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:

Policy D-120.956, “Electronic Prescribing and Conflicting Federal Guidelines”:

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.

© 2017 American Medical Association. All rights reserved.
Policy D-120.958, “Federal Roadblocks to E-Prescribing”:
1. Our AMA will initiate discussions with the Centers for Medicare and Medicaid Services and state Medicaid directors to remove barriers to electronic prescribing including removal of the Medicaid requirement that physicians write, in their own hand, "brand medically necessary" on a paper prescription form. 2. Our AMA will initiate discussions with the Drug Enforcement Administration to allow electronic prescribing of Schedule II prescription drugs. 3. It is AMA policy that physician Medicare or Medicaid payments not be reduced for non-adoption of E-prescribing. 4. Our AMA will work with federal and private entities to ensure universal acceptance by pharmacies of electronically transmitted prescriptions. 5. Our AMA will advocate for appropriate financial and other incentives to physicians to facilitate electronic prescribing adoption. 6. Our AMA will: (A) investigate regulatory barriers to electronic prescription of controlled substances so that physicians may successfully submit electronic prescriptions for controlled substances; and (B) work with the Centers for Medicare & Medicaid Services to eliminate from any program (e.g., the Physician Quality Reporting System, meaningful use, and e-Prescribing) the requirement to electronically prescribe controlled substances, until such time that the necessary protocols are in place for electronic prescribing software vendors and pharmacy systems to comply. 7. Our AMA will work with representatives of pharmacies, pharmacy benefits managers, and software vendors to expand the ability to electronically prescribe all medications. 8. Our AMA will petition the Centers for Medicare & Medicaid Services and the federal government to have all pharmacies, including government pharmacies, accept e-prescriptions or to temporarily halt the e-prescribing requirements of meaningful use until this is accomplished.

Policy H-120.957, “Prescription of Schedule II Medications by Fax and Electronic Data Transmission”:
Our AMA: (1) encourages the Drug Enforcement Administration to rewrite Section 1306 of Title 21 of the Code of Federal Regulations to accommodate encrypted electronic prescriptions for Schedule II controlled substances, as long as sufficient security measures are in place to ensure the confidentiality and integrity of the information. (2) Our AMA supports the concept that public key infrastructure (PKI) systems or other signature technologies designed to accommodate electronic prescriptions should be readily adaptable to current computer systems, and should satisfy the criteria of privacy and confidentiality, authentication, incorruptibility, and nonrepudiation. (3) Because sufficient concerns exist about privacy and confidentiality, authenticity, and other security measures, the AMA does not support the use of "hard copy" facsimile transmissions as the original written prescription for Schedule II controlled substances, except as currently allowed in Section 1306 of Title 21 of the Code of Federal Regulations.

DISCUSSION

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

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

Centers for Medicare & Medicaid Services (CMS)

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

U.S. Drug Enforcement Administration

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

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

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

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

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

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

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

Recent Efforts

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

CONCLUSION

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

RECOMMENDATIONS

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

1. That current AMA Policy D-120-956, “Electronic Prescribing and Conflicting Federal 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-E-prescribing.
4. Our AMA will work with the largest and nearly exclusive national electronic pharmacy network, all related state pharmacy regulators, and with federal and private entities to ensure universal acceptance by pharmacies of electronically transmitted prescriptions.
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.
67. 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.