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REPORT OF THE BOARD OF TRUSTEES

BOT Report 6-I-17

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

Presented by: Gerald E. Harmon, MD, Chair

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

INTRODUCTION

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

AMA POLICY

Current AMA policy provides:


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

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Policy D-120.958, “Federal Roadblocks to E-Prescribing”

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

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

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

DISCUSSION

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

State Laws

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

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

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

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

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

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

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

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

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

Recent Efforts

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

CONCLUSION

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

RECOMMENDATIONS

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

Guidelines,”

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

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

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

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

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

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

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

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

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

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

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

Fiscal note: Less than $500.
AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 201
(I-17)

Introduced by: Resident and Fellow Section

Subject: Improving FDA Expedited Approval Pathways

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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


RELEVANT AMA POLICY

FDA H-100.992
(1) Our AMA reaffirms its support for the principles that: (a) an FDA decision to approve a new drug, to withdraw a drug's approval, or to change the indications for use of a drug must be based on sound scientific and medical evidence derived from controlled trials and/or postmarket incident reports as provided by statute; (b) this evidence should be evaluated by the FDA, in consultation with its Advisory Committees and expert extramural advisory bodies; and (c) any risk/benefit analysis or relative safety or efficacy judgments should not be grounds for limiting access to or indications for use of a drug unless the weight of the evidence from clinical trials and postmarket reports shows that the drug is unsafe and/or ineffective for its labeled indications.
(2) The AMA believes that social and economic concerns and disputes per se should not be permitted to play a significant part in the FDA's decision-making process in the course of FDA devising either general or product specific drug regulation.
(3) It is the position of our AMA that the Food and Drug Administration should not permit political considerations or conflicts of interest to overrule scientific evidence in making policy decisions; and our AMA urges the current administration and all future administrations to consider our best and brightest scientists for positions on advisory committees and councils regardless of their political affiliation and voting history. (Res. 119, A-80; Reaffirmed: CLRPD Rep. B, I-90; Reaffirmed: Sunset Report, I-00; Reaffirmation, A-06; Appended: Sub. Res. 509, A-06; Reaffirmation, I-07; Reaffirmation, I-09; Reaffirmation, I-10)

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

Food and Drug Administration H-100.980
(1) AMA policy states that a strong and adequately funded FDA is essential to ensuring that safe and effective medical products are made available to the American public as efficiently as possible. (2) Our AMA: (a) continue to monitor and respond appropriately to legislation that affects the FDA and to regulations proposed by the FDA; (b) continue to work with the FDA on controversial issues concerning food, drugs, biologics, radioactive tracers and pharmaceuticals, and devices to try to resolve concerns of physicians and to support FDA initiatives of potential benefit to patients and physicians; and (c) continue to affirm its support of an adequate budget for the FDA so as to favor the agency's ability to function efficiently and effectively. (3) Our AMA will continue to monitor and evaluate proposed changes in the FDA and will respond as appropriate. (Sub. Res. 548, A-92; BOT Rep. 32, A-95; BOT Rep. 32, A-95; BOT Rep. 18, A-96; Reaffirmed: BOT Rep. 7, I-01; Reaffirmation I-07; Reaffirmed: Sub. Res. 504, A-10; Reaffirmation A-15; Reaffirmed: CMS Rep. 06, I-16)
Whereas, The Violence Against Women Reauthorization Act of 2013 requires state, tribal and local governments to offer medical forensic examinations to victims of sexual assault despite whether the victim participates in the criminal justice system;¹,² and

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

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

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

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

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

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

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

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

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

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

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

RESOLVED, That our AMA collaborate with relevant stakeholders to develop recommendations for implementing best practices in the treatment of sexual assault survivors, including through engagement with the joint working group established for this purpose under the Survivor’s Bill of Rights Act of 2016. (Directive to Take Action)
WHEREAS, In 2017 physicians are increasingly required to send prescriptions electronically to pharmacies, also known as e-prescribing; and

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

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

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

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

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

Received: 09/18/17
Introduction by: Virginia, North Carolina, American Urological Association, American Association of Clinical Urologists

Subject: EHR Vendors Responsible for Health Information Technology

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

RESOLVED, That our American Medical Association oppose legislation that reduces or eliminates access to federal child nutrition programs (New HOD Policy); and be it further

RESOLVED, That our AMA reaffirm Policy H-150.962, “Quality of School Lunch Program.” (Reaffirm HOD Policy)

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

Received: 09/20/17

RELEVANT AMA POLICY

Quality of School Lunch Program H-150.962

See also:
Support for Uniform, Evidence-Based Nutritional Rating System H-150.936;
Rating System for Processed Foods H-150.942
Excess Sodium in the Diet H-150.997
Promotion of Healthy Lifestyles I: Reducing the Population Burden of Cardiovascular Disease by Reducing Sodium Intake H-150.929
American's Health H-440.859
Addressing Obesity D-440.954
Combating Obesity and Health Disparities H-150.944
Obesity as a Major Public Health Problem H-150.953
Prevention of Obesity Through Instruction in Public Schools H-170.961
Sustainable Food D-150.978
Culturally Responsive Dietary and Nutritional Guidelines D-440.978
Recognizing and Taking Action in Response to the Obesity Crisis D-440.980

\textsuperscript{16} Roberts P. Senator Roberts: USDA Grants Flexibility on School Meals; Waste and Cost Remain a Concern. United States Senate Committee on Agriculture, Nutrition, and Forestry.
\textsuperscript{17} “Ag Secretary Perdue Moves to Make School Meals Great Again.” USDA, United States Department of Agriculture Press, 1 May 2017, \url{www.usda.gov/media/press-releases/2017/05/01/ag-secretary-perdue-moves-make-school-meals-great-again}. 
WHEREAS, There is a surplus of unused medications in the US including long-term care facilities discarding $2 billion worth of medications already paid for by federal and state governments annually, leaving a potential $700 million to be saved by reusing these discarded medications;¹,² while hospital pharmacies and other health care providers spend approximately $1 billion on unused medications annually;³ and

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

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

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

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

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

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

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

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

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

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

Received: 09/20/17

RELEVANT AMA POLICY

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

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

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

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

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

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

WHEREAS, Our AMA has affirmed that “physical and verbal violence between law enforcement officers and public citizens, particularly within racial and ethnic minority populations, is a social determinant of health” (AMA Policy H-515.955); and

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

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

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

Received: 09/20/17

**RELEVANT AMA POLICY**

Research the Effects of Physical or Verbal Violence Between Law Enforcement Officers and Public Citizens on Public Health Outcomes H-515.955
Initiatives Regarding Minorities H-350.971
Use of Conducted Electrical Devices by Law Enforcement Agencies H-145.977
Guns in Hospitals H-215.977
AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 209
(I-17)

Introduced by: Indiana

Subject: Government Mandated Sequester

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

Whereas, EMR mandates do not increase relative value unit (RVU) values; and
Whereas, There are unfunded mandates for quality; and
Whereas, Funding was approved as appropriate before sequester; therefore be it
RESOLVED, That our American Medical Association advocate to remove the sequester provision for Part B Medicare reimbursement. (Directive to Take Action)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Whereas, Prices for medical services vary greatly across the country\(^1\); and

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

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

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

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

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

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

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

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

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

Received: 09/29/17

RELEVANT AMA POLICY

Price Transparency D-155.987
1. Our AMA encourages physicians to communicate information about the cost of their professional services to individual patients, taking into consideration the insurance status (e.g., self-pay, in-network insured, out-of-network insured) of the patient or other relevant information where possible.
2. Our AMA advocates that health plans provide plan enrollees or their designees with complete information regarding plan benefits and real time cost-sharing information associated with both in-network and out-of-network provider services or other plan designs that may affect patient out-of-pocket costs.
3. Our AMA will actively engage with health plans, public and private entities, and other stakeholder groups in their efforts to facilitate price and quality transparency for patients and physicians, and help ensure that entities promoting price transparency tools have processes in place to ensure the accuracy and relevance of the information they provide.
4. Our AMA will work with states to support and strengthen the development of all-payer claims databases.
5. Our AMA encourages electronic health records vendors to include features that assist in facilitating price transparency for physicians and patients.
6. Our AMA encourages efforts to educate patients in health economics literacy, including the development of resources that help patients understand the complexities of health care pricing and encourage them to seek information regarding the cost of health care services they receive or anticipate receiving.
7. Our AMA will request that the Centers for Medicare and Medicaid Services expand its Medicare Physician Fee Schedule Look-up Tool to include hospital outpatient payments.

Citation: CMS Rep. 4, A-15; Reaffirmed in lieu of: Res. 121, A-16

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

Citation: (CMS Rep. 4, A-09)

Physicians’ Freedom to Establish Their Fees H-380.994
Our AMA (1) affirms that it is a basic right and privilege of each physician to set fees for service that are reasonable and appropriate, while always remaining sensitive to the varying resources of patients and retaining the freedom to choose instances where courtesy or charity could be extended in a dignified and ethical manner; (2) supports the concept that health insurance should be treated like any other insurance (i.e., a contract between a patient and a third party for indemnification for expense or loss incurred by virtue of obtaining medical or other health care services); and (3) believes that the contract for care and payment is between the physician and patient.

Citation: (BOT Rep. JJ, I-83; Reaffirmed: CLRPD Rep. 1, I-93; Reaffirmed: Sub. Res. 704 and Reaffirmation A-01; Reaffirmation A-09)
Whereas, Our AMA continues to advocate that physicians are best qualified by their education and training to lead the health care team; and

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

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

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

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

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

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

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

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

Received: 09/29/17

REFERENCES

RELEVANT AMA POLICY

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

Resolution: 215
(I-17)

Introduced by: Michigan

Subject: Relieve Burden for Living Organ Donors

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

Whereas, Studies have shown that direct costs to living organ donors average approximately $5,000.00, which is greater than one month’s wage for 76 percent of donors; and

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

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

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

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

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

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

Accessed December 1, 2016.
4 Purnell TST. Advances in chronic kidney disease: Understanding and overcoming barriers to living kidney donation among racial and ethnic minorities in the United States. WB Saunders Company; 07/2012;19:244.
Whereas, Federal law grants federal employees seven days paid leave for bone marrow
donation and 30 days for organ donation in addition to annual and sick leave; and

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

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

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

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

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

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

Received: 09/29/17

RELEVANT AMA POLICY:

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

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


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

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

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

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

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

Received: 09/29/17

RELEVANT AMA POLICY

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

5. AMA policy is that insurance coverage options offered in a health insurance exchange be self-supporting, have uniform solvency requirements; not receive special advantages from government subsidies; include payment rates established through meaningful negotiations and contracts; not require provider participation; and not restrict enrollees’ access to out-of-network physicians.

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

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

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

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

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

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

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

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

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

Increasing Collaboration Between Physicians and the Public to Address Problems in Health Care Delivery H-160.904

Our American Medical Association will continue to consider and implement the most strategic and sustainable approaches to stay engaged with physician and non-physician stakeholders essential to our endeavor to improve the delivery of quality medical care.

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

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

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

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

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

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

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

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

Received: 09/29/17
RELEVANT AMA POLICY

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

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

Food and Drug Administration H-100.980
(1) AMA policy states that a strong and adequately funded FDA is essential to ensuring that safe and effective medical products are made available to the American public as efficiently as possible. (2) Our AMA: (a) continue to monitor and respond appropriately to legislation that affects the FDA and to regulations proposed by the FDA; (b) continue to work with the FDA on controversial issues concerning food, drugs, biologics, radioactive tracers and pharmaceuticals, and devices to try to resolve concerns of physicians and to support FDA initiatives of potential benefit to patients and physicians; and (c) continue to affirm its support of an adequate budget for the FDA so as to favor the agency's ability to function efficiently and effectively. (3) Our AMA will continue to monitor and evaluate proposed changes in the FDA and will respond as appropriate.
Whereas, The American Medical Association has numerous and extensive policy on electronic health records (EHRs) that support current advocacy efforts to improve EHRs and advance health information technology (HIT); and

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

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

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

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

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

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

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

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

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

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

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

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

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

Received: 10/02/17
RELEVANT AMA POLICY

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

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

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

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

Resolution: 219
(I-17)

Introduced by: Maryland

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

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

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

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

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

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

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

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

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

Received: 10/09/17
Whereas, Recently introduced proposed legislation, H.R. 620: The ADA Education and Reform Act of 2017, would amend the Americans with Disabilities Act of 1990 to promote compliance through education, to clarify the requirements for demand letters, and to provide for a notice and cure period before the commencement of a private civil action; and

Whereas, H.R. 620 provides for the Disability Rights Section of the Department of Justice to develop a program to educate state and local governments and property owners on strategies for promoting access for persons with a disability; and

Whereas, The most concerning portion of this proposed legislation, the “notice and cure” period, would essentially require a person with a disability to send a letter of notification to a business or other public facility that it was out of compliance with the law, and allows a grace period before one could file suit. This provision allows for the business or other public facility to report on how the situation will be fixed within 60 days, and allows another 120 days for the business to fix or make substantial progress toward rectification; and

Whereas, This provision would remove the incentive for businesses and other public facilities to voluntarily comply with the ADA’s accessibility requirements; and

Whereas, This bill was designed to prevent non-meritorious lawsuits based on noncompliance with Title III of the ADA; however, the courts already have tools to address fraudulent or unscrupulous claims; and

Whereas, It would become the responsibility of the persons with a disability to act to address the barriers to access with the business owner, placing the heaviest burden of responsibility on individuals with disabilities, who the law was intended to protect; and

Whereas, Similar legislation has been recently introduced, such as H.R. 1493: ADA Law Suit Clarification Act of 2017, and H.R. 3571: The Reasonable ADA Compliance Act of 2017; therefore be it

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

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

Received: 10/10/17

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

RELEVANT AMA POLICY

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

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

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

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

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

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

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

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

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

Fiscal Note: Modest - between $1,000 - $5,000.
Received: 10/12/17
AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 222
(I-17)

Introduced by: American Academy of Sleep Medicine
Subject: The Clinical Use of a Home Sleep Apnea Test
Referred to: Reference Committee B
(Ralph J. Nobo, Jr., MD, Chair)

Whereas, For the purposes of this resolution, the term “physician” refers to a medical provider who is licensed to practice medicine; and

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

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

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

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

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

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

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

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

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

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

Received: 10/11/17
AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 223
(I-17)

Introduced by: American Association of Public Health Physicians
Washington

Subject: Treating Opioid Use Disorder in Correctional Facilities

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

Whereas, The opioid epidemic has become a critical threat to public health in the U.S., with drug overdoses now the leading cause of accidental death and opioids being responsible for 61 percent of those deaths\(^1\); and

Whereas, Approximately one-third of heroin users pass through correctional facilities annually\(^2\) and up to 60 percent of the incarcerated population has a substance use disorder\(^3\); and

Whereas, Individuals recently released from prison have a high risk of overdose death, particularly during the first two weeks after release when their risk is 130 times greater than that of the non-incarcerated population\(^4\); and

Whereas, Correctional facilities rarely treat opioid withdrawal with opioid agonist therapy, which is the most effective, evidence-based treatment for this condition, and rarely provide opioid agonist therapy even to inmate-patients who have been stabilized on it prior to entry\(^5,6\), resulting in unnecessary suffering and sometimes death; and

Whereas, Effective treatment for opioid use disorder, including pharmacotherapy, improves medical and mental health outcomes\(^7\) and reduces spread of infectious diseases\(^8\) and, in the incarcerated population, reduces deaths during incarceration\(^9\), reduces deaths immediately following release\(^10\), and reduces recidivism\(^11\); and

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\(^3\) Fazel S, Baillargeon J. The health of prisoners. Lancet 2011; 377: 956–65


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

RESOLVED, That our American Medical Association advocate for legislation, standards, policies and funding that encourage correctional facilities to increase access to evidence-based treatment of opioid use disorder, including initiation and continuation of opioid replacement therapy, in correctional facilities within the United States (New HOD Policy); and be it further

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

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

Received: 10/12/17

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

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

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

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

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

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

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


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

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

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

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

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

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

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

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

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

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

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

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

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

Received: 10/12/17

1 Medicare Program; CY 2018 Updates to the Quality Payment Program, 82 Federal Register 125, 30010-30500 (June 30, 2017) (to be codified at 42 CFR Part 414), 30150.

RELEVANT AMA POLICY

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

1. Our AMA will advocate that Centers for Medicare and Medicaid Services (CMS) implement the Merit-Based Payment Incentive Payment System (MIPS) and Alternative Payment Models (APMs) as is consistent with congressional intent when the Medicare Access and Children's Health Insurance Program (CHIP) Reauthorization Act (MACRA) was enacted.

2. Our AMA will advocate that CMS provide for a stable transition period for the implementation of MACRA, which includes assurances that CMS has conducted appropriate testing, including physicians' ability to participate and validation of accuracy of scores or ratings, and has necessary resources to implement provisions regarding MIPS and APMs.

3. Our AMA will advocate that CMS provide for a stable transition period for the implementation of MACRA that includes a suitable reporting period.

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

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

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

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

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

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

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

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

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

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

Whereas, Current AMA Policy D-110.983 specifically addresses importation by drug wholesalers and importation via Internet sales, it does not address the issue of importation from a Canadian pharmacy for personal use only; therefore be it

RESOLVED, That our American Medical Association support legislation that would allow for the personal purchase and importation of prescription drugs obtained directly from a licensed Canadian pharmacy, provided such drugs are for personal use and of a limited quantity. (New HOD Policy)

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

Received: 10/12/17

RELEVANT AMA POLICY

Prescription Drug Importation and Patient Safety D-100.983

Our AMA will:
(1) support the legalized importation of prescription drug products by wholesalers and pharmacies only if: (a) all drug products are Food and Drug Administration (FDA)-approved and meet all other FDA regulatory requirements, pursuant to United States laws and regulations; (b) the drug distribution chain is "closed," and all drug products are subject to reliable, "electronic" track and trace technology; and (c) the Congress grants necessary additional authority and resources to the FDA to ensure the authenticity and integrity of prescription drugs that are imported;
(2) oppose personal importation of prescription drugs via the Internet until patient safety can be assured;
(3) review the recommendations of the forthcoming report of the Department of Health and Human Services (HHS) Task Force on Drug Importation and, as appropriate, revise its position on whether or how patient safety can be assured under legalized drug importation; and
(4) educate its members regarding the risks and benefits associated with drug importation and reimportation efforts.

Citation: BOT Rep. 3, I-04; Reaffirmation A-09; Reaffirmed in lieu of: Res. 817, I-16