

Reference Committee B

BOT Report(s)

- 09 Council on Legislation Sunset Review of 2009 House Policies
- 14 Reforming the Orphan Drug Act; An Optional National Prescription Drug Formulary; Reform of Pharmaceutical Pricing: Negotiated Payment Schedules
- 17 Ban on Medicare Advantage "No Cause" Network Terminations
- 18 Increased Use of Body-Worn Cameras by Law Enforcement Officers
- 19 FDA Conflict of Interest
- 20 Safe and Efficient E-Prescribing
- 21 Augmented Intelligence in Health Care
- 22 Inappropriate Use of CDC Guidelines for Prescribing Opioids
- 23 Prior Authorization Requirements for Post-Operative Opioids
- 30 Opioid Treatment Programs Reporting to Prescription Monitoring Programs

Resolution(s)

- 201 Assuring Patient Access to Kidney Transplantation
- 202 Reducing the Hassle Factor in Quality Improvement Programs
- 203 Medicare Part B and Part D Drug Price Negotiation
- 204 Holding the Pharmaceutical Industry Accountable for Opioid-Related Costs
- 205 Use of Patient or Co-Worker Experience/Satisfaction Surveys Tied to Employed Physician Salary
- 206 Changing the Paradigm: Opposing Present and Obvious Restraint of Trade
- 207 Direct-to-Consumer Genetic Tests
- 208 Repeal or Modification of the Sunshine Act
- 209 Mandates by ACOs Regarding Specific EMR Use
- 210 Air Ambulances
- 211 Use of FAIR Health
- 212 Pharmacy Benefit Managers
- 213 Financial Penalties and Clinical Decision-Making
- 214 The Term Physician
- 215 Reimbursement for Health Information Technology
- 216 Eliminate the Word Provider from Healthcare Contracts
- 217 Medicare Vaccine Billing
- 218 Payment for Medications Used Off Label for Treatment of Pain
- 219 Medical Marijuana License Safety
- 220 Study of Confidentiality and Privacy Protection in the Treatment of Substance Disorders
- 221 Extending Medicaid Coverage to 12-Months Postpartum
- 222 Protecting Patients from Misleading and Potentially Harmful "Bad Drug" Ads
- 223 Simplification and Clarification of Smoking Status Documentation in the Electronic Health Record
- 224 Extending Pregnancy Medicaid to One Year Postpartum
- 225 DACA in GME
- 226 Physician Access to Their Medical and Billing Records
- 227 Controlled Substance Management
- 228 Truth in Advertising
- 229 Clarification of CDC Opioid Prescribing Guidelines

REPORT OF THE BOARD OF TRUSTEES

B of T Report 9-A-19

Subject: Council on Legislation Sunset Review of 2009 House Policies

Presented by: Jack Resneck, Jr., MD, Chair

Referred to: Reference Committee B
(Charles Rothberg, MD, Chair)

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.
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 <u>physicians in private practice 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.

Policy Number	Title	Text	Recommendation
D-330.993	Explanation of Public-Private Partnerships that Exist between Government and the AMA	<p>Our AMA: (1) continues to employ a variety of tactics to advocate CMS adoption of AMA policy positions;</p> <p>(2) continues to work cooperatively with CMS, when possible, to achieve its policy objectives;</p> <p>(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</p> <p>(4) use appropriate legal means, including suing CMS, when appropriate and warranted.</p> <p>Citation: (BOT Rep. 17, A-99; Reaffirmed: CLRPD Rep. 1, A-09)</p>	Retain. This policy remains relevant.
D-385.965	Insurance Companies Use of Contractors to Recover Payments	<p>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.</p> <p>(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.</p> <p>(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.</p> <p>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.</p> <p>Citation: (Res. 215, A-09)</p>	Retain. This policy is remains relevant.
D-435.973	Quantifying Medical Tort Reform	<p>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.</p> <p>Citation: (Res. 216, I-09)</p>	Rescind. Policy is implemented. AMA on an annual basis publicly issues MLR Now!, which includes costs of defensive medicine, financial impact, and state and federal efforts in liability reform.

Policy Number	Title	Text	Recommendation
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	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	Retain. This policy is remains relevant.

Policy Number	Title	Text	Recommendation
		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. Citation: (Res. 227, A-09; Reaffirmation I-09)	
D-65.993	Pain and Suffering in Darfur	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) our concerns related to 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 medical services as a weapon of war, as has occurred in Darfur and Sri Lanka, 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)	Rescind. This directive has been accomplished.
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.

Policy Number	Title	Text	Recommendation
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

Policy Number	Title	Text	Recommendation
			and ambulance providers for emergency health services provided to undocumented aliens and certain other specified aliens. The funding 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.	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

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		Citation: (BOT Rep. 17, I-98; Reaffirmed: BOT Rep. 23, A-09)	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. Citation: (Res. 623, A-96; Reaffirmation A-99; Reaffirmed: CLRPD Rep. 1, A-09)	Retain. This policy remains relevant.
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	Retain. This policy remains relevant.

Policy Number	Title	Text	Recommendation
		<p>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.</p> <p>Citation: (Res. 716, A-98; Reaffirmation A-99; Reaffirmed: BOT Rep. 23, A-09)</p>	
H-30.977	Alcoholism as a Disease	<p>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.</p> <p>Citation: (Res. 112, A-88; Reaffirmed: Sunset Report, I-98; Reaffirmed: BOT Rep. 23, A-09)</p>	Retain. This policy remains relevant.
H-315.986	Confidentiality of Patient Records	<p>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.</p> <p>Citation: (Res. 243, I-94; Appended: Res 231, I-97; Reaffirmation I-98; Reaffirmation I-99; Reaffirmed: CEJA Rep. 8, A-09)</p>	Retain. This policy remains relevant.
H-330.986	Physician ("Doctors") Services Costs as Reported by HHS and Medicare	<p>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.</p> <p>Citation: (Res. 71, A-88; Reaffirmed: Sunset Report, I-98; Reaffirmation I-99; Reaffirmation A-02; Reaffirmation I-09)</p>	Retain. This policy remains relevant.
H-335.991	Medical Necessity Denial Screens	<p>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.</p>	Retain. This policy remains relevant.

Policy Number	Title	Text	Recommendation
		Citation: (Res. 272, A-89; Reaffirmed: Res. 239, A-99; Reaffirmed: BOT Rep. 23, A-09)	
H-340.898	Medicare Review Activities: Peer Review Organization Sixth Scope of Work, Medicare Integrity Program, and Carrier Post-Payment Audit Processes	<p>Our AMA: (1) strongly urges CMS to provide physician organizations with the opportunity for significant comment and input <u>in on the development of Medicare Integrity Program task orders before they are implemented</u>;</p> <p>(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;</p> <p>(3) continues to advocate for the ongoing involvement of physician organizations and hospital and organized medical staffs in refining and implementing <u>any Medicare review contractor’s activities the Medicare Peer Review Organization (PRO) Sixth Scope of Work, especially the Payment Error Prevention Program</u>, 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 from the Payment Error Prevention Program in the Medicare PRO Sixth Scope of Work</u>; and</p> <p>(5) urges CMS to clarify <u>that in any Statement of Work or contract with a Medicare review contractor the PRO Sixth Scope of Work</u> 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>	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
H-340.928	Quality Improvement Organization Physician Advisory Confidentiality	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. Citation: (Sub. Res. 200, A-91; Reaffirmation A-99; Modified and Reaffirmed: CMS Rep. 5, A-09)	Retain. This policy remains relevant.
H-345.989	Psychologist Prescribing	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.. Citation: (Sub. Res. 214, A-89; Res. 204, A-97; Reaffirmation A-99; Reaffirmed: CMS Rep. 5, A-09)	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	Our AMA will: (1) continue to work with the Federation in developing necessary state advocacy resource tools to assist the Federation in: (a) addressing the development of practice agreements between practicing physicians and advance practice nurses, and (b) responding to or developing state legislation or regulations governing these practice agreements, and that the AMA make these tools available on the AMA Advocacy Resource Center Web site; and (2) support the development of methodologically valid research comparing physician-APRN practice agreements and their respective effectiveness. Citation: (BOT Rep. 28, A-09)	Retain. This policy remains relevant.

Policy Number	Title	Text	Recommendation
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 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.</p> <p>Citation: (Res. 213, A-98; Reaffirmed: BOT Rep. 23, A-09)</p>	Retain in part. The reference to the letter is no longer relevant.
H-360.985	Performance of Diagnostic X-Rays by Nurses Without Physician Supervision	<p>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.</p> <p>Citation: (Res. 201, I-99; Reaffirmed: CMS Rep. 5, A-09)</p>	Retain. This policy remains relevant.
H-383.991	Right to Privately Contract	<p>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.</p> <p>Citation: (Res. 203, A-09)</p>	Retain. This policy remains relevant.
H-385.969	Assistants at Surgery	<p>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</p>	Retain. This policy remains relevant.

Policy Number	Title	Text	Recommendation
		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)	
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 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)	Retain. This policy remains relevant.

Policy Number	Title	Text	Recommendation
H-405.997	Physician-Patient Relationship	<p>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.</p> <p>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)</p>	Retain. This policy remains relevant.
H-406.990	Work of the Task Force on the Release of Physician Data	<p>Release of Claims and Payment Data from Governmental Programs</p> <p>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.</p> <p>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.</p> <p>Raw claims and payment data resulting from government health care programs, including, but not limited to, the Medicare</p>	<p>Retain. This policy remains relevant.</p> <p>[Note: grammatical correction—delete the word “the” before the word “their” in the last sentence.]</p>

Policy Number	Title	Text	Recommendation
		<p>and Medicaid programs should only be released:</p> <ol style="list-style-type: none"> 1, when appropriate patient privacy is preserved via de-identified data aggregation or if written authorization for release of individually identifiable patient data has been obtained from such patient in accordance with the requirements of the Health Insurance Portability and Accountability Act (HIPAA) and applicable regulations; 2. upon request of physicians [or their practice entities] to the extent the data involve services that they have provided; 3. to law enforcement and other regulatory agencies when there is reasonable and credible reason to believe that a specific physician [or practice entity] may have violated a law or regulation, and the data is relevant to the agency's investigation or prosecution of a possible violation; 4. to researchers/policy analysts for bona fide research/policy analysis purposes, provided the data do not identify specific physicians [or their practice entities] unless the researcher or policy analyst has (a) made a specific showing as to why the disclosure of specific identities is essential; and, (b) executed a written agreement to maintain the confidentiality of any data identifying specific physicians [or their practice entities]; 5. to other entities only if the data do not identify specific physicians [or their practice entities]; or 6. if a law is enacted that permits the government to release raw physician-specific Medicare and/or Medicaid claims data, or allows the use of such data to construct profiles of identified physicians or physician practices. Such disclosures must meet the following criteria: <ol style="list-style-type: none"> (a) the publication or release of this information is deemed imperative to safeguard the public welfare; (b) the raw data regarding physician claims from governmental healthcare programs is: <ol style="list-style-type: none"> (i) published in conjunction with appropriate disclosures and/or explanatory 	

Policy Number	Title	Text	Recommendation
		<p>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</p>	

Policy Number	Title	Text	Recommendation
		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. Citation: (BOT Rep. 18, A-09)	
H-415.98	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.

Policy Number	Title	Text	Recommendation
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.

REPORT OF THE BOARD OF TRUSTEES

B of T Report 14-A-19

Subject: 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)

Presented by: Jack Resneck, Jr., MD, Chair

Referred to: Reference Committee B
 (Charles Rothberg, MD, Chair)

1 At the 2018 Annual Meeting, the American Medical Association’s (AMA) House of Delegates
2 (HOD) referred three resolutions for a combined Board of Trustees (BOT) Report (Report) at the
3 2019 Annual Meeting. The first resolution, Resolution 217-A-18, “Reforming the Orphan Drug
4 Act,” was introduced by the Medical Student Section and asks that:

5
6 Our AMA: (1) support efforts to reform the Orphan Drug Act (ODA) by closing loopholes
7 identified by the Food and Drug Administration [(FDA)] in order to protect the Act’s original
8 intent of promoting therapies targeting rare diseases; (2) support increased transparency in
9 development costs, post-approval regulation and overall earnings for pharmaceuticals
10 designated as “Orphan Drugs” and (3) support modifications to the exclusivity period of
11 “Orphan Drugs” to increase access to these pharmaceutical drugs for patients with rare
12 diseases.

13
14 The second resolution, Resolution 227-A-18, “An Optional National Prescription Drug
15 Formulary,” was introduced by the Florida Delegation and asks that:

16
17 Our AMA: (1) develop a set of principles for a National Prescription Drug Formulary (NPD
18 Formulary) that are designed to lower prescription drug prices to the patient, and be
19 transparent, independent, non-profit, and fee-based, with a report back to the AMA HOD at the
20 2018 Interim Meeting; (2) produce model legislation for an NPD Formulary with input from
21 appropriate stakeholders based on a set of principles for such a Formulary that the AMA will
22 develop; and (3) that our AMA join with appropriate stakeholders to advocate that Congress
23 authorize the establishment of this NPD Formulary that will be available to all Americans as an
24 option to their healthcare insurance program in an actuarially appropriate manner.

25
26 The third resolution, Resolution 238-A-18, “Reform of Pharmaceutical Pricing: Negotiated
27 Payment Schedules,” was introduced by the Illinois Delegation and asks that:

28
29 Our AMA: (1) support federal legislation that modifies the Hatch-Waxman Act and the
30 Biologics Price Competition and Innovation Act (Biosimilars Act) to institute the replacement
31 of time-specific patent protections with negotiated payment schedules and indefinite

1 exclusivity for U.S. Food and Drug Administration-approved drugs in the Medicare Part D
2 Program.
3

4 The reference committee heard varying testimony on Resolutions 217, 227, and 238. There was
5 testimony providing strong support for the current strategic focus of AMA advocacy and initiatives
6 to increase market competition as well as increased transparency of cost and price along the
7 pharmaceutical supply chain. There was testimony in response to Resolution 217 noting that
8 incentives are needed to support innovation in drug development for rare diseases and general
9 support for the intent of the ODA, but there was concern that manufacturers are manipulating ODA
10 exclusivities and may be driving higher drug costs to vulnerable patient populations. The reference
11 committee heard testimony on Resolution 227 that a new national not-for-profit pharmaceutical
12 benefit manager (which is referred to in the resolution as a national formulary) would not
13 necessarily promote innovation and competition and could substantially limit patient access to
14 medically necessary options. The reference committee heard testimony on Resolution 238 that it
15 did not accurately identify the federal laws that would have to be amended in order to institute the
16 replacement of time-specific patent protections with negotiated payment schedules and indefinite
17 exclusivity for FDA-approved drugs in the Medicare Part D benefit prescription drug program.
18 Testimony was offered noting it would require marked changes to the U.S. Patent Act, the U.S.
19 Food, Drug, and Cosmetic Act (FDCA), and the Social Security Act (SSA). Furthermore,
20 testimony was offered that such changes could limit patient access to clinically necessary
21 alternative options and depress innovation while interjecting significant confusion and complexity
22 in the patent system and the FDA regulatory regime. The reference committee found that all three
23 resolutions are either a potentially complex solution to address the high cost of prescription drugs,
24 or too narrowly crafted. Given these concerns, the reference committee recommended referral for a
25 consolidated report.
26

27 AMA STRATEGIC FOCUS: INCREASING TRANSPARENCY AND COMPETITION 28

29 The varied contributing causes fueling the rise in prescription medication prices and the
30 proliferation in barriers faced by patients who need medically necessary medication have resulted
31 in the HOD adopting a wide-range of policies concerning prescription medication affordability and
32 access. In order to prioritize impactful and viable policies that would enable the AMA to
33 effectively advocate at the federal and state levels, Policy H-110.987, "Pharmaceutical Costs,"
34 adopted in 2015 directed the AMA to convene a task force of appropriate AMA Councils, state
35 medical societies, and national medical specialty societies to develop principles to guide advocacy
36 and grassroots efforts aimed at addressing pharmaceutical costs and improving patient access and
37 adherence to medically necessary prescription drug regimens. Accordingly, the AMA convened a
38 Task Force on Pharmaceutical Costs, which met four times in the first six months of 2016 to
39 develop principles to guide advocacy and grassroots efforts aimed at addressing pharmaceutical
40 costs. The Task Force agreed that increasing transparency among pharmaceutical companies,
41 health plans, and pharmacy benefit managers (PBMs) should be the initial focus of the campaign,
42 which led to the launch of a grassroots campaign in the third quarter of 2016, and the launch of the
43 TruthinRx website, TruthinRx.org, on November 1, 2016. The foregoing was done in concert with
44 the AMA's long-standing advocacy to increase competition. Based on the foregoing the AMA has
45 vigorously supported the focus of policymakers at the federal and state levels to address
46 pharmaceutical supply chain transparency and accelerated and expanded legislative and regulatory
47 action to increase pharmaceutical market competition by, among other things, combating anti-
48 competitive practices.

Increase Pharmaceutical Market Competition and Combat Anticompetitive Practices

Polymakers 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

1 manufacturers to publicly disclose a variety of information, which could include research and
 2 development costs, expenditures on clinical trials, total costs incurred in production, and marketing
 3 and advertising costs; (3) requiring PBMs to apply manufacturer rebates and pharmacy price
 4 concessions to drug prices at the point-of-sale to ensure that patients benefit from discounts as well
 5 as eliminate some incentives for higher drug list prices; (4) requiring insurers to provide increased
 6 transparency in formularies, prescription drug cost-sharing, and utilization management
 7 requirements for patients and physicians at the point-of-prescribing as well as when beneficiaries
 8 make annual enrollment elections; and (5) prohibiting removal of drugs from a formulary or
 9 moving to a higher cost tier during the duration of the patient's plan year unless a change is made
 10 for safety reasons.

11 12 AMA POLICY

13
 14 The AMA has extensive policy relevant to the issues raised in all three resolutions. In general, the
 15 AMA opposes the use of price controls in any segment of the health care industry, and continues to
 16 promote market-based strategies to achieve access to and affordability of health care goods and
 17 services (Policy H-155.962, "Maximum Allowable Cost of Prescription Medications").¹ The AMA
 18 has adopted comprehensive policy to address anti-competitive measures by manufacturers and to
 19 promote increased cost and price transparency (Policy H-110.987, "Pharmaceutical Costs"). AMA
 20 policy provides support for action by federal agencies to address manufacturer price gouging.
 21 AMA policy also outlines support for the FTC in its efforts to stop "pay for delay" arrangements by
 22 pharmaceutical companies and federal legislation to expand the FTC's existing authorities to stop
 23 such arrangements (Policy H-110.989, "Pay for Delay Arrangement by Pharmaceutical
 24 Companies"). The AMA also supports FDA implementation of the biosimilar pathway established
 25 under the Biologics Price Competition and Innovation Act of 2009 in order to ensure patient
 26 access, protect patient safety, and preserve market competition and innovation (Policy H-125.980,
 27 "Abbreviated Pathway for Biosimilar Approval").
 28

29 In support of driving increased competition, AMA policy provides for ongoing evaluation of
 30 strategies by manufacturers to extend the patent life of pharmaceuticals, and to work with Congress
 31 and the Administration where such actions are pursued for anti-competitive purposes (Policy D-
 32 110.994, "Inappropriate Extension of Patent Life of Pharmaceuticals"). The AMA also continues to
 33 advocate that the FDA and Congress ascertain the pervasiveness of brand manufacturers forcing
 34 switching from an established drug formulation about to lose market exclusivity and patent
 35 protection to another formulation that retains such protections. This practice is called evergreening
 36 and AMA policy provides that a balance must be struck between incentivizing innovation (superior
 37 formulations) versus anti-competitive practices designed to slow generic competition (Policy H-
 38 125.978, "Patient Protection from Forced Switching of Patent-Protected Drugs"). AMA policy also
 39 provides that physicians who develop medical innovations may ethically patent their discoveries or
 40 products but should uphold the following guidelines: (a) Not use patents (or other means, such as
 41 trade secrets or confidentiality agreements) to limit the availability of medical innovations and
 42 patent protection should not hinder the goal of achieving better medical treatments and
 43 technologies; and (b) Not allow patents to languish and physicians who hold patents should
 44 negotiate and structure licensing agreements in such a way as to encourage the development of
 45 better medical technology (Policy H-110.988, "7.2.3 Patents & Dissemination of Research
 46 Products").
 47

48 The AMA supports collaboration with federal and state agencies, policymakers and key
 49 stakeholders (e.g., the FTC, FDA, and the Generic Pharmaceutical Association) to identify and
 50 promote adoption of policies to address the already high and escalating costs of generic
 51 prescription drugs (Policy H-110.988, "Controlling the Skyrocketing Costs of Generic Prescription

1 Drugs”). The same policy provides that the AMA will also seek to advance with interested parties
2 legislation to ensure fair and appropriate pricing of generic medications. The policy also provides
3 that the AMA encourages the development of methods that increase choice and competition in the
4 development and pricing of generic prescription drugs and the AMA supports measures that
5 increase price transparency for generic prescription drugs.

6
7 The AMA has policy to support programs that are designed to contain the rising costs of
8 prescription drugs, provided that physicians have significant input into the development and
9 maintenance of such programs and such programs must encourage optimum prescribing practices
10 and quality of care (Policy H-110.997, “Cost of Prescription Drugs”). Furthermore, under this
11 AMA policy all patients must have access to all prescription drugs necessary to treat their illnesses
12 and physicians must have the freedom to prescribe the most appropriate drug(s) and method of
13 delivery for the individual patient; and the freedom to use either generic or brand name
14 pharmaceuticals in prescribing drugs for their patients. In addition, AMA policy provides support
15 for consumer choice of at least two options for their pharmaceutical benefits program. This must
16 include a fee-for-service option where restrictions on patient access and physician autonomy to
17 prescribe any FDA-approved medication are prohibited and reaffirms support for physicians to use
18 either generic or brand name pharmaceuticals in prescribing drugs for their patients. Finally, the
19 AMA policy provides support for a managed pharmaceutical benefit option with market-driven
20 mechanisms to control costs, provided cost control strategies satisfy AMA policies and standards
21 defined in AMA Policy H-125.991 (Policy H-100.964, “Drug Issues in Health System Reform”).

22
23 The AMA also has a growing body of policy concerning PBMs given growing concerns with their
24 role on patient costs. Policy adopted last year provides that the AMA will gather more data on the
25 erosion of physician-led medication therapy management in order to assess the impact PBM tactics
26 may have on patients’ timely access to medications, patient outcomes, and the physician-patient
27 relationship (Policy D-120.933, “Pharmacy Benefit Managers Impact on Patients”). In addition, the
28 same AMA policy provides for an examination of PBM-related clawbacks and direct and indirect
29 remuneration (DIR) fees to better inform existing advocacy efforts. AMA policy further provides
30 that physicians should report to the FDA MedWatch reporting program any instances of adverse
31 consequences (including therapeutic failures and adverse drug reactions) that have resulted from
32 the switching of therapeutic alternates precipitated by PBM actions (Policy H-125.986,
33 “Pharmaceutical Benefits Management Companies”). The policy provides support for increased
34 oversight by the FTC to assess the relationships between pharmaceutical manufacturers and PBMs,
35 especially with regard to manufacturers’ influences on PBM drug formularies and drug product
36 switching programs, and to take enforcement actions as appropriate where there are indicia of anti-
37 trust and anti-competitive practices. Further, AMA policy provides that certain actions/activities by
38 PBMs and others constitute the practice of medicine without a license and interfere with
39 appropriate medical care to patients. The policy also outlines support for effort to ensure that
40 reimbursement policies established by PBMs are based on medical need; these policies include, but
41 are not limited to, prior authorization, formularies, and tiers for compounded medication.

42 43 DISCUSSION

44
45 The AMA is engaged in a comprehensive advocacy campaign at the state and federal level to
46 advance legislation and agency action to increase patient access to affordable prescription
47 medication by increasing market competition and increasing price and cost transparency along the
48 pharmaceutical supply chain. Two of the resolutions and associated resolves would materially
49 depart from this strategy and existing policy. The two resolutions are Resolution 227-A-18, which
50 would involve a major initiative to advance the creation of a not-for-profit PBM fashioned as a
51 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. (Reaffirm HOD Policy)
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. (New HOD Policy)

Fiscal Note: Less than \$500

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.

REPORT OF THE BOARD OF TRUSTEES

B of T Report 17-A-19

Subject: Ban on Medicare Advantage “No Cause” Network Terminations

Presented by: Jack Resneck, Jr., MD, Chair

Referred to: Reference Committee B
(Charles Rothberg, MD, Chair)

1 INTRODUCTION

2
3 At the 2018 Annual Meeting, the House of Delegates (HOD) adopted Policy D-285.961, “Ban on
4 Medicare Advantage ‘No Cause’ Network Terminations,” with a progress report back at the 2019
5 Annual Meeting. This policy asks that:

6
7 Our American Medical Association (AMA) develop a set of reform proposals addressing the
8 way that Medicare Advantage plans develop and modify their physician networks with the aim
9 of improving the stability of networks, the ability of patients to obtain needed primary and
10 specialty care from in-network physicians, physician satisfaction, and communication with
11 patients about network access with report back to the House of Delegates at the 2019 Annual
12 Meeting.

13
14 This report provides background on the issues involved in Medicare Advantage (MA) physician
15 networks and concerns that physicians have raised about the ways that plans form and manage
16 these networks, as well as their communications with patients about their networks. The report
17 recommends that the AMA adopt a set of reform proposals and advocate their adoption. The HOD
18 also reaffirmed existing AMA Policies D-285.998, “Creation of Joint AMA Committee with
19 Representatives from the America’s Health Insurance Plans,” which it further strengthened, Policy
20 H-285.908, “Network Adequacy,” and Policy H-285.991, “Qualifications and Credentialing of
21 Physicians Involved in Managed Care,” which directly dealt with termination issues as part of the
22 overall action and consideration of this whole issue.

23 24 BACKGROUND

25
26 MA plans are health insurance plans offered to people with Medicare by private companies that
27 contract with the Medicare program. MA plans must provide all Medicare Parts A and B benefits,
28 they may provide Part D prescription drug coverage, and they often offer extra benefits that
29 traditional Medicare does not cover, such as vision, hearing and dental care coverage. In 2018, over
30 20 million Medicare beneficiaries, or 34 percent, were enrolled in MA. The Congressional Budget
31 Office estimates that MA enrollment will continue expanding its market share with MA plans
32 projected to include about 42 percent of beneficiaries by 2028.¹

33
34 There are relatively few insurers in the MA market, with most MA enrollees in plans operated by
35 UnitedHealthcare, Humana, or BCBS affiliates.² On average, seniors have a choice of 21 plans,³
36 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 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.
 - 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. (Directive to Take Action)
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 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. (Directive to Take Action)
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. (Directive to Take Action)
 - 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

1 simplify the process for beneficiaries to compare network size and accessibility by
2 expanding the information for each MA plan on Medicare Plan Finder to include: A. the
3 number of contracted physicians in each specialty and county; B. the extent to which a
4 plan's network exceeds minimum standards in each specialty and county; and C. the
5 percentage of the physicians in each specialty and county participating in Medicare who
6 are included in the plan's network. (Directive to Take Action)
7

- 8 4. That our AMA urge CMS to measure the stability of networks by calculating the percentage
9 change in the physicians in each specialty in an MA plan's network compared to the previous
10 year and over several years and post that information on Plan Finder. (Directive to Take
11 Action)
12
- 13 5. That our AMA urge CMS to develop a marketing/communication plan to effectively
14 communicate with patients about network access and any changes to the network that may
15 directly or indirectly impact patients; including updating the Medicare Plan Finder website.
16 (Directive to Take Action)
17
- 18 6. That our AMA urge CMS to develop process improvements for recurring input from in-
19 network physicians regarding network policies by creating a network adequacy task force.
20 (Directive to Take Action)
21
- 22 7. That our AMA rescind Policy D-285.961, which directed the AMA to conduct the study
23 herein. (Rescind AMA Policy)

Fiscal Note: Less than \$3,500.

REFERENCES

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- ¹⁶ <https://www.hioscar.com/ny>
- ¹⁷ Online Health Search 2006 - <http://www.pewinternet.org/2006/10/29/part-1-113-million-internet-users-look-for-health-information-online/>
- ¹⁸ Older Adults and Technology Use - <http://www.pewinternet.org/2014/04/03/older-adults-and-technology-use/>
- ¹⁹ How are Seniors Choosing and Changing Health Insurance Plans? - <https://www.kff.org/medicare/report/how-are-seniors-choosing-and-changing-health-insurance-plans/>
- ²⁰ Modernizing Medicare Plan Finder - Evaluating and Improving Medicare's Online Comparison Shopping Experience <https://www.ncoa.org/wp-content/uploads/CC-2018-MedicarePF-Report-Final-0418.pdf>

REPORT OF THE BOARD OF TRUSTEES

B of T Report 18-A-19

Subject: Increased Use of Body-Worn Cameras by Law Enforcement Officers
(Resolution 208-I-17)

Presented by: Jack Resneck, Jr., MD, Chair

Referred to: Reference Committee B
(Charles Rothberg, MD, Chair)

1 INTRODUCTION

2
3 At the 2018 Interim Meeting, the American Medical Association (AMA) House of Delegates
4 (HOD) referred Board of Trustees (BOT) Report 4-I-18, “Increased Use of Body-Worn Cameras
5 by Law Enforcement Officers.” The BOT Report 4-I-18 followed referral of Resolution 208-I-17,
6 “Increased Use of Body-Worn Cameras by Law Enforcement Officers,” introduced by the Medical
7 Student Section, which asked:

8
9 That our American Medical Association advocate for legislative, administrative, or
10 regulatory measure to expand funding for (1) the purchase of body-worn cameras and
11 (2) training and technical assistance required to implement body-worn camera programs.
12

13 The reference committee heard supportive testimony of BOT Report 4-I-18, though many
14 requested further study into issues of confidentiality and privacy when body-worn cameras are
15 taken into patient care areas in health care settings.
16

17 This Board report provides background, discussion of body-worn cameras by law enforcement
18 officers, including a discussion of body-worn cameras in health care settings, and a
19 recommendation.
20

21 BACKGROUND

22
23 Following a number of high-profile incidents involving deadly force used against minorities, law
24 enforcement agencies have increasingly adopted body-worn cameras for their officers. Often
25 affixed to the torso, body-worn cameras are small, wearable audio, video or photographic recording
26 systems that record events in which law enforcement officers are involved. The recordings can be
27 used to demonstrate transparency to the community, to document events and to deter inappropriate,
28 illegal or unethical behavior by both the wearer of the camera and the public.
29

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

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

8
9 In 2015, the U.S. Department of Justice (DOJ) Bureau of Justice Assistance (BJA) awarded
10 \$22.5 million in grant assistance to state and local law enforcement departments as part of the
11 Body-Worn Camera Pilot Implementation Program. The Consolidated Appropriations Act, 2018
12 appropriated \$22.5 million for a competitive matching grant program for purchases of body-worn
13 cameras for state, local and tribal law enforcement. The BJA expects to make up to 28 awards for a
14 three-year period, which began on October 1, 2018. State and local funding is also available for
15 body-worn cameras.

16 17 DISCUSSION

18
19 Predicated on whether the AMA ought to support funding of body camera programs is the question
20 of whether the AMA ought to support the expanded use of body cameras and whether the devices
21 achieve their intended outcomes.

22 23 *Policing Activity*

24
25 The underlying theory in support of body-worn cameras is that both officers and members of the
26 community will change their behaviors for the better if their actions are being recorded. Indeed, a
27 large body of research suggests that people act differently when they believe they are being
28 watched. In the context of law enforcement, body-worn cameras are expected to increase self-
29 awareness and thus deter unprofessional, inappropriate and illegal behavior by officers and
30 civilians alike. As law enforcement officers are more likely to use force against minority
31 community members, many hope body-worn cameras will improve policing behavior toward
32 minorities, using force only when warranted and de-escalation tactics have failed.^{4,5} In cases where
33 law enforcement officers do use force, body-worn cameras offer contemporaneous evidence of the
34 officers' actions so that improper behavior can be disciplined. Evidence about the impact of
35 cameras on policing activity generally, though not universally, supports this theory.

36
37 An early study conducted in the Rialto, California police department found use-of-force incidents
38 declined 58.3 percent over a three-year period after a body camera program was implemented.⁶
39 Importantly, researchers later found that use of force rates were higher in the same Rialto,
40 California police force despite the presence of a camera when officers were allowed discretion to
41 turn off cameras.⁷ Another randomized controlled trial conducted between 2014 and 2015 in the
42 Las Vegas Metropolitan Police Department found that officers wearing body cameras were
43 12.5 percent less likely to be involved in a use of force incident.⁸ Similar results were found in
44 Orlando, Florida.⁹ In contrast, the largest randomized controlled study to date, conducted in
45 2015 with the Metropolitan Police Department of the District of Columbia, found no statistically
46 significant difference in the rates of police use of force.¹⁰

47
48 Research has found mixed results about other forms of police activity. In the study conducted in
49 Las Vegas, body camera use was not associated with a change in the number of police-community
50 interactions, but body cameras were associated with a 6.8 percent increase in the number of
51 citations issued and a 5.2 percent increase in the number of events that resulted in an arrest. A 2015

1 study conducted in Mesa, Arizona found officers wearing a camera were less likely to perform
2 stop-and-frisks and make arrests, but were more likely to give citations and initiate encounters.¹¹ In
3 Phoenix, Arizona use of body-worn cameras were associated with a 17 percent increase in arrests.¹²
4 However, other studies have found body-worn cameras are associated with slightly lower incidents
5 of arrest.¹³

6 7 *Community Relations*

8
9 Changing policing behaviors is not the only way body-worn cameras could provide benefits. Many
10 communities and law enforcement agencies see body cameras as a valuable way to improve
11 policing transparency and community relations. Indeed, in 2015 when DOJ grants were announced,
12 then-US Attorney General Loretta Lynch stated that body-worn cameras hold “tremendous promise
13 for enhancing transparency, promoting accountability, and advancing public safety for law
14 enforcement officers and the communities they serve.”¹⁴ Body cameras are lauded as a way for the
15 public to better understand what transpires between law enforcement officers and civilians.
16 Officers may also view body cameras positively, as recordings demonstrate to the community the
17 difficult and dangerous job required of them.

18
19 Few studies have taken a comprehensive look at community attitudes toward police after the
20 introduction of body-worn cameras.¹⁵ One such study conducted by the Urban Institute found that
21 body-worn cameras do improve community members’ satisfaction with police encounters.¹³
22 Another study found that individuals viewed officers as having greater legitimacy, professionalism
23 and satisfaction, but did not find significant differences between citizens’ perceptions of officers
24 depending on whether the officer was wearing a camera.¹⁶

25
26 The evidence is clearer, however, that body-worn cameras are associated with decreased rates of
27 complaints filed against law enforcement officers. For example, one early study found complaints
28 against officers dropped 88 percent following implementation of a body cameras program.⁶ In
29 Rialto, California, citizen complaints declined by 60 percent. In the Las Vegas Metropolitan Police,
30 officers wearing body cameras were 14 percent less likely to be the subject of a citizen complaint.⁸
31 In Phoenix, complaints against officers who wore the cameras declined by 23 percent, compared to
32 a 10.6 percent increase among comparison officers.¹² In contrast, research in the District of
33 Columbia found no statistically significant difference in the rates of civilian complaints.

34
35 The available evidence does not identify the underlying behavioral changes responsible for the
36 decline in complaint rates, however. It may be that body-worn cameras have the intended effect of
37 changing officer behavior for the better, thus reducing circumstances that warrant citizen
38 complaints. It may be that cameras have a “civilizing” effect on members of the public as well.
39 Some evidence also suggests that frivolous complaints are less likely to be filed when recordings
40 are available.¹⁵

41
42 It is important to note, however, that use of body cameras will not automatically foster greater trust
43 between law enforcement and members of the community and should not be viewed, as one
44 evaluation noted, as a “plug-and-play” solution.¹⁰ Notably, the Urban Institute found body-worn
45 cameras improved community satisfaction to a lesser extent than did procedurally just practices,
46 defined in that study as behaving fairly and acting with empathy.¹³

47 48 *Privacy Considerations*

49
50 Though the use of body cameras promises greater transparency of law enforcement behavior and
51 actions, they also present new problems, namely intrusion into the privacy of victims, witnesses

1 and bystanders. For instance, law enforcement officers frequently enter individuals' homes and in-
2 home recordings would become part of the public record. Similarly, interactions and conversations
3 with victims and witnesses could make those individuals uncomfortable or put those individuals in
4 danger. Heavily policed communities—often minority communities—will be more heavily recorded.

5
6 These privacy concerns could be addressed with policies to limit recording during such encounters
7 and by limiting the circumstances under which recordings are made available to the public. The
8 American Civil Liberties Union (ACLU) recommends use of body cameras with significant
9 privacy protections. Officer privacy may also be a concern. Some law enforcement unions have
10 opposed body-worn cameras, arguing that adoption of the technology must be negotiated as part of
11 the collective bargaining agreement.

12
13 This report acknowledges the significant privacy concerns raised by the ubiquitous use of body-
14 worn cameras, but notes that questions about when cameras need to be turned on and off, how long
15 to keep footage, when recordings will be made publicly available and other policy details are
16 beyond the expertise of the AMA.

17 18 *Privacy considerations in the health care setting*

19
20 Body-worn cameras present a unique threat to privacy in a health care setting when, for example,
21 law enforcement officers enter facilities to interview victims and witnesses or retrieve evidence.
22 Law enforcement agencies are not covered entities under the Health Information Portability and
23 Accountability Act (HIPAA) and do not have the same obligation to prevent the disclosure of
24 patient health information as do health care providers and facilities. Providers and facilities, on the
25 other hand, do have a legal obligation under HIPAA to prevent against third-party recording of
26 individually identifiable health information (e.g., patients' faces).

27
28 Few states regulate body-worn camera recordings of medical treatment and the preservation of
29 privacy depends instead on cooperation between law enforcement and health care providers.
30 According to the Leadership Conference on Civil and Human Rights, which created a scorecard of
31 body-worn camera policies across the country, many law enforcement agencies have developed
32 policies and procedures which generally prohibit recordings in health care settings except under
33 certain circumstances. Such policies vary considerably in scope and specificity.

34
35 Even when privacy laws and regulations are not implicated, the patient-physician relationship is
36 foremost based on trust and the presence of cameras may interfere with honest communication
37 between a physician and patient, particularly when treatment involves sensitive matters such as
38 sexual activity, substance use and mental health. Policies must ensure that recordings are not
39 permitted when they may interfere in the patient-physician relationship, including during clinical
40 interviews, evaluations and treatments.

41 42 *Nexus with the AMA's Mission*

43
44 The AMA does not have policy specifically addressing the use of body-worn cameras among law
45 enforcement. During the debate over Resolution 208 during the 2017 Interim Meeting, the
46 reference committee heard testimony questioning whether this topic is within the scope of the
47 AMA's expertise. This concern is reasonable, as AMA has not historically delved into issues of
48 policing and significant resources would be required to bring the AMA into the public policy
49 debates surrounding community policing efforts. Further, while there are dozens of organizations
50 (the Police Executive Research Forum, Leadership Conference on Civil and Human Rights, ACLU,

1 etc.) that are actively engaged on this issue, it does not appear that any other major medical
2 associations have emerged as significant stakeholders.

3
4 Nevertheless, there is a connection between health and police activity, particularly in terms of
5 minority fatality rates. Research has demonstrated that minority communities are disproportionately
6 subject to police force. Specifically, according to an analysis of FBI statistics, African-Americans
7 account for 31 percent of police-involved shootings, but comprise 13 percent of the U.S.
8 population.⁴ African-American males are particularly at risk. According to another analysis,
9 African-American males are three times more likely to be killed by police than non-Hispanic white
10 males.⁵

11
12 Research has also shown a correlation between policing and other health outcomes. In particular, a
13 recent study found that police killings of unarmed African-Americans were associated with
14 1.7 days of poor mental health annually among African-Americans. The findings were seen
15 regardless of whether the individual affected had a personal relationship with the victim or whether
16 the incident was experienced vicariously. In addition, the numbers of police stops, coupled with the
17 level of invasiveness during police encounters, is associated with increased levels of stress and
18 anxiety.^{17, 18} African-American men report more anxiety and post-traumatic stress disorder and
19 more morbidity from these psychiatric conditions than Caucasian men.⁵ In addition, research of
20 data from the New York Police Department revealed that residents in neighborhoods with higher
21 rates of stop-and-frisks were more likely to be in poor health, measured in terms of high blood
22 pressure, diabetes, asthma and self-rated health.¹⁸ Research on the correlation between health and
23 policing, however, remains sparse and warrants further research.

24 25 RELEVANT AMA POLICIES

26
27 Existing AMA policy does not address the use or funding of body-worn cameras. However, AMA
28 policy does state that physical or verbal violence between law enforcement officers and the public,
29 particularly within ethnic and racial minority communities, is a social determinant of health and
30 supports research into the public health effects of violent interactions (Policy H-515.955). In
31 addition, Policy H-350.971 instructs the AMA to establish a mechanism to facilitate the
32 development and implementation of a comprehensive, long-range, coordinated strategy to address
33 issues and concerns affecting minorities, including minority health.

34
35 Policy adopted during the 2018 Annual Meeting encourages states to require the reporting of legal
36 intervention deaths and law enforcement officer homicides to public health agencies. New policy
37 also encourages appropriate stakeholders, including law enforcement and public health
38 communities, to define “serious injuries” for the purpose of systematically collecting data on law
39 enforcement-related non-fatal injuries among civilians and officers.

40
41 Additionally, Policy H-145.977 cautions against excessive use of conducted electrical devices
42 (often called Tasers) and recommends that law enforcement departments and agencies should have
43 in place specific guidelines, rigorous training and an accountability system for the use of conducted
44 electrical devices. AMA policy recommends research into the health impacts of conducted
45 electrical device use and development of a standardized protocol developed with the input of the
46 medical community for the evaluation, management and post-exposure monitoring of subjects
47 exposed to conducted electrical devices.

1 RECOMMENDATIONS
2

3 The Board recommends that the following be adopted in lieu of Resolution 208-I-17, and that the
4 remainder of the report be filed.
5

- 6 1. That our American Medical Association (AMA) work with interested state and national
7 medical specialty societies to support state legislation and/or regulation addressing
8 implementation of body-worn camera programs for law enforcement officers, including
9 funding for the purchase body-worn cameras, training for officers and technical assistance for
10 law enforcement agencies. (Directive to Take Action);
11
- 12 2. That our AMA continue to monitor privacy issues raised by body-worn cameras in health care
13 settings. (Directive to Take Action); and
14
- 15 3. That our AMA recommend that law enforcement policies governing the use of body-worn
16 cameras in health care settings be developed and evaluated with input from the medical
17 community and not interfere with the patient-physician relationship. (Directive to Take Action)

Fiscal Note: Less than \$5,000

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REPORT OF THE BOARD OF TRUSTEES

B of T Report 19-A-19

Subject: FDA Conflict of Interest
(Resolution 216-A-18)

Presented by: Jack Resneck, Jr., MD, Chair

Referred to: Reference Committee B
(Charles Rothberg, MD, Chair)

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 (New HOD Policy); 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 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. (Reaffirm HOD Policy)
2. That our AMA adopt the following new policy:

It is the position of the American Medical Association that decisions of the Food and Drug Administration (FDA) must be trustworthy. Patients, the public, physicians, other health care professionals and health administrators, and policymakers must have confidence that FDA decisions and the recommendations of FDA advisory committees are ethically and scientifically credible and derived through a process that is rigorous, independent, transparent, and accountable. Rigorous policies and procedures should be in place to minimize the potential for financial or other interests to influence the process at all key steps. These should include,

1 but not necessarily be limited to: a) required disclosure of all relevant actual or potential
2 conflicts of interest, both financial and personal; b) a mechanism to independently audit
3 disclosures when warranted; c) clearly defined criteria for identifying and assessing the
4 magnitude and materiality of conflicts of interest; and d) clearly defined processes for
5 preventing or terminating the participation of a conflicted member, and mitigating the
6 influence of identified conflicts of interest (such as prohibiting individuals from participating in
7 deliberations, drafting, or voting on recommendations on which they have conflicts) in those
8 limited circumstances when an individual's participation cannot be terminated due to the
9 individual's unique or rare skillset or background that is deemed highly valuable to the process.
10 Further, clear statements of COI policy and procedures, and disclosures of FDA advisory
11 committee members' conflicts of interest relating to specific recommendations, should be
12 published or otherwise made public. Finally, it is recognized that, to the extent feasible in
13 accordance with the principles stated above, participation on advisory committees should be
14 facilitated through appropriate balancing of the relative scarcity or uniqueness of an
15 individual's expertise and ability to contribute to the process, on the one hand, as compared to
16 the feasibility and effectiveness of mitigation measures including those noted above. (New
17 HOD Policy)

18
19 3. That our AMA adopt the following new policy:

20
21 It is the position of the American Medical Association that the FDA should undertake an
22 evaluation of pay-later conflicts of interest (e.g., where a FDA advisory committee member
23 develops a financial conflict of interest only after his or her initial appointment on the advisory
24 committee has expired) to assess whether these undermine the independence of advisory
25 committee member recommendations and whether policies should be adopted to address this
26 issue. (New HOD Policy)

Fiscal Note: Less than \$500

REFERENCES

¹ FDA Advisory Committees, Accessed on February 25, 2019

² Id. Products include blood, vaccines and other biologics; human drugs; food; medical devices; patient engagement; pediatric; radiation-emitting products; risk communication; science board; toxicological research; veterinary; and tobacco.

³ See, for example, the FDA Amendments Act (FDAA) of 2007 which mandated that by 2012 no more than thirteen percent of committee advisors per year could receive COI waivers. The FDA reduced the maximum size of financial interests eligible for waivers from a combined financial interest of up to \$100,000, to a maximum of \$50,000. See also Draft Guidance for the Public, FDA Advisory Committee Members, and FDA Staff on Procedures for Determining COI and Eligibility for Participation in FDA Advisory Committees (March 2007); Public Availability of Advisory Committee Members' Financial Interest Information and Waivers-Final Guidance (2014); and, Procedures for Evaluating Appearance Issues and Granting Authorizations for Participation in FDA Advisory Committees (2016).

⁴ Related persons and organizations include: the employee's spouse, minor child, or general partner; an organization or entity for which the employee serves as officer, director, trustee, general partner, or employee; and a person with whom the employee is negotiating for, or has an arrangement concerning, prospective employment.

⁵ In preparation for advisory committee meetings involving particular matters, SGEs invited to participate in the meetings are required to report to FDA any financial interests related to the subject matter of the advisory committee meeting. 5 CFR § 2634.904(a)(2). Permanent government employees also report financial interests on a yearly basis and/or just prior to the advisory committee meeting they are planning to attend. 5 CFR §§ 2634.202 and 2634.904(a)(1). The FDA reviews not only the financial interests of a potential advisory committee participant and the individual's immediate family, but also the financial interests, of which the individual has knowledge, of the participant's business partners, organizations for which the individual serves as officer, director, trustee, general partner, or employee, and any prospective employer of the member (if there are ongoing employment negotiations or an agreement regarding future employment). See 18 U.S.C. § 208(a).

⁶ 5 CFR 2640.302(b)

⁷ 5 CFR 2640.301(b)

⁸ Food, Drug, and Cosmetic Act section 505 (n)(4) "Each member of a panel shall publicly disclose all conflicts of interest that member may have with the work to be undertaken by the panel. No member of a panel may vote on any matter where the member or the immediate family of such member could gain financially from the advice given to the Secretary. The Secretary may grant a waiver of any conflict of interest requirement upon public disclosure of such conflict of interest if such waiver is necessary to afford the panel essential expertise, except that the Secretary may not grant a waiver for a member of a panel when the member's own scientific work is involved."

⁹ Draft Guidance for the Public, FDA Advisory Committee Members, and FDA Staff on Procedures for Determining COI and Eligibility for Participation in FDA Advisory Committees March 2007

¹⁰ Id.

¹¹ Wood SF, Mador JK. *Science and regulation. Uncapping conflict of interest?* Science (2013)

¹² Lurie P. *Suggestions for Improving Conflict of Interest Processes in the US Food and Drug Administration Advisory Committees—Past Imperfect*. JAMA Intern Med. 2018;178(7):997–998. doi:10.1001/jamainternmed.2018.1324

¹³ Report to Congress Food and Drug Administration Safety and Innovation Act, Section 712 (e) of the Federal Food, Drug, and Cosmetic Act, Fiscal Year 2016 Annual Report on FDA Advisory Committee Vacancies and Public Disclosures Accessed on February 27, 2019

¹⁴ The FDA does not publicly disclose financial interest information if it is exempt from disclosure under the Freedom of Information Act or otherwise protected from disclosure by statute or regulation, except if necessary to describe the type, nature, and magnitude of the financial conflict being waived.

¹⁵ This information must be published within specified time frames before advisory committee meetings. Food, Drug, and Cosmetic Act section 712(c).

¹⁶ FDA Guidance on Publication of Financial COI waivers.

https://www.fda.gov/RegulatoryInformation/Guidances/ucm391034.htm#_ftn11

¹⁷ Political party as described in 26 U.S.C. 527(e)

¹⁸ Participation is active if, for example, it involves service as an official of the organization or in a capacity similar to that of a committee or subcommittee chairperson or spokesperson, or participation in directing the activities of the organization. In other cases, significant time devoted to promoting specific programs of the organization, including coordination of fundraising efforts, is an indication of active participation. Payment of dues or the donation or solicitation of financial support does not, in itself, constitute active participation.

¹⁹ Pham-Kanter G., Revisiting Financial Conflicts of Interest in FDA Advisory Committees, Milbank Quarterly, September 2014 Volume 92, Issue 3 (pages 446–470), DOI: 10.1111/1468-0009.12073

²⁰ Id.

²¹ Id.

²² Cooper J., Golec J. Conflicts of Interest on Expert Committees: The Case of FDA Drug Advisory Committees, University of Connecticut School of Business Research Paper No. 17-02, April 2018 Accessed February 24, 2019

²³ Id.

²⁴ Piller C., You J. Hidden conflicts? Pharma payments to FDA advisers after drug approvals spark ethical concerns, Science Magazine, July 5, 2018 Accessed February 24, 2019

²⁵ Id.

²⁶ Id.

²⁷ Piller C., You J. Hidden conflicts? Pharma payments to FDA advisers after drug approvals spark ethical concerns, Science Magazine, July 5, 2018 Accessed February 24, 2019

²⁸ Sullivan, T., FDA Conflicts of Interest Rules Means Fewer Experts on Advisory Panels, Policy and Medicine Blog, May 5, 2018 Accessed on February 24, 2019.

²⁹ FDA website – online Percent of FDA advisory committee member positions vacant at the end of the month Accessed February 27, 2019

³⁰ FDA website – online Percent of FDA advisory committee member positions vacant at the end of the month Accessed February 27, 2019

APPENDIX: RELEVANT AMA POLICY

Policy H-100.992, “FDA”

(1) Our AMA reaffirms its support for the principles that: (a) an FDA decision to approve a new drug, to withdraw a drug’s approval, or to change the indications for use of a drug must be based on sound scientific and medical evidence derived from controlled trials and/or postmarket incident reports as provided by statute; (b) this evidence should be evaluated by the FDA, in consultation with its Advisory Committees and expert extramural advisory bodies; and (c) any risk/benefit analysis or relative safety or efficacy judgments should not be grounds for limiting access to or indications for use of a drug unless the weight of the evidence from clinical trials and postmarket reports shows that the drug is unsafe and/or ineffective for its labeled indications.

(2) The AMA believes that social and economic concerns and disputes per se should not be permitted to play a significant part in the FDA’s decision-making process in the course of FDA devising either general or product specific drug regulation.

(3) It is the position of our AMA that the Food and Drug Administration should not permit political considerations or conflicts of interest to overrule scientific evidence in making policy decisions; and our AMA urges the current administration and all future administrations to consider our best and brightest scientists for positions on advisory committees and councils regardless of their political affiliation and voting history.

7.1.4 Conflicts of Interest in Research

Increasing numbers of physicians, both within and outside academic health centers, are becoming involved in partnerships with industry to conduct biomedical and health research. As they do so, physicians must be mindful of the conflicts such engagement poses to the integrity of the research and the welfare of human participants. In addition to financial conflicts of interest created by

incentives to conduct trials and recruit subjects, physicians must be sensitive to the differing roles of clinician and investigator, which may require them to balance dual commitments to participants and science. This conflict of commitment is particularly acute when a physician-investigator has treated or continues to treat a patient who is eligible to enroll as a participant in a clinical trial the physician is conducting.

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

Physicians who engage in research should:

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

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

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

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

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

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

REPORT 20 OF THE BOARD OF TRUSTEES (A-19)
Safe and Efficient e-Prescribing
(Reference Committee B)

EXECUTIVE SUMMARY

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, opportunities for improvement, and recommendations for multiple stakeholders.

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. Despite the numerous advantages of e-prescribing over the former paper prescription systems, there are barriers to the safe and efficient use of e-prescribing systems, suggesting there are opportunities for improvement to maximize efficiency and safety.

REPORT OF THE BOARD OF TRUSTEES

B of T Report 20-A-19

Subject: Safe and Efficient e-Prescribing

Presented by: Jack Resneck, Jr., MD, Chair

Referred to: Reference Committee B
(Charles Rothberg, MD, Chair)

1 INTRODUCTION

2
3 At the 2018 Annual Meeting Policy D-120.972, “Electronic Prescribing,” was amended by the
4 House of Delegates (HOD) with additional directives from Resolution 237-A-18. The policy asks
5 the American Medical Association (AMA) to study current electronic prescribing (e-prescribing)
6 processes and make recommendations to improve these processes to make them as safe as possible
7 for patients and as efficient as possible for prescribers.

8
9 This report provides the requested study of current e-prescribing processes, including benefits and
10 challenges, examples of interventional case studies, and opportunities for improvement.

11 BACKGROUND

12
13
14 The electronic exchange of prescription and medication history information between prescribers,
15 pharmacies, and payers/pharmacy benefit managers, referred to as e-prescribing, has been shown to
16 improve efficiency, patient safety, and cost savings. E-prescribing has also been shown to reduce
17 medication errors and increase efficiencies in patient care.¹ In 2017 almost 70% of prescribers and
18 98% of pharmacies were utilizing e-prescribing.² Despite vast increases in adoption of e-
19 prescribing and the improvements realized thus far, there are still areas for improvement in e-
20 prescribing. For example, functions of the electronic systems, such as excessive or unnecessary
21 alerts,^{1,3} and the processes required for prescribing controlled substances, are perceived as
22 remaining barriers to the optimal use of e-prescribing.¹ The authors of Resolution 237-A-18
23 expressed concern that some steps required to order an e-prescription, such as selecting a pharmacy
24 to which the prescription should be filled, are error-prone and not efficient use of physician time.
25 The current two-factor authentication process required to electronically prescribe controlled
26 substances (EPCS) has also been noted as a cumbersome requirement lacking efficiency and
27 contributing to the slower adoption of EPCS compared to non-controlled substances. In 2017 21%
28 of controlled substances were prescribed electronically compared to 90% of non-controlled
29 substances.⁴ Despite the numerous advantages of e-prescribing over the former paper prescription
30 systems, the systems and processes still have opportunities for improvement to maximize
31 efficiency and safety.⁵

32 AMA POLICY

33
34
35 The AMA supports e-prescribing for both controlled and non-controlled substances and has
36 numerous policies expressing its commitment to advocating for better regulations and better
37 systems that enable more efficient, safe, and less burdensome use of e-prescribing. The AMA

1 supports programs that incentivize adoption of e-prescribing systems, but opposes a funding
2 structure that financially penalizes physicians that have not adopted such technology (Policy H-
3 478.991, “Federal EMR and Electronic Prescribing Incentive Program”). The AMA continues to
4 work with the Centers for Medicare and Medicaid Services (CMS) to ensure that the e-prescribing
5 policies and reporting procedures provide the greatest flexibility to physicians who participate in
6 the program (Policy D-120.957, “Electronic Prescribing Incentive Program”). The AMA
7 encourages states to implement modernized PDMPs that are seamlessly integrated into the
8 physician's normal workflow, and provide clinically relevant, reliable information at the point of
9 care (Policy H-95.939, “Development and Promotion of Single National Prescription Drug
10 Monitoring Program”).

11
12 Recognizing that EPCS continues to pose administrative burdens for physicians, in 2017 the AMA
13 modified existing policy to continue to advocate before federal and state agencies and legislative
14 bodies for elimination of cumbersome, confusing and burdensome requirements relating to
15 electronic transmission of physicians’ controlled substance prescriptions to pharmacies,” (Policy
16 D-120.956, “Electronic Prescribing and Conflicting Federal Guidelines”). The AMA also supports
17 action requiring that the U.S. Drug Enforcement Administration (DEA) establish reasonable
18 requirements enabling the use of e-prescribing for controlled substances (Policy H-120.941, “e-
19 Prescribing of Scheduled Medications”). In addition, the AMA is committed to reducing federal
20 roadblocks to e-prescribing and is working with the CMS and states to remove or reduce barriers to
21 electronic prescribing of both controlled substances and non-scheduled prescription drugs. Through
22 this work the AMA will reduce regulatory burdens to facilitate further adoption of e-prescribing,
23 including for controlled substances (Policy D-120.958, “Federal Roadblocks to E-Prescribing”).

24
25 The AMA advocates for changing the national standards for controlled substance prescriptions so
26 that prescriptions for controlled substances can be transmitted electronically directly to the
27 pharmacy in a secure manner and is committed to working with stakeholders to encourage the use
28 of standards that allow direct physician/pharmacist communication within existing electronic
29 health record (EHR) or e-prescribing systems (Policy D-120.944, “Improvement of Electronic
30 Prescription Software”). The AMA sought from CMS and the DEA a requirement that all
31 pharmacies and Pharmacy Benefits Managers (PBMs) acquire and implement the appropriate
32 electronic prescribing of controlled substances software to accept electronically transmitted
33 controlled substance prescriptions from prescriber systems that comply with CMS and DEA
34 certification requirements (Policy D-120.945, “Completing the Electronic Prescription Loop for
35 Controlled Substances”). The AMA also works with pharmacy benefit managers, payers and
36 pharmacists to make accurate, real-time formulary information available at the point of care. It is
37 AMA’s priority to promote procedural policies that ensure changes in formulary information are
38 communicated promptly to prescribers so alternative medication can be provided to patients in a
39 timely manner (Policy H-125.979, “Private Health Insurance Formulary Transparency”).

40
41 The AMA recognizes the importance of patient safety in the e-prescribing process, and is
42 committed to working with pharmaceutical, e-prescribing and point of care resource stakeholders
43 to increase physician awareness of risk evaluation and mitigation strategies to improve patient
44 safety in the e-prescription process (Policy D-100.971, “Physician Awareness and Education About
45 Pharmaceutical and Biological Risk Evaluation and Mitigation”). In addition, the AMA urges
46 Congress to unify state prescription standards to facilitate further adoption of e-prescribing, and
47 supports efforts to amend federal law to allow for the e-prescribing of a medication needed by a
48 patient with a mental health or behavioral health diagnosis when a valid patient-physician
49 relationship has been established through telemedicine (Policy D-120.972, “Electronic
50 Prescribing”). Last, in support of efforts to reduce medication errors by increasing efficiency and
51 safety in the process of cancelling electronic prescriptions, the AMA supports the creation,

1 standardization, and implementation of electronic prescription cancellation from all electronic
2 medical records vendors and that these orders be accepted by pharmacies and pharmacy benefit
3 managers (Policy H-478.983, “Electronic Prescription Cancellation”).
4

5 DISCUSSION

6 *E-prescribing overview*

7
8
9 E-prescribing is the computer-based electronic generation, transmission, and filling of a
10 prescription, that replaces the need for paper and faxed prescriptions. CMS describes e-prescribing
11 as “the ability for a prescriber to electronically send an accurate, error-free and understandable
12 prescription directly to a pharmacy from the point-of-care.”⁶
13

14 E-prescribing eliminates the need for paper prescriptions, which can create hazards and increase
15 risk of medical errors. E-prescribing systems can reduce medical errors, decrease pharmacy costs,
16 improve both prescriber and pharmacy efficiency, eliminate handwriting interpretation errors,
17 reduce phone calls between pharmacists and physicians, reduce data entry, and expedite
18 prescription refill requests.⁷ In addition, e-prescribing can improve efficiencies by introducing an
19 automatic process to reconcile drug-drug interactions and patient allergies at the point of
20 prescribing. E-prescribing platforms also facilitate the ability to monitor prescribing patterns,
21 which can help organizations ensure high-quality and cost-effective care.⁸
22

23 Although e-prescribing was not new and many practices had already transitioned from paper to
24 electronic systems, in 2012 CMS implemented the Medicare eRx Incentive Program to encourage
25 electronic prescribing by eligible professionals. The eRx program provided an incentive payment to
26 eligible professionals who successfully e-prescribed for covered Medicare Part B services, and
27 applied payment adjustments to those who did not. The eRx program ended in 2013 and was
28 replaced with the Meaningful Use Incentive Program, which ended in 2017. E-prescribing
29 measurement continues within the Merit Based Incentive Payment System track of the Medicare
30 Quality Payment Program. In addition, CMS requires Medicare Part D sponsors, prescribers, and
31 drug dispensers that transmit prescriptions and prescription-related information electronically to
32 support and comply with the National Council for Prescription Drug Programs (NCPDP) SCRIPT
33 standard when filing prescriptions electronically. CMS will adopt a revised SCRIPT standard on
34 January 1, 2020.⁹ The new standard will include support for several functions that aim to improve
35 efficiency, clinical decision-making and patient safety. New functionalities will include support for
36 grouping of multiple prescriptions and the reporting of allergies and adverse events, enhancements
37 to digital signatures, and the choice of whether or not to receive RxFill notifications.¹⁰
38

39 *Improvements gained from e-prescribing*

40
41 With the introduction of EHRs and industry movement to leverage more technology solutions in
42 patient care, e-prescribing has become a key component of the daily clinical workflow. E-
43 prescribing has been shown to provide many benefits in comparison to traditional paper prescribing
44

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

1 medication errors have been reduced to as little as one-seventh of their previous level as a result of
2 e-prescribing.¹

3
4 The reduction in medical errors and improved quality outcomes have led to significant cost savings
5 to the overall healthcare system. It is estimated that improved patient outcomes and decreased
6 patient visits may result in between \$140 billion and \$240 billion in cost avoidance over 10 years
7 for practices that implement e-prescribing.¹ E-prescribing also assists with cost savings by reducing
8 fraud, abuse and drug diversion. Through e-prescribing, prescriptions and usage are more
9 effectively tracked, and the elimination of a paper script reduces the risk of fraud and illegal
10 prescription sales. The secure and safe transfer of data and prescriptions to a pharmacy also serves
11 as another protective safe guard in preventing drug diversion, as well as enhanced safety.

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

19
20 E-prescribing has also been shown to improve patient satisfaction. Many patients prefer the ease
21 and quick transmission of prescriptions to their pharmacy as well as the convenience of eliminating
22 paper prescriptions and reduced wait time at the pharmacy. Many platforms are also providing
23 more information on cost-effective medication options based on a patient's particular health plan,
24 leading to cost-savings for the patient and health system.¹⁵

25
26 Despite the potential additional time and steps required for e-prescribing, the impacts to workflow
27 should be minimal if systems are implemented effectively.¹ Most prescribers feel the benefits of e-
28 prescribing outweigh the burdens created by additional steps, and that the extra time spent in the e-
29 prescribing system is offset by the efficiencies gained in the overall process.^{1, 5}

30
31 The patient safety benefits and efficiencies of e-prescribing can be further enhanced through the
32 use of Structured and Codified Sig (short for Signatura). Structured and Codified Sig is designed to
33 communicate prescription dosing instructions in a codified way to the pharmacy that can then be
34 conveyed to the patient, thus reducing the opportunity for transcription errors and improving
35 efficiencies and work flows for prescribers and pharmacists. Unfortunately, despite its potential
36 benefits, Structured and Codified Sig has neither been widely utilized by prescribers nor supported
37 by EHRs that allow e-prescribing. NCPDP, which develops and maintains the SCRIPT standard,
38 convened a task group to review these utilization and support issues and developed a Structured
39 and Codified Sig Format Implementation Guide to support Structured and Codified Sig. Greater
40 utilization of Structured and Codified Sig will present prescribers, pharmacists, and patients with
41 an opportunity to improve safety and enhance workflow efficiency.

42 *Barriers to adoption and use*

43
44
45 Studies show unintended consequences of e-prescribing systems include changes in
46 communication patterns, generation of new kinds of errors, more and new work for clinicians,
47 unfavorable workflow issues, overdependence on technology, continuous demands for system
48 upgrades, persistence of paper, negative emotions toward the technology, and changes in power
49 structure and work roles.^{16, 17}

1 A principal barrier and challenge to e-prescription adoption is implementation. The cost of
2 implementing e-prescribing technology can be the primary limiting factor. According to the Health
3 Resources and Services Administration, the total cost of implementing an e-prescribing system was
4 found to be \$42,332, with annual costs after implementation of about \$14,725 per year for a
5 practice of 10 full-time equivalent psychiatrists.¹ A 2007 study by Scalise and colleagues revealed
6 that the cost to implement a basic e-prescribing program ranges from \$1,500 to \$4,000 per
7 physician and the price for an advanced system with alerts, reminders and system integration is
8 \$29,000 per physician in the first year and \$4,000 per physician every year thereafter.¹⁸ The DEA
9 in 2010 estimated the costs to implement the appropriate systems for EPCS, across pharmacies,
10 hospitals and practitioners, to be between \$43 million and \$1.54 billion, annualized over 15 years.¹⁹
11 In addition to the cost of implementing e-prescribing technology, the time investment and training
12 required can also present barriers to adoption.

13
14 Another challenge associated with e-prescribing is related to system errors and network challenges.
15 A key concern for system errors in e-prescribing is related to the impact on quality and the
16 potential to cause medical errors. Many systems have CDS tools, but there are considerable
17 variances of capabilities across platforms. Design issues with CDS tools can present serious risks,
18 for example in the programming of too few or too many alerts. A lack of alert specificity can result
19 in missing an adverse drug reaction, while an overload of alerts can produce the phenomenon
20 known as alert fatigue, which can result in providers overlooking and ignoring important alerts.²⁰ In
21 addition, many physicians report technical problems and poor network connectivity as a key barrier
22 in e-prescribing adoption. In some instances, pharmacies are not reliably receiving and processing
23 prescriptions sent electronically due to poor connectivity or network issues. This also has a
24 negative downstream effect on patients due to delays in filling medications.

25
26 Privacy and security issues also present concerns with e-prescribing processes. It is important for
27 prescribers to have appropriate security parameters in place to safeguard protected health
28 information (PHI). Protecting data securely is an ongoing and constant requirement and challenge
29 for providers, especially with many web-based tools and multiple opportunities for information to
30 be stolen or compromised. In addition, many information breaches often originate from internal
31 employee actions, which can be costly and require additional and ongoing training and security.²¹

32
33 Other barriers to efficient e-prescribing result from regulations of EPCS, enforced by the DEA. In
34 2010, the DEA legalized e-prescribing for Schedule II to Schedule V controlled substances. A
35 dozen states have passed laws mandating the use of e-prescribing for controlled substances, some
36 of which will be effective in 2020. The DEA ruling enforces strict standards for implementation
37 and utilization, including identity proofing, two-factor authentication, digital certificates, monthly
38 logs, third-party audits of software, and a requirement to keep two years of records.¹⁹ The
39 SUPPORT for Patients and Communities Act, enacted in 2018, further requires that all providers
40 use EPCS by January 1, 2021.²²

41
42 Two-factor authentication adds multiple additional steps to a prescriber's process.⁵ Board of
43 Trustees Report 6-I-17 described in detail the barriers associated with two-factor authentication:
44 While authentication through a combination of personal identification numbers (PINs), passwords,
45 and biometrics increases the security of EPCS, it also contributes to frequent workflow disruptions
46 and increases costs for many physicians. An AMA survey found that primary care physicians write
47 up to 100 prescriptions per day. Other specialists usually write an average of 10 to 25 prescriptions
48 per day. This volume of prescriptions makes compliance with two-factor authentication,
49 particularly as a distinct process from e-prescribing of non-controlled substances onerous and a
50 significant strain on practice workflows. Few health information technology (HIT) vendors
51 currently support EPCS, and those that do often require physicians to purchase add-on modules or

1 pay separate monthly service fees outside those of normal product maintenance. In speaking with
2 many DEA-registered physicians, the AMA has found that many methods and processes HIT
3 vendors utilize for EPCS are not well-aligned with normal e-prescribing workflows. In most
4 instances, physicians must initiate an entirely new set of computer programs and windows each
5 time they wish to use EPCS. The AMA shared with the DEA that cumbersome workflows and
6 applications that do not take physician needs into account are the primary impediment to physician
7 EPCS uptake and should be squarely addressed by system designers and product implementers.
8 The DEA requirement that biometric devices comply with Federal Information Processing
9 Standards (FIPS) compounds this problem by limiting many user-friendly consumer electronics
10 already found in physicians' offices from being utilized. The AMA asked that the DEA reexamine
11 the scope of technology that is compliant with EPCS requirements and allow for lower-cost, high-
12 performing biometric devices (e.g., fingerprint readers on laptop computers and mobile phones) to
13 be leveraged in two-factor authentication.²³ The SUPPORT for Patients and Communities Act
14 requires the DEA to update its regulations pertaining to how prescribers authenticate prescriptions
15 using biometric devices.²²

16
17 In addition to the requirements and time to e-prescribe controlled substances, providers also cite
18 general clinic operational inefficiencies. Commonly cited challenges are time pressure on busy
19 clinic days and frustration with time devoted to administrative portions of the e-prescription
20 process, such as pharmacy selection and populating e-prescribing systems with patients'
21 identifying information.¹⁵ Real-time benefit check applications integrated into the EHR can help
22 gain efficiencies, but are not yet a universally utilized tool. Cancelling an electronic prescription
23 often involves multiple steps and phone calls to the pharmacy, which can be burdensome and time-
24 consuming, and can add to the risk of medication errors. Integration of state prescription drug
25 monitoring program (PDMP) data into the e-prescribing software could also help reduce workflow
26 burdens. CMS in 2018 encouraged states to improve their PDMP systems to enable integration of
27 PDMP data with EHRs.²⁴

28
29 Another documented barrier is the excessive cost of complying with EPCS requirements. As
30 reported in BOT 6-I-17, many physicians—especially those in small and solo practices—face high
31 fees associated with the extensive technical, security, and other standard requirements (e.g., costs
32 for identity proofing, access control training and the setting of access controls, hardware, software
33 or application purchase and maintenance, reprogramming, and audit requirements), along with
34 workflow adjustments needed for EPCS. In addition to the costs of compliance with EPCS, there
35 are also monthly fees levied by HIT vendors. These fees and costs pose a significant barrier to
36 EPCS adoption. The DEA registration fee for EPCS is \$731 for three years and covers the costs of
37 its diversion control program.

38
39 Finally, some prescribers perceive the process of searching and selecting a pharmacy each time a
40 prescription is ordered electronically to be time-consuming and error-prone. Challenges can occur
41 when prescriptions need to be transferred from one pharmacy to another, sometimes a result of
42 patients relocating or changing health plans. Disruption in adherence can occur if pharmacies don't
43 stock particular medications and it becomes difficult for patients to fill their prescriptions. Health
44 plan changes also sometimes result in changes in pharmacy network status, which can lead to
45 unexpected coverage gaps. Additional costs to obtain a non-preferred pharmacy prescription may
46 only be realized when the patient picks up the prescription, resulting in phone calls from the patient
47 back to the prescriber for help. Most commercial e-prescription systems offer a function to select a
48 preferred pharmacy for patients. Other systems may also feature a "previously used pharmacy"
49 option, which keeps a list of pharmacies at which the patient has historically filled prescriptions.
50 Use of either of these functions, and regular verification of the indicated pharmacy, saves time and
51 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.

- 1 • Implementation teams can enable functionality of pharmacy directories and preferred
2 pharmacy options. Leadership can encourage the practice of inputting a patient's preferred
3 pharmacy at registration, and re-confirming it upon check-in at all subsequent visits.
- 4 • Implementation teams can enhance EHR function to require residents assign an authorizing
5 attending physician.
- 6 • Organizational leadership can implement e-prescribing systems that feature more robust
7 clinical decision support, but ensure prescriber preferences are tested and seriously
8 considered in implementation decisions.
- 9 • Organizational leadership can assign e-prescribing as the default prescription method.
- 10 • The DEA can allow for lower-cost, high-performing biometric devices (e.g., fingerprint
11 readers on laptop computers and mobile phones) to be leveraged in two-factor
12 authentication.
- 13 • Health insurers, pharmacies and e-prescribing software vendors should enable real-time
14 benefit check applications that enable more up to date prescription coverage information
15 and allow notification when a patient changes health plans or a health insurer has changed
16 a pharmacy's network status.
- 17 • States can allow PDMP/EHR integration to reduce workflow burden and increase
18 efficiency.

19 20 CONCLUSION

21
22 The increase in use of e-prescribing and the incentive programs aimed at encouraging its adoption
23 have invigorated progress in improving the safety and efficiency of prescribing medications, but
24 there is still much room for improvement. While errors related to legibility issues or
25 misinterpretation of handwriting have been reduced, rates of medication errors have declined, and
26 organizations have experienced better patient satisfaction and cost savings, the trade-off is the
27 additional time prescribers spend maneuvering multiple platforms and completing data entry tasks
28 required to order prescriptions. Many physicians appreciate the benefits that e-prescribing has
29 provided, but recognize that improvements can still be realized to make them as safe as possible for
30 patients and efficient as possible for prescribers. These improvements may be possible through the
31 recommendations outlined in this report.

32 33 RECOMMENDATIONS

34
35 The Board of Trustees recommends that the following be adopted in lieu of Resolution 237-A-18
36 and that the remainder of this report be filed:

- 37
38 1. That our American Medical Association (AMA) reaffirm the following policies:
 - 39 a. H-125.979, "Private Health Insurance Formulary Transparency"
 - 40 b. D-120.956, "Electronic Prescribing and Conflicting Federal Guidelines"
 - 41 c. H-120.941, "e-Prescribing of Scheduled Medications"
 - 42 d. D-120.958, "Federal Roadblocks to E-Prescribing"
 - 43 e. D-120.945. "Completing the Electronic Prescription Loop for Controlled Substances"
44 (Reaffirm HOD Policy)
- 45
46 2. That the second paragraph of AMA Policy D-120.972, "Electronic Prescribing," be rescinded
47 as having been fulfilled by this report. (Rescind HOD Policy)
- 48
49 3. That our AMA encourage health care stakeholders to improve electronic prescribing practices
50 in meaningful ways that will result in increased patient safety, reduced medication error,

1 improved care quality, and reduced administrative burden associated with e-prescribing
2 processes and requirements. Specifically, the AMA encourages:

- 3
- 4 • E-prescribing system implementation teams to conduct an annual audit to evaluate the
- 5 number, frequency and user acknowledgment/dismissal patterns of e-prescribing system
- 6 alerts and provide an audit report to the software vendors for their consideration in future
- 7 releases.
- 8 • Health care organizations and implementation teams to improve prescriber end-user
- 9 training and on-going education.
- 10 • Implementation teams to prioritize the adoption of features like structured and codified Sig
- 11 formats that can help address quality issues.
- 12 • Implementation teams to enable functionality of pharmacy directories and preferred
- 13 pharmacy options.
- 14 • Organizational leadership to encourage the practice of inputting a patient's preferred
- 15 pharmacy at registration, and re-confirming it upon check-in at all subsequent visits.
- 16 • Implementation teams to establish interoperability between the e-prescribing system and
- 17 the EHR to allow prescribers to easily confirm continued need for e-prescription refills and
- 18 to allow for ready access to pharmacy choice and selection during the refill process.
- 19 • Implementation teams to enhance EHR and e-prescribing system functions to require
- 20 residents assign an authorizing attending physician.
- 21 • Organizational leadership to implement e-prescribing systems that feature more robust
- 22 clinical decision support, and ensure prescriber preferences are tested and seriously
- 23 considered in implementation decisions.
- 24 • Organizational leadership to designate e-prescribing as the default prescription method.
- 25 • The DEA to allow for lower-cost, high-performing biometric devices (e.g., fingerprint
- 26 readers on laptop computers and mobile phones) to be leveraged in two-factor
- 27 authentication.
- 28 • States to allow integration of PDMP data into EHR systems.
- 29 • Health insurers, pharmacies and e-prescribing software vendors to enable real-time benefit
- 30 check applications that enable more up to date prescription coverage information and allow
- 31 notification when a patient changes health plans or a health insurer has changed a
- 32 pharmacy's network status. (New HOD Policy)

Fiscal Note: Minimal - Less than \$500

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REPORT 21 OF THE BOARD OF TRUSTEES (A-19)
Augmented Intelligence (AI) in Health Care
(Reference Committee B)

EXECUTIVE SUMMARY

At the 2018 Annual Meeting of the American Medical Association (AMA), the House of Delegates (HOD) adopted amended policy recommendations of Board of Trustees (BOT) Report 41, “Augmented Intelligence (AI) in Health Care,” 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 referral was prompted in part due to testimony that the resolve was too narrowly focused and should address payment policy for health care AI. Since the resolve was referred, there has been significant federal and state legislative and regulatory activity related to health care AI, including the U.S. Food and Drug Administration’s authorization of several AI-enabled software systems for clinical practice and the Centers for Medicare & Medicaid Services launch of an AI Health Outcomes Challenge in partnership with the American Academy of Family Physicians in order to incorporate AI in the implementation of both current and new payment and service delivery models. This underscores the benefit of developing AMA policy to address payment for AI systems without limits on medical specialty, practice setting, or payment model.

Existing health care AI policy provides that our AMA will “[p]romote development of thoughtfully designed, high-quality, clinically validated health care AI that is designed and evaluated in keeping with best practices in user-centered design, particularly for physicians and other members of the health care team; is transparent; conforms to leading standards for reproducibility; 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 safeguards patients’ and other individuals’ privacy interests and preserves the security and integrity of personal information. The policy also provides that the AMA will 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.” This report summarizes the need for additional AMA policy that is relevant to payment and use of health care AI; provides definitions of related terms; and addresses key issues that impact physician adoption of new health care technologies and delivery modalities, including clinical efficacy, usability and workflow integration, and liability. The recommendations build upon existing AMA policy and will enhance our AMA’s continued engagement with a broad cross-section of stakeholders and policymakers to ensure that the perspective of physicians in various practice settings informs and influences the dialogue as this technology continues to develop.

REPORT OF THE BOARD OF TRUSTEES

B of T Report 21-A-19

Subject: Augmented Intelligence (AI) in Health Care

Presented by: Jack Resneck, Jr., MD, Chair

Referred to: Reference Committee B
(Charles Rothberg, MD, Chair)

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.

- 1 • A set of techniques, including machine learning, that is designed to approximate a cognitive
- 2 task.
- 3 • An artificial system designed to act rationally, including an intelligent software agent or
- 4 embodied robot that achieves goals using perception, planning, reasoning, learning,
- 5 communicating, decision making, and acting.²⁸
- 6

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

16
 17 In February 2019, the House Energy and Commerce Committee Subcommittee on Consumer
 18 Protection and Commerce scheduled a hearing on diversity in the technology industry. Though it
 19 had to be rescheduled, the Committee Chairman Frank Pallone (D-NJ) and subcommittee
 20 Chairwoman Jan Schakowsky (D-IL) issued a joint statement concerning AI systems and bias.
 21 Specifically, they noted that a lack of diversity can affect the design of AI. And, the foregoing
 22 could compound the risks of AI systems as the data used to train certain AI systems may amplify
 23 bias and lead to discriminatory outcomes.

24 *White House*

25
 26 In May 2018, the White House hosted a summit with business leaders, government officials, and
 27 academics to identify how the U.S. government could increase AI research and prepare the U.S.
 28 workforce for the disruptions that AI will bring. Officials from most cabinet-level agencies
 29 participated including the HHS Deputy Secretary as well as the HHS Chief Technology Officer.
 30 The health care AI panelists included representatives from CVS, Johnson & Johnson, Medtronic,
 31 Quest Diagnostics, Google, IBM, and Verily, a subsidiary of Google. At the conclusion, the
 32 Administration announced the establishment of an advisory committee comprised of federal
 33 agencies and issued a report and memorandum.²⁹

34
 35
 36 In February 2019, a Presidential Executive Order was issued launching the American AI Initiative.
 37 The Initiative encompasses five key areas: (1) prioritization of investment by all federal agencies in
 38 AI research and development (R&D); (2) requiring federal agencies to make federal data, models,
 39 and computing resources more available to U.S.-based AI R&D experts, researchers, while
 40 maintaining the safety, security, civil liberties, privacy, and confidentiality protections of
 41 Americans; (3) establishing guidance for AI development and use across different types of
 42 technology and industrial sectors and directing the National Institute of Standards and Technology
 43 (NIST) to lead the development of appropriate technical standards for reliable, robust, trustworthy,
 44 secure, portable, and interoperable AI systems; (4) requiring federal agencies to prioritize
 45 fellowship and training programs to help U.S. workers gain AI-relevant skills through
 46 apprenticeships, skills programs, fellowships, and education in computer science and other growing
 47 Science, Technology, Engineering, and Math (STEM) fields; and (5) requiring federal agencies to
 48 develop and implement an action plan to protect the advantage of the U.S. in AI and technology
 49 critical to U.S. national and economic security interests against strategic competitors and foreign
 50 adversaries.³⁰

1 *Food and Drug Administration (FDA)*

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

15
16 The issue of levels of automation in the context of clinical care has become a central question from
17 both a regulatory perspective and for purposes of payment and coverage because a clinically
18 validated autonomous system is labeled by the FDA to perform a service without medical specialist
19 interpretation. The FDA did not identify specific criteria it used to designate the IDx-DR system as
20 autonomous; however, it did set precedent for autonomous AI by requiring a preregistered clinical
21 trial to establish safety, efficacy, and equity, as reflected by the three corresponding trial endpoints.
22 Narrowly defined, equity means that the AI is accurate and effective for all subgroups of the
23 intended population, including age groups, races and ethnicities, not just for one or a few. It
24 requires both design and validation of the AI to address potential bias and sources of bias. Thus,
25 equity is a component of both safety and efficacy. The FDA also established special controls for
26 the autonomous IDx-DR device including software documentation requirements, the requirement
27 for clinical data to evaluate image acquisition as part of the system, the requirement for human
28 factors validation, and the requirement for labeling to include instructions for obtaining quality
29 images and how performance is affected by users interacting with the system.

30
31 Also last year, the FDA permitted marketing of clinical decision support software that alerts
32 providers of a potential stroke in patients. The Viz.AI Contact application is intended for use by
33 neurovascular specialists and other professionals with similar training. The Viz.AI Contact
34 application analyzes CT images of the brain and sends a text notification to a neurovascular
35 specialist if a suspected large vessel blockage has been identified. The AI system automatically
36 notifies the specialist during the same time that the first-line provider is conducting a standard
37 review of the images, thereby involving the specialist sooner than the usual workflow in which a
38 radiologist reviews CT images and then notifies a neurovascular specialist. The specialist still
39 reviews the images on a clinical workstation. The application is limited to analysis of imaging data
40 and has not been authorized by the FDA as a replacement of a full patient evaluation or to be relied
41 upon solely to make or confirm a diagnosis.

42
43 Although AI system developers are able to utilize existing FDA regulatory pathways to secure
44 approval, or *de novo* authorization for AI systems, the FDA has indicated that the Agency’s
45 alternative framework for oversight of software as a medical device (SaMD) could also serve as
46 potential pathway to market AI systems considered medical devices. Software that is intended for
47 use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or
48 prevention of disease, in humans meets the definition of medical device and is FDA regulated.
49 However, certain software that would have met this definition of medical device is no longer
50 subject to FDA oversight due to passage of the 21st Century Cures Act of 2016.

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

9
 10 Early in 2019, the FDA issued an updated version of the proposed Precertification Program. The
 11 FDA states that it contemplates that AI systems would be able to use the Precertification Program.
 12 Throughout 2019, the FDA intends to pilot the Precertification Program in order to assess how the
 13 program could maintain FDA standards for assuring safe and effective products, while still
 14 achieving its aim of modernizing and streamlining the FDA's review of novel digital health
 15 products. The FDA will test how the Precertification Program approach utilizing the streamlined *de*
 16 *novo* authorization pathway compares to the traditional FDA submission pathway. The AMA
 17 continues to provide comments and evaluate carefully the Precertification Program to assess
 18 whether it will ensure the safety and efficacy of software, particularly AI-enabled software that
 19 would be cleared, authorized, or approved through this pathway.

20 21 *Centers for Medicare & Medicaid Services (CMS)*

22
 23 In November 2018, the CMS Center for Medicare & Medicaid Innovation (CMMI) announced a
 24 cross-industry challenge competition to innovate how AI can be implemented in current and future
 25 health care models dubbed the AI Health Outcomes Challenge. CMS noted it would seek
 26 applications for AI and analytics that can boost clinical care and improve overall patient health.
 27 The competition is open to technology vendors, clinicians, scientists, academics and patients who
 28 are innovating their uses of AI for quality improvement. In February 2019, it was announced that
 29 the challenge was being launched in partnership with the American Academy of Family
 30 Physicians. Reportedly, CMS is "brainstorming how [the Agency] can incorporate AI in the
 31 implementation of both our current and new payment and service delivery models."³¹

32 33 *National Institutes of Health (NIH)*

34
 35 In July 2018, the NIH hosted a full-day public workshop titled Harnessing Artificial Intelligence
 36 and Machine Learning to Advance Biomedical Research. Subsequently, the NIH established an AI
 37 Working Group comprised of twelve members—drawn primarily from industry and universities.
 38 The AI Work Group is co-chaired by an engineering director at Verily, and the NIH's Principal
 39 Deputy Director. In December 2018 the AI Work Group provided an update as part of the Meeting
 40 of the Advisory Committee to the NIH Director. The charge of the AI Work Group includes
 41 making recommendations to address the following questions: (1) Are there opportunities for cross-
 42 NIH effort in AI? How could these efforts reach broadly across biomedical topics and have positive
 43 effects across many diverse fields? (2) How can NIH help build a bridge between the computer
 44 science community and the biomedical community? (3) What can NIH do to facilitate training that
 45 marries biomedical research with computer science? and (4) Identify the major ethical
 46 considerations as they relate to biomedical research and using AI/ML/deep learning for health-
 47 related research and care, and suggest ways that NIH can build these considerations into its AI-
 48 related programs and activities.

49
 50 The AI Work Group will offer interim recommendations in June 2019 and final recommendations
 51 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;

1 reducing power, data, and performance inefficiencies; and pioneering the next generation of AI
2 algorithms and applications, such as “explainability” and common sense reasoning.

3 4 *Federation of State Medical Boards*

5
6 In April 2018, the FSMB House of Delegates resolved to convene relevant stakeholders, subject
7 matter experts, including representatives from state medical boards, the AMA, and the American
8 Osteopathic Association to discuss AI and its potential impact on patient safety, decision-making
9 and regulation.³² In November 2018, FSMB hosted AI in Health Care: The Role of Medical
10 Boards. The Summit was comprised of a cross-section of stakeholders including representatives
11 from the AMA and various state medical boards, FSMB leadership, staff, and industry. The
12 discussion centered on the regulatory environment in which health related AI technology is
13 deployed, the mission of state medical boards and approaches to AI regulation taken in other
14 jurisdictions, and the appropriate role and function of medical boards in the deployment of health
15 AI technology.

16 17 POLICY

18
19 The AMA’s foundational Policy H-480.940, “Augmented Intelligence in Health Care,” provides
20 that the perspective of practicing physicians should be included in the development, design,
21 validation, and implementation of health care AI. Furthermore, the policy provides that
22 thoughtfully designed, high-quality, clinically validated health care AI must be designed and
23 evaluated in keeping with best practices in user-centered design, particularly for physicians and
24 other members of the health care team; be transparent; conform to leading standards for
25 reproducibility; identify and take steps to address bias and avoid introducing or exacerbating health
26 care disparities including when testing or deploying new AI tools on vulnerable populations; and
27 safeguard patients’ and other individuals’ privacy interests and preserves the security and integrity
28 of personal information. The policy also provides that our AMA will address the legal implications
29 of health care AI, such as issues of liability or intellectual property, and advocate for appropriate
30 professional and governmental oversight for safe, effective, and equitable use of and access to
31 health care AI.

32
33 In addition, AMA policy concerning payment for digital medicine and integration of health
34 information technology are related to payment and use of AI systems in health care as the latter are
35 a subset of the former.

36
37 AMA Policy H-480.946, “Coverage of and Payment for Telemedicine,” provides that payment and
38 coverage should only occur when delivered consistent with applicable regulatory and oversight
39 requirements designed to ensure patient safety and consistent with clinical practice guidelines
40 developed by national medical specialty societies and other evidence-based practice guidelines, to
41 ensure patient safety, quality of care and positive health outcomes. Furthermore, the policy
42 specifies appropriate disclosure, informed consent, and care coordination must be in place. The
43 policy also provides that digital modalities should comply with laws addressing privacy and
44 security of patients’ medical information and urges physicians to verify that their medical liability
45 insurance policy covers use of such technologies. In this latter regard, it will be important that
46 physicians verify that AI system developers have taken steps to be legally responsible and
47 accountable for the AI system where there is a lack of transparency or the developer is providing or
48 marketing a fully autonomous AI system.

49
50 AMA policies (H-480.946 and H-480.940) outline the importance of: research to build the
51 evidence base for digital medicine; federally funded pilots to assess new delivery models, scaling,

1 quality, and payment; and physician organizations and national medical specialty societies in
2 particular in developing standards and clinical practice guidelines. The policies provide that
3 physician organizations should collaborate with other key stakeholders in the development of
4 technical standards for digital medicine, to the extent practicable, and to take the lead in the
5 development of clinical practice guidelines. AMA policy also provides support for research to
6 develop appropriate practice parameters to address the various applications of digital medicine
7 modalities and to guide quality assessment and liability issues.

8
9 In addition to outlining essential prerequisites to payment such as evidence of clinical usefulness,
10 compliance with state and federal legal requirements to ensure patient safety, and adherence to
11 clinical practice guidelines, AMA Policy H-480.974, “Evolving Impact of Telemedicine,” provides
12 support for pathways to payment under existing payment and delivery models while also specifying
13 that the AMA will work with CMS and other payers to develop and test through demonstration
14 projects appropriate reimbursement mechanisms.

15
16 AMA also has policy concerning the acquisition and cost of health information technology. AMA
17 Policy D-478.990, “Clinical Information Technology Assistance,” provides that the AMA will seek
18 a full refundable federal tax credit or equivalent financial mechanism to indemnify physician
19 practices for the cost of purchasing and implementing clinical information technology, including
20 electronic medical record systems, e-prescribing and other clinical information technology tools, in
21 compliance with applicable safe harbors. And, a related Policy D-478.996, “Information
22 Technology Standards and Cost,” provides that our AMA will work with Congress and insurance
23 companies to appropriately align incentives as part of the development of a National Health
24 Information Infrastructure (NHII), so that the financial burden on physicians is not disproportionate
25 when they implement these technologies in their offices and to take into account the cost to
26 physicians at the office-based level; and to continue to advocate for and support initiatives that
27 minimize the financial burden to physician practices of adopting and maintaining electronic
28 medical records. Finally, the policy provides that our AMA will advocate that physicians not be
29 financially penalized for certified EHR technology not meeting current standards.

30 31 DISCUSSION

32
33 The recommendation referred for report raises many of the same questions and concerns that
34 physicians across medical specialty and practice sites have expressed when adopting new digital
35 medicine modalities or when acquiring, implementing, and maintaining health information
36 technology, as discussed below. In addition, since the referral, payment and use of AI systems in
37 health care has rapidly taken on relevance as the FDA has authorized or cleared for use AI-enabled
38 systems for clinical practice, including, as detailed above, the first autonomous AI-system. And,
39 CMS in collaboration with the American Academy of Family Physicians has launched a challenge
40 competition to innovate how AI can be implemented in current and future health care payment and
41 delivery models.

42
43 AMA policies related to payment and coverage of digital medicine and acquisition of health
44 information technology are directly applicable to funding, payment, and access to AI systems for
45 health administration, population health, practice management, clinical care, and related use.
46 However, AI systems do raise additional issues. Also, these challenges (and potential benefits) may
47 impact physicians and their patients differently depending on the practice size, setting, and
48 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) clinical evidence.

- 1 4. Payment and coverage for health care AI systems must (a) be informed by real world workflow
2 and human-centered design principles; (b) enable physicians to prepare for and transition to
3 new care delivery models; (c) support effective communication and engagement between
4 patients, physicians, and the health care team; (d) seamlessly integrate clinical, administrative,
5 and population health management functions into workflow; and (e) seek end-user feedback to
6 support iterative product improvement.
7
- 8 5. Payment and coverage policies must advance affordability and access to AI systems that are
9 designed for small physician practices and patients and not limited to large practices and
10 institutions. Government-conferred exclusivities and intellectual property laws are meant to
11 foster innovation, but constitute interventions into the free market, and therefore, should be
12 appropriately balanced with the need for competition, access, and affordability.
13
- 14 6. Physicians should not be penalized if they do not use AI systems while regulatory oversight,
15 standards, clinical validation, clinical usefulness, and standards of care are in flux.
16 Furthermore, our AMA opposes:
17 a. Policies by payers, hospitals, health systems, or governmental entities that mandate use of
18 health care AI systems as a condition of licensure, participation, payment, or coverage.
19 b. The imposition of costs associated with acquisition, implementation, and maintenance of
20 healthcare AI systems on physicians without sufficient payment.
21
- 22 7. Liability and incentives should be aligned so that the individual(s) or entity(ies) best positioned
23 to know the AI system risks and best positioned to avert or mitigate harm do so through design,
24 development, validation, and implementation. Our AMA will further advocate:
25 a. Where a mandated use of AI systems prevents mitigation of risk and harm, the individual
26 or entity issuing the mandate must be assigned all applicable liability.
27 b. Developers of autonomous AI systems with clinical applications (screening, diagnosis,
28 treatment) are in the best position to manage issues of liability arising directly from system
29 failure or misdiagnosis and must accept this liability with measures such as maintaining
30 appropriate medical liability insurance and in their agreements with users.
31 c. Health care AI systems that are subject to non-disclosure agreements concerning flaws,
32 malfunctions, or patient harm (referred to as gag clauses) must not be covered or paid and
33 the party initiating or enforcing the gag clause assumes liability for any harm.
34
- 35 8. Our AMA, national medical specialty societies, and state medical associations—
36 a. Identify areas of medical practice where AI systems would advance the quadruple aim;
37 b. Leverage existing expertise to ensure clinical validation and clinical assessment of clinical
38 applications of AI systems by medical experts;
39 c. Outline new professional roles and capacities required to aid and guide health care AI
40 systems; and
41 d. Develop practice guidelines for clinical applications of AI systems.
42
- 43 9. There should be federal and state interagency collaboration with participation of the physician
44 community and other stakeholders in order to advance the broader infrastructural capabilities
45 and requirements necessary for AI solutions in health care to be sufficiently inclusive to benefit
46 all patients, physicians, and other health care stakeholders. (New HOD Policy)

Fiscal Note: Less than \$5000

REFERENCES

- ¹ In developing this BOT Report and the recommendations, the BOT received substantial input from the Council on Legislation, which considered input from a range of experts in health care AI systems including physician AI innovators involved in the design, development, validation, and deployment of health care AI systems.
- ² Even within the computer science community there has been a lack of consensus with regard to both conceptualizing and defining artificial intelligence.
- ³ Clabum, T. IBM: AI Should Stand for ‘Augmented Intelligence.’ InformationWeek, August 4, 2016 Accessed on February 20, 2019 and Afzal, A. Augmented Intelligence, NOT Artificial Intelligence! IBM Blog January 31, 2017 Accessed February 20, 2019.
- ⁴ Interview with John Mattison, MD, Assistant Medical Director and Chief Medical Information Office, Kaiser Permanente-Southern California Region and founding member of KP Innovation Fund and Board of Directors, March 1, 2019, and subsequent posts by John Mattison
- ⁵ Chen JH, Asch SM. Machine learning and prediction in medicine—beyond the peak of inflated expectations. *N Engl J Med* 2017;376:2507–2509. At the 2019, Healthcare Information and Management Systems Society (HIMSS) annual global conference there was day-long program on “Machine Learning and AI for Healthcare” where nationally recognized health care AI innovators presented. One of the key themes from this day-long meeting included discussions subsequently characterized as the “Human/Machine Dyad” where “[p]resenters noted that AI is best understood as “augmented intelligence” in which machine learning serves as an ever evolving tool to the healthcare professional. Greatest success was noted when clinicians and data scientists collaborate closely so that clinicians trust the technology and it fits within their existing workflows.” JDSUPRA Blog Post, February 14, 2019 Accessed February 20, 2019. See also, Alwardt, S. AI Will Converge with Physician-Directed Care, OncLive, January 5, 2019 Accessed on February 26, 2019.
- ⁶ Nundy, S, Hodgkins, M. The Application of AI to Augment Physicians and Reduce Burnout, Health Affairs Blog. September 18, 2018.
- ⁷ Augmented Intelligence & IA: the New Way to Think of About AI, MONDO Blog Post Accessed February 20, 2019
- ⁸ 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.
- ⁹ Buyers, John. *Artificial Intelligence: the Practical Legal Issues* (2018). Another way to describe ML is a mathematical model which makes predictions based on pattern identification within data.
- ¹⁰ Daniel, G., Silcox C., Sharma, I., Wright, M. Bennett. Current State and Near-term Priorities for AI Enable Diagnostic Support Software in Health Care, Duke Margolis Center for Health Policy (January 2019) Accessed February 20, 2019
- ¹¹ Id.
- ¹² Id.
- ¹³ Daniel, G., Silcox C., Sharma, I., Wright, M. Bennett. Current State and Near-term Priorities for AI Enable Diagnostic Support Software in Health Care, Duke Margolis Center for Health Policy (January 2019) Accessed February 20, 2019
- ¹⁴ Challen R, Denny J, Pitt M, et al. Artificial intelligence, bias, and clinical safety, *BMJ Qual Saf* Epub doi:10.1136/ bmjqs-2018-008370
- ¹⁵ Maddox TM, Rumsfeld JS, Payne PRO. Questions for Artificial Intelligence in Health Care. *JAMA*.2019;321(1):31–32. doi:10.1001/jama.2018.18932
- ¹⁶ Knight, W. Forget Killer Robots—Bias is the Real AI Danger, MIT Technology Review, October 3, 2017 Accessed February 26, 2019
- ¹⁷ Topol, E. High -performance medicine: the convergence of human and artificial intelligence, *Nature Medicine* (January 2019)
- ¹⁸ Russell, S. Dewey, D. Tegmark, M. Research Priorities for Robust and Beneficial AI, AAAI (2015) Accessed February 22, 2019
- ¹⁹ The emergence of artificial intelligence and machine learning algorithms in health care: Recommendations to support governance and regulation BSI and AAMI (February 2019) Accessed February 22, 2019
- ²⁰ A future report addressing the practices, standards, and legal requirements followed by health systems designing, developing, validating, and deployment that may or may not be subject to oversight under the Food, Drug and Cosmetic Act may be needed.

²¹ [Artificial Intelligence: Healthcare's New Nervous System](#), Accenture Accessed February 20, 2019.

²² [The AI Industry Series: Top Health Care AI Trends to Watch](#), CB Insights Accessed on February 20, 2019

²³ Id.

²⁴ Columbus, L., [Microsoft Leads the AI Patent Race Going into 2019](#), Forbes, January 6, 2019, Accessed on February 25, 2019 and see also [graph](#) of patents in various industries including health care over series of years.

²⁵ There has been significant government activity involving the work the National Institute of Standards and Technology (NIST) and certain operating and staffing divisions of the Department of Health and Human Services (HHS) including the Office of the National Coordinator for Health Information Technology (ONC), the Office of Civil Rights (OCR), and the Centers for Medicare and Medicaid Services (CMS) related to data uses and access.

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.

REPORT OF THE BOARD OF TRUSTEES

B of T Report 22-A-19

Subject: Inappropriate Use of CDC Guidelines for Prescribing Opioids
(Resolution 235-I-18)

Presented by: Jack Resneck, Jr., MD, Chair

Referred to: Reference Committee B
(Charles Rothberg, MD, Chair)

1 INTRODUCTION

2
3 At the 2018 Annual Meeting, the House of Delegates (HOD) referred the second resolve of
4 alternate Resolution 235, “Inappropriate Use of CDC Guidelines for Prescribing Opioids.” The
5 second resolve in the alternate resolution asked:

6
7 [T]hat our AMA actively continue to communicate and engage with the nation’s largest
8 pharmacy chains, pharmacy benefit managers, National Association of Insurance
9 Commissioners, Federation of State Medical Boards, and National Association of Boards of
10 Pharmacy in opposition to communications being sent to physicians that include a blanket
11 proscription against filing prescriptions for opioids that exceed numerical thresholds without
12 taking into account the diagnosis and previous response to treatment for a patient and any
13 clinical nuances that would support such prescribing as falling within standards of good quality
14 patient care.

15
16 This report provides an update on those communications, highlights complementary AMA
17 advocacy and provides recommendations.

18 19 DISCUSSION

20
21 The nation’s opioid epidemic has led to extensive policy development in multiple areas—from
22 several hundred new state laws and regulations to hundreds of millions of dollars earmarked by
23 federal legislation for treatment of opioid use disorder, harm reduction efforts and other initiatives.
24 Debating the merits of the new laws and regulations would go beyond the scope of this report, but
25 it should be noted that each new law or regulation occurred within a notice and comment period as
26 well as extensive public debate informed by stakeholder advocacy that underpins the lawmaking
27 process. Medical societies may not have supported each piece of legislation or agreed with the
28 regulatory agencies charged with rulemaking, but organized medicine has been an active
29 participant in every state, in Congress and with the relevant federal agencies.

30
31 That is not, however, the only type of policymaking that has occurred. Health insurance companies,
32 national pharmacy chains and pharmacy benefit management companies (PBMs) all have—to
33 varying degrees—implemented their own policies governing physician prescribing of controlled
34 substances as well as patients’ abilities to have a controlled substance prescription dispensed to
35 them. The result of this type of quasi-regulation is incredibly difficult to quantify on a large scale
36 basis due to the lack of transparency in the public sphere, but the AMA and many medical societies

1 continue to receive concerns from physicians and patients as to the disruptive nature of health plan,
2 pharmacy chain or PBM interference in the patient-physician relationship. The concern and/or
3 perceived interference has included pharmacists calling to ask about a patient's diagnosis or request
4 patient records, a pharmacist asking for clarification about a prescription or alerting the physician to
5 red flags, a pharmacist recommending a different medication strategy, and in some cases, a
6 pharmacist informing the physician that the prescription will not be filled. This concern and/or
7 interference has even gone so far as a pharmacist demanding patients taper their opioid
8 prescriptions, telling them that the U. S. Drug Enforcement Administration (DEA) identified the
9 patient's prescription as "exceeding the maximum Morphine Milligram Equivalents (MME) as
10 defined by the Centers for Disease Control and Prevention (CDC)." ¹ In response to this last
11 incident, the DEA and CDC, among others, stated to the AMA (and the Medical Association of
12 Georgia) that the pharmacist's actions and interpretation of CDC and DEA rules and guidelines
13 were incorrect and inappropriate. MAG informed the AMA of this situation, and the AMA, in turn,
14 reached out to the DEA, CDC, National Association of Boards of Pharmacy and others—all of
15 whom quickly engaged with the AMA to register their disapproval of the pharmacy action and state
16 that they would take all relevant actions in Georgia. Your Board appreciates the fact that DEA,
17 CDC, NABP and others took action to support the concerns of MAG and the AMA.

18
19 These different physician-pharmacist interactions, however, are often the inevitable result of
20 policies mainly focused on the dose and/or number of days for a prescription for opioid analgesics.
21 It should be noted at the outset that the AMA strongly supports physicians' efforts to ensure that if
22 a prescription for an opioid analgesic is warranted to help treat a patient's pain, physicians should
23 prescribe the lowest effective dose only for the shortest duration of time. The AMA also supports
24 pharmacists as key partners in helping ensure medication safety and as part of the patient-
25 physician-pharmacist therapeutic triad. The Board and the AMA Opioid Task Force point out that
26 physicians' efforts to make more judicious prescribing decisions have led to a more than 22 percent
27 reduction in retail opioid prescriptions dispensed between 2013-2017, and that these reductions
28 began prior to nearly all legislative, regulatory and other efforts focused on reducing opioid supply.
29

30 Concurrent with and despite this progress, national pharmacy chains, health insurance companies
31 and PBMs have implemented their own restrictive opioid prescribing policies. This report will not
32 detail every iteration and difference between the policies except to say that most of the policies are
33 some variation of the "CDC Guideline for Prescribing Opioids for Chronic Pain—United States,
34 2016" (the CDC Guideline). ² In the CDC Guideline's introduction, CDC stated:

35
36 [T]he recommendations in the guideline are voluntary, rather than prescriptive standards. They
37 are based on emerging evidence, including observational studies or randomized clinical trials
38 with notable limitations. Clinicians should consider the circumstances and unique needs of
39 each patient when providing care.

40
41 Yet, the CDC Guideline goes on to make two recommendations that appear in nearly all the
42 pharmacy, payer and PBM policies:

43
44 [Recommendation] 5. When opioids are started, clinicians should prescribe the lowest effective
45 dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully
46 reassess evidence of individual benefits and risks when considering increasing dosage to ≥ 50
47 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥ 90
48 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

1 The AMA's work with the FSMB, moreover, also pre-dated the issuance of the CDC Guideline.
2 One prominent outcome from the FSMB was adoption, in 2017, of an updated "Guidelines for the
3 Chronic Use of Opioid Analgesics."⁹ The AMA was a member of the workgroup that provided
4 input to the FSMB during its deliberations and strongly voiced its concern about "one-size-fits-all"
5 thresholds. The FSMB, to its great credit, supported those concerns and the resulting policy reflects
6 support for ensuring patient-focused care. For example, the FSMB states:

7
8 [T]he "focus of the [FSMB] Guidelines that follow is on the general overall safe and evidence-
9 based prescribing of opioids and treatment of chronic, non-cancer pain with the specific
10 limitation and restriction that these Guidelines do not operate to create any specific standard of
11 care, which standard must depend upon fact-specific totality of circumstances surrounding
12 specific quality-of-care events."

13
14 In addition to the FSMB's ongoing support for patient-focused care, the development of the NABP
15 consensus statement also resulted in the development of close relationships with pharmacy
16 counterparts at several national chain pharmacies. When issues have arisen in select states where a
17 physician reports a concern with the dispensing decision of a pharmacy, these relationships have
18 enabled AMA to work directly with the national chain and the state medical society to resolve the
19 issue—a resolution based on specific facts rather than a one-size-fits-all approach. The AMA also
20 has remained in close contact with the NABP to share information and work collaboratively where
21 interests align, including efforts to bolster constructive relationships between physicians and
22 pharmacists. It also is worth highlighting that some pharmacy boards are taking steps to remind
23 their licensees about the need to ensure dispensing determinations are made on an individualized
24 patient basis.¹⁰

25
26 Despite continued efforts by AMA to constructively engage Walmart, Inc. (Walmart), however, the
27 national pharmacy chain has taken a markedly different course. Specifically, Walmart has sent an
28 unknown number of what can be considered "blacklist" letters to physicians. These unsigned letters
29 from Walmart's corporate headquarters have been sent in multiple states and only include a generic
30 email address for the physician to respond to if the letter was believed to be sent in error. The letter
31 typically states that the physician in question had his or her "prescribing patterns and practices"
32 reviewed and as a result, "[Walmart] determined that we will not be able to continue filling your
33 controlled substance prescriptions." AMA has sent multiple letters, email and voice messages to
34 Walmart opposing its policy and seeking explanation—all without meaningful response.¹¹ Others,
35 including the Texas Medical Association, also have not received a meaningful response from
36 Walmart.¹² In one instance, the overly broad and vague Walmart policy targeted a rural Idaho
37 addiction medicine physician who prescribed buprenorphine, but did not prescribe opioid
38 analgesics. As CDC has stated, buprenorphine for the treatment of opioid use disorder should not
39 be used in an MME calculation,¹³ but resolution of this matter required extensive commitment from
40 the Idaho Medical Association and Idaho Board of Pharmacy—and resulted in patients being
41 forced to find alternate pharmacies to continue their care.

42
43 With respect to health insurance companies, the AMA has made inquiries but is not aware of any
44 widespread action by payers to send physicians letters or other communication "that include a
45 blanket proscription against filing prescriptions for opioids that exceed numerical thresholds
46 without taking into account the diagnosis and previous response to treatment for a patient and any
47 clinical nuances would support such prescribing as falling within standards of good quality patient
48 care." Rather, AMA is acutely aware of health insurance companies implementing hard-threshold
49 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. (New HOD Policy)
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. (New HOD Policy)

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- ⁷ Physicians and patients can learn more about American Medical Association advocacy to broadly address prior authorization issues at www.FixPriorAuth.org
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- 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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REPORT OF THE BOARD OF TRUSTEES

B of T Report 23-A-19

Subject: Prior Authorization Requirements for Post-Operative Opioids
(Resolution 208-A-18)

Presented by: Jack Resneck, Jr., MD, Chair

Referred to: Reference Committee B
(Charles Rothberg, MD, Chair)

1 INTRODUCTION

2
3 At the 2018 Annual Meeting, the American Medical Association (AMA) House of Delegates
4 (HOD) referred Resolution 208-A-18, “Prior Authorization Requirements for Post-Operative
5 Analgesia,” introduced by the Pennsylvania Delegation, which asked:

6
7 That our American Medical Association strongly oppose prior authorization requirements for
8 postoperative analgesia equivalent to five days or less so as to prevent patient suffering.
9

10 Reference committee testimony generally was supportive of the original resolution given
11 physicians’ and patients’ experiences with legislative and other policies focused on hard thresholds
12 for opioid prescribing post-surgery and other acute care settings. Yet, there was concern raised
13 regarding taking a position to oppose all prior authorization or other utilization management
14 protocols. The AMA Council on Medical Service and Council on Legislation were among those
15 who asked that our Board take this resolution back for consideration, discussion and present clear
16 recommendations to further the intent of the original resolution.
17

18 DISCUSSION

19
20 There are multiple, competing and often contradictory trends that define the nation’s opioid
21 epidemic. Opioid-related mortality continues to increase, but data from the Centers for Disease
22 Control and Prevention (CDC)¹ show that the nation’s opioid overdose and death epidemic
23 continues to be driven by increases in death due to illicit fentanyl. Deaths due to prescription
24 opioid- and heroin-related causes appear to have plateaued but remain at historic highs. In 2017:

- 25
26 • 28,466 died from illicit fentanyl-related overdose (19,413 in 2016).
27 • 15,482 died from heroin-related overdose (15,469 in 2016).
28 • 14,495 died from prescription opioid-related overdose (14,487 in 2016). (More than 60
29 percent of people who misused prescription opioids steal them or obtain them from a
30 family member or friend.²)
31 • 3,194 died from methadone-related causes—the lowest number since 2003. (The data does
32 not distinguish whether methadone was used for pain or for the treatment of opioid use
33 disorder.³)
34

35 At the same time, opioid prescribing in the United States continues to decrease. Between 2013-
36 2017, retail filled opioid prescriptions decreased by 22.2 percent with a total of 196 million opioid

1 prescriptions filled in 2017.⁴ Decreases occurred in every state. The most common opioid
2 prescription was for less than 30 days and less than 50 morphine milligram equivalents (MME).
3 From 2014 to 2016, opioid prescriptions written for fewer than 30 days decreased from 150.4
4 million to 126.5 million; and opioid prescriptions of less than 50 MME decreased from 175.6
5 million in 2014 to 158.0 million in 2016.⁵

6
7 Policymakers for the past several years have focused almost entirely on mandating a few specific
8 policies or approaches that they believe would help end the epidemic. These include enacting
9 legislation in nearly four out of five states to require physicians to use a state prescription drug
10 program (PDMP); mandating content-specific continuing medical education (CME) in more than
11 half of the states; and prohibiting a prescription for an opioid analgesic if it is greater than a certain
12 number of days or for a greater than a certain MME.

13
14 Restrictions on opioid prescribing also have been implemented by health plans, national pharmacy
15 chains and pharmacy benefit management companies.⁶ Many of these policies follow the
16 publication from the CDC entitled, “CDC Guideline for Prescribing Opioids for Chronic Pain —
17 United States, 2016 (the Guideline).”⁷ In the Guideline’s introduction, CDC stated:

18
19 The recommendations in the guideline are voluntary, rather than prescriptive standards. They
20 are based on emerging evidence, including observational studies or randomized clinical trials
21 with notable limitations. Clinicians should consider the circumstances and unique needs of
22 each patient when providing care.

23
24 Many of the state legislative and other policies enacted and/or implemented since then, however,
25 justify the day/dose limit for acute pain based on the CDC Guideline. The HOD addressed this in
26 Policy D-120.932, “Inappropriate Use of CDC Guidelines for Prescribing Opioids.” And while it is
27 common for state opioid restriction policies to allow for exceptions for patients with cancer, in
28 hospice or who require palliative care, to name a few, there generally is no exception for when
29 post-operative surgical care might require a prescription for a greater number of days or dose
30 strength than a particular state might allow.

31
32 State policymaking also has resulted in no consistency between opioid restriction or other laws. For
33 example, some states require checking the PDMP prior to prescribing any controlled substance or
34 limited to only opioid analgesics. Other states require a PDMP check every 90 days (or another
35 interval) for repeated prescriptions, and other states require a check only once per year. With
36 respect to CME mandates, the number of hours and specific nature of the CME vary by state. The
37 Board notes that the AMA Opioid Task Force has gathered more than 400 state- and specialty-
38 specific resources to help promote the availability of education and training that is relevant and
39 meaningful to a physician’s specific practice and patient population.⁸ The Board thanks all those
40 Federation partners who have contributed to this effort.

41
42 With respect to opioid prescribing, physicians and other prescribers of controlled substances have
43 borne a considerable amount of blame. The AMA and countless physician organizations have
44 accepted responsibility for both working to reduce patients’ pain and the medical community
45 acknowledges its role in having in the past increased opioid prescribing as one way to help
46 alleviate patients’ pain. The AMA also has supported efforts by law enforcement and others to stop
47 illegal activities such as pill mills and the AMA and countless physician organizations have made
48 considerable progress in urging physicians to be more judicious in their prescribing decisions as the
49 above data show. The Board knows, however, that there is much more work to do before the
50 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

1 care. This includes promoting safe opioid prescribing and promoting a public health approach to
2 ending the nation's opioid epidemic (e.g., Policy D-160.981, Policy H-95.990, "Promotion of
3 Better Pain Care and Drug Abuse Related to Prescribing Practices"). And, it includes AMA strong
4 support for "timely and appropriate access to non-opioid and non-pharmacologic treatments for
5 pain, including removing barriers to such treatments when they inhibit a patient's access to care."
6 (Policy D-450.956, "Pain as the Fifth Vital Sign.") It should also be stressed that AMA's efforts to
7 reduce prior authorization burdens and protect patients' access to medically necessary therapy
8 extend far beyond only post-operative pain care (e.g., Policy H-320.939, "Prior Authorization and
9 Utilization Management Reform" and the grassroots advocacy campaign based on the online hub,
10 FixPriorAuth.org).

11 RECOMMENDATIONS

12
13
14 The Board recommends that the following recommendation be adopted in lieu of Resolution 208-
15 A-18, and that the remainder of the report be filed.

- 16
17 1. That our American Medical Association (AMA) advocate for state legislatures and other
18 policymakers, health insurance companies and pharmaceutical benefit management companies
19 to remove barriers, including prior authorization, to non-opioid pain care. (New HOD Policy)
20
- 21 2. That our AMA support amendments to opioid restriction policies to allow for exceptions that
22 enable physicians, when medically necessary in the physician's judgment, to exceed statutory,
23 regulatory or other thresholds for post-operative care and other medical procedures or
24 conditions. (New HOD Policy)
25
- 26 3. That our AMA oppose health insurance company and pharmacy benefit management company
27 utilization management policies, including prior authorization, that restrict access to post-
28 operative pain care, including opioid analgesics, if those policies are not based upon sound
29 clinical evidence, data and emerging research. (New HOD Policy)

Fiscal Note: Less than \$500.

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REPORT OF THE BOARD OF TRUSTEES

B of T Report 30-A-19

Subject: Opioid Treatment Programs Reporting to Prescription Monitoring Programs
(Resolution 507-A-18)

Presented by: Jack Resneck, Jr., MD, Chair

Referred to: Reference Committee B
(Charles Rothberg, MD, Chair)

1 INTRODUCTION

2
3 At the 2018 American Medical Association (AMA) House of Delegates (HOD) Annual Meeting,
4 the Medical Student Section introduced Resolution 507-A-18, asking that our AMA amend Policy
5 D-95.980, “Opioid Treatment and Prescription Drug Monitoring Programs,” by deletion as follows:
6

7 Our AMA will seek changes to ~~allow states the flexibility to~~ require opioid treatment programs
8 to report to prescription monitoring programs.
9

10 The resolution was ultimately referred. There was considerable testimony at the reference
11 committee identifying numerous issues to both support and oppose the resolution. This report
12 provides a current update of prescription drug monitoring programs (PDMPs), the privacy
13 protections patients are afforded with respect to PDMPs, relevant federal laws governing opioid
14 treatment programs (OTPs), highlights relevant AMA policy, and presents a recommendation.
15

16 DISCUSSION

17 *Prescription drug monitoring programs*

18 PDMPs are generally described as electronic interfaces that allow physicians and other authorized
19 users to view a patient’s-controlled substance prescription history. Every state except Missouri has
20 a PDMP, although some are more advanced than others. The AMA supports physicians registering
21 for and using PDMPs as part of the clinical decision-making process.
22
23
24

25 At present, at least 44 states require physicians and other clinicians who prescribe controlled
26 substances to query the PDMP under certain circumstances. These mandates range from requiring a
27 query prior to prescribing any controlled substances every time a prescription for a controlled
28 substance is issued to every six months or a year; to queries limited only to the prescribing of
29 opioid analgesics and benzodiazepines.
30

31 Emerging data suggests that PDMPs have not led to reductions in opioid-related mortality as
32 proponents have predicted. From 2014 and 2017, physicians’ and other health care professionals’
33 use of PDMPs increased from 61.4 million queries to more than 300.3 million queries; and
34 registration to use a PDMP increased from 471,896 to more than 1.5 million registered users.¹
35 Opioid-related mortality, however, has increased considerably. From 2012 to 2017, prescription
36 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.

1 In the courts, the AMA and nine state medical societies argued to the Ninth Circuit Court of
2 Appeals against the United States Drug Enforcement Administration efforts to access the Oregon
3 PDMP with only an administrative warrant that “patients have a basic right to privacy of their
4 medical information. That privacy should be honored unless there is meaningful waiver by the
5 patient or a strong countervailing public health or safety interest, and then only with stringent
6 safeguards.”⁹ The AMA and California Medical Association also argued against unfettered access
7 to patients’ prescription information in *Lewis v. Medical Board of California*, where “a Medical
8 Board of California investigator testified that the board routinely obtains confidential prescribing
9 records from [the California PDMP] for all patients of physicians subject to medical board
10 investigations, even where the complaint is unrelated to the patients or the physician’s prescribing
11 practices.”¹⁰

12
13 Additionally, before enacting a law requiring that police and prosecutors obtain warrants before
14 searching in sensitive patient information in the state’s prescription monitoring database,
15 Massachusetts allowed police and prosecutors to view patient medical records without warrants
16 nearly 11,000 times—or about 20 times per day—between August 2016 and March 2018.¹¹

17
18 Unauthorized access also can occur when law enforcement inappropriately pressures pharmacists
19 to query a PDMP without judicial oversight. The American Pharmacists Association counsels that:

20
21 The information in PDMP reports is personal and private. Patients expect that pharmacists will
22 maintain the confidentiality of this information, and this is a key aspect of the professional
23 relationship of trust between pharmacists and patients.¹²

24
25 Unauthorized access and inappropriate use of an individual’s person health information can have
26 devastating effects, such as occurred to a Utah firefighter whose PDMP information was accessed
27 and misinterpreted at multiple steps during several year long legal battle. Ultimately, all charges
28 were dismissed, but not before the damage had been done.¹³

29
30 Notwithstanding the legal requirements, case law and news items noted above, states generally
31 have strong protections regarding the unauthorized use of information within a PDMP. While
32 important work is being done to remove stigma and regard SUD as a medical condition like any
33 other, the fact remains that illicit substance use is illegal, which is decidedly unlike any other
34 medical issue.¹⁴ Inappropriate disclosure of SUD data can result in consequences exponentially
35 more harmful to a patient than the improper disclosure of his or her hypertension (e.g., loss of
36 housing,¹⁵ loss of child custody,¹⁶ discrimination from medical professionals,¹⁷ loss of benefits¹⁸ or
37 loss of employment,¹⁹ among others).²⁰ Any discussion of increasing the exchange of SUD
38 information must contemplate the potential for such outcomes.

39
40 The AMA supports the refinement of PDMPs and development and implementation of technology
41 that assists physicians with sharing information on prescriptions for controlled substances among
42 states. AMA also calls for appropriate balance when the information in question relates to patients
43 who receive treatment in an OTP—patients who often experience a much higher degree of
44 stigmatization and prejudice than other patients with a chronic medical disease.

45
46 Further, even if a patient receiving care in an OTP authorized the disclosure of prescription
47 information to be entered into a PDMP, it is unclear how that authorization would protect the
48 patient against further re-disclosure. That is, proponents of removing OTP privacy and disclosure
49 protections suggest that the PDMP already has sufficient safeguards against unauthorized use, but
50 as noted above, that is not actually the reality. In addition, the patient privacy and consent
51 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.

1 RECOMMENDATION

2

3 The Board of Trustees recommends that Resolution 507-A-18 not be adopted and the remainder of
4 this report be filed.

Fiscal Note: Less than \$500.

REFERENCES

¹ AMA survey of state PDMP officials, 2018. Available at <https://www.end-opioid-epidemic.org/wp-content/uploads/2018/05/PDMP-registration-and-use-2014-to-2017-FINAL-updated.pdf>

² Elinore F. McCance-Katz MD, PhD Assistant Secretary for Mental Health and Substance Use Substance Abuse and Mental Health Services Administration U.S. Department of Health and Human Services. The National Survey on Drug Use and Health: 2017. Available at <https://www.samhsa.gov/data/sites/default/files/nsduh-ppt-09-2018.pdf>

³ Finley EP, Garcia A, Rosen K, McGeary D, Pugh MJ, Potter JS. Evaluating the impact of prescription drug monitoring program implementation: a scoping review. *BMC Health Serv Res.* 2017;17(1):420. Published 2017 Jun 20. doi:10.1186/s12913-017-2354-5. Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5477729/>

⁴ Young Hee Nam, PhD; Dennis G. Shea, PhD; Yunfeng Shi, PhD; and John R. Moran, PhD. "State Prescription Drug Monitoring Programs and Fatal Drug Overdoses." *The American Journal of Managed Care*, May 26, 2017. Available at <https://www.ajmc.com/journals/issue/2017/2017-vol23-n5/state-prescription-drug-monitoring-programs-and-fatal-drug-overdoses>

⁵ Chen Q, Larochelle MR, Weaver DT, et al. Prevention of Prescription Opioid Misuse and Projected Overdose Deaths in the United States. *JAMA Netw Open.* 2019;2(2):e187621. doi:10.1001/jamanetworkopen.2018.7621

⁶ AMA letter to Roger Severino, Director, Office for Civil Rights, U.S. Department of Health and Human Services, February 8, 2019. Available at <https://searchlf.ama-assn.org/undefined/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2019-2-8-Letter-to-Severino-re-HIPAA-RFI-Response.pdf>

⁷ Law Enforcement Access to PDMP Reports, The Prescription Drug Monitoring Program Training and Technical Assistance Center (PDMP TTAC) at Brandeis University. Available at http://www.pdmpassist.org/pdf/Law_Enforcement_Access_Methods_20180801.pdf

⁸ PDMPs Authorized and Engaged in Sending Solicited and Unsolicited Reports to Public and Private Insurance Entities, The Prescription Drug Monitoring Program Training and Technical Assistance Center (PDMP TTAC) at Brandeis University. Available at http://www.pdmpassist.org/pdf/Insurance_Entity_Table_20180801.pdf

⁹ *Oregon Prescription Drug Monitoring Program, ACLU Foundation Of Oregon, Inc., et al., v. United States Drug Enforcement Administration.* AMA amicus brief available at <https://searchlf.ama-assn.org/undefined/documentDownload?uri=%2Funstructured%2Fbinary%2Fcasebriefs%2Foregon-pdmp-v-dea.pdf>. The medical societies joining the AMA were the Oregon Medical Association, Alaska State Medical Association, Arizona Medical Association, California Medical Association, Hawaii Medical Association, Idaho Medical Association, Montana Medical Association, Nevada State Medical Association and the Washington State Medical Association.

¹⁰ "CMA fights to protect patient privacy in CURES prescription database," January 10, 2014. Available at <http://cplh.org/blog/detail/?article=cma-fights-to-protect-patient-privacy-in-cures>. Also see https://searchlf.ama-assn.org/case/documentDownload?uri=/unstructured/binary/case/Case-Summary_Lewis-v-Superior-Court-Med-Board-CA.pdf

¹¹ <https://www.aclum.org/en/publications/victory-police-massachusetts-must-now-get-warrant-access-sensitive-patient-data>

¹² Unauthorized police access to PDMP data. American Pharmacists Association. July 1, 2013. Available at <https://www.pharmacist.com/unauthorized-police-access-pdmp-data>

¹³ Sweeney, Marlis Silver. ArsTechnica, “The big drug database in the sky: One firefighter’ s year-long legal nightmare,” May 12, 2015. Available at <https://arstechnica.com/tech-policy/2015/05/the-big-drug-database-in-the-sky-one-firefighters-year-long-legal-nightmare/>

¹⁴ <https://www.wkbn.com/ohio-news/overdose-victims-cited-in-one-ohio-city/1067863977>

¹⁵ <https://www.huduser.gov/portal/periodicals/cityscape/vol15num3/ch2.pdf>

¹⁶ <https://www.childwelfare.gov/pubPDFs/drugexposed.pdf>

¹⁷ <https://www.ncbi.nlm.nih.gov/pubmed/23490450>

¹⁸ <https://www.ssa.gov/policy/docs/rsnotes/rsn2001-02.html>

¹⁹ <https://corporate.findlaw.com/litigation-disputes/the-americans-with-disabilities-act-and-current-illegal-drug.html>

²⁰ <http://www.healthaffairs.org/doi/10.1377/hblog20170413.059618/full/>; see also

<https://www.macpac.gov/wp-content/uploads/2018/06/Substance-Use-Disorder-Confidentiality-Regulations-and-Care-Integration-in-Medicaid-and-CHIP.pdf>, p. 25.

²¹ 45 CFR 164.506(b)(1).

²² <https://lac.org/112-nations-leading-patient-advocacy-health-care-organizations-launch-campaign-protect-patient-privacy-rights/>

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>

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 201
(A-19)

Introduced by: American Society of Transplant Surgeons

Subject: Assuring Patient Access to Kidney Transplantation

Referred to: Reference Committee B
(Charles Rothberg, MD, Chair)

Whereas, Kidney transplantation is often the best and most cost-effective treatment for patients with End Stage Renal Disease (ESRD); and

Whereas, Some for-profit health-care entities have sought to remove control of kidney transplantation decision-making from many physicians and their patients¹; and

Whereas Some for-profit health care entities have sought to create monetary incentives that would sharply curtail patient access to transplantation; and

Whereas, There exists comprehensive patient-oriented care models such as the Centers for Medicare and Medicaid Innovation Comprehensive ESRD Care Model² that do not threaten access to transplantation; and

Whereas, Dialysis and transplant professional³⁻⁵ as well as patient-centered groups^{5,6} oppose limitations on physician-advised patient choice of kidney transplantation in ESRD treatment; therefore be it

RESOLVED, That our American Medical Association work with professional and patient-centered organizations to advance patient and physician-directed coordinated care for End Stage Renal Disease (ESRD) patients (Directive to Take Action); and be it further

RESOLVED, That our AMA actively oppose any legislative or regulatory efforts to remove patient choice and physician involvement in ESRD care decisions (Directive to Take Action); and be it further

RESOLVED, That our AMA actively oppose any legislative or regulatory effort that would create financial incentives that would curtail the access to organ transplantation (Directive to Take Action); and be it further

RESOLVED, That our AMA House of Delegates be advised in a timely fashion regarding any legislative or regulatory efforts to abrogate patient and physician-advised decision-making regarding modality of care for ESRD. (Directive to Take Action)

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

Received: 04/30/19

1 Dialysis PATIENTS Demonstration Act of 2017" (S. 2065) (HR 4143): <https://www.congress.gov/bill/115th-congress/house-bill/4143/text>

2 Center for Medicare and Medicaid Innovation Comprehensive ESRD Care Model: <https://innovation.cms.gov/initiatives/comprehensive-esrd-care/>

- 3 American Society of Transplant Surgeons: The ASTS-AST-AOPO-AAKP Joint Letter on Dialysis PATIENTS Demonstration Act of 2017: https://asts.org/docs/default-source/legislative/joint-letter-on-the-house-patients-act-december-1-2017.pdf?sfvrsn=94227ed3_2
- 4 DCI: Letter 2 November, 2017: http://asts.org/docs/default-source/test-document-library/dci-h-r-4143-letter-11-02-17.pdf?sfvrsn=83987fd3_2
- 5 American Association of Kidney Patients and the American Society of Nephrology: Letter 28 February, 2018: http://asts.org/docs/default-source/test-document-library/asn-aakpletter-patientact-housesenate_2018-2-18.pdf?sfvrsn=82987fd3_4
- 6 The FAIR Foundation: www.FAIRfoundation.org : Policy adopted 28 January, 2018

RELEVANT AMA POLICY

Equal Access to Organ Transplantation for Medicaid Beneficiaries H-370.962

Our AMA supports federal funding of organ transplants for Medicaid patients.

Citation: (BOT Rep. 15, A-13)

Ethical Procurement of Organs for Transplantation H-370.967

Our AMA will continue to monitor ethical issues related to organ transplantation and develop additional policy as necessary.

Citation: BOT Rep. 13, A-08; Reaffirmed: CEJA Rep. 06, A-18

UNOS Kidney Paired Donation Program H-370.960

Our AMA: (1) encourages the continued expansion of the United Network for Organ Sharing's (UNOS) Kidney Paired Donation program which provides a national registry of living donors, carries out ongoing data collection on key issues of concern in transplantation from living donors, and through its operational guidelines provides consistent, national standards for the transplant community; and (2) encourages voluntary coordination among private donor registries and UNOS to enhance the availability of organs for transplantation.

Citation: (BOT Action in response to referred for decision Res. 2, A-13)

Cost-Saving Public Coverage for Renal Transplant Patients H-370.963

1. Our AMA supports private and public mechanisms that would extend insurance coverage for evidence-based treatment of renal transplant care for the life of the transplanted organ.

2. Our AMA will continue to offer technical assistance to individual state and specialty societies when those societies lobby state or federal legislative or executive bodies to implement evidence-based cost-saving policies within public health insurance programs.

Citation: (Res. 104, A-13)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 202
(A-19)

Introduced by: California

Subject: Reducing the Hassle Factor in Quality Improvement Programs

Referred to: Reference Committee B
(Charles Rothberg, MD, Chair)

Whereas, The Center for Medicare and Medicaid Services (CMS) is soliciting suggestions for improving the current Merit-Based Incentive Payment System (MIPS) in the Quality Payment Program (QPP) to reduce administrative burdens as part of their "Patients Over Paperwork" Initiative; and

Whereas, Physicians are asked to participate in Certification/Maintenance of Certification by the American Board of Medical Specialties (ABMS) including the American Board of Internal Medicine (ABIM); and

Whereas, The CMS-stated goal of MIPS is to improve quality of care and the MOC program goals are to maintain and improve quality of care with emphasis on knowledge base, and

Whereas, Both MIPS and MOC take a significant amount of time away from patient care, and have increased the administrative burden and stress on the practicing physician; and

Whereas, Our AMA, the state medical associations, and the national specialty societies all agree on the importance of reducing the hassle factor for physicians; therefore be it

RESOLVED, That our American Medical Association recommend to the Centers for Medicare and Medicaid Services (CMS) and physician certifying boards, such as the American Board of Medical Specialties, that maintenance of certification (MOC) participation count toward satisfying the quality category of the Merit-Based Incentive Payment Program (MIPS) (Directive to Take Action); and be it further

RESOLVED, That our AMA also recommend that successful reporting in the quality category of the Merit-Based Incentive Payment Program (MIPS) count toward satisfying the practice performance assessment section of a certifying board's MOC requirements) (Directive to Take Action); and be it further

RESOLVED, That our AMA study MOC and Medicare MIPS reciprocity and work with the state and national specialty societies to develop a plan to reduce quality measure duplication and administrative burdens in both the MIPS and MOC programs. (Directive to Take Action)

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

Received: 04/29/19

RELEVANT AMA POLICY

Maintenance of Certification and Osteopathic Continuous Certification D-275.954

Our AMA will:

1. Continue to monitor the evolution of Maintenance of Certification (MOC) and Osteopathic Continuous Certification (OCC), continue its active engagement in discussions regarding their implementation, encourage specialty boards to investigate and/or establish alternative approaches for MOC, and prepare a yearly report to the House of Delegates regarding the MOC and OCC process.
2. Continue to review, through its Council on Medical Education, published literature and emerging data as part of the Council's ongoing efforts to critically review MOC and OCC issues.
3. Continue to monitor the progress by the American Board of Medical Specialties (ABMS) and its member boards on implementation of MOC, and encourage the ABMS to report its research findings on the issues surrounding certification and MOC on a periodic basis.
4. Encourage the ABMS and its member boards to continue to explore other ways to measure the ability of physicians to access and apply knowledge to care for patients, and to continue to examine the evidence supporting the value of specialty board certification and MOC.
5. Work with the ABMS to streamline and improve the Cognitive Expertise (Part III) component of MOC, including the exploration of alternative formats, in ways that effectively evaluate acquisition of new knowledge while reducing or eliminating the burden of a high-stakes examination.
6. Work with interested parties to ensure that MOC uses more than one pathway to assess accurately the competence of practicing physicians, to monitor for exam relevance and to ensure that MOC does not lead to unintended economic hardship such as hospital de-credentialing of practicing physicians.
7. Recommend that the ABMS not introduce additional assessment modalities that have not been validated to show improvement in physician performance and/or patient safety.
8. Work with the ABMS to eliminate practice performance assessment modules, as currently written, from MOC requirements.
9. Encourage the ABMS to ensure that all ABMS member boards provide full transparency related to the costs of preparing, administering, scoring and reporting MOC and certifying examinations.
10. Encourage the ABMS to ensure that MOC and certifying examinations do not result in substantial financial gain to ABMS member boards, and advocate that the ABMS develop fiduciary standards for its member boards that are consistent with this principle.
11. Work with the ABMS to lessen the burden of MOC on physicians with multiple board certifications, particularly to ensure that MOC is specifically relevant to the physician's current practice.
12. Work with key stakeholders to (a) support ongoing ABMS member board efforts to allow multiple and diverse physician educational and quality improvement activities to qualify for MOC; (b) support ABMS member board activities in facilitating the use of MOC quality improvement activities to count for other accountability requirements or programs, such as pay for quality/performance or PQRS reimbursement; (c) encourage ABMS member boards to enhance the consistency of quality improvement programs across all boards; and (d) work with specialty societies and ABMS member boards to develop tools and services that help physicians meet MOC requirements.
13. Work with the ABMS and its member boards to collect data on why physicians choose to maintain or discontinue their board certification.
14. Work with the ABMS to study whether MOC is an important factor in a physician's decision to retire and to determine its impact on the US physician workforce.
15. Encourage the ABMS to use data from MOC to track whether physicians are maintaining certification and share this data with the AMA.
16. Encourage AMA members to be proactive in shaping MOC and OCC by seeking leadership positions on the ABMS member boards, American Osteopathic Association (AOA) specialty certifying boards, and MOC Committees.
17. Continue to monitor the actions of professional societies regarding recommendations for modification of MOC.
18. Encourage medical specialty societies' leadership to work with the ABMS, and its member boards, to identify those specialty organizations that have developed an appropriate and relevant MOC process for its members.
19. Continue to work with the ABMS to ensure that physicians are clearly informed of the MOC requirements for their specific board and the timelines for accomplishing those requirements.
20. Encourage the ABMS and its member boards to develop a system to actively alert physicians of the due dates of the multi-stage requirements of continuous professional development and performance in practice, thereby assisting them with maintaining their board certification.
21. Recommend to the ABMS that all physician members of those boards governing the MOC process be required to participate in MOC.
22. Continue to participate in the National Alliance for Physician Competence forums.

23. Encourage the PCPI Foundation, the ABMS, and the Council of Medical Specialty Societies to work together toward utilizing Consortium performance measures in Part IV of MOC.
 24. Continue to assist physicians in practice performance improvement.
 25. Encourage all specialty societies to grant certified CME credit for activities that they offer to fulfill requirements of their respective specialty board's MOC and associated processes.
 26. Support the American College of Physicians as well as other professional societies in their efforts to work with the American Board of Internal Medicine (ABIM) to improve the MOC program.
 27. Oppose those maintenance of certification programs administered by the specialty boards of the ABMS, or of any other similar physician certifying organization, which do not appropriately adhere to the principles codified as AMA Policy on Maintenance of Certification.
 28. Ask the ABMS to encourage its member boards to review their maintenance of certification policies regarding the requirements for maintaining underlying primary or initial specialty board certification in addition to subspecialty board certification, if they have not yet done so, to allow physicians the option to focus on maintenance of certification activities relevant to their practice.
 29. Call for the immediate end of any mandatory, secured recertifying examination by the ABMS or other certifying organizations as part of the recertification process for all those specialties that still require a secure, high-stakes recertification examination.
 30. Support a recertification process based on high quality, appropriate Continuing Medical Education (CME) material directed by the AMA recognized specialty societies covering the physician's practice area, in cooperation with other willing stakeholders, that would be completed on a regular basis as determined by the individual medical specialty, to ensure lifelong learning.
 31. Continue to work with the ABMS to encourage the development by and the sharing between specialty boards of alternative ways to assess medical knowledge other than by a secure high stakes exam.
 32. Continue to support the requirement of CME and ongoing, quality assessments of physicians, where such CME is proven to be cost-effective and shown by evidence to improve quality of care for patients.
 33. Through legislative, regulatory, or collaborative efforts, will work with interested state medical societies and other interested parties by creating model state legislation and model medical staff bylaws while advocating that Maintenance of Certification not be a requirement for: (a) medical staff membership, privileging, credentialing, or recredentialing; (b) insurance panel participation; or (c) state medical licensure.
 34. Increase its efforts to work with the insurance industry to ensure that maintenance of certification does not become a requirement for insurance panel participation.
 35. Advocate that physicians who participate in programs related to quality improvement and/or patient safety receive credit for MOC Part IV.
 36. Continue to work with the medical societies and the American Board of Medical Specialties (ABMS) member boards that have not yet moved to a process to improve the Part III secure, high-stakes examination to encourage them to do so.
 37. Through its Council on Medical Education, continue to be actively engaged in following the work of the ABMS Continuing Board Certification: Vision for the Future Commission.
 38. (a) Submit commentary to the American Board of Medical Specialties (ABMS) Continuing Board Certification: Vision for the Future initiative, asking that junior diplomates be given equal opportunity to serve on ABMS and its member boards; and (b) work with the ABMS and member boards to encourage the inclusion of younger physicians on the ABMS and its member boards.
 39. Continue studying the certifying bodies that compete with the American Board of Medical Specialties and provide an update in the Council on Medical Education's annual report on maintenance of certification at the 2019 Annual Meeting.
- Citation: CME Rep. 2, I-15; Appended: Res. 911, I-15; Appended: Res. 309, A-16; Appended: CME Rep. 02, A-16; Appended: Res. 307, I-16; Appended: Res. 310, I-16; Modified: CME Rep. 02, A-17; Reaffirmed: Res. 316, A-17; Reaffirmed in lieu of: Res. 322, A-17; Appended: CME Rep. 02, A-18; Appended: Res. 320, A-18; Appended: Res. 957, I-18

MIPS and MACRA Exemption H-390.838

Our AMA will advocate for an exemption from the Merit-Based Incentive Payment System (MIPS) and Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) for small practices.

Citation: Res. 208, I-16; Reaffirmation: A-17; Reaffirmation: I-17; Reaffirmation: A-18

Reducing MIPS Reporting Burden D-395.999

Our AMA will work with the Centers for Medicare and Medicaid Services (CMS) to advocate for improvements to Merit-Based Incentive Payment System (MIPS) that have significant input from practicing physicians and reduce regulatory and paperwork burdens on physicians. In the interim, our AMA will work with CMS to shorten the yearly MIPS data reporting period from one-year to a minimum of 90-days (of the physicians choosing) within the calendar year.

Citation: Res. 236, A-18

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 203
(A-19)

Introduced by: California

Subject: Medicare Part B and Part D Drug Price Negotiation

Referred to: Reference Committee B
(Charles Rothberg, MD, Chair)

Whereas, In 2016, total prescription drug spending reached \$328 billion, more than double what was spent in 2002 and physicians are concerned that patients cannot afford necessary medications that will improve their health; and

Whereas, One in four patients report that they or another family member did not fill a prescription in the last year because of cost. One in four patients with cancer are choosing not to fill a prescription or are taking less due to cost; and

Whereas, Prices for commonly used brand name drugs increased 164% and Medicare Part D spending doubled over the last decade; and

Whereas, Under the current Medicare program, drug manufacturers set the price for Medicare Part D and Part B prescription drugs while all other providers (physicians, hospitals, home health, nursing homes) are subject to a government fee schedule; and

Whereas, According to an analysis published in *JAMA Internal Medicine*, if Medicare Part D paid prices for prescription medications similar to what the Department of Veterans Affairs pays, there could be an estimated annual savings of 38-50% because the VA has the ability to directly negotiate with pharmaceutical manufacturers; and

Whereas, Under Medicare Part B, a pharmaceutical manufacturer can charge physicians as much as it wants for physician-administered drugs--unconstrained by any fee schedule or price limits. Moreover, physicians do not have access to the discounted drug prices that pharmacies and health plans enjoy, which make these drugs more costly; and

Whereas, Many policy-makers are considering proposals to make it more difficult for physicians to provide important Medicare Part B medications in their offices; and

Whereas, Medicaid is authorized to negotiate best prices for drugs and thus, allowing Medicare to negotiate drug prices with drug-makers would make a meaningful difference in controlling costs in both the Medicare program and the private sector; and

Whereas, According to the Centers for Disease Control and Prevention (CDC), about 500,000 Americans age 60 and older get shingles (caused by the varicella zoster virus) every year. Individuals aged 60 and older are vulnerable to certain diseases that could be prevented by vaccines; and

1 Whereas, Both the Medicare Part D and Part B programs have made it difficult for physicians to
 2 administer and patients to gain access to important vaccines; and
 3

4 Whereas, Elderly patients should have the choice of receiving important vaccines and other
 5 medications in their physicians office, thereby allowing physicians to efficiently provide
 6 comprehensive care, particularly to those high-risk, chronically-ill patients; therefore be it
 7

8 RESOLVED, That our American Medical Association advocate for Medicare to cover all
 9 physician-recommended adult vaccines in both the Medicare Part D and the Medicare Part B
 10 programs (Directive to Take Action); and be it further
 11

12 RESOLVED, That our AMA make it a priority to advocate for a mandate on pharmaceutical
 13 manufacturers to negotiate drug prices with the Centers for Medicare and Medicaid Services for
 14 Medicare Part D and Part B covered drugs (Directive to Take Action); and be it further
 15

16 RESOLVED, That our AMA explore all options with the state and national specialty societies to
 17 ensure that physicians have access to reasonable drug prices for the acquisition of Medicare
 18 Part B physician-administered drugs and that Medicare reimburse physicians for their actual
 19 drug acquisition costs, plus appropriate fees for storage, handling, and administration of the
 20 medications, to ensure access to high-quality, cost-effective care in a physician's office.
 21 (Directive to Take Action)

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

Received: 04/29/19

RELEVANT AMA POLICY

Appropriate Reimbursements and Carve-outs for Vaccines D-440.981

Our AMA will: (1) continue to work with the Centers for Medicare and Medicaid Services (CMS) and provide comment on the Medicare Program payment policy for vaccine services; (2) continue to pursue adequate reimbursement for vaccines and their administration from all public and private payers; (3) encourage health plans to recognize that physicians incur costs associated with the procurement, storage and administration of vaccines that may be beyond the average wholesale price of any one particular vaccine; and (4) seek legislation mandating that health insurance companies in applicable states either adequately pay for vaccines recommended by the Advisory Committee on Immunization Practices, or clearly state in large bold font in their notices to patients and businesses that they do not follow the federal advisory body on vaccine recommendations, the Advisory Committee on Immunization Practices. Citation: (BOT Rep. 20, A-03; Reaffirmation A-07; Res. 128, A-09; Reaffirmation I-10; Reaffirmed: Res. 807, I-11

Financing of Adult Vaccines: Recommendations for Action H-440.860

1. Our AMA supports the concepts to improve adult immunization as advanced in the Infectious Diseases Society of America's 2007 document "Actions to Strengthen Adult and Adolescent Immunization Coverage in the United States," and support the recommendations as advanced by the National Vaccine Advisory Committee's 2008 white paper on pediatric vaccine financing.

2. Our AMA will advocate for the following actions to address the inadequate financing of adult vaccination in the United States:

Provider-related

a. Develop a data-driven rationale for improved vaccine administration fees.

b. Identify and explore new methods of providing financial relief for adult immunization providers through, for example, vaccine company replacement systems/deferred payment/funding for physician inventories, buyback for unused inventory, and patient assistance programs.

c. Encourage and facilitate adult immunization at all appropriate points of patient contact; e.g., hospitals, visitors to long-term care facilities, etc.

d. Encourage counseling of adults on the importance of immunization by creating a mechanism through which immunization counseling alone can be reimbursed, even when a vaccine is not given.

Federal-related

a. Increase federal resources for adult immunization to: (i) Improve Section 317 funding so that the program can meet its purpose of improving adult immunizations; (ii) Provide universal coverage for adult vaccines and minimally, uninsured adults should be covered; (iii) Fund an adequate universal reimbursement rate for all federal and state immunization programs.

b. Optimize use of existing federal resources by, for example: (i) Vaccinating eligible adolescents before they turn 19 years of age to capitalize on VFC funding; (ii) Capitalizing on public health preparedness funding.

c. Ease federally imposed immunization burdens by, for example: (i) Providing coverage for Medicare-eligible individuals for all vaccines, including new vaccines, under Medicare Part B; (ii) Creating web-based billing mechanisms for physicians to assess coverage of the patient in real time and handle the claim, eliminating out-of-pocket expenses for the patient; (iii) Simplifying the reimbursement process to eliminate payment-related barriers to immunization.

d. The Centers for Medicare & Medicaid Services should raise vaccine administration fees annually, synchronous with the increasing cost of providing vaccinations.

State-related

a. State Medicaid programs should increase state resources for funding vaccines by, for example: (i) Raising and funding the maximum Medicaid reimbursement rate for vaccine administration fees; (ii) Establishing and requiring payment of a minimum reimbursement rate for administration fees; (iii) Increasing state contributions to vaccination costs; and (iv) Exploring the possibility of mandating immunization coverage by third party payers.

b. Strengthen support for adult vaccination and appropriate budgets accordingly.

Insurance-related

1. Provide assistance to providers in creating efficiencies in vaccine management by: (i) Providing model vaccine coverage contracts for purchasers of health insurance; (ii) Creating simplified rules for eligibility verification, billing, and reimbursement; (iii) Providing vouchers to patients to clarify eligibility and coverage for patients and providers; and (iv) Eliminating provider/public confusion over insurance payment of vaccines by universally covering all Advisory Committee on Immunization Practices (ACIP)-recommended vaccines.

b. Increase resources for funding vaccines by providing first-dollar coverage for immunizations.

c. Improve accountability by adopting performance measurements.

d. Work with businesses that purchase private insurance to include all ACIP-recommended immunizations as part of the health plan.

e. Provide incentives to encourage providers to begin immunizing by, for example: (i) Including start up costs (freezer, back up alarms/power supply, reminder-recall systems, etc.) in the formula for reimbursing the provision of immunizations; (ii) Simplifying payment to and encouraging immunization by nontraditional providers; (iii) Facilitating coverage of vaccines administered in complementary locations (e.g., relatives visiting a resident of a long-term care facility).

Manufacturer-related

Market stability for adult vaccines is essential. Thus: (i) Solutions to the adult vaccine financing problem should not deter research and development of new vaccines; (ii) Solutions should consider the maintenance of vibrant public and private sector adult vaccine markets; (iii) Liability protection for manufacturers should be assured by including Vaccine Injury Compensation Program coverage for all ACIP-recommended adult vaccines; (iv) Educational outreach to both providers and the public is needed to improve acceptance of adult immunization.

3. Our AMA will conduct a survey of small- and middle-sized medical practices, hospitals, and other medical facilities to identify the impact on the adult vaccine supply (including influenza vaccine) that results from the large contracts between vaccine manufacturers/distributors and large non-government purchasers, such as national retail health clinics, other medical practices, and group purchasing programs, with particular attention to patient outcomes for clinical preventive services and chronic disease management.

Citation: (CSAPH Rep. 4, I-08; Reaffirmation I-10; Reaffirmation: I-12; Reaffirmation I-14

Prescription Drug Prices and Medicare D-330.954

1. Our AMA will support federal legislation which gives the Secretary of the Department of Health and Human Services the authority to negotiate contracts with manufacturers of covered Part D drugs.
2. Our AMA will work toward eliminating Medicare prohibition on drug price negotiation.
3. Our AMA will prioritize its support for the Centers for Medicare & Medicaid Services to negotiate pharmaceutical pricing for all applicable medications covered by CMS.

Citation: Res. 211, A-04; Reaffirmation I-04; Reaffirmed in lieu of Res. 201, I-11; Appended: Res. 206, I-14; Reaffirmed: CMS Rep. 2, I-15; Appended: Res. 203, A-17

Cuts in Medicare Outpatient Infusion Services D-330.960

1. Our AMA will actively support efforts to seek legislation to ensure that Medicare payments for drugs fully cover the physician's acquisition, inventory and carrying cost and that Medicare payments for drug administration and related services are adequate to ensure continued patient access to outpatient infusion services.
2. Our AMA will continue strong advocacy efforts working with relevant national medical specialty societies to ensure adequate physician payment for Part B drugs and patient access to biologic and pharmacologic agents.

Citation: Res. 926, I-03; Reaffirmed and Modified: CMS Rep. 3, I-08; Reaffirmation A-15; Reaffirmed: CMS Rep. 10, A-16; Reaffirmation: I-18

Opposition to the CMS Medicare Part B Drug Payment Model D-330.904

1. Our AMA will request that the Centers for Medicare & Medicaid Services (CMS) withdraw the proposed Part B Drug Payment Model.
2. Our AMA will support and actively work to advance Congressional action to block the proposed Part B Drug Payment Model if CMS proceeds with the proposal.
3. Our AMA will advocate against policies that are likely to undermine access to the best course of treatment for individual patients and oppose demonstration programs that could lead to lower quality of care and do not contain mechanisms for safeguarding patients.
4. Our AMA will advocate for ensuring that CMS solicits and takes into consideration feedback from patients, physicians, advocates, or other stakeholders in a way that allows for meaningful input on any Medicare coverage or reimbursement policy that impacts patient access to medical therapies, including policies on coverage and reimbursement.

Citation: Res. 241, A-16

Restoring High Quality Care to the Medicare Part D Prescription Drug Program D-330.933

Our AMA will:

- a. work to eliminate prior authorizations under the Medicare Part D Prescription Drug Program which undermine a physician's best medical judgment;
- b. work with the Centers for Medicare and Medicaid Services (CMS) to enforce the Medicare Part D Prescription Drug Program statutory requirement that all Part D plans include at least two drugs proven to be equally effective in each therapeutic category or pharmacologic class, if available, to be used by the physician in deciding the best treatment options for their patients;
- c. work with CMS to place reasonable copays in the Medicare Part D Prescription Drug Program;
- d. work with other interested parties to simplify the CMS prior authorization process such that a diagnosis or reason written on the prescription should be accepted as documentation for non formulary request; and
- e. work with CMS to develop a one-page form for physicians and patients to utilize in appealing a prescription coverage denial.

Citation: (Res. 106, A-07; Reaffirmation A-08; Reaffirmation A-14

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 204
(A-19)

Introduced by: California

Subject: Holding the Pharmaceutical Industry Accountable for Opioid-Related Costs

Referred to: Reference Committee B
(Charles Rothberg, MD, Chair)

1 Whereas, The ongoing opioid epidemic in the United States has been labeled a public health
2 crisis by the President of the United States, with significant attendant financial costs to hospitals,
3 health systems, insurers, communities, families, patients, and many others; and
4

5 Whereas, It has been alleged that the pharmaceutical industry has long promoted overuse of
6 opioids through a wide range of tactics to misbrand and misrepresent the risk of addiction and
7 abuse; and
8

9 Whereas, A new NPR/IPSOS poll found that 57% of Americans now say pharmaceutical
10 companies should be held responsible for making the opioid crisis worse. An even larger
11 majority of those polled (70%) said even after companies pay fines and penalties, they should
12 be forced to publicly disclose details of the role they played in fueling the epidemic; and
13

14 Whereas, When “big tobacco” was shown to have known of and promoted harmful products,
15 eventual legal action compelled large financial settlements to be distributed to those negatively
16 impacted by their products; and
17

18 Whereas, Similar legal actions are now being pursued against pharmaceutical manufacturers
19 around the nation to hold drug-makers accountable and to assist negatively impacted providers,
20 patients and state and local governments; therefore be it
21

22 RESOLVED, That our American Medical Association advocate that the relevant pharmaceutical
23 industry organizations be held financially responsible for the health care and other economic
24 costs related to their unethical and deceptive misbranding, marketing, and advocacy of opioids.
25 (Directive to Take Action)

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

Received: 04/29/19

RELEVANT AMA POLICY

Prevention of Opioid Overdose D-95.987

1. Our AMA: (A) recognizes the great burden that opioid addiction and prescription drug abuse places on patients and society alike and reaffirms its support for the compassionate treatment of such patients; (B) urges that community-based programs offering naloxone and other opioid overdose prevention services continue to be implemented in order to further develop best practices in this area; and (C) encourages the education of health care workers and opioid users about the use of naloxone in preventing opioid overdose fatalities; and (D) will continue to monitor the progress of such initiatives and respond as appropriate.

2. Our AMA will: (A) advocate for the appropriate education of at-risk patients and their caregivers in the signs and symptoms of opioid overdose; and (B) encourage the continued study and implementation of appropriate treatments and risk mitigation methods for patients at risk for opioid overdose.

3. Our AMA will support the development and implementation of appropriate education programs for persons in recovery from opioid addiction and their friends/families that address how a return to opioid use after a period of abstinence can, due to reduced opioid tolerance, result in overdose and death.

Citation: Res. 526, A-06; Modified in lieu of Res. 503, A-12; Appended: Res. 909, I-12;

Reaffirmed: BOT Rep. 22, A-16; Modified: Res. 511, A-18; Reaffirmed: Res. 235, I-18

Prescription Drug Monitoring to Prevent Abuse of Controlled Substances H-95.947

Our AMA:

(1) supports the refinement of state-based prescription drug monitoring programs and development and implementation of appropriate technology to allow for Health Insurance Portability and Accountability Act (HIPAA)-compliant sharing of information on prescriptions for controlled substances among states;

(2) policy is that the sharing of information on prescriptions for controlled substance with out-of-state entities should be subject to same criteria and penalties for unauthorized use as in-state entities;

(3) actively supports the funding of the National All Schedules Prescription Electronic Reporting Act of 2005 which would allow federally funded, interoperable, state based prescription drug monitoring programs as a tool for addressing patient misuse and diversion of controlled substances;

(4) encourages and supports the prompt development of, with appropriate privacy safeguards, treating physician's real time access to their patient's controlled substances prescriptions;

(5) advocates that any information obtained through these programs be used first for education of the specific physicians involved prior to any civil action against these physicians;

(6) will conduct a literature review of available data showing the outcomes of prescription drug monitoring programs (PDMP) on opioid-related mortality and other harms; improved pain care; and other measures to be determined in consultation with the AMA Task Force to Reduce Opioid Abuse;

(7) will advocate that U.S. Department of Veterans Affairs pharmacies report prescription information required by the state into the state PDMP;

(8) will advocate for physicians and other health care professionals employed by the VA to be eligible to register for and use the state PDMP in which they are practicing even if the physician or other health care professional is not licensed in the state; and

(9) will seek clarification from SAMHSA on whether opioid treatment programs and other substance use disorder treatment programs may share dispensing information with state-based PDMPs.

Citation: BOT Rep. 3, A-08; Reaffirmed: BOT Rep. 12, A-15; Reaffirmed: BOT Rep. 5, I-15;

Reaffirmation A-16; Appended: BOT Rep. 13, A-17

9.6.7 Direct-to-Consumer Advertisement of Prescription Drugs

Direct-to-consumer advertising may raise awareness about diseases and treatment and may help inform patients about the availability of new diagnostic tests, drugs, treatments, and devices. However, direct-to-consumer advertising also carries the risk of creating unrealistic expectations for patients and conflicts of interest for physicians, adversely affecting patients' health and safety, and compromising patient-physician relationships.

In the context of direct-to-consumer advertising of prescription drugs, physicians individually should:

- (a) Remain objective about advertised tests, drugs, treatments, and devices, avoiding bias for or against advertised products.
- (b) Engage in dialogue with patients who request tests, drugs, treatments, or devices they have seen advertised to:
 - (i) assess and enhance the patients' understanding of the test, drug or device;
 - (ii) educate patients about why an advertised test, drug, or device may not be suitable for them, including providing cost-effectiveness information about different options.
- (c) Resist commercially induced pressure to prescribe tests, drugs, or devices that may not be indicated.
- (d) Obtain informed consent before prescribing an advertised test, drug, or device, in keeping with professional standards.
- (e) Deny requests for an inappropriate test, drug, or device.
- (f) Consider reporting to the sponsoring manufacturer or appropriate authorities direct-to-consumer advertising that:
 - (i) promotes false expectations;
 - (ii) does not enhance consumer education;
 - (iii) conveys unclear, inaccurate, or misleading health education messages;
 - (iv) fails to refer patients to their physicians for additional information;
 - (v) does not identify the target population at risk;
 - (vi) encourages consumer self-diagnosis and treatment.

Collectively, physicians should:

- (g) Encourage and engage in studies that examine the impact of direct-to-consumer advertising on patient health and medical care.
- (h) Whenever possible, assist authorities to enforce existing law by reporting advertisements that do not:
 - (i) provide a fair and balanced discussion of the use of the drug product for the disease, disorder, or condition;
 - (ii) clearly explain warnings, precautions, and potential adverse reactions associated with the drug product;
 - (iii) present summary information in language that can be understood by the consumer
 - (iv) comply with applicable regulations;
 - (v) provide collateral materials to educate both physicians and consumers.

[AMA Principles of Medical Ethics: II,III](#)

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

Issued: 2016

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 205
(A-19)

Introduced by: Illinois

Subject: Use of Patient or Co-Worker Experience/Satisfaction Surveys Tied to
Employed Physician Salary

Referred to: Reference Committee B
(Charles Rothberg, MD, Chair)

Whereas, Patient or coworker observation experience surveys are increasingly used by healthcare centers in evaluating physician clinical care and are often tied to physician salaries; and

Whereas, These patient surveys focus on patient perspectives and brand management while not addressing any specific quality metrics of complicated clinical care; and

Whereas, Coworker observation metrics have not been validated as a reliable monitoring tool for patient care or clinical professional behavior; and

Whereas, Patient or coworker experience surveys depend upon active responses and thus may exhibit reporting bias due to complaints frequently unrelated to the providers' actual clinical care; and

Whereas, It has been demonstrated that higher patient satisfaction scores are associated with higher health care and prescription expenditures; and

Whereas, Patient satisfaction utilization can promote job dissatisfaction, attrition, and inappropriate clinical care (the very opposite of high-value clinical care); and

Whereas, Patient surveys or coworker observation metrics are not conducted nor evaluated in a peer-review environment; and

Whereas, These surveys and metrics are performed anonymously and thus cannot be adequately addressed by the clinician; and

Whereas, These metrics are usually utilized only to negatively impact an employed physician's salary in a punitive manner (with no potential for positive impact); and

Whereas, A clinician's overall work product cannot be distilled to a few numerical metrics; and

Whereas, Health care centers may publish the results of patient or coworker surveys regarding individual providers in an effort to be "transparent"; and

Whereas, It is apparent that patient satisfaction surveys or coworkers' observation reporting symptoms produce "scores" that are not related to any clinical quality metric, have questionable validity, and are often taken out of context; therefore be it

1 RESOLVED, That our American Medical Association adopt policy opposing any association
 2 between anonymous patient satisfaction scores (e.g. "loyalty scores") or the coworkers'
 3 observation reporting system, and employed physicians' salaries (New HOD Policy); and be it
 4 further

5
 6 RESOLVED, That our AMA adopt policy opposing any publication of anonymous patient
 7 satisfaction scores or coworkers' observation reporting system information directed at an
 8 individual physician (New HOD Policy); and be it further

9
 10 RESOLVED, That our AMA adopt policy opposing the use of any anonymous patient
 11 satisfaction scores or any individually and anonymously posted patient or co-worker comments
 12 in formulating or impacting employed physician salaries or in relation to any other physician
 13 compensation program. (New HOD Policy)
 14

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

Received: 04/25/19

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AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 206
(A-19)

Introduced by: Illinois

Subject: Changing the Paradigm: Opposing Present and Obvious Restraint of Trade

Referred to: Reference Committee B
(Charles Rothberg, MD, Chair)

1 Whereas, Many healthcare providers and established, quality-based referral patterns are
2 threatened or already overtaken by monopoly network interests; and
3

4 Whereas, Many private and employed physicians' voices are not being heard clearly because of
5 some degree of risk of network exclusion/termination; and
6

7 Whereas, Despite the fact that the most valuable part within the network is the group of
8 physicians, large provider systems will continue to commoditize physicians and physician
9 services, and continue to compete on price, negatively impacting the already diminishing and
10 set value share (compensation) of physicians in and out of large networks; and
11

12 Whereas, Delivering compassionate and personalized care to a patient is the most agreed-upon
13 interest that we serve, and the foundation of this is a trusting doctor patient relationship, and
14 now increasingly other interests are entering into and compromising this relationship; and
15

16 Whereas, Insurance providers and health delivery systems have inadvertently, or intentionally,
17 added incredible levels of "red tape" to true health service; therefore be it
18

19 RESOLVED, That our American Medical Association seek legislative or regulatory changes to
20 allow physicians to collectively negotiate professional fees, compensation and contract terms
21 without integration. (Directive to Take Action)

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

Received: 04/25/19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 207
(A-19)

Introduced by: Illinois

Subject: Direct-to-Consumer Genetic Tests

Referred to: Reference Committee B
(Charles Rothberg, MD, Chair)

Whereas, Direct-to-consumer genetic testing, such as 23andMe and AncestryDNA.com, is publicly promoted and commercially available to bring personal insight into ancestry, genealogy, and inherited traits by means of a genetic blueprint (Personal Genome Service or PGS); and

Whereas, The genetic testing may or may not reveal variants associated with a higher risk of certain diseases such as Alzheimer's, Parkinson's, or Macular Degeneration, which may not have clinical merit, but could result in emotional distress upon discovery; and

Whereas, The PGS is deemed a medical device by the US Food and Drug Administration,¹ but is also a mechanism for massive information-gathering whereby personal, self-disclosed information, including a person's genome, can be used by the company or third parties for selling the consumer products and services; and

Whereas, PGS companies have different policies regarding managing and disseminating information for research purposes, including academic institutions, non-profit foundations, and pharmaceutical companies for journal publications, and some have indicated that their database-sifting scientific work does not constitute research on human subjects¹; and

Whereas, Some genetic testing companies have direct financial relationships with pharmaceutical (GlaxoSmithKline, Pfizer) and biotechnology (Genentech) companies and universities (University of Chicago) to name a few²; and

Whereas, Privacy breaches have occurred, including the hacking of a genetic testing company, MyHeritage, which affected 92,000,000 individuals,³ with the potential for other abuse by governments, companies, or criminals with direct or indirect access (e.g. hacking, sale by unauthorized persons, release by disgruntled employees); and

Whereas, In up to 12-18% of cases, the consumers using information on recreational genetic genealogy databases are at risk for re-identification in the event of a data breach if their genetic information were cross-referenced against other information, such as their date of birth and state of residence⁴; and

Whereas, The Health Information Portability and Accountability Act (HIPAA) allows the transfer of date of birth and state of residence information without penalty; and

Whereas, The Genetic Information Non-Discrimination Act (GINA, 2008)⁵ prevents discrimination by health insurance companies and employers based on acquired genetic information, but these restrictions do not apply to life, disability, or long-term care insurance companies, possibly causing some insurance application rejections; and

Whereas, Only 17 states have additional laws restricting the use of genetic information in determining life and disability insurance coverage, and only eight states for long-term care insurance; and

Whereas, Genetic information and research continues to evolve, resulting in technology advancements whereby past user information may be used negatively against those individuals; therefore be it

RESOLVED, That our American Medical Association regard research using consumer genome data derived from saliva or cheek swab samples as research on human subjects requiring consents in compliance with the Health and Human Services (HHS) Office for Human Research Protection (OHRP), and recommend an “opt in” option to allow more consumer choice in the consent process (Directive to Take Action); and be it further

RESOLVED, That our AMA amend Policy H-315.983, “Patient Privacy and Confidentiality,” by addition to align with current research and privacy infringement findings, as follows:

1. Our AMA affirms the following key principles that should be consistently implemented to evaluate any proposal regarding patient privacy and the confidentiality of medical information: (a) That there exists a basic right of patients to privacy of their medical information and records, and that this right should be explicitly acknowledged; (b) 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; (c) That patients' privacy should be honored in the context of gathering and disclosing information for clinical research and quality improvement activities, and that any necessary departures from the preferred practices of obtaining patients' informed consent and of de-identifying all data be strictly controlled; (d) That any information disclosed should be limited to that information, portion of the medical record, or abstract necessary to fulfill the immediate and specific purpose of disclosure; and (e) That the Health Insurance Portability and Accountability Act of 1996 (HIPAA) be the minimal standard for protecting clinician-patient privilege, regardless of where care is received, while working with the Department of Health and Human Services (HHS) to stop the transfer of birthdates and state of residence by genetic testing companies and their affiliates, unless there is explicit user approval, to prevent re-identification of the test user by way of surname inference methods.

2. Our AMA affirms: (a) that physicians and medical students who are patients are entitled to the same right to privacy and confidentiality of personal medical information and medical records as other patients, (b) that when patients exercise their right to keep their personal medical histories confidential, such action should not be regarded as fraudulent or inappropriate concealment, and (c) that physicians and medical students should not be required to report any aspects of their patients' medical history to governmental agencies or other entities, beyond that which would be required by law.

1 3. Employers and insurers should be barred from unconsented access to identifiable
2 medical information lest knowledge of sensitive facts form the basis of adverse decisions
3 against individuals. (a) Release forms that authorize access should be explicit about to
4 whom access is being granted and for what purpose, and should be as narrowly tailored as
5 possible. (b) Patients, physicians, and medical students should be educated about the
6 consequences of signing overly-broad consent forms. (c) Employers and insurers should
7 adopt explicit and public policies to assure the security and confidentiality of patients'
8 medical information. (d) A patient's ability to join or a physician's participation in an
9 insurance plan should not be contingent on signing a broad and indefinite consent for
10 release and disclosure.

11
12 4. Whenever possible, medical records should be de-identified for purposes of use in
13 connection with utilization review, panel credentialing, quality assurance, and peer review.

14
15 5. The fundamental values and duties that guide the safekeeping of medical information
16 should remain constant in this era of computerization. Whether they are in computerized or
17 paper form, it is critical that medical information be accurate, secure, and free from
18 unauthorized access and improper use.

19
20 6. Our AMA recommends that the confidentiality of data collected by race and ethnicity as
21 part of the medical record, be maintained.

22
23 7. Genetic information should be kept confidential and should not be disclosed to third
24 parties without the explicit informed consent of the tested individual. Our AMA regards
25 studies using consumer genome data derived from saliva, cheek swab, or other human
26 tissue samples as research on human subjects requiring consents in compliance with the
27 HHS Office for Human Research Protections (OHRP). An "opt in" option is recommended to
28 allow more consumer choice in the consent process.

29
30 8. When breaches of confidentiality are compelled by concerns for public health and safety,
31 those breaches must be as narrow in scope and content as possible, must contain the least
32 identifiable and sensitive information possible, and must be disclosed to the fewest possible
33 to achieve the necessary end.

34
35 9. Law enforcement agencies requesting private medical information should be given
36 access to such information only through a court order. This court order for disclosure should
37 be granted only if the law enforcement entity has shown, by clear and convincing evidence,
38 that the information sought is necessary to a legitimate law enforcement inquiry; that the
39 needs of the law enforcement authority cannot be satisfied by non-identifiable health
40 information or by any other information; and that the law enforcement need for the
41 information outweighs the privacy interest of the individual to whom the information pertains.
42 These records should be subject to stringent security measures.

10. Our AMA must 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. Whenever possible, de-identified data should be used for these purposes. In those contexts where personal identification is essential for the collation of data, review of identifiable data should not take place without an institutional review board (IRB) approved justification for the retention of identifiers and the consent of the patient. In those cases where obtaining patient consent for disclosure is impracticable, our AMA endorses the oversight and accountability provided by an IRB.

11. Marketing and commercial uses of identifiable patients' medical information may violate principles of informed consent and patient confidentiality. Patients divulge information to their physicians only for purposes of diagnosis and treatment. If other uses are to be made of the information, patients must first give their uncoerced permission after being fully informed about the purpose of such disclosures

12. Our AMA, in collaboration with other professional organizations, patient advocacy groups and the public health community, should 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 physicians' 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.

13. Our AMA will pursue an aggressive agenda to educate patients, the public, physicians and policymakers at all levels of government about concerns and complexities of patient privacy and confidentiality in the variety of contexts mentioned.

14. Disclosure of personally identifiable patient information to public health physicians and departments is appropriate for the purpose of addressing public health emergencies or to comply with laws regarding public health reporting for the purpose of disease surveillance.

15. In the event of the sale or discontinuation of a medical practice, patients should be notified whenever possible and asked for authorization to transfer the medical record to a new physician or care provider. 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.

16. The most appropriate jurisdiction for considering physician breaches of patient confidentiality is the relevant state medical practice act. Knowing and intentional breaches of patient confidentiality, particularly under false pretenses, for malicious harm, or for monetary gain, represents a violation of the professional practice of medicine.

17. Our AMA Board of Trustees will actively monitor and support legislation at the federal level that will afford patients protection against discrimination on the basis of genetic testing. The AMA will work with Congress and HHS to modify the Genetic Information Nondiscrimination Act of 2008 (GINA), which bans genome-based policy and hiring decisions by health insurance companies and employers, by adding Long-Term Care, Life Insurance, and Disability Insurance to the Act to prevent applicant rejection based on their genetic make up.

18. Our AMA supports privacy standards that would require pharmacies to obtain a prior written and signed consent from patients to use their personal data for marketing purposes.

a. Our AMA supports privacy standards that would prohibit pharmaceutical companies, biotechnology companies, universities, and all other entities with financial ties to the genetic testing company from sharing identified information with other parties without the consent of the user. An exception would be made when requested by law enforcement authorities or when keeping the information would seriously threaten their health or that of others. If a data security breach occurs with the Direct-To –Consumer genetic company or its collaborators, then the company has the responsibility to inform all users of the breach and the impact of the unprotected private data on those individuals;

19. Our AMA supports privacy standards that require pharmacies and drug store chains to disclose the source of financial support for drug mailings or phone calls.

20. Our AMA supports privacy standards that would prohibit pharmacies from using prescription refill reminders or disease management programs as an opportunity for marketing purposes.

21. Our AMA will draft model state legislation requiring consent of all parties to the recording of a physician-patient conversation (Modify Current HOD Policy); and be it further

RESOLVED, That our AMA work with the Department of Health and Human Services or other relevant parties to modify the rules to prevent genetic testing entities from transferring information about the user's date of birth and state of residence to third parties which may result in the re-identification of the user based on surname inference (Directive to Take Action); and be it further

RESOLVED, That our AMA work with Congress and the Department of Health and Human Services to extend the consumer protections of the Genetic Information Non-Discrimination Act (GINA) of 2008 by adding long-term care, disability insurance, and life insurance to the Act, modeled after the laws of other states, such as California. (Directive to Take Action)

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

Received: 04/25/19

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AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 208
(A-19)

Introduced by: Illinois

Subject: Repeal or Modification of the Sunshine Act

Referred to: Reference Committee B
(Charles Rothberg, MD, Chair)

1 Whereas, The Physician Payments Sunshine Act was part of the 2010 Affordable Care Act as a
2 way to document publicly the financial interactions between industry and physicians by requiring
3 the medical industry, including Pharma, device manufacturers, and group purchasing
4 organizations, to document any payments and gifts valued above \$10; and
5

6 Whereas, The Sunshine Act data includes cash, in-kind items or services, stock, consulting
7 fees, honoraria, gifts, entertainment, food, travel, research, charitable contributions, royalties or
8 licenses, current or prospective ownership or investment interest, speaker compensation for
9 CME, and grants; and
10

11 Whereas, The Centers for Medicare and Medicaid Services (CMS) maintains the CMS Open
12 Payments website, which has been up and running since 2014, with data collection having
13 begun in 2013; and
14

15 Whereas, Advocates of the Sunshine Act sought to make the public aware of the relationship
16 between industry and the medical community, such that physicians would become less willing to
17 accept payments from industry in order to reduce the influence of industry on the practice of
18 medicine; and
19

20 Whereas, Recent data from the CMS website shows the number of records published has
21 remained at about 12 million since 2014; the total value, including research and investments,
22 was \$7.86 billion in 2014 and has increased to almost \$8 billion in subsequent years; and the
23 number of physicians with payment records was roughly 625,000 in 2014 and has continued to
24 climb to 631,000 in 2016, the most recent year for which data has been published; showing that
25 the number of physicians and the value of payment records has not had the anticipated effect of
26 reduced industry-physician relationship and influence; and
27

28 Whereas, The Sunshine Act has created an undue burden on practicing physicians to maintain
29 records and review the accuracy of the data submitted, and has not been shown to curtail the
30 financial interactions between manufacturers and group purchasing organizations with
31 physicians; therefore be it
32

33 RESOLVED, That our American Medical Association adopt as policy opposition to the Physician
34 Payments Sunshine Act as it currently is written and implemented (New HOD Policy); and be it
35 further

1 RESOLVED, That our AMA support either repeal of the current Sunshine Act or significant
2 modifications to the Sunshine Act, such as substantially increasing the monetary threshold for
3 reporting, that will decrease the burden and “hassle factor” and support efforts at administrative
4 simplification for physicians, which the Center for Medicare and Medicaid Services and the
5 organized medical community has supported, if any portion of the Act is maintained. (New HOD
6 Policy)

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

Received: 04/25/19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 209
(A-19)

Introduced by: Illinois

Subject: Mandates by ACOs Regarding Specific EMR Use

Referred to: Reference Committee B
(Charles Rothberg, MD, Chair)

1 Whereas, The private practice of medicine has protected the relationship between doctor and
2 patient; and
3

4 Whereas, The patient chart and its data are protected under HIPAA; and
5

6 Whereas, The ownership of the chart rests with the doctor originating the chart; and
7

8 Whereas, The continued art and science of the practice of medicine depends on the protected
9 relationship of the doctor and the patient, and the documentation of that relationship; and
10

11 Whereas, Electronic medical records have improved the documentation of the doctor-patient
12 relationship; and
13

14 Whereas, The access to the patient chart is protected by HIPAA; and
15

16 Whereas, The private practice is affected by forces in the free marketplace; and
17

18 Whereas, The access and ownership of the patient chart has effect on its value in the
19 marketplace; and
20

21 Whereas, The ownership of the chart has not been ruled on in most states; and
22

23 Whereas, The spread of Accountable Care Organizations (ACOs) may direct referrals within a
24 geographic area and have restricted trade; and
25

26 Whereas, All electronic medical records are to move to interoperability as defined and
27 mandated by the Centers for Medicare and Medicaid Services (CMS) for compliance with
28 federal programs; and
29

30 Whereas, There are means of sharing data between organizations in accordance with HIPAA
31 via alliances like CommonWell Health Alliance and Carequality Interoperability Framework that
32 are in common usage for patient data and its interoperability; and
33

34 Whereas, The use of alliances such as CommonWell Health Alliance and Carequality
35 Interoperability Framework have accelerated the ability of unrelated healthcare entities including
36 inpatient and outpatient facilities to share data through interoperability; and

1 Whereas, ACOs have begun to mandate the use of single and specific EMR software vendors;
2 therefore be it

3
4 RESOLVED, That our American Medical Association adopt policy stating that Accountable Care
5 Organizations cannot mandate their membership to use a single specific Electronic Medical
6 Record (EMR) (New HOD Policy); and be it further

7
8 RESOLVED, That our AMA move to effect legislation that prevents Accountable Care
9 Organizations from imposing EMR mandates. (Directive to Take Action)

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

Received: 04/25/19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 210
(A-19)

Introduced by: New York

Subject: Air Ambulances

Referred to: Reference Committee B
(Charles Rothberg, MD, Chair)

1 Whereas, Across the country, less populated areas are being served by both not-for-profit and
2 for-profit air medevac services; and
3

4 Whereas, Most communities in the US are serviced by land-based non-profit providers such as
5 police or fire departments; and
6

7 Whereas, In urban communities, hospitals frequently offer air ambulance services while rural
8 communities must rely heavily on privately owned medevac ambulance service companies; and
9

10 Whereas, For-profit companies compete with land-based, non-profit services by cleverly
11 monitoring police and fire department emergency radio bands; and
12

13 Whereas, States face poor regulation of air ambulance business overseen by the FAA; and
14

15 Whereas, There is a concern about the excessive costs of the private medevac sector; and
16

17 Whereas, Research states that 60% of patients transported by air would not have suffered a
18 lower standard of medical care if they had been transported by land; and
19

20 Whereas, Land-based services are less expensive and less dangerous; and
21

22 Whereas, Exorbitant, poorly regulated fees can leave a patient with an out-of-pocket bill of
23 upwards of \$40,000-\$60,000 after insurance payments which has caused some patients to file
24 bankruptcy; and
25

26 Whereas, Several states have introduced legislation to limit the predatory behaviors of private
27 medevac companies but some states believe that legislation should be addressed at the federal
28 level; therefore be it
29

30 RESOLVED, That our American Medical Association support federal legislation which would:
31

32 1. Establish an expedited independent dispute resolution system to resolve payment
33 disputes between emergency air ambulance providers and health insurers; and
34

35 2. Ensure that such independent dispute resolution process would ensure the patient be
36 "held harmless" except for applicable insurance policy in-network cost-sharing
37 requirements. (New HOD Policy)

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

Received: 04/25/19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 211
(A-19)

Introduced by: New York

Subject: Use of FAIR Health

Referred to: Reference Committee B
(Charles Rothberg, MD, Chair)

1 Whereas, For FAIR Health to serve its purpose, it must continue to report Usual and Customary
2 Rate (UCR) data as it has been doing; and
3

4 Whereas, Tremendous effort was expended to create FAIR Health as an independent database,
5 that would accurately report the charge data and not be influenced to alter the collected data;
6 and
7

8 Whereas, FAIR Health's database contains 28 billion claims collected from all 50 states; and
9

10 Whereas, FAIR Health's database is used a reference point for charge data by numerous
11 states; and
12

13 Whereas, There is increasing usage by states of so-called "all payer databases" (APDs) that
14 contain payment data supplied by health insurance companies; and
15

16 Whereas, Such APDs often contain incomplete data, such as excluding data from self-insured
17 health plan sources; and
18

19 Whereas, Congress is currently debating whether to enact legislation that would set forth
20 payment standards and/or processes to determine payments for out of network surprise hospital
21 medical bills; and
22

23 Whereas, Some legislators have indicated a preference for use of APD payment data for an out
24 of network payment benchmark instead of use of comprehensive charge data supplied by
25 physicians; and
26

27 Whereas, Failure to fairly account for charge data in an out of network surprise bill benchmark
28 could have disastrous consequences for physicians attempting to negotiate fair contracts with
29 health insurance companies; therefore be it
30

31 RESOLVED, That our American Medical Association advocate that any legislation addressing
32 surprise out of network medical bills use FAIR Health usual and customary data and not all
33 payer database data. (Directive to Take Action)

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

Received: 04/25/19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 212
(A-19)

Introduced by: New York

Subject: Pharmacy Benefit Managers

Referred to: Reference Committee B
(Charles Rothberg, MD, Chair)

Whereas, Pharmacy Benefit Managers (PBMs) choose medications based on the cost; and

Whereas, Patients have different responses to medications and need a variety of medications available to them; and

Whereas, There have been instances where health insurers and PBMs refuse to continue to continue covering needed pain management medications for severely ill patients when such patients are transitioned from a hospital to a community based care setting such as hospice; and

Whereas, Failure to sufficiently address patients' pain control needs is one factor that leads to patients seeking medical assistance to end their life prematurely; therefore be it

RESOLVED, That our American Medical Association advocate through all appropriate means to ensure that medications used to stabilize palliative and hospice patients for pain and delirium in the hospital continue to be covered by pharmacy benefit plans after patients are transitioned out of the hospital. (Directive to Take Action)

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

Received: 04/25/19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 213
(A-19)

Introduced by: New York

Subject: Financial Penalties and Clinical Decision-Making

Referred to: Reference Committee B
(Charles Rothberg, MD, Chair)

1 Whereas, Physicians along with other stakeholders share the goal of providing cost effective
2 care; and
3

4 Whereas, Other stakeholders (such as payers – who as a group have access to enormous
5 amounts of utilization data) can be helpful in identifying cost centers and even in the
6 development of targets to work toward in order to achieve the shared goal of providing cost
7 effective care; and
8

9 Whereas, It is physicians who have a perspective unique among the stakeholders to assess the
10 clinical course and outcomes (the other variables in calculating cost effectiveness) – particularly
11 when outcomes data is insufficient to draw objective conclusions; and
12

13 Whereas, Recently a New York insurer (one with significant market share) observed that
14 despite increasing reimbursement for a less expensive injectable drug (although one
15 unapproved for this indication), physicians did not change their utilization patterns in favor of this
16 drug in the manner sought by that insurer; and
17

18 Whereas, This insurer is now being investigated by the New York Department of Financial
19 Services for this practice; and
20

21 Whereas, In response, rather than assess all the factors (rather than just the economic ones)
22 that contribute to physician preferences in their choice of therapy (such as indication,
23 effectiveness, therapeutic failure/responses, dosing, safety), the company elected to instead
24 impose financial penalties on practices that have a member that is a statistical outlier when
25 compared to the aggregate of physicians within the plan; and
26

27 Whereas, Those penalties apply not only to the individual outlier physician but to all the services
28 rendered by all of the members of the practice – the penalties extend even to those physicians
29 whose utilization is within the target (and, presumably, to those who do not even use these
30 drugs); therefore be it
31

32 RESOLVED, That our American Medical Association oppose the practice of a payer utilizing
33 statistical targets alone (and not outcomes data) to determine 'cost effectiveness' of a
34 therapeutic choice (New HOD Policy); and be it further
35

36 RESOLVED, That our AMA oppose the practice of a payer imposing financial penalties upon
37 physicians and/or associated physicians based upon the use of statistical targets without first
38 considering the clinical factors unique to each patient's claim. (New HOD Policy)

Fiscal Note: Minimal - less than \$1,000.
Received: 04/25/19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 214
(A-19)

Introduced by: New York

Subject: The Term Physician

Referred to: Reference Committee B
(Charles Rothberg, MD, Chair)

1 Whereas, Allied health professionals are continually trying to extend their scope of service; and

2
3 Whereas, There needs to be transparency for patients to know who is treating them and to be
4 able to evaluate the credentials of that provider of care; and

5
6 Whereas, There are doctorate degrees being granted to many allied health professionals and
7 the term doctor in the clinical setting may be misinterpreted by patients; therefore be it

8
9 RESOLVED, That our American Medical Association seek the passage of federal regulation
10 and/or legislation that mandates that the term physician be limited to those people trained in
11 accordance with Accreditation Council for Graduate Medical Education guidelines and have an
12 MD, DO or a recognized equivalent physician degree and that the term not be used by any
13 other organization or person involved in healthcare. (Directive to Take Action)

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

Received: 04/25/19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 215
(A-19)

Introduced by: New York

Subject: Reimbursement for Health Information Technology

Referred to: Reference Committee B
(Charles Rothberg, MD, Chair)

1 Whereas, The delivery of healthcare is being transformed through the use of technology; and

2
3 Whereas, Physician practices need to keep up with new technology; and

4
5 Whereas, Technology has resulted in an increase in costs to physician practices that did not
6 exist 10 years ago and these costs include transactional costs for each E prescription that is
7 sent, monthly fees for the electronic medical record, the purchase of hardware, financing and
8 staff support needed to maintain this technology; and

9
10 Whereas, Reimbursement for physicians has not kept pace with these increased expenses; and

11
12 Whereas, Physician practices need to innovate; and

13
14 Whereas, E/M codes were never designed to support these expenses or innovation; therefore
15 be it

16
17 RESOLVED, That our American Medical Association seek the passage of federal regulation
18 and/or legislation that mandates that third party payers allow physician practices to charge a
19 technology fee equal to the copayment of the patient's plan. (Directive to Take Action)

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

Received: 04/25/19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 216
(A-19)

Introduced by: New York

Subject: Eliminate the Word "Provider" from Healthcare Contracts

Referred to: Reference Committee B
(Charles Rothberg, MD, Chair)

1 Whereas, Many healthcare contracts from insurers and government agencies use the word
2 "provider" to mean "physicians" and all other "healthcare professionals"; and
3

4 Whereas, The word "provider" is dictionary defined as one of the following: "wage earner",
5 "income producer", "job holder", "laborer", "meal ticket", and "one who brings home the bacon";
6 and
7

8 Whereas, It is demeaning to call a highly-educated physicians and healthcare professionals
9 "providers"; therefore be it
10

11 RESOLVED, That our American Medical Association seek legislation to ensure that all
12 references to physicians in government and insurance contracts, agreements, published
13 descriptions, and printed articles eliminate the word "provider" and substitute the accurate and
14 proper term "physician". (Directive to Take Action)

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

Received: 04/25/19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 217
(A-19)

Introduced by: New York

Subject: Medicare Vaccine Billing

Referred to: Reference Committee B
(Charles Rothberg, MD, Chair)

1 Whereas AMA Policy D-440.981, "Appropriate Reimbursements and Carve-outs for Vaccines,"
2 states:

3
4 Our AMA will: (1) continue to work with the Centers for Medicare and Medicaid Services
5 (CMS) and provide comment on the Medicare Program payment policy for vaccine
6 services; (2) continue to pursue adequate reimbursement for vaccines and their
7 administration from all public and private payers; (3) encourage health plans to
8 recognize that physicians incur costs associated with the procurement, storage and
9 administration of vaccines that may be beyond the average wholesale price of any one
10 particular vaccine; and (4) seek legislation mandating that health insurance companies
11 in applicable states either adequately pay for vaccines recommended by the Advisory
12 Committee on Immunization Practices, or clearly state in large bold font in their notices
13 to patients and businesses that they do not follow the federal advisory body on vaccine
14 recommendations, the Advisory Committee on Immunization Practices; and
15

16 Whereas, Medicare continues to not reimburse physicians for the cost of some immunizations;
17 and
18

19 Whereas, Medicare will reimburse pharmacies for those immunizations, creating an incentive to
20 go to a pharmacy for all vaccinations; therefore be it
21

22 RESOLVED, That our American Medical Association advocate that a physician's office can bill
23 Medicare for all vaccines and that the patient shall only pay the applicable copay to prevent
24 fragmentation of care. (Directive to Take Action)

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

Received: 04/25/19

RELEVANT AMA POLICY

Appropriate Reimbursements and Carve-outs for Vaccines D-440.981

Our AMA will: (1) continue to work with the Centers for Medicare and Medicaid Services (CMS) and provide comment on the Medicare Program payment policy for vaccine services; (2) continue to pursue adequate reimbursement for vaccines and their administration from all public and private payers; (3) encourage health plans to recognize that physicians incur costs associated with the procurement, storage and administration of vaccines that may be beyond the average wholesale price of any one particular vaccine; and (4) seek legislation mandating that health insurance companies in applicable states either adequately pay for vaccines recommended by the Advisory Committee on Immunization Practices, or clearly state in large bold font in their notices to patients and businesses that they do not follow the federal advisory body on vaccine recommendations, the Advisory Committee on Immunization Practices.

Citation: (BOT Rep. 20, A-03; Reaffirmation A-07; Res. 128, A-09; Reaffirmation I-10;

Reaffirmed: Res. 807, I-11

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 218
(A-19)

Introduced by: New York

Subject: Payment for Medications Used Off Label for Treatment of Pain

Referred to: Reference Committee B
(Charles Rothberg, MD, Chair)

1 Whereas, There is an epidemic of opioid abuse in America; and

2
3 Whereas, The efforts to combat that epidemic is to restrict the use of opioids; and

4
5 Whereas, Insurance companies and government programs restrict the off-label use of
6 medications to Federal Drug Administration (FDA) approved indications and many current pain
7 medications were not approved by the FDA for pain management or have a very narrow
8 indication for pain treatment; and

9
10 Whereas, Many pharmacy benefit plans will not cover these medications, leaving a treatment
11 gap for patients with pain; therefore be it

12
13 RESOLVED, That our American Medical Association petition the Centers for Medicare and
14 Medicaid Services to allow reimbursement for off label use of medications like gabapentin or
15 lidocaine patches at the lowest copayment tier for the indication of pain so that patients can be
16 effectively treated for pain and decrease the number of opioid prescriptions written. (Directive to
17 Take Action)

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

Received: 04/25/19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 219
(A-19)

Introduced by: Oklahoma

Subject: Medical Marijuana License Safety

Referred to: Reference Committee B
(Charles Rothberg, MD, Chair)

1 Whereas, Our American Medical Association supports the voluntary use of state-based
2 prescription drug monitoring programs (PDMP) when clinically appropriate; and
3

4 Whereas, Our AMA encourages states to implement modernized PDMPs that are seamlessly
5 integrated into the physician's normal workflow, and provide clinically relevant, reliable
6 information at the point of care within the safeguards applicable to protected health information;
7 and
8

9 Whereas, Our AMA encourages all states to determine how to use a PDMP to enhance
10 treatment for substance use disorder and pain management; and
11

12 Whereas, Our AMA encourages states to share access to PDMP data across state lines; and
13

14 Whereas, By 2018, 33 states, the District of Columbia, Guam, and Puerto Rico, have passed
15 legislation to legalize medical marijuana, including Oklahoma; and
16

17 Whereas, In 2018, Oklahoma State Question 788, Medical Marijuana Legalization Initiative,
18 became law of the land and lacks adequate patient safeguards in multiple areas; and
19

20 Whereas, Patient safety standards have not been implemented in all state legislation that have
21 legalized medical marijuana; and
22

23 Whereas, Physicians need accurate and reliable information to give high-level care to their
24 patients; therefore be it
25

26 RESOLVED, That our American Medical Association draft model state legislation to amend
27 states' prescription drug monitoring programs to include a medical marijuana license registry.
28 (Directive to Take Action)

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

Received: 04/15/19

RELEVANT AMA POLICY

Development and Promotion of Single National Prescription Drug Monitoring Program H-95.939

Our American Medical Association (1) supports the voluntary use of state-based prescription drug monitoring programs (PDMP) when clinically appropriate; (2) 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; (3) supports the ability of physicians to designate a delegate to perform a check of the PDMP, where allowed by state law; (4) encourage states to foster increased PDMP use through a seamless registration process; (5) encourages all states to determine how to use a PDMP to enhance treatment for substance use disorder and pain management; (6) encourages states to share access to PDMP data across state lines, within the safeguards applicable to protected health information; and (7) encourages state PDMPs to adopt uniform data standards to facilitate the sharing of information across state lines.

Citation: BOT Rep. 12, A-15; Reaffirmed: BOT Rep. 5, I-15; Reaffirmation A-16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 220
(A-19)

Introduced by: Pennsylvania

Subject: Study of Confidentiality and Privacy Protection in the Treatment of Substance Disorders

Referred to: Reference Committee B
(Charles Rothberg, MD, Chair)

1 Whereas, Privacy rules are established in the "Health Information Protection and Accountability
2 Act" (HIPAA, 1996). These rules protect personal health information, setting conditions on
3 disclosures and allowing patient information to be shared to coordinate care without obtaining
4 additional consents; and

5
6 Whereas, Confidentiality regulations were established in 1972 in the "Confidentiality of Alcohol
7 and Drug Abuse Patient Records Act" (42 CFR Part 2). These regulations are applied to the
8 disclosure and re-disclosure of patient information. Part 2, (not HIPAA), prohibits sharing of
9 information that could identify a patient seeking treatment for a substance related disorder; and

10
11 Whereas, Because of Part 2, treatment records for substance related disorders are separated
12 from a patient's medical record, acting as a life-threatening barrier preventing medical providers
13 from having access to their patients' full medical histories, limiting integration, hindering
14 coordination and resulting in less robust, whole person, safe, and optimally effective care; and

15
16 Whereas, The opioid epidemic (among other substance related disorders) which has resulted in
17 excess mortality in every community across the country, and costs in the billions of dollars
18 annually, may indicate that these protections have failed to reduce reluctance to enter
19 treatment; and

20
21 Whereas, It is not clear nearly 50 years later, that Part 2 confidentiality is a concern preventing
22 individuals from seeking treatment for their addictions, or that patients considering treatment,
23 care more about confidentiality than coordination of care; therefore be it

24
25 RESOLVED, That our American Medical Association study whether the confidentiality
26 protections of 42 CFR Part 2 outweigh the potential benefits of coordinating care with HIPAA
27 privacy protections in the treatment of substance related disorders. (Directive to Take Action)

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

Received: 04/26/19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 221
(A-19)

Introduced by: American College of Obstetricians and Gynecologists,
American Psychiatric Association, New Jersey, Illinois
American Academy of Pediatrics, American Academy of
Child and Adolescent Psychiatry

Subject: Extending Medicaid Coverage to 12-Months Postpartum

Referred to: Reference Committee B
(Charles Rothberg, MD, Chair)

Whereas, Medicaid is the largest single payer of maternity care in the United States, covering 42.6 percent of births and playing a critical role in ensuring healthy moms and babiesⁱ; and

Whereas, Medicaid is a women's health success story and is the pathway to jobs and financial stability for women and girls. Girls enrolled in Medicaid as children are more likely to attend college, and Medicaid coverage during pregnancy and a newborn's first year of life increases the likelihood that the child will experience upward mobility^{ii,iii}; and

Whereas, Medicaid pregnancy coverage lapses at the end of the month after 60-days postpartum; and

Whereas, The postpartum period is simultaneously a time of vulnerability and maternal health risk, and a transition period with often unmet maternal health needs^{iv,v}; and

Whereas, The American College of Obstetricians and Gynecologists emphasize the importance of the "fourth trimester" and optimizing postpartum care to improve maternal health outcomes and support ongoing health and well-being^{vi}; and

Whereas, The United States is the only industrialized nation with a rising maternal mortality rate^{vii}; and

Whereas, A report from nine maternal mortality review committees estimated that more than 60 percent of maternal deaths are preventable^{viii}; and

Whereas, Findings from state maternal mortality review committees reveal a growing number of maternal deaths linked to cardiovascular disease, cardiomyopathy, and overdose and suicide, with many of these deaths occurring during the postpartum period^{ix}; and

Whereas, Missouri was the first state to pass legislation extending Medicaid coverage to 12-months postpartum for women in active treatment for a substance use disorder^x; and

Whereas, The Texas Maternal Mortality and Morbidity Task Force recommended extending Medicaid coverage to 12-months postpartum to ensure that "medical and behavioral health conditions can be managed and treated before becoming progressively severe."^{xi}; and

1 Whereas, Legislation in several states, including Texas, Illinois, California, and New Jersey, has
2 been introduced in 2019 to extend Medicaid coverage to 12-months postpartum; and
3

4 Whereas, Federal legislation has been introduced in 2019 to extend Medicaid coverage to 12-
5 months postpartum; therefore be it
6

7 RESOLVED That our American Medical Association support and actively work toward
8 enactment of state legislation, Section 1115 waiver applications, and federal legislation to
9 extend Medicaid coverage to 12-months postpartum. (Directive to Take Action)

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

Received: 05/01/19

ⁱ Martin JA, Hamilton BE, Osterman MJK, Driscoll AK, and Drake P. Births: Final Data for 2016. National vital statistics reports; vol 67 no 1. Hyattsville, MD: National Center for Health Statistics. 2018. Retrieved from https://www.cdc.gov/nchs/data/nvsr/nvsr67/nvsr67_01.pdf.

ⁱⁱ National Women's Law Center. Medicaid at 50: Celebrating Medicaid's Contributions to Women's Economic Security (July 2015). Retrieved from https://nwlc-ciw49tixgw5lbab.stackpathdns.com/wp-content/uploads/2015/08/final_nwlc_medicaid50th_whitepaper_3.pdf.

ⁱⁱⁱ Brown, DW, Kowalski, AE, and Lurie, IZ (2015). Medicaid As an Investment in Children: What Is the Long-Term Impact on Tax Receipts?, National Bureau of Economic Research Working Paper, 20835. Retrieved from <http://www.nber.org/papers/w20835>.

^{iv} Spelke B and Werner E. The Fourth Trimester of Pregnancy: Committing to Maternal Health and Well-Being Postpartum. R I Med J (2013). 2018 Oct 1;101(8):30-33.

^v Tully KP, Stuebe AM, and Verbiest SB. The fourth trimester: a critical transition period with unmet maternal health needs. Am J Obstet Gynecol. 2017 Jul;217(1):37-41.

^{vi} Optimizing postpartum care. ACOG Committee Opinion No. 736. American College of Obstetricians and Gynecologists. Obstet Gynecol 2018;131:e140–50.

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^x Vestal, Christine. "For Addicted Women, the Year After Childbirth Is the Deadliest." Pew Stateline. 14 Aug 2018. Retrieved from <https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2018/08/14/for-addicted-women-the-year-after-childbirth-is-the-deadliest>.

^{xi} Maternal Mortality and Morbidity Task Force and Department of State Health Services Joint Biennial Report, September 2018. Retrieved from <https://www.dshs.texas.gov/mch/pdf/MMMTFJointReport2018.pdf>.

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 222
(A-19)

Introduced by: Kentucky, Mississippi, Oklahoma, West Virginia

Subject: Protecting Patients from Misleading and Potentially Harmful "Bad Drug" Ads

Referred to: Reference Committee B
(Charles Rothberg, MD, Chair)

1 Whereas, In 2016, the American Medical Association House of Delegates adopted Resolution
2 208 relating to patients being potentially endangered by ubiquitous television commercials that
3 seek plaintiffs regarding medications; and
4

5 Whereas, Since that time the issue has become even more pervasive, and new research in
6 addition to direct physician experiences has indicated that actual patient harm is occurring; and
7

8 Whereas, Many of these advertisements utilize misleading techniques, including the use of
9 terms like "Medical Alert" to imply the advertisement is some kind of public service
10 advertisement, the use of the term "recall" even when a drug or other device remains approved
11 by the US Food and Drug Administration, or the use of governmental logos to imply that the
12 advertisement is associated with a governmental agency; and
13

14 Whereas, Few of the advertisements fairly identify the sponsor and purpose of the
15 advertisement in any meaningful or understandable manner, leading individuals to potentially
16 provide their private and protected health information to third parties under misleading
17 circumstances; and
18

19 Whereas, While there is clearly a potential for danger when stopping or altering a course of care
20 agreed upon with a physician or seeking to modify or remove a medical device without first
21 consulting a physician about that change, few of the advertisements provide this very important
22 safety information in any meaningful way; and
23

24 Whereas, The state of Tennessee has recently adopted new rules creating common-sense
25 regulations to protect patient health and fairly address these other concerns; therefore be it
26

27 RESOLVED, That our American Medical Association encourage state legislatures to consider
28 and adopt legislation that helps protect patient health by creating fair rules and regulations
29 around attorney advertisements that:
30

- 31 1. Prohibit misuse of governmental logos or the term "recall"
- 32 2. Provide clear warning of the dangers in stopping a course of treatment without consulting
33 with a physician and
- 34 3. Require written consent before sharing personal health information. (Directive to Take
35 Action)

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

Received: 05/01/19

RELEVANT AMA POLICY

Attorney Ads on Drug Side Effects H-105.985

Our AMA will advocate for a requirement that attorney advertising which may cause patients to discontinue medically necessary medications have appropriate and conspicuous warnings that patients should not discontinue medications without seeking the advice of their physician.

Citation: Res. 208, A-16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 223
(A-19)

Introduced by: Wisconsin

Subject: Simplification and Clarification of Smoking Status Documentation in the Electronic Health Record

Referred to: Reference Committee B
(Charles Rothberg, MD, Chair)

1 Whereas, Addiction involving tobacco use remains our nation's leading cause of preventable
2 death; and

3
4 Whereas, Adult cigarette smoking rates have dropped to about 14%, certain populations e.g.,
5 the poor, and persons with behavioral health conditions, continue to smoke at much higher
6 rates, and still about 20% of adult deaths each year are attributable to tobacco use; and

7
8 Whereas, Passive exposure to tobacco smoke contributes about 10% of the tobacco-related
9 mortality in our nation so that even non-smokers experience potentially lethal health impacts
10 from the tobacco smoking of others; and

11
12 Whereas, Aligned with the first step in quality improvement is measurement (to know the current
13 state before interventions that might improve it are implemented), the first step in disease
14 control is surveillance--knowing baseline levels of disease incidence and prevalence so that the
15 results of interventions to reduce disease onset, duration and impact can be accurately
16 measured against a reference point; and

17
18 Whereas, Case definitions, and the words used to make up those definitions, are of critical
19 importance in epidemiology and in clinical medicine, so that there is concurrence and
20 consistency in the description and enumeration of clinical states, and so that public health
21 surveillance efforts are accurate; and

22
23 Whereas, Health records in North America have shifted predominantly to electronic health
24 records (EHRs), in which words used by clinicians are transformed into computer language and
25 stored as digital information that comprise chart documents; and

26
27 Whereas, The Office of National Coordinator of Health Information Technology (ONC) is a
28 component of the federal Department of Health and Human Services (DHHS) and is charged by
29 Congress, among other things, with recommending uniform standards for computer language in
30 EHRs to interface with the human language of physicians and other members of health care
31 clinical teams; and

32
33 Whereas, SNOMED is the systematized standard nomenclature format for terms used in EHR
34 software designed and sold by health information technology (HIT) vendors, and provides a
35 standardized, consistent language by which computer software designers fit human words into
36 categories of digitally recognized terms to describe symptoms, illnesses, medical and surgical
37 procedures, and even outcome measures in healthcare today; and

Whereas, Proclamations and directives from the ONC are influential in guiding HIT vendors in their design of EHR software in a standardized way across commercial EHR platforms, allowing for interoperability of software systems, standardized collation of health information into databases and information exchange platforms, and activities of health care practitioners and public health officials alike to improve health care processes to generate better outcomes for patients and populations of patients; and

Whereas, Current terminology in SNOMED¹ regarding a patient's smoking status are overlapping and therefore imprecise and confusing, and lead to problems with data analysis and, arguably more significantly, problematic data entry by clinicians as they are not sure which categorization of smoking status to enter into a patient's electronic health record; and

Whereas, SNOMED terminology¹ regarding smoking status and passive smoking exposure can be simplified by elimination of the vague, undefined, and overlapping terms "heavy tobacco smoker" and "light tobacco smoker" and consolidating the terms "smoker, current status unknown" and "unknown if ever smoked" into the single item "smoking status unknown" (Appendix A), making it more likely that clinicians will enter such data into EHRs at both higher rates and with more precision, to inform their care and inform epidemiologists about trends in improvement or worsening in our nation's population health statistics regarding tobacco-related health conditions and their impacts²; and

Whereas, These simplifications have been developed by the Center for Tobacco Research and Intervention (CTRI) at the University of Wisconsin School of Medicine and Public Health (UWSMPH), and endorsed by the Association for the Treatment of Tobacco Use and Dependence²; therefore be it

RESOLVED, That our American Medical Association support the streamlining of the SNOMED categories for smoking status and passive smoking exposure documentation in the electronic medical record so that the categories are discrete, non-overlapping, and better understood per The Association for the Treatment of Tobacco Use and Dependence 2019 recommendations as follows:

Smoking status categories: Current Every Day Smoker, Current Some Day Smoker
Former Smoker, Never Smoker, and Smoking Status Unknown

Passive smoking exposure: Exposure to Second Hand Tobacco Smoke, Past Exposure to Second Hand Tobacco Smoke, No Known Exposure to Second Hand Tobacco Smoke
(Directive to Take Action)

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

Received: 05/01/19

References:

¹ The Office of the National Coordinator for Health Information Technology (ONC). Representing patient tobacco use (smoking status). Available at: <https://www.healthit.gov/isa/representing-patient-tobacco-use-smoking-status> Accessed April 24, 2019.

² Association for the Treatment of Tobacco Use and Dependence. Provider Information. The Association for the Treatment of Tobacco Use and Dependence (ATTUD) Recommendation for Recording Smoking Status and Passive Smoke Exposure in the Electronic Health Record Available at:

<https://www.attud.org/pdf/ATTUD%20Recommendations%20for%20Recording%20Smoking%20Status%20in%20EHR.pdf>
Accessed April 24, 2019.

RELEVANT AMA POLICY

Tobacco Control Content in Electronic Health Records H-478.990

Our AMA encourages: (1) physicians to capture information from all their patients on tobacco use, secondhand smoke exposure, cessation interest, and past quit attempts; and (2) the development of EHR systems that provide physicians with the ability to capture information on specific health behaviors deemed appropriate by the physician and that provide physicians the option to utilize automated reminders to benefit their patients.

Citation: (BOT Rep. 15, A-09

Appendix A:

Smoking Status Documentation in the Electronic Health Record Background and Context:

The Centers for Medicare and Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC) have played a major role in encouraging the adoption and utilization of EHRs in the United States. In part, because of CMS's Meaningful Use of EHRs Program, outpatient and inpatient clinical settings today almost universally screen and document patients for smoking and document patient "Smoking Status" in the EHR. "Smoking Status" is a required component for ONC's CEHRT/Health IT Certification Program EHR software certification.

However, confusion remains for many clinicians and health care systems about the *categories to document smoking status*. The current SNOMED CT options overlap. As a result, they often create confusion at the point of care.

History of "Smoking Status" Classification/Documentation in the EHR

CMS Meaningful Use (MU) recommends the following criteria for smoking status using a classification based on the National Health Interview Survey (NHIS):

- Current every day smoker
- Current some day smoker
- Former smoker
- Never smoker
- Smoker, current status unknown
- Unknown if ever smoked
- Heavy tobacco smoker
- Light tobacco smoker

2015 Health Information Technology Certification Criteria Final Rule removed the requirement that reporting entities must use the 8 SNOMED CT codes to document smoking status. Specifically, the 2015 Health Information Technology Certification Criteria Final Rule described reporting on "Smoking Status" in the following way:

*"We have adopted a "smoking status" certification criterion that does not reference a standard."....."In consideration of the concerns expressed by commenters regarding development burden and the proper mapping of all available smoking status codes within SNOMED CT to the specified 8 SNOMED CT1 for exchange, we believe that the best path forward is **the adoption of a "smoking status" criterion that would simply require a Health IT Module to demonstrate that it can enable a user to record, change, and access a patient's smoking status.**"*

Looking Forward

In an effort to further **clarify and simplify "Smoking Status" documentation**, we encourage ONC to advise health information technology developers, health care systems, hospitals and health care providers to use non-overlapping criteria to document smoking status. An example of such non-overlapping criteria/classifications are shown below for smoking status and passive smoke exposure:

Smoking Status	SNOMED CT Code
Current Every Day Smoker	449868002
Current Some Day Smoker	428041000124106

Former Smoker	8517006
Never Smoker	266919005
Smoking Status Unknown	266927001

Passive Smoking Exposure	SNOMED CT Code
Exposure to Second Hand Tobacco Smoke	16090371000119103
Past Exposure to Second Hand Tobacco Smoke	99009004
No Known Exposure to Second Hand Tobacco Smoke	711563001

Tobacco Control Content in Electronic Health Records H-478.990

Our AMA encourages: (1) physicians to capture information from all their patients on tobacco use, secondhand smoke exposure, cessation interest, and past quit attempts; and (2) the development of EHR systems that provide physicians with the ability to capture information on specific health behaviors deemed appropriate by the physician and that provide physicians the option to utilize automated reminders to benefit their patients. (Policy Timeline: BOT Rep. 15, A-09)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 224
(A-19)

Introduced by: Resident and Fellow Section

Subject: Extending Pregnancy Medicaid to One Year Postpartum

Referred to: Reference Committee B
(Charles Rothberg, MD, Chair)

Whereas, Medicaid covers postpartum care for women with pregnancy Medicaid for only sixty days after giving birth; and

Whereas, Thirteen states did not adopt the Affordable Care Act's Medicaid expansion plan and thus pregnant women living in these states cannot obtain health care coverage through Medicaid after pregnancy; and

Whereas, Women with pregnancy induced hypertension, gestational diabetes, post-partum depression and/or other comorbidities require further follow-up with a primary care physician, however are unable to continue their medical care due to the current sixty-day policy; and

Whereas, Approximately one in five pregnant women have one or more chronic medical conditions that may complicate pregnancy and increase the risk of pregnancy-related death, which is defined as the death of a woman during pregnancy or within one year of giving birth; and

Whereas, The United States has the worst maternal mortality rate amongst developed countries; therefore be it

RESOLVED, That our American Medical Association petition the Centers for Medicare and Medicaid Services to extend pregnancy Medicaid to a minimum of one year postpartum.
(Directive to Take Action)

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

Received: 05/01/19

References:

1. ACOG Committee Opinion (2018). "ACOG Committee Opinion No. 736: Optimizing postpartum care". Obstetrics and Gynecology 131(5): e140-e150.
2. Kaiser Family Foundation (2017). "Medicaid coverage of pregnancy and perinatal benefits: Results from a state survey". Retrieved Oct 23 from <https://www.kff.org/womens-health-policy/report/medicaid-coverage-of-pregnancy-and-perinatal-benefits-results-from-a-state-survey/>.
3. Kaiser Family Foundation (2018). "Status of state action on the Medicaid expansion decision". Retrieved Oct 23 from <https://www.kff.org/health-reform/state-indicator/state-activity-around-expanding-medicare-under-the-affordable-care-act/#notes>.
4. Bouscaren, D (2017). "Researchers make case for extending Medicaid coverage to low-income mothers". Retrieved Oct 23 from <http://news.stlpublicradio.org/post/researchers-make-case-extending-medicare-coverage-low-income-mothers#stream/0>.
5. CDC (2018). "Pregnancy mortality surveillance system". Retrieved Oct 23 from <https://www.cdc.gov/reproductivehealth/maternalinfanthealth/pregnancy-mortality-surveillance-system.htm>.
6. Medicaid and CHIP Payment and Access Commission (2014). "Chapter 3: Issues in pregnancy coverage under Medicaid and exchange plans". Retrieved Oct 23 from https://www.macpac.gov/wp-content/uploads/2015/01/Issues_in_pregnancy_Coverage_under_Medicaid_and_Exchange_Plans.pdf

RELEVANT AMA POLICY

Disparities in Maternal Mortality D-420.993

Our AMA: (1) will ask the Commission to End Health Care Disparities to evaluate the issue of health disparities in maternal mortality and offer recommendations to address existing disparities in the rates of maternal mortality in the United States; (2) will work with the CDC, HHS, state and county health departments to decrease maternal mortality rates in the US; (3) encourages and promotes to all state and county health departments to develop a maternal mortality surveillance system; and (4) will work with stakeholders to encourage research on identifying barriers and developing strategies toward the implementation of evidence-based practices to prevent disease conditions that contribute to poor obstetric outcomes, maternal morbidity and maternal mortality in racial and ethnic minorities.

Citation: CSAPH Rep. 3, A-09; Appended: Res. 403, A-11; Appended: Res. 417, A-18

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 225
(A-19)

Introduced by: Resident and Fellow Section

Subject: DACA in GME

Referred to: Reference Committee B
(Charles Rothberg, MD, Chair)

Whereas, There is an anticipated shortage of over 100,000 doctors by the year 2030, especially in primary care; and

Whereas, A recent study in the Journal of Graduate Medical education found that “there are simply not enough US-trained physicians to fill all the available residency and fellowship positions” in primary care specialties⁶; and

Whereas, A 2018 study by the American Medical Association on non-US IMGs found that 64% are working in primary care, and 66% of non-US IMGs that matched in 2018 did so in primary care fields; and

Whereas, In 2014-2015, there were 1,879 physicians from Muslim-majority countries including many on the travel ban list, practicing on a J-1 visa, a visa obtained during residency training that upon completion of training, requires holders to find “J-1 waiver” jobs which recruit physicians into underserved areas³,” and

Whereas, A New York Times article described “changes in visa policies prevent foreign graduate (IMG) doctors from practicing and increase medical provider shortages especially in rural communities²,” and

Whereas, 2018 saw the lowest number of non-US IMG applicants since 2005¹⁶; and

Whereas, An open-letter by ACGME described the “profound moral distress [a travel ban] has provoked within the health care community¹,” and

Whereas, ECFMG Statement to Supreme Court (2018) “In the United States, where one-quarter of our physicians have received their medical degree outside the United States and Canada, the ability to provide accessible, high-quality health care depends on our ability to continue to attract highly qualified physicians from around the world. Anything that disrupts the flow of these talented and qualified professionals into the United States will have a negative and potentially long-term impact on patient care. We urge immigration policymakers to consider the many contributions that foreign national physicians make to our healthcare system and our economy, and to ensure that United States remains an attractive option for the best and brightest minds from around the world”⁴; and

Whereas, New data shows that in 2017, U.S. Citizenship and Immigration Services denied more H-1B petitions, preventing more foreign nationals from working in America,¹² and there is concern that these rejections will affect medical residents in training in the U.S¹³; and

Whereas, Multiple US medical organizations including the Accreditation Council for Graduate Medical Education (ACGME), the Association of American Medical Colleges, Alliance for Academic Internal Medicine, American Academy of Family Medicine, American Academy of Pediatrics, and the American College of Physicians have expressed concern over executive orders limiting immigration and their impact on graduate medical education^{1, 6-11}; therefore be it

RESOLVED, That American Medical Association Policy D-255.991, "Visa Complications for IMGs in GME," be reaffirmed (Reaffirm HOD Policy); and be it further

RESOLVED, That AMA Policy D-350.986, "Evaluation of DACA-Eligible Medical Students, Residents and Physicians in Addressing Physician Shortages," be reaffirmed. (Reaffirm HOD Policy)

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

Received: 05/01/19

References:

- 1 Accreditation Council for Graduate Medical Education. Nasca immigration letter. February 2, 2017. <https://www.acgme.org/Portals/0/PDFs/Nasca-Community/Nasca-Letter-Immigration-2-2-17.pdf>. Accessed August 19/2018.
- 2 Rural Areas Brace for a Shortage of Doctors Due to Visa Policy. March 18, 2017. <https://www.nytimes.com/2017/03/18/us/doctor-shortage-visa-policy.html>
- 3 Masri, A and Senussi, M. Trump's Executive Order on Immigration — Detrimental Effects on Medical Training and Health Care. New England Journal of Medicine. 2017(376):e39. Accessed August 21, 2018.
- 4 ECFMG Statement on Supreme Court Decision to Uphold Visa Restrictions in Presidential Proclamation. June 26, 2018; <https://www.ecfm.org/news/2018/06/26/ecfm-statement-on-supreme-court-decision-to-uphold-visa-restrictions-in-presidential-proclamation/>
- 5 Poll-Hunter, Norma I. et al. Values Guide Us in Times of Uncertainty: DACA and Graduate Medical Education. Academic Medicine Nov 2017.
- 6 Reem A. Mustafa, Fadi Bdaire, M. Hassan Murad, and David Wooldridge (2017) Immigration, Graduate Medical Education, and Ethical Dilemmas. Journal of Graduate Medical Education: June 2017, Vol. 9, No. 3, pp. 280-282.
- 7 Association of American Medical Colleges. AAMC statement on President Trump's executive order on immigration. January 30, 2017. <https://news.aamc.org/press-releases/article/executive-order-immigration-013017>. Accessed April 24, 2017. [Google Scholar]
- 8 Alliance for Academic Internal Medicine. AAIM statement on the executive order on immigration. February 2, 2017. <http://www.im.org/p/cm/ld/fid=1653>. Accessed August 24, 2018.
- 9 American Academy of Family Physicians. ABFM statement regarding executive order travel ban. February 2, 2017. <https://www.theabfm.org/about/travelban2017.pdf>. Accessed August 24, 2018
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- 11 Damle NS. American College of Physicians issues comprehensive statement on US immigration policy. January 31, 2017. <https://www.acponline.org/acp-newsroom/acp-comprehensive-statement-us-immigration-policy>. August 24, 2018
- 12 Anderson S. New evidence USCIS policies increased denials of H-1B visas." <https://www.forbes.com/sites/stuartanderson/2018/07/25/new-evidence-uscis-policies-increased-denials-of-h-1b-visas/#24c56ac85a9f>. September 2, 2018
- 13 Ducharme J. Trump's immigration policies are making it harder for foreign doctors to work in the U.S. - and that could hurt patients. <http://time.com/5299488/international-medical-graduates/>. September 2, 2018
- 14 <http://www.nrmp.org/wp-content/uploads/2018/06/Charting-Outcomes-in-the-Match-2018-IMGs.pdf>
- 15 (https://news.aamc.org/press-releases/article/workforce_report_shortage_04112018/)
- 16 <http://www.nrmp.org/wp-content/uploads/2018/04/Main-Match-Result-and-Data-2018.pdf>

RELEVANT AMA POLICY

AMA Principles on International Medical Graduates H-255.988

Our AMA supports:

1. Current U.S. visa and immigration requirements applicable to foreign national physicians who are graduates of medical schools other than those in the United States and Canada.
2. Current regulations governing the issuance of exchange visitor visas to foreign national IMGs, including the requirements for successful completion of the USMLE.
3. The AMA reaffirms its policy that the U.S. and Canada medical schools be accredited by a nongovernmental accrediting body.

4. Cooperation in the collection and analysis of information on medical schools in nations other than the U.S. and Canada.
5. Continued cooperation with the ECFMG and other appropriate organizations to disseminate information to prospective and current students in foreign medical schools. An AMA member, who is an IMG, should be appointed regularly as one of the AMA's representatives to the ECFMG Board of Trustees.
6. Working with the Accreditation Council for Graduate Medical Education (ACGME) and the Federation of State Medical Boards (FSMB) to assure that institutions offering accredited residencies, residency program directors, and U.S. licensing authorities do not deviate from established standards when evaluating graduates of foreign medical schools.
7. In cooperation with the ACGME and the FSMB, supports only those modifications in established graduate medical education or licensing standards designed to enhance the quality of medical education and patient care.
8. The AMA continues to support the activities of the ECFMG related to verification of education credentials and testing of IMGs.
9. That special consideration be given to the limited number of IMGs who are refugees from foreign governments that refuse to provide pertinent information usually required to establish eligibility for residency training or licensure.
10. That accreditation standards enhance the quality of patient care and medical education and not be used for purposes of regulating physician manpower.
11. That AMA representatives to the ACGME, residency review committees and to the ECFMG should support AMA policy opposing discrimination. Medical school admissions officers and directors of residency programs should select applicants on the basis of merit, without considering status as an IMG or an ethnic name as a negative factor.
12. The requirement that all medical school graduates complete at least one year of graduate medical education in an accredited U.S. program in order to qualify for full and unrestricted licensure.
13. Publicizing existing policy concerning the granting of staff and clinical privileges in hospitals and other health facilities.
14. The participation of all physicians, including graduates of foreign as well as U.S. and Canadian medical schools, in organized medicine. The AMA offers encouragement and assistance to state, county, and specialty medical societies in fostering greater membership among IMGs and their participation in leadership positions at all levels of organized medicine, including AMA committees and councils and state boards of medicine, by providing guidelines and non-financial incentives, such as recognition for outstanding achievements by either individuals or organizations in promoting leadership among IMGs.
15. Support studying the feasibility of conducting peer-to-peer membership recruitment efforts aimed at IMGs who are not AMA members.
16. AMA membership outreach to IMGs, to include a) using its existing publications to highlight policies and activities of interest to IMGs, stressing the common concerns of all physicians; b) publicizing its many relevant resources to all physicians, especially to nonmember IMGs; c) identifying and publicizing AMA resources to respond to inquiries from IMGs; and d) expansion of its efforts to prepare and disseminate information about requirements for admission to accredited residency programs, the availability of positions, and the problems of becoming licensed and entering full and unrestricted medical practice in the U.S. that face IMGs. This information should be addressed to college students, high school and college advisors, and students in foreign medical schools.
17. Recognition of the common aims and goals of all physicians, particularly those practicing in the U.S., and support for including all physicians who are permanent residents of the U.S. in the mainstream of American medicine.
18. Its leadership role to promote the international exchange of medical knowledge as well as cultural understanding between the U.S. and other nations.
19. Institutions that sponsor exchange visitor programs in medical education, clinical medicine and public health to tailor programs for the individual visiting scholar that will meet the needs of the scholar, the institution, and the nation to which he will return.
20. Informing foreign national IMGs that the availability of training and practice opportunities in the U.S. is limited by the availability of fiscal and human resources to maintain the quality of medical education and patient care in the U.S., and that those IMGs who plan to return to their country of origin have the opportunity to obtain GME in the United States.

21. U.S. medical schools offering admission with advanced standing, within the capabilities determined by each institution, to international medical students who satisfy the requirements of the institution for matriculation.

22. The Federation of State Medical Boards, its member boards, and the ECFMG in their willingness to adjust their administrative procedures in processing IMG applications so that original documents do not have to be recertified in home countries when physicians apply for licenses in a second state.

Citation: BOT Rep. Z, A-86; Reaffirmed: Res. 312, I-93; Modified: CME Rep. 2, A-03; Reaffirmation I-11; Reaffirmed: CME Rep. 1, I-13; Modified: BOT Rep. 25, A-15; Modified: CME Rep. 01, A-16; Appended: Res. 304, A-17; Modified: CME Rep. 01, I-17

Evaluation of DACA-Eligible Medical Students, Residents and Physicians in Addressing Physician Shortages D-350.986

1. Our American Medical Association will study the issue of Deferred Action for Childhood Arrivals-eligible medical students, residents, and physicians and consider the opportunities for their participation in the physician profession and report its findings to the House of Delegates.

2. Our AMA will issue a statement in support of current US healthcare professionals, including those currently training as medical students or residents and fellows, who are Deferred Action for Childhood Arrivals recipients.

Citation: Res. 305, A-15; Appended: Late Res. 1001, I-16

Strategies for Enhancing Diversity in the Physician Workforce D-200.985

1. Our AMA, independently and in collaboration with other groups such as the Association of American Medical Colleges (AAMC), will actively work and advocate for funding at the federal and state levels and in the private sector to support the following: a. Pipeline programs to prepare and motivate members of underrepresented groups to enter medical school; b. Diversity or minority affairs offices at medical schools; c. Financial aid programs for students from groups that are underrepresented in medicine; and d. Financial support programs to recruit and develop faculty members from underrepresented groups.

2. Our AMA will work to obtain full restoration and protection of federal Title VII funding, and similar state funding programs, for the Centers of Excellence Program, Health Careers Opportunity Program, Area Health Education Centers, and other programs that support physician training, recruitment, and retention in geographically-underserved areas.

3. Our AMA will take a leadership role in efforts to enhance diversity in the physician workforce, including engaging in broad-based efforts that involve partners within and beyond the medical profession and medical education community.

4. Our AMA will encourage the Liaison Committee on Medical Education to assure that medical schools demonstrate compliance with its requirements for a diverse student body and faculty.

5. Our AMA will develop an internal education program for its members on the issues and possibilities involved in creating a diverse physician population.

6. Our AMA will provide on-line educational materials for its membership that address diversity issues in patient care including, but not limited to, culture, religion, race and ethnicity.

7. Our AMA will create and support programs that introduce elementary through high school students, especially those from groups that are underrepresented in medicine (URM), to healthcare careers.

8. Our AMA will create and support pipeline programs and encourage support services for URM college students that will support them as they move through college, medical school and residency programs.

9. Our AMA will recommend that medical school admissions committees use holistic assessments of admission applicants that take into account the diversity of preparation and the variety of talents that applicants bring to their education.

10. Our AMA will advocate for the tracking and reporting to interested stakeholders of demographic information pertaining to URM status collected from Electronic Residency

Application Service (ERAS) applications through the National Resident Matching Program (NRMP).

11. Our AMA will continue the research, advocacy, collaborative partnerships and other work that was initiated by the Commission to End Health Care Disparities.

12. Our AMA opposes legislation that would undermine institutions' ability to properly employ affirmative action to promote a diverse student population.

Citation: CME Rep. 1, I-06; Reaffirmation I-10; Reaffirmation A-13; Modified: CCB/CLRPD Rep. 2, A-14; Reaffirmation: A-16; Appended: Res. 313, A-17; Appended: Res. 314, A-17; Modified: CME Rep. 01, A-18; Appended: Res. 207, I-18

Impact of Immigration Barriers on the Nation's Health D-255.980

1. Our AMA recognizes the valuable contributions and affirms our support of international medical students and international medical graduates and their participation in U.S. medical schools, residency and fellowship training programs and in the practice of medicine.

2. Our AMA will oppose laws and regulations that would broadly deny entry or re-entry to the United States of persons who currently have legal visas, including permanent resident status (green card) and student visas, based on their country of origin and/or religion.

3. Our AMA will oppose policies that would broadly deny issuance of legal visas to persons based on their country of origin and/or religion.

4. Our AMA will advocate for the immediate reinstatement of premium processing of H-1B visas for physicians and trainees to prevent any negative impact on patient care.

5. Our AMA will advocate for the timely processing of visas for all physicians, including residents, fellows, and physicians in independent practice.

6. Our AMA will work with other stakeholders to study the current impact of immigration reform efforts on residency and fellowship programs, physician supply, and timely access of patients to health care throughout the U.S.

Citation: Alt. Res. 308, A-17; Modified: CME Rep. 01, A-18

Visa Complications for IMGs in GME D-255.991

1. Our AMA will: (A) work with the ECFMG to minimize delays in the visa process for International Medical Graduates applying for visas to enter the US for postgraduate medical training and/or medical practice; (B) promote regular communication between the Department of Homeland Security and AMA IMG representatives to address and discuss existing and evolving issues related to the immigration and registration process required for International Medical Graduates; and (C) work through the appropriate channels to assist residency program directors, as a group or individually, to establish effective contacts with the State Department and the Department of Homeland Security, in order to prioritize and expedite the necessary procedures for qualified residency applicants to reduce the uncertainty associated with considering a non-citizen or permanent resident IMG for a residency position.

2. Our AMA International Medical Graduates Section will continue to monitor any H-1B visa denials as they relate to IMGs' inability to complete accredited GME programs.

3. Our AMA will study, in collaboration with the Educational Commission on Foreign Medical Graduates and the Accreditation Council for Graduate Medical Education, the frequency of such J-1 Visa reentry denials and its impact on patient care and residency training.

4. Our AMA will, in collaboration with other stakeholders, advocate for unfettered travel for IMGs for the duration of their legal stay in the US in order to complete their residency or fellowship training to prevent disruption of patient care.

Citation: (Res. 844, I-03; Reaffirmation A-09; Reaffirmation I-10; Appended: CME Rep. 10, A-11; Appended: Res. 323, A-12

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 226
(A-19)

Introduced by: New York

Subject: Physician Access to their Medical and Billing Records

Referred to: Reference Committee B
(Charles Rothberg, MD, Chair)

1 Whereas, Contracts include language that medical and billing records are proprietary and the
2 property of the employer and may limit access to the treating physician during employment or
3 after separation; and
4

5 Whereas, Billing is frequently signed by physicians or billed under the physician's identifier; and
6

7 Whereas, Physician review is crucial to any compliance program; therefore be it
8

9 RESOLVED, That our American Medical Association advocate that licensed physicians must
10 always have access to all medical and billing records for their patients from and after date of
11 service including after physician termination (Directive to Take Action); and be it further
12

13 RESOLVED, That our AMA press for legislation or regulation to eliminate contractual language
14 that bars or limits the treating physician's access to the medical and billing records such as
15 treating these records as trade secrets or proprietary. (Directive to Take Action)

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

Received: 04/25/19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 227
(A-19)

Introduced by: Alabama

Subject: Controlled Substance Management

Referred to: Reference Committee B
(Charles Rothberg, MD, Chair)

1 Whereas, Physicians continue to play a key role in combatting the US opioid crisis; and

2
3 Whereas, Physicians who prescribe controlled substances must be vigilant regarding potential
4 diversion or other misuse of the medications they prescribe; and

5
6 Whereas, Many states require physicians to access their state's prescription monitoring
7 program data for patients receiving controlled substance prescriptions from them; and

8
9 Whereas, Pill counts can also be an effective part of a patient's opioid management plan; and

10
11 Whereas, Many state medical licensing boards strongly encourage physicians to conduct pill
12 counts to combat diversion of controlled substances; and

13
14 Whereas, Accessing patient data in a prescription monitoring program database and pill counts,
15 whether performed by the physician or delegated to someone else in their practice, carry with
16 them a labor cost borne by the physician; and

17
18 Whereas, There is currently no mechanism for physicians to be fairly compensated for this
19 additional work effort; therefore be it

20
21 RESOLVED, That our American Medical Association work with the Centers for Medicare and
22 Medicaid Services (CMS) and interested physician groups to strongly advocate for a
23 mechanism by which physicians may be compensated for controlled substance management
24 (Directive to Take Action); and be it further

25
26 RESOLVED, That our AMA strongly encourage CMS and private payers to recognize and
27 establish equitable payment for controlled substance management. (Directive to Take Action)

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

Received: 04/30/19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 228
(A-19)

Introduced by: American Society of Anesthesiologists

Subject: Truth in Advertising

Referred to: Reference Committee B
(Charles Rothberg, MD, Chair)

Whereas, Our American Medical Association (AMA) supports nonphysician providers' role within the patient-centered, physician-led health care team; and

Whereas, Nonphysician providers' contributions to the delivery of care should not be confused with being a medical specialist; and

Whereas, Physicians receive 12 to 14 years of education, including medical school, and 12,000 to 16,000 hours of clinical training to specialize in the practice of medicine with the necessary knowledge to understand and treat the entire human body; and

Whereas, In 2018 the American Association of Nurse Anesthetists (AANA) approved the descriptor "nurse anesthesiologist" as an appropriate term to refer to a nurse anesthetist; and

Whereas, In 2018 the New Hampshire Board of Nursing issued a position statement that recognizes "Nurse Anesthesiologist" and "Certified Registered Nurse Anesthesiologist" as optional, accurate descriptors¹; and

Whereas, Having strong truth-in-advertising laws helped safeguard patients in Texas, where the Texas Association of Nurse Anesthetists shared its awareness of the AANA approval of the "nurse anesthesiologist" term and cautioned its members that any nomenclature comparing nurses to physicians that misleads patients could result in disciplinary or legal action; and

Whereas, Our AMA policy provides that anesthesiology is the practice of medicine; and

Whereas, To avoid unnecessary confusion by other health care providers, the public and especially patients and their families, efforts must be taken to prevent the misappropriation of medical specialties titles; therefore be it

RESOLVED, That our American Medical Association reaffirm support of the Scope of Practice Partnership's Truth in Advertising Campaign to ensure patients receive accurate information about who is providing their care (AMA Policy H-405.969) (Reaffirm HOD Policy); and be it further

¹ Available at <https://www.oplc.nh.gov/nursing/documents/nh-bon-nurse-anesthesiologist.pdf>

- 1 RESOLVED, That our AMA oppose any misappropriation of medical specialties' titles and work
- 2 with state medical societies to advocate for states and administrative agencies overseeing
- 3 nonphysician providers to authorize only the use of titles and descriptors that align with the
- 4 nonphysician providers' state issued licenses and national board certification. (Directive to Take
- 5 Action)

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

Received: 05/01/19

RELEVANT AMA POLICY

Anesthesiology is the Practice of Medicine H-160.929

It is the policy of the AMA that anesthesiology is the practice of medicine. Our AMA seeks legislation to establish the principle in federal and state law and regulation that anesthesia care requires the personal performance or supervision by an appropriately licensed and credentialed doctor of medicine, osteopathy, or dentistry.

Citation: (Sub. Res. 216, I-98; Reaffirmed: BOT Rep. 23, A-09; Reaffirmed: BOT Rep. 9, I-11

Definition of a Physician H-405.969

1. The AMA affirms that a physician is an individual who has received a "Doctor of Medicine" or a "Doctor of Osteopathic Medicine" degree or an equivalent degree following successful completion of a prescribed course of study from a school of medicine or osteopathic medicine.

2. AMA policy requires anyone in a hospital environment who has direct contact with a patient who presents himself or herself to the patient as a "doctor," and who is not a "physician" according to the AMA definition above, must specifically and simultaneously declare themselves a "non-physician" and define the nature of their doctorate degree.

3. Our AMA actively supports the Scope of Practice Partnership in the Truth in Advertising campaign.

Citation: CME Rep. 4-A-94; Reaffirmed by Sub. Res. 712, I-94; Reaffirmed and Modified: CME Rep. 2, A-04; Res. 846, I-08; Reaffirmed in lieu of Res. 235, A-09; Reaffirmed: Res. 821, I-09; Appended: BOT Rep. 9, I-09; Reaffirmed: BOT Rep. 9, I-11; Reaffirmation A-13; Reaffirmation A-15; Reaffirmed in lieu of: Res. 225, A-17

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 229
(A-19)

Introduced by: American Society of Clinical Oncology

Subject: Clarification of CDC Opioid Prescribing Guidelines

Referred to: Reference Committee B
(Charles Rothberg, MD, Chair)

1 Whereas, The Centers for Disease Control and Prevention (CDC) published their *Guideline for*
2 *Prescribing Opioids for Chronic Pain* in 2016 to provide recommendations for the prescribing of
3 opioid pain medication for patients 18 and older in primary care settings; and
4

5 Whereas, The CDC explicitly stated in this guideline that it was developed for primary care
6 clinicians who prescribe opioids for chronic pain outside of active cancer treatment, palliative
7 care, and end-of-life care; and
8

9 Whereas, By February of 2019, over half of all states had enacted laws in response to these
10 guidelines that restrict the prescribing or dispensing of opioids for acute pain, codifying 7-day
11 prescription fill limits into statute¹; and
12

13 Whereas, New Hampshire, Ohio, Oregon, Rhode Island, Utah, Vermont, Virginia, Washington
14 and Wisconsin have all passed legislation authorizing state regulatory entities to set their own
15 enforceable opioid prescribing limits or guidelines²; and
16

17 Whereas, A 2018 study performed by the American Cancer Society Cancer Action Network
18 (ACS CAN) together with the Patient Quality of Life Coalition (PQLC) showed that nearly half of
19 cancer patients (48 percent) and more than half of those with other serious illnesses (56
20 percent) surveyed said their doctor indicated treatment options for their pain were limited by
21 laws, guidelines or insurance coverage;³ and
22

23 Whereas, The CDC issued a letter to the National Comprehensive Cancer Network (NCCN), the
24 American Society of Clinical Oncology (ASCO), and the American Society of Hematology (ASH)
25 on February 28, 2019 clarifying that clinical practice guidelines specific to cancer treatment,
26 palliative care, and end of life care should be used to guide treatment and reimbursement
27 decisions regarding the use of opioids as part of pain control in these circumstances⁴; and

¹ National Conference of State Legislators. Prescribing Policies: States Confront Opioid Overdose Epidemic. NCSL website. <http://www.ncsl.org/research/health/prescribing-policies-states-confront-opioid-overdose-epidemic.aspx> . Published October 31, 2018. Accessed April 19, 2019.

² Ibid.

³ American Cancer Society Cancer Action Network. New Data: Some Measures Meant to Address Opioid Abuse Are Having Adverse Impact on Access to Legitimate Pain Care For Patients. ACS CAN Press Release. <https://www.fightcancer.org/releases/new-data-some-measures-meant-address-opioid-abuse-are-having-adverse-impact-access>. Published July 14, 2018. Accessed April 22, 2018.

⁴ U.S. Department of Health and Human Services. CDC Opioid Guideline Clarification Letter. <https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2019-CDC-Opioid-Guideline-Clarification-Letter-to-ASCO-ASH-NCCN.pdf>. Published February 28, 2019.

1 Whereas, ASCO and NCCN have each published clinical practice guidelines addressing pain
2 control for cancer survivors subsequent to the release of the CDC's Guideline for Prescribing
3 Opioids for Chronic Pain; therefore be it
4

5 RESOLVED, That our American Medical Association reaffirm Policy D-120.932, "Inappropriate
6 Use of Centers for Disease Control and Prevention Guidelines for Prescribing Opioids";
7 (Reaffirm HOD Policy) and be it further
8

9 RESOLVED, That our AMA incorporate into their advocacy that clinical practice guidelines
10 specific to cancer treatment, palliative care, and end of life be utilized in lieu of the CDC's
11 Guideline for Prescribing Opioids for Chronic Pain as per the CDC's clarifying recommendation.
12 (Directive to Take Action)

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

Received: 05/01/19

RELEVANT AMA POLICY

Inappropriate Use of CDC Guidelines for Prescribing Opioids D-120.932

1. Our AMA applauds the Centers for Disease Control and Prevention (CDC) for its efforts to prevent the incidence of new cases of opioid misuse, addiction, and overdose deaths.
2. Our AMA will 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 filling 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. A report is due back to the House of Delegates at the 2019 Annual Meeting.
3. Our AMA affirms that some patients with acute or chronic pain can benefit from taking opioid pain medications at doses greater than generally recommended in the CDC Guideline for Prescribing Opioids for Chronic Pain and that such care may be medically necessary and appropriate.
4. Our AMA will advocate against misapplication of the CDC Guideline for Prescribing Opioids 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.
5. Our AMA will advocate that no entity should use MME (morphine milligram equivalents) thresholds as anything more than guidance, and physicians should not be subject to professional discipline, loss of board certification, loss of clinical privileges, criminal prosecution, civil liability, or other penalties or practice limitations solely for prescribing opioids at a quantitative level above the MME thresholds found in the CDC Guideline for Prescribing Opioids.

Citation: Res. 235, I-18