc_6-16-09-Revised_8-14-09-add.pdf.
2. Physicians face pre-payment and postpayment scrutiny from a variety of government entities and contractors including CMS, Medicare Administrative Contractors (MAC), Recovery Audit Contractors (RAC), Unified Program Integrity Contractors (UPIC) (combining program safeguard, zone program integrity, and Medicaid integrity contractors), Quality Improvement Organizations (QIO), Comprehensive Error Rate Testing (CERT), and Supplemental Medical Review Contractors (SMRC).
3. Fraud and Abuse Within the Medicare System, (H-175.981).
4. Kennedy-Kassebaum: Fraud and Abuse, H-175.985.
5. Due Process for Physicians, H-175.982.
6. Expedited Review for Clerical Errors on Medicare Enrollment Applications, D-330.905.
7. Medicare Guidelines for Evaluation and Management Codes, H-70.952.
8. *Id.*
9. Medicare Prepayment and Postpayment Audits, H-330.921; Medical Office Screens, H-335.981.
10. Creating a Fair and Balanced Medicare and Medicaid RAC Program D-320.991.
11. E.g., AMA Letter to CMS, *Medicare and Medicaid Programs: Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction (CMS-3346-P)* (Nov. 19, 2018).
12. Street RL et al., Provider Interaction with the Electronic Health Record: The Effects on Patient-Centered Communication in Medical Encounters. *Patient Educ. Couns.*, 2014; Kazmi Z, Effects of Exam Room EHR Use on Doctor-Patient Communication: A Systematic Literature Review. *Inform Prim Care*, 2013; Farber NJ et al., EHR Use and Patient Satisfaction: What We Learned. *J Fam Pract* 2015.
13. Colligan L, Sinsky C, Goeders L, Schmidt-Bowman M, Tutty M. *Sources of physician satisfaction and dissatisfaction and review of administrative tasks in ambulatory practice: A qualitative analysis of physician and staff interviews*, Oct. 2016.

APPENDIX - AMA POLICIES

Policy H-175.981, “Fraud and Abuse Within the Medicare System”

(1) Our AMA stands firmly committed to eradicate true fraud and abuse from within the Medicare system. Furthermore, the AMA calls upon the DOJ, OIG, and CMS to establish truly effective working relationships where the AMA can effectively assist in identifying, policing, and deterring true fraud and abuse.

(2) Physicians must be protected from allegations of fraud and abuse and criminal and civil penalties and/or sanctions due to differences in interpretation and or inadvertent errors in coding of the E&M documentation guidelines by public or private payers or law enforcement agencies.

(3) The burden of proof for proving fraud and abuse should rest with the government at all times.

(4) Congressional action should be sought to enact a "knowing and willful" standard in the law for civil fraud and abuse penalties as it already applies to criminal fraud and abuse penalties with regard to coding and billing errors and insufficient documentation.

(5) Physicians must be accorded the same due process protections under the Medicare audit system or Department of Justice investigations, that are afforded all US citizens.

Sub. Res. 801, A-98 Reaffirmed: Res. 804, I-98 Reaffirmed: BOT Rep. 6, A-00 Reaffirmation I-01 Modified: CMS Rep. 7, A-11

Policy H-175.982, "Due Process for Physicians"

It is the policy of the AMA to review current legislation governing fraud and abuse investigations and propose additional legislation and/or regulations as necessary and be prepared to take legal action in order to assure physicians due process in the conduct of fraud and abuse investigations.

Our AMA requests the United States Department of Justice to establish a specific procedure for audit of a physician's office records which includes, but is not limited to, the following:

(1) Patient care in the physician's office must not be interrupted during the course of the audit;

(2) Patient ingress and egress must not be hindered during the course of an audit;

(3) Normal telephonic communication must not be interrupted during the course of an audit; and

(4) Normal routine of physician's care of patients in hospital or at home must not be interrupted.

AMA policy is to pursue legislative, regulatory or other avenues to eliminate fines for inadvertent Medicare billing errors.

Sub. Res. 229, I-97 Reaffirmation A-99 Reaffirmation I-00 Reaffirmation I-01 Reaffirmed: Res. 12, A-06 Reaffirmation I-07 Reaffirmed: BOT Rep. 22, A-17

Policy H-175.985, "Kennedy-Kassebaum: Fraud and Abuse"

Our AMA: (1) will work to alleviate the oppressive, burdensome effects on physicians of the Health Insurance Portability and Accountability Act of 1996 (HIPAA);

(2) opposes efforts to repeal provisions in Health Insurance Portability and Accountability Act of 1996 (HIPAA) that would alter the standard of proof in criminal and civil fraud cases or that would eliminate the ability of physicians to obtain advisory opinions regarding anti-kickback issues; and thoroughly evaluate and oppose other fraud and abuse proposals that are inappropriately punitive to physicians;

(3) will ensure that any proposed criminal fraud and abuse proposals retain the current intent standard of "willfully and knowingly" to be actionable fraud; and that the AMA oppose any effort to lower this evidentiary standard;

(4) will vigorously oppose efforts by the Department of Justice to punish and harass physicians for unintentional errors in Medicare claims submissions and the legitimate exercise of professional judgment in determining medically necessary services;

(5) continues its efforts to educate the entire Federation about the AMA's successful amendment of the Health Insurance Portability and Accountability Act (also commonly referred to as the Kassebaum-Kennedy bill) which resulted in language being added so that physicians cannot be prosecuted or fined for inadvertent billing errors, absent an intent to "knowingly and willfully" defraud;

(6) educates the public and government officials about the distinction under the law, between inadvertent billing errors and fraud and abuse; and

(7) responds vigorously to any public statements that fail to distinguish between inadvertent billing errors and fraud and abuse.

Sub. Res. 222, A-97 Appended: Res. 202, I-98 Reaffirmation A-99 Reaffirmation A-01 Reaffirmation I-01 Reaffirmation A-02 Reaffirmed: BOT Rep. 19, A-12

Policy H-175.979, "Medicare "Fraud and Abuse" Update"

Our AMA seeks congressional intervention to halt abusive practices by the federal government and refocus enforcement activities on traditional definitions of fraud rather than inadvertent billing errors.

BOT Rep. 34, I-98 Reaffirmation A-99 Reaffirmation A-00 Reaffirmation I-00 Reaffirmation I-01 Reaffirmed: BOT Rep. 22, A-11

Policy H-70.952, "Medicare Guidelines for Evaluation and Management Codes"

Our AMA (1) seeks Federal regulatory changes to reduce the burden of documentation for evaluation and management services;

(2) will use all available means, including development of new Federal legislation and/or legal measures, if necessary, to ensure appropriate safeguards for physicians, so that insufficient documentation or inadvertent errors in the patient record, that does not meet evaluation and management coding guidelines in and of itself, does not constitute fraud or abuse;

(3) urges CMS to adequately fund Medicare Carrier distribution of any documentation guidelines and provide funding to Carriers to sponsor educational efforts for physicians;

(4) will work to ensure that the additional expense and time involved in complying with documentation requirements be appropriately reflected in the Resource Based Relative Value Scale (RBRVS);

(5) will facilitate review and corrective action regarding the excessive content of the evaluation and management documentation guidelines in collaboration with the national medical specialty societies and to work to suspend implementation of all single system examination guidelines until approved by the national medical specialty societies affected by such guidelines,

(6) continues to advise and educate physicians about the guidelines, any revisions, and their implementation by CMS,

(7) urges CMS to establish a test period in a specific geographic region for these new guidelines to determine any effect their implementation will have on quality patient care, cost effectiveness and efficiency of delivery prior to enforcement of these mandated regulations;

(8) opposes adoption of the Medicare evaluation and management documentation guidelines for inclusion in the CPT; and

(9) AMA policy is that in medical documentation the inclusion of any items unrelated to the care provided (e.g., irrelevant negatives) not be required.

Sub. Res. 801, I-97 Reaffirmation I-00 Reaffirmed: CMS Rep. 6, A-10

Policy D-330.905, "Expedited Review for Clerical Errors on Medicare Enrollment Applications"

1. Our AMA will urge the Centers for Medicare and Medicaid Services (CMS) to create an expedited process to review minor clerical errors on enrollment applications that result in CMS deactivating the physician's billing privileges.

2. Our AMA will urge CMS to remove a physician from a potential fraud and abuse review if there is proof that the error is only related to a clerical mistake.

3. Our AMA will urge CMS to create a process that not only reactivates a physician's billing privileges but also retroactively applies the effective date to the initial date when the minor clerical error occurred and applies no penalty to payments due for care provided to Medicare beneficiaries during this time frame.

Res. 222, A-16

Policy D-320.991, "Creating a Fair and Balanced Medicare and Medicaid RAC Program"

1. Our AMA will continue to monitor Medicare and Medicaid Recovery Audit Contractor (RAC) practices and recovery statistics and continue to encourage the Centers for Medicare and Medicaid Services (CMS) to adopt new regulations which will impose penalties against RACs for abusive practices.

2. Our AMA will continue to encourage CMS to adopt new regulations which require physician review of all medical necessity cases in post-payment audits, as medical necessity is quintessentially a physician determination and judgment.

3. Our AMA will assist states by providing recommendations regarding state implementation of Medicaid RAC rules and regulations in order to lessen confusion among physicians and to ensure that states properly balance the interest in overpayment and underpayment audit corrections for Recovery Contractors.

4. Our AMA will petition CMS to amend CMS' rules governing the use of extrapolation in the RAC audit process, so that the amended CMS rules conform to Section 1893 of the Social Security Act Subsection (f) (3) - Limitation on Use of Extrapolation; and insists that the amended rules state that when an RAC initially contacts a physician, the RAC is not permitted to use extrapolation to determine overpayment amounts to be recovered from that physician by recoupment, offset, or otherwise, unless (as per Section 1893 of the Social Security Act) the Secretary of Health and Human Services has already determined, before the RAC audit, either that (a) previous, routine pre- or post-payment audits of the physician's claims by the Medicare Administrative Contractor have found a sustained or high level of previous payment errors, or that (b) documented educational intervention has failed to correct those payment errors.

5. Our AMA, in coordination with other stakeholders such as the American Hospital Association, will seek to influence Congress to eliminate the current RAC system and ask CMS to consolidate its audit systems into a more balanced, transparent, and fair system, which does not increase administrative burdens on physicians.

6. Our AMA will: (A) seek to influence CMS and Congress to require that a physician, and not a lower level provider, review and approve any RAC claim against physicians or physician-decision making, (B) seek to influence CMS and Congress to allow physicians to be paid any denied claim if appropriate services are rendered, and (C) seek the enactment of fines, penalties and the recovery of costs incurred in defending against RACs whenever an appeal against them is won in order to discourage inappropriate and illegitimate audit work by RACs.

7. Our AMA will advocate for penalties and interest to be imposed on the auditor and payable to the physician when a RAC audit or appeal for a claim has been found in favor of the physician.

Citation: Res. 215, I-11; Appended: Res. 209, A-13; Appended: Res. 229, A-13; Appended: Res. 216, I13; Reaffirmed: Res. 223, I-13

32. IMPACT OF HIGH CAPITAL COSTS OF HOSPITAL EHRs ON THE MEDICAL STAFF

Reference committee hearing: see report of Reference Committee G.

HOUSE ACTION: RECOMMENDATIONS ADOPTED REMAINDER OF REPORT FILED

INTRODUCTION

At the 2018 Annual Meeting Policy D-225.974, “Impact of the High Capital Cost of Hospital EHRs on the Medical Staff,” was adopted by the House of Delegates (HOD). The policy asks the American Medical Association (AMA) to study the long-term economic impact for physicians and hospitals of EHR system procurement, including but not limited to its impact on downsizing of medical staffs and its effect on physician recruitment and retention.

This report provides the requested study of documented economic and financial impacts of procuring electronic health record systems.

BACKGROUND

Electronic health records (EHRs) are an integral part of the vast majority of health care delivery in the United States. In 2017, 99 percent of large, 97 percent of medium, and 93 percent of small rural non-federal hospitals had a certified EHR product in operation.¹ In 2015, the most recent year for which data could be found, 84 percent of non-federal acute care hospitals had at least a basic EHR in operation, and 87 percent of office-based physicians were using an EHR.² The benefits of EHR use are well-documented, however, so are the growing concerns with the amount of time and types of tasks required in using an EHR in practice.^{3, 4} There is also evidence showing the often-burdensome financial investment that implementing and maintaining an EHR system requires. Although there are several studies quantifying the financial investment, the reported costs of EHR implementation vary greatly across studies,^{5, 6} owing most likely to differences in geographic locations, practice size and type, and EHR type. One study estimated EHR implementation in a five-physician practice would cost \$233,297, or \$46,659 per physician, in the first year.⁷ In 2017 some hospitals and health systems reported EHR implementations costing from \$25 million up to \$10 billion.⁸ The differences in practice size and type, EHR type, health information technology (HIT) budgets, specialty, and rural/urban location, make it difficult to accurately quantify costs that are representative across health care practices in the U.S. In addition, the Centers for Medicare & Medicaid Services (CMS) has not updated the practice expense component of the resource-based relative value scale (RBRVS) physician fee schedule in nearly a decade, compounding the lack of valid comparisons and the potential underpayment to physicians for expenses required to maintain a current EHR system. Notwithstanding the challenges in quantifying costs, it is important to consider and understand the long-term impacts of the financial commitment required to implement or upgrade an EHR, including the effects on the physician and clinician workforce.

The financial costs of implementing an EHR system comprise many factors, including software licensing, projected maintenance, fees, and costs for initial and ongoing training and labor. Some hospitals include the salaries of existing HIT staff in their cost estimates. Others may include the costs of hardware such as new computers, tablets or other devices. These costs can add up to millions, and even billions of dollars for the largest purchasers.⁹ Additional costs arise when expenses exceed budgets and when organizations invest in upgrading or optimizing their original EHR system. Other costs, sometimes attributable to EHR implementation, can occur in the form of workforce attrition that happens when organizations cut staff to reduce costs or physicians reduce work hours or leave practice due to frustrations with administrative burden created by EHRs. Despite these challenges, EHRs will continue to be a principal component of health care delivery in the U.S. However, for the technology to be a viable and sustainable solution for practices of all sizes and types, it will be important to know the potential long-term effects the high implementation, optimization, and maintenance costs will have on the ability to sustain existing medical staff and recruit new staff to meet the growing demand of patients’ needs.

AMA POLICY

The AMA has extensive policy supporting the use of EHRs and encouraging stakeholders to implement policies, technology improvements, and utilization standards to minimize the financial burden and maximize efficiency and safety in the use of EHRs.

The AMA is committed to working with Congress and insurance companies to appropriately align incentives as part of the development of a National Health Information Infrastructure, so that the financial burden on physicians is not disproportionate when they implement health care technologies in their offices. The AMA also continues to advocate for and support initiatives that minimize the financial burden to physician practices of adopting and maintaining EHRs (Policy D-478.996, “Information Technology Standards and Costs”). The AMA is working with EHR vendors to promote transparency of actual costs of EHR implementation, maintenance and interface production (Policy D-478.973, “Principles for Hospital Sponsored Electronic Health Records”).

The AMA supports the drive for innovation in the use of EHRs to develop best practices concerning key EHR features that can improve the quality, safety, and efficiency of health care (Policy D-478.976, “Innovation to Improve Usability and Decrease Costs of EHR Systems for Physicians”). In addition, the AMA advocates for 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. The AMA works 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 (Policy D-478.995, “National Health Information Technology”).

It is AMA policy that the cost of installing, maintaining, and upgrading information technology should be specifically acknowledged and addressed in reimbursement schedules, which if represented appropriately would help offset these costs for many practices (Policy H-478.981, “Health Information Technology Principles”). Furthermore, the AMA advocates for inclusion of payment supplements in the current and proposed payment systems specifically to cover the costs of maintaining (including upgrades of) EHRs and continuously evaluates and monitors the cost to physicians and their practices of maintaining and upgrading EHRs (Policy D-478.975, “Maintenance Payments for Electronic Health Records”).

DISCUSSION

Costs of implementing or upgrading an EHR system

The costs associated with implementing and/or optimizing an EHR system have been shown to vary significantly across practices and organizations. This is based on a variety of factors, including but not limited to, practice type and size, infrastructure needs, staffing resources, and maintenance fees. Due to the variability of factors, precise costs are difficult to confirm across practice settings.

Several studies and reports have endeavored to document and estimate the immediate and ongoing costs of EHR implementation. One study estimated EHR implementation for a solo physician in practice to cost \$163,765, inclusive of labor and hardware costs. In the same study, it was estimated EHR implementation in a five-physician practice would cost \$233,297, or \$46,659 per physician, in the first year.⁷ In 2017 some hospitals and health systems reported EHR implementations costing from \$25 million up to \$10 billion.⁸

In conjunction with evaluating the costs of implementation, several studies have also described the cost-benefit analysis of EHRs in various practice settings. A 2003 study of EHR implementation in a primary care practice estimated the net benefit from using an electronic medical record for a five-year period was \$86,400 per provider. Benefits resulted primarily from savings in drug expenditures, improved utilization of radiology tests, better capture of charges, and decreased billing errors. Using a five-way sensitivity analysis that accounted for variables such as proportion of capitated patients, patient panel size, and software and hardware costs, this study showed results ranging from a \$2,300 net cost to a \$330,900 net benefit to the organization. However, among fee-for-service patients, a large portion of the savings from improved utilization may accrue to the payer instead of the provider organization.¹⁰ This study was completed using data from an internally developed EMR at Partners HealthCare, an integrated network formed by Brigham and Women’s Hospital and Massachusetts General Hospital.

Another study found that implementation of EHRs in solo or small practices incurred initial costs of approximately \$44,000 per FTE provider per year, including software, hardware and lost revenue from reduced productivity. Ongoing costs were estimated at \$8,500 per FTE provider per year, including software and hardware maintenance or replacement, and support staff. This study also found the average practice paid for its initial and cumulative ongoing EHR costs within two and a half years, and began to see more than \$23,000 in net benefits per FTE provider per year.

Also of note, participants in this evaluation reported that providers worked longer hours for about four months after implementation, as they became more familiar with the system.¹¹

A 2013 projection of return on investment (ROI) five years after an EHR pilot predicted each physician would lose nearly \$44,000 and only 27% of practices surveyed would achieve a positive ROI. An additional 14% would experience a net gain if they received the federal meaningful use incentive. This analysis revealed the largest difference between practices with a positive return on investment and those with a negative return would be the extent to which they used their EHRs to increase revenue, primarily by seeing more patients per day or by improved billing that resulted in fewer rejected claims and more accurate coding.¹²

A 2014 ROI analysis found that primary care practices recovered their EHR investments within an average period of 10 months. An observed increase in the number of active patients, the increase in the active-patients-to-clinician-FTE ratio, and the increase in the clinic net revenue are positively associated with the EHR implementation, likely contributing substantially to the 10-month average break-even point.¹³

In addition to initial implementation costs, upgrades and optimizations require significant resources, but can help the organization realize cost and time efficiencies. In 2017, 38 percent of health care CIOs indicated “EMR optimization” as their organization’s top item planned for capital investment through 2020.¹⁴ A 2018 case study at a Colorado hospital employed an optimization strategy that saved them between \$300,000 and \$500,000 per year, in addition to a 53 percent increase in cash collections since go-live, a 15 percent decrease in days in accounts receivable, assistance from time-saving tools that automatically track changes to payer rules, authorization management services that free up staff to take on high-value work, and reduced operating costs with transparent pricing that includes upgrades and interfaces.¹⁵

Furthermore, to encourage organizations to adopt HIT technology and specifically EHR systems, the federal government provided incentives to those providers who met “meaningful use” standards through the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009. As of October 2018, CMS reported payments of \$38.4 billion to almost 550,000 Medicare and Medicaid providers, or approximately \$65,000 per provider. The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) sunset the meaningful use program for physicians participating in Medicare. Physicians and hospitals participating in CMS programs now fall under Promoting Interoperability (PI) program requirements.¹⁶ The Quality Payment Program, which replaced the Medicare meaningful use program, sunset the HITECH Act meaningful use incentives. However, PI participants in Medicaid are still eligible for incentive payments through 2021. It should be noted, however, that practices that did not implement an EHR system or were not eligible for the meaningful use program did not receive incentive payments.

Staff/workforce reductions resulting from EHR investment

Many healthcare organizations have reported reductions in workforce over recent years. The reasons for staff reductions vary from lowered reimbursements, realignment towards value-based care, optimizing operational efficiency, and EHR-related costs. Organizations citing workforce reductions related to excessive EHR costs have widely reported layoffs in the areas of general operations, administration, revenue cycle and information technology, not in the positions of direct patient care, such as physicians, advanced practice providers and nursing.¹⁷ In a recent statement from Tenet Healthcare, leadership reported the intent to offshore more than 1,000 jobs, likely in the area of corporate functions. Tenet leadership also expressly stated direct patient care employees, such as physicians and nurses, would not be affected by the change.¹⁸

Reports of workforce reduction or job outsourcing specifically due to investments in EHR technology exist, but are few. For example, in 2015 Lahey Health in Massachusetts lost \$21 million due to both lost business and expenses related to EHR implementation. The shortfall prompted Lahey to lay off 130 people, which their CEO attributed partly to unplanned training expenses connected to the EHR implementation.¹⁹ Also in 2015, Southcoast Hospital reduced its workforce by one percent after expenses related to their EHR implementation exceeded what they budgeted.²⁰

At the end of 2015, Brigham and Women’s Hospital reported lower financial gains than they had originally anticipated with their EHR implementation after falling \$53 million short of the \$121 million expectation. These losses led to the subsequent elimination of 80 open positions and 20 staff members. Hospital president Betsy Nabel, MD, credited this in part to reduced reimbursements from payers, high labor expenses among a largely unionized workforce, and high capital costs, including those related to new facilities and their Epic implementation.²¹ The hospital budgeted \$47

million for its implementation, but faced \$27 million in unexpected costs.²² In 2017, even while finances were improving, Brigham and Women's was still facing a shortfall, forcing them to commit to a \$50 million reduction in operating expenses, including offering a buyout to more than 1,000 senior employees, including nursing staff.²³

In 2017, MD Anderson Cancer Center cut between 800 and 900 administrative positions after experiencing significant losses after EHR implementation. MD Anderson also reported decreased patient revenues resulting from EHR implementation but did not provide details on how the EHR affected patient revenue.²⁴ However, they reported operating margins were net positive at fiscal year-end 2017.²⁵ Wake Forest Baptist Medical Center and Moses Cone Memorial Hospital in North Carolina have both experienced downgraded bond ratings and significant operating losses after implementing EHR systems. They have both also cut staff to make up for these losses.²⁶

EHR implementation was undoubtedly a major factor in the financial circumstances that prompted workforce reductions for these organizations. No one factor can be considered the sole catalyst, however, as other significant costs, such as investments in new facilities, acquisition of other practices, losses on investments, changing reimbursement rates, and increased operational costs contributed to the budget holes that forced these hospitals to take cost-saving measures.²⁷ It is also important to consider that hospitals and health systems reduce workforce for many reasons, including forces entirely separate from EHR implementation, such as changing patient population, specialty mix, or community needs.

Considerable costs, unbudgeted expenses, unforeseen training needs, and lost productivity due to learning curves and unexpected downtime, are all known risks of implementing any new or upgraded EHR.²⁸ Despite these accounts of losses and financial distress, some organizations implement EHRs without issue and the long-term gains outweigh the short term financial losses. It is also of note that the cases described above all involve the same EHR vendor product, therefore generalizing these adverse experiences to all EHRs is not advised.

In addition to staff/workforce reductions driven by budgetary reasons, EHR implementation is transforming the personnel needs and roles for healthcare organizations. A 2016 publication from the North Carolina Medical Journal highlights the need for new jobs to assist before, during, and after EHR implementation, such as technical software support staff, medical scribe specialists, health care quality improvement specialists, and health care data scientists.²⁹ The most common areas of staff reduction due to EHR implementation are in the areas of medical records, transcription, and billing by replacing paper-related processes.^{29,30}

An indirect cost of EHR implementation can be seen in the effects EHRs have on physicians in practice, including increasing administrative burden, reducing face-to-face time with patients, and even prompting reduction in work hours or leaving medicine altogether.³¹ Nearly 40 percent of doctors list EHR design as one of the two things they find least satisfying about their jobs. Fifty-six percent say the requirement has reduced efficiency and 66 percent report EHR use has reduced the amount of time they spend with patients.³² In a 2017 survey, nearly one in five physicians indicated they planned to reduce work hours within the following year. Dissatisfaction with the EHR was an independent predictor of a physician's intent to leave practice or reduce clinical hours.³¹

Effects of EHR investment on the financial state of hospitals

Implementing an EHR system is a significant undertaking for any practice or health care organization. Adequate implementation can be costly and time consuming, resulting in many organizations assuming a financial loss for a duration of time, a factor to be included in the capital planning and budgetary process. Many eligible providers received incentive payments for the adoption and use of EHRs,¹⁶ and the majority of eligible hospitals have demonstrated meaningful use of certified HIT through participation in the EHR incentive program.¹

Common drivers and challenges contribute to the financial impact of EHR implementation. During the implementation process, an increase in overall operational expenses occurs due to training of personnel and the need for additional staff, consultants, and upfront product purchases. During this time, the organization simultaneously experiences a reduction in productivity resulting in decreased patient revenue. In addition to these two factors, some organizations discover they underestimated the full costs of EHR implementation. For example, primary budgeting may only account for the cost reported by the vendor, and the organization does not consider the expenses of staff, training, infrastructure costs, and ongoing maintenance, resulting in significant unexpected costs.

Other areas of additional or unexpected costs include compliance with regulatory requirements, credit challenges, and vendor deficiencies. With the introduction of meaningful use requirements and government incentives, additional costs are often incurred to comply with regulatory requirements.³³ Some hospitals have reported credit challenges in having adequate financial reserves to support the initial capital investment required for implementing an EHR platform.³⁴ Other organizations have cited additional costs due to vendor shortcomings. For example, Mountainview Medical Center in White Sulphur Springs, Montana filed a lawsuit against NextGen for failing to install a compliant system on time.³⁴

As technology advances and regulatory requirements for data collection evolve, EHR implementation and optimization projects are becoming more comprehensive. As a result, many organizations have reported initial financial losses. However, recovery of net operating income and a return to prior productivity levels occur within a short period of time. In 2015 and 2016, Partners HealthCare, the site of the 2003 study previously discussed,¹⁰ implemented a new EHR system. Partners HealthCare reported a decline of \$74.1 million in operating income for the last quarter of 2015 compared to the same quarter the prior year, due in part to the organization's EHR implementation. By the second quarter of 2016, leadership reported gains in operating income, despite simultaneously experiencing costs of \$18 million in EHR-related upgrades and expenses.³⁵

In the first quarter of 2016, Allegheny Health Network reported an operating loss of \$17.8 million due to EHR implementation expenses, \$8.1 million more than the same period in the prior year. In planning, the health system projected \$9.4 million in net losses for the first quarter of the year, yet reported \$20.6 million. Leadership stated that in addition to decreased patient volumes, much of the costs were attributed to a one-time investment in the EHR system.³⁵

While there is evidence that practices have incurred financial losses during EHR implementation and optimization,³⁵ an extensive literature search does not identify an instance of any practice or organization closing or changing their physician recruitment and retention practices specifically due to exorbitant HIT/EHR costs. In addition, there is no requirement for medical staffs to report to a state or national database why a medical staff member decides to resign, nor is there a requirement to report the number of medical staff members and their membership status (e.g., active, courtesy, consulting, emeritus making it further difficult to quantify such effects.

Long-term economic impacts

There are very few studies available about the long-term economic impacts or effects of EHR implementation. One 2015 study attempted to examine financial and clinical work day productivity outcomes associated with the use of an EHR over nine years. The difference in net clinical revenue per provider per year did not change significantly after EHR implementation. Charge capture, the proportion of higher- and lower-level visit codes for new and established patients, and patient visits per provider remained stable, and a total savings of \$188,951 in transcription costs occurred over a 4-year time period post-EHR implementation.³⁶ Another 2014 study evaluated the long-term financial impact of EHR implementation in ambulatory practice. Practice productivity was tracked over two years post-EHR implementation and demonstrated that the implementation was associated with increased revenue, even after accounting for observed reduction in the number of patient visits.³⁷ The AMA inquired with leadership at the American Hospital Association to determine if they had additional research, content, or resources on the subject of EHR cost impacts on hospitals and medical staffs, and they indicated they do not currently have any materials or resources available.

CONCLUSION

It is evident from the literature that the costs, break-even point, and ROI all vary dramatically depending on practice type, size, patient panel, specialty, and location. Given these disparate representations, and the limited amount of recent, rigorous long-term study, it is difficult to establish a universal ROI-focused narrative that makes a case that EHRs are either a wise or poor long-term investment for hospitals or health systems, or any practice type. While there is anecdotal evidence of physicians retiring early due to the implementation costs of EHR's there is little to no data available to assert that investments in EHR technology will lead to subsequent reductions in medical staff. Although EHR investments have contributed to temporary financial losses for some organizations, there are no reports of hospitals or health systems forced to make sweeping reductions in medical staff or completely closing explicitly due to investments in EHR technology. One could speculate that organizations cutting or outsourcing non-direct patient care staff may not be in a financial position to add more physicians to the staff, however there is no data to support

this. Although the impacts of staffing cuts inevitably affect care teams and patients, there is little to no evidence that physicians have been included in the groups of workers laid off by organizations that have made cuts.

A common theme throughout the available literature on cost-benefit analysis is that realizing the benefits and achieving a positive ROI depend heavily on the engagement with and optimization of the EHR as a tool for efficiency and process change. Simply installing the system without proper training and feature customization will slow productivity and create new problems. Partial implementation of an EHR, i.e., the continued use of paper for some record keeping, will inhibit the benefits of implementing an EHR and reduce the total return on investment. Organizational policies that promote EHR-enabled changes, such as EHR-supported clinic workflow, along with more thorough research and planning for the implementation process, could facilitate the realization of positive ROI and reduce the potential need for workforce reduction.

RECOMMENDATION

The Board of Trustees recommends that Policy D-225.974, “Impact of the High Capital Cost of Hospital EHRs on the Medical Staff,” be rescinded as having been fulfilled by this report and that the remainder of this report be filed.

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33. SPECIALTY SOCIETY REPRESENTATION IN THE HOUSE OF DELEGATES: FIVE-YEAR REVIEW

Reference committee hearing: see report of Reference Committee on Amendments to Constitution and Bylaws.

HOUSE ACTION: RECOMMENDATIONS ADOPTED REMAINDER OF REPORT FILED

See Policy D-600.984

The Board of Trustees (BOT) has completed its review of the specialty organizations seated in the House of Delegates (HOD) scheduled to submit information and materials for the 2019 American Medical Association (AMA) Annual Meeting in compliance with the five-year review process established by the House of Delegates in Policy G-600.020, "Summary of Guidelines for Admission to the House of Delegates for Specialty Societies," and AMA Bylaw 8.5, "Periodic Review Process."

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

The following organizations were reviewed for the 2019 Annual Meeting:

- American Association of Gynecologic Laparoscopists
- American Academy of Cosmetic Surgery
- American Association for Thoracic Surgery
- American Association of Plastic Surgeons
- American Association of Public Health Physicians
- American College of Allergy, Asthma and Immunology
- American Society for Aesthetic Plastic Surgery
- American Society for Metabolic and Bariatric Surgery
- American Society of Interventional Pain Physicians
- Association of University Radiologists
- Infectious Diseases Society of America
- International Society for the Advancement of Spine Surgery
- Society of Laparoendoscopic Surgeons

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

The materials submitted indicate that: American Association of Gynecologic Laparoscopists, American Academy of Cosmetic Surgery, American Association for Thoracic Surgery, American Association of Plastic Surgeons, American Association of Public Health Physicians, American College of Allergy, Asthma and Immunology, American Society

for Metabolic and Bariatric Surgery, and the Society of Laparoendoscopic Surgeons meet all guidelines and are in compliance with the five-year review requirements of specialty organizations represented in the HOD.

The materials submitted also indicated that: American Society for Aesthetic Plastic Surgery, American Society of Interventional Pain Physicians, Association of University Radiologists, Infectious Diseases Society of America and the International Society for the Advancement of Spine Surgery did not meet all guidelines and are not in compliance with the five-year review requirements of specialty organizations represented in the HOD.

RECOMMENDATIONS

The Board of Trustees recommends that the following be adopted and the remainder of this report be filed:

1. That American Association of Gynecologic Laparoscopists, American Academy of Cosmetic Surgery, American Association for Thoracic Surgery, American Association of Plastic Surgeons, American Association of Public Health Physicians, American College of Allergy, Asthma and Immunology, American Society for Metabolic and Bariatric Surgery, and the Society of Laparoendoscopic Surgeons retain representation in the American Medical Association House of Delegates.
2. Having failed to meet the requirements for continued representation in the AMA House of Delegates as set forth in AMA Bylaw B-8.50, American Society for Aesthetic Plastic Surgery, American Society of Interventional Pain Physicians, Association of University Radiologists, Infectious Diseases Society of America and the International Society for the Advancement of Spine Surgery be placed on probation and be given one year to work with AMA membership staff to increase their AMA membership.

APPENDIX

Exhibit A - Summary Membership Information

Organization	AMA Membership of Organization's Total Eligible Membership
American Association of Gynecologic Laparoscopists	1,571 of 4,046 (39%)
American Academy of Cosmetic Surgery	319 of 901 (35%)
American Association for Thoracic Surgery	226 of 959 (24%)
American Association of Plastic Surgeons	193 of 801 (24%)
American Association of Public Health Physicians	48 of 81 (59%)
American College of Allergy, Asthma and Immunology	544 of 2068 (26%)
American Society for Aesthetic Plastic Surgery	341 of 1,894 (18%)
American Society for Metabolic and Bariatric Surgery	271 of 1,390 (20%)
American Society of Interventional Pain Physicians	701 of 3,616 (19%)
Association of University Radiologists	147 of 836 (18%)
Infectious Diseases Society of America	537 of 3,950 (14%)
International Society for the Advancement of Spine Surgery	55 of 235 (23%)
Society of Laparoendoscopic Surgeons	985 of 2,548 (39%)

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

1. The organization must not be in conflict with the Constitution and Bylaws of the American Medical Association with regard to discrimination in membership.
2. The organization must:
 - (a) represent a field of medicine that has recognized scientific validity;
 - (b) not have board certification as its primary focus; and
 - (c) not require membership in the specialty organization as a requisite for board certification.
3. The organization must meet one of the following criteria:
 - (a) a specialty organization must demonstrate that it has 1,000 or more AMA members; or
 - (b) a specialty organization must demonstrate that it has a minimum of 100 AMA members and that twenty percent (20%) of its physician members who are eligible for AMA membership are members of the AMA; or
 - (c) a specialty organization must demonstrate that it was represented in the House of Delegates at the 1990 Annual Meeting and that twenty percent (20%) of its physician members who are eligible for AMA membership are members of the AMA.

4. The organization must be established and stable; therefore it must have been in existence for at least five years prior to submitting its application.
5. Physicians should comprise the majority of the voting membership of the organization.
6. The organization must have a voluntary membership and must report as members only those who are current in payment of dues, have full voting privileges, and are eligible to hold office.
7. The organization must be active within its field of medicine and hold at least one meeting of its members per year.
8. The organization must be national in scope. It must not restrict its membership geographically and must have members from a majority of the states.
9. The organization must submit a resolution or other official statement to show that the request is approved by the governing body of the organization.
10. If international, the organization must have a US branch or chapter, and this chapter must be reviewed in terms of all of the above guidelines.

Exhibit C

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

- 8.2.1** To cooperate with the AMA in increasing its AMA membership.
- 8.2.2** To keep its delegate(s) to the House of Delegates fully informed on the policy positions of the society or association so that the delegates can properly represent the society or association in the House of Delegates.
- 8.2.3** To require its delegate(s) to report to the society on the actions taken by the House of Delegates at each meeting.
- 8.2.4** To disseminate to its membership information as to the actions taken by the House of Delegates at each meeting.
- 8.2.5** To provide information and data to the AMA when requested.

Exhibit D – AMA Bylaws on Specialty Society Periodic Review

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

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

- 8.5.1** If a specialty society or a professional interest medical association fails or refuses to provide the information and data requested by the SSS for the review process, so that the SSS is unable to conduct the review process, the SSS shall so report to the House of Delegates through the Board of Trustees. In response to such report, the House of Delegates may terminate the representation of the specialty society or the professional interest medical association in the House of Delegates by majority vote of delegates present and voting, or may take such other action as it deems appropriate.
- 8.5.2** If the SSS report of the review process finds the specialty society or the professional interest medical association to be in noncompliance with the current guidelines for representation in the House of Delegates or the responsibilities under Bylaw 8.2, the specialty society or the professional interest medical association will have a grace period of one year to bring itself into compliance.
- 8.5.3** Another review of the specialty society's or the professional interest medical association's compliance with the current guidelines for representation in the House of Delegates and the responsibilities under Bylaw 8.2 will then be conducted, and the SSS will submit a report to the House of Delegates through the Board of Trustees at the end of the one-year grace period.
 - 8.5.3.1** If the specialty society or the professional interest medical association is then found to be in compliance with the current guidelines for representation in the House of Delegates and the responsibilities under Bylaw 8.2, the specialty society or the professional interest medical association will continue to be represented in the House of Delegates and the current review process is completed.
 - 8.5.3.2** If the specialty society or the professional interest medical association is then found to be in noncompliance with the current guidelines for representation in the House of Delegates, or the responsibilities under Bylaw 8.2, the House may take one of the following actions:

- 8.5.3.2.1** The House of Delegates may continue the representation of the specialty society or the professional interest medical association in the House of Delegates, in which case the result will be the same as in Bylaw 8.5.3.1.
- 8.5.3.2.2** The House of Delegates may terminate the representation of the specialty society or the professional interest medical association in the House of Delegates. The specialty society or the professional interest medical association shall remain a member of the SSS, pursuant to the provisions of the Standing Rules of the SSS. The specialty society or the professional interest medical association may apply for reinstatement in the House of Delegates, through the SSS, when it believes it can comply with all of the current guidelines for representation in the House of Delegates.

REPORT OF THE SPEAKERS

The following report was presented by Susan R. Bailey, MD, Speaker; and Bruce A. Scott, Vice Speaker:

1. RECOMMENDATIONS FOR POLICY RECONCILIATION

Informational report; no reference committee hearing.

HOUSE ACTION: **FILED**

RECOMMENDED ACTIONS ACCOMPLISHED

Policy G-600.111, "Consolidation and Reconciliation of AMA Policy," calls on your Speakers to "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 to deal with policies, or portions of policies, that are no longer relevant or that were affected by actions taken at the recent meetings of the House of Delegates. Suggestions on other policy statements that your Speakers might address should be sent to hod@ama-assn.org for possible action. Where changes to policy language will be made, additions are shown with underscore and deletions are shown with strikethrough.

RECOMMENDED RECONCILIATIONS

Policies to be rescinded in their entirety

The following directives will be rescinded in full, as the requested activity has been completed, with reports presented to the House of Delegates when required.

- D-615.978, "Creation of LGBTQ Health Specialty Section Council" (to be rescinded)
Our AMA will establish a Specialty Section Council on LGBTQ Health.

This directive can be rescinded as the action has been accomplished. The glossary to the AMA Bylaws along with other documents, such as website and HOD Reference Manual note the newly established Specialty Section Council on LGBTQ Health.

- D-620.988, "Analysis of American Board of Internal Medicine (ABIM) Finances" (to be rescinded)
 1. Our AMA, prior to the end of December 2016, will formally, directly and openly ask the American Board of Internal Medicine (ABIM) if they would allow an independent outside organization, representing ABIM physician stakeholders, to independently conduct an open audit of the finances of both the American Board of Internal Medicine (ABIM), a 501(c)(3) tax-exempt, non-profit organization, and its Foundation.
 2. In its request, our AMA will seek a formal and rapid reply from the ABIM so that issues of concern that currently exist between the ABIM and its Foundation and many members of the AMA and the physician community at large can be addressed in a timely, effective and efficient fashion.
 3. Our AMA will share the response to this request, as well as the results of any subsequent analysis, with our AMA House of Delegates and our membership at large as soon as it is available.
 4. Our AMA will call on the American Board of Medical Specialties and its component specialty boards to provide the physicians of America with financial transparency, independent financial audits and enhanced mechanisms for communication with and feedback from their diplomate physicians.

This directive was acted on in December 2016, immediately after the policy was adopted at the 2016 Interim Meeting. The American Board of Internal Medicine's verbatim responses to the questions were shared with the House in an email from your Speakers on January 23, 2017.

Policy H-515.975, "Alcohol, Drugs, and Family Violence" has been incorporated word for word into Policy H-515.965, "Family and Intimate Partner Violence," and is therefore redundant. The former will be rescinded, the latter retained.

- H-515.975, “Alcohol, Drugs, and Family Violence” (to be rescinded)
Given the association between alcohol and family violence, physicians should be alert to look for the presence of one behavior given a diagnosis of the other. Thus, a physician with patients with alcohol problems should screen for family violence, while physicians with patients presenting with problems of physical or sexual abuse, should screen for alcohol use. (2) Physicians should avoid the assumption that if they treat the problem of alcohol or substance use and abuse they also will be treating and possibly preventing family violence. (3) Physicians should be alert to the association, especially among female patients, between current alcohol or drug problems and a history of physical, emotional, or sexual abuse. The association is strong enough to warrant complete screening for past or present physical, emotional, or sexual abuse among patients who present with alcohol or drug problems.

H-515.965, “Family and Intimate Partner Violence” (to be retained)

...

- (6) Substance abuse and family violence are clearly connected. For this reason, our AMA believes that:
 - (a) Given the association between alcohol and family violence, physicians should be alert for the presence of one behavior given a diagnosis of the other. Thus, a physician with patients with alcohol problems should screen for family violence, while physicians with patients presenting with problems of physical or sexual abuse should screen for alcohol use.
 - (b) Physicians should avoid the assumption that if they treat the problem of alcohol or substance use and abuse they also will be treating and possibly preventing family violence.
 - (c) Physicians should be alert to the association, especially among female patients, between current alcohol or drug problems and a history of physical, emotional, or sexual abuse. The association is strong enough to warrant complete screening for past or present physical, emotional, or sexual abuse among patients who present with alcohol or drug problems.

Policies dealing with the AMA-convened Physician Consortium for Performance Improvement® (AMA-PCPI®)

Several policies deal with the AMA-PCPI which was initially established as a program of the AMA. The AMA-PCPI ceased all activities upon activation of an independent 501(c)(3) organization, the PCPI Foundation® (PCPI®). Consequently, some policies should be rescinded and others amended to clarify these changes and our AMA's role in the successor organization. Policies D-450.983 and D-478.974 should be rescinded as they no longer accurately reflect our AMA's roles and responsibilities. The latter policy also references activity that was concluded years ago.

- D-450.983, “Expansion of Scope of Activities of AMA Physician Consortium for Performance Improvement” (to be rescinded)
Our AMA will:
 - (1) expand the AMA Physician Consortium for Performance Improvement (Consortium) to include representatives from all national medical specialty societies and state medical societies who wish to participate;
 - (2) expand the scope of the Consortium to include development of clinical performance measures, validation of clinical performance measures, and direction on appropriate implementation of clinical performance measures;
 - (3) study and prepare a report to clarify the role and authority of the National Quality Forum and identify pathways that may allow the Consortium and physicians to have greater influence in the validation of clinical performance measures;
 - (4) continue to advocate for the AMA-convened Physician Consortium for Performance Improvement (PCPI) as a leading measure development organization that addresses measures of underuse, overuse, and appropriateness;
 - (5) continue to engage with the national medical specialty society members of the PCPI to identify topics to expand the PCPI portfolio of quality measures addressing, in particular, overuse and appropriateness;
 - (6) engage national medical specialty societies who are leaders with the PCPI in developing measures of overuse and appropriateness to submit editorials and distribute society member communications announcing the availability and importance of these measures developed by the profession;
 - (7) continue to seek opportunities to align measures of quality with measures of cost; and
 - (8) ensure that the PCPI provides opportunities for active involvement by all affected specialties in the measure development and approval process.

- D-478.974, “Quality Improvement in Clinical / Population Health Information Systems” (to be rescinded)
Our American Medical Association will invite other expert physician associations into the AMA consortium to further the quality improvement of electronic health records and population health as discussed in the consortium letter of January 21, 2015 to the National Coordinator of Health Information Technology.

Obsolete references to be deleted from PCPI-related policies

The following two policies require minor changes to reflect our AMA’s role in PCPI as well as the organization’s name. Other, more substantive changes to the policies would need to be addressed through other vehicles. Renumbering of paragraphs will be accomplished as necessary. Only the relevant portion of Policy H-406.990 is quoted below.

- H-406.990, “Work of the Task Force on the Release of Physician Data”
Release of Claims and Payment Data from Governmental Programs

The AMA encourages the use of physician data to benefit both patients and physicians and to improve the quality of patient care and the efficient use of resources in the delivery of health care services. The AMA supports this use of physician data only when it preserves access to health care and is used to provide accurate physician performance assessments.

...

- (c) any physician profiling which draws upon this raw data acknowledges that the data set is not representative of the physicians' entire patient population and uses a methodology that ensures the following:
 - (i) the data are used to profile physicians based on quality of care provided - never on utilization of resources alone - and the degree to which profiling is based on utilization of resources is clearly identified.
 - (ii) data are measured against evidence-based quality of care measures, created by physicians across appropriate specialties, ~~such as the PCPI-AMA convened Physician Consortium for Performance Improvement~~....
- D-450.978, “~~PCPI Physician Consortium for Performance Improvement~~; Unfunded Performance Improvement Projects”
Our AMA will:
 - (1) ~~continue to expand the Physician Consortium for Performance Improvement (Consortium), inviting all medical societies in the AMA House of Delegates to participate;~~
 - (2) continue to promote the ~~PCPI® Consortium~~ as the leading resource for performance measures development and maintenance;
 - (3) continue to advocate for appropriate implementation of performance measures;
 - (4) continue to encourage the testing and evaluation of ~~PCPI Consortium~~ measures by appropriate entities;
 - (5) continue to communicate organized medicine's strong objections to implementation of mandatory, unfunded performance improvement projects and offer our assistance to rectify deficiencies in these programs;
 - (6) continue to promote the AMA guidelines that provide operational boundaries that can be applied to specific components of pay-for-performance programs; and
 - (7) monitor the ~~newly established~~ National Quality Forum, a merger of the National Quality Forum and the National Committee for Quality Health Care, to determine its current and future scope.

The changes outlined above do not reset the sunset clock and will be implemented when this report is filed.