INTRODUCTION

At the 2017 Annual Meeting, the American Medical Association (AMA) House of Delegates (HOD) referred Resolution 212-A-17, submitted by the American College of Legal Medicine (ACLM). The resolution asked that our AMA:

- Join the American College of Legal Medicine to advocate federally-mandated interfaces between provider/dispenser electronic health record systems in the clinical, hospital and pharmacy environments and state prescription drug databases and/or prescription drug management plans;
- Advocate that the cost of generating these interfaces be borne by the commercial EHR and dispensing program providers;
- Advocate that the interface should include automatic query of any opioid prescription, from a provider against the state prescription drug database/prescription drug management plan (PDMP) to determine whether such a patient has received such a medication, or another Schedule II drug from any provider in the preceding ninety (90) days;
- Advocate that the prescriber and the patient’s EHR-listed dispensing pharmacy should then be notified of the existence of the referenced patient in the relevant PDMP database, the substance of the previous prescription(s) (including the medication name, number dispensed and prescriber’s directions for use) in real time and prior to the patient receiving such medication;
- Advocate that the electronic record management program at the pharmacy filling the relevant prescription, contemporaneously as it enters the filling of the prescription by the pharmacist, likewise be required to automatically query the state PDMP as a secondary mechanism to prevent inappropriate prescribing, forgery, duplication and/or too great a frequency of use of the involved controlled medication;
- Work with ACLM and other concerned societies to urge Congress to timely enact and implement such a statutory scheme supported by a workable and concise regulatory framework, chiefly concentrating on the interfacing of all applicable electronic health record and pharmaceutical dispensing systems with every individual state’s PDMP, thereafter designating a timeframe wherein all treating providers and dispensing pharmacists would be
required to perform such queries, in concert with the routine ordering of and filling of a
controlled substance to be used in the treatment of patients;

Advocate that oversight of the appropriate prescribing of and filling of prescriptions for
controlled substances remain with the involved individual federal and state criminal law
enforcement agencies, the involved state departments of health, or similar entities and the
involved relevant state provider and/or pharmacy licensure authorities; and

Advocate that statistics be maintained and reviewed on a periodic basis by state PDMP
personnel and relayed to state departments of health or agencies similarly situated so as to
identify and possibly treat those patients identified through this screening mechanism as
potential drug abusers and/or at risk of addiction.

Board of Trustees (BOT) Report 12-A-18 summarized work that the AMA has done in support of
ensuring accurate, reliable Prescription Drug Monitoring Programs (PDMPs) that support clinical
decision-making. It also addressed many of the complexities raised in the original resolution,
including evolution of PDMPs, and their integration with electronic health records (EHRs) and
electronic prescribining of controlled substances (EPCS).

After debate, the HOD referred BOT Report 12-A-18 back for consideration. While general
support existed for the recommendations contained in the report, the HOD asked for additional
information on the evolution of PDMPs. This report, therefore, updates and expands upon the

DISCUSSION

More than 300 million queries of state PDMPs were made in 2017, more than doubling the 136
million queries in 2016, and five times the 61 million queries submitted in 2014.¹ Physician
adoption of EHRs also continues to grow. The Office of the National Coordinator for Health
Information Technology maintains that nearly 90 percent of office-based physicians are using
EHRs.²

A major goal of AMA advocacy and many others continues to be the integration of electronic
systems that can support efforts to address the opioid epidemic. To effectively support physician
and public health efforts to prevent opioid overdose deaths, the AMA has urged that electronic
systems be interoperable and integrated into medical practice workflows. As noted in BOT
Report 12-A-18, information exchanged with EHRs is not well incorporated into the physician’s
workflow. Obtaining important information, including PDMP data, often requires multiple
“clicks,” opening multiple windows, and the use of separate logins even before the physician
locates what he or she is looking for—and that situation must be repeated for each patient and
every prescription for a controlled substance. Effective PDMP and EHR integration means that the
workflow must achieve “functional interoperability,” or the ability for systems to exchange,
incorporate and display data in a meaningful and contextual manner.

The Centers for Medicare & Medicaid Services highlighted this in a recent letter to state Medicaid
directors, noting that when integration occurs, it “removes the requirement for providers to log in to
a separate system, manage a separate log in, and disrupt their workflow to query the PDMP. Single
sign-on interoperability between EHR and PDMP such that PDMP results are displayed when the
EHR indicates a controlled substance is prescribed could be supported, as an example.”³
Many consider the ideal practice to be a “one-click” solution with PDMP data and EPCS integrated into physicians’ EHR systems. On one hand, many EHR vendors are pulled in too many directions to focus on this need. Federal regulations require vendors to develop EHRs that meet administrative requirements. To achieve the ideal for PDMP and EPCS integration, more must be done to reduce the regulatory pressure on health IT development, allowing vendors the flexibility to respond to physician and patient needs, rather than spending the bulk of their time complying with administrative demands.

Yet, there have been reports of progress of successful PDMP-EHR integration. For example, the University of North Carolina (UNC) Health Care at Chapel Hill, reported that efforts to integrate its Epic EHR with the state PDMP have been positive. A news report from July found that “[i]n the first two weeks, more than 540 UNC clinicians used the PDMP when treating some 2,950 patients, which officials said has saved physicians about 119 hours already.”¹⁴ Oschner Health System in New Orleans, Louisiana, also has used Epic to integrate the EHR with the state PDMP.⁵ Deaconess Health, which operates several hospitals in Indiana, also has made strides to integrate EHRs with the state PDMP. And there are many different options in the commercial market, although your Board notes that a Google search of effective PDMP-EHR integration efforts results in dozens of options.⁶

In addition to growing physician use of PDMPs, interstate interoperability has expanded considerably. According to the National Association of Boards of Pharmacy, 44 states now can securely share PDMP information across state lines.⁷ The effects of expanded PDMP use on patient care are mostly unknown; physicians and other health care professionals are not the only ones interested in using the PDMP data.

As noted above, PDMP use among physicians and other health care professionals has significantly increased in recent years; however, opioid-related mortality continues to increase, driven principally by heroin, illicit fentanyl, and other synthetic derivatives. Moreover, as PDMP use increases and opioid prescribing rates decrease, it is not clear that PDMPs are making a significant impact on improving patients’ pain care. One review concluded that “[e]vidence that PDMP implementation either increases or decreases nonfatal or fatal overdoses is largely insufficient, as is evidence regarding positive associations between specific administrative features and successful programs. Some evidence showed unintended consequences. Research is needed to identify a set of “best practices” and complementary initiatives to address these consequences.”⁸

There may also be a need for additional clarity on how PDMP data may be used by non-health care professionals, including health insurance companies, pharmacy benefit management companies (PBMs), and law enforcement. For example, earlier this year, the U.S. Department of Justice and 48 attorneys general reached an agreement to share data. According to the news release, “Drug Enforcement Agency DEA will provide the Attorneys General with that data, and the states will provide their own information, often from prescription drug monitoring programs (PDMPs) to DEA. Under the agreement, both state and federal law enforcement will have more information at their disposal to find the tell-tale signs of crime.” It is not clear what these “tell-tale signs” might be.

Progress has been considerably slower in achieving EPCS uptake,⁹ largely due to outdated regulations from the DEA. The combination of personal identification numbers (PINs), passwords, and biometrics required to meet DEA standards for “two-factor authentication” increase EPCS security but add to workflow disruptions and increase costs. DEA, EPCS requirements include onerous limits on use of biometric devices, which must comply with federal standards that set an unnecessarily high bar and prevent use of user-friendly consumer electronics already found in
physicians’ offices for two-factor authentication. The biometric fingerprint scanners found on these consumer devices, i.e., smart phone, tablets, and laptop computers, are used for secure access to other sensitive information, like banking and medical records, but typically do not comport with rigid rules for EPCS.

The AMA views EPCS as important to support high-quality patient care. Physicians commonly report that they are frustrated that they can e-prescribe non-controlled substance medications but must still use written prescriptions for controlled substances. More than 70 percent of physicians are e-prescribing non-controlled drugs but only 20 percent used EPCS. One reason for this is due to the fact that not all EHR vendors understand or can satisfy EPCS requirements—state EPCS mandates have increased uptake, but implementation has been delayed due to questions about system certification, cost to providers, and patient concerns, i.e., transferring prescriptions between pharmacies. Moreover, EHR vendor processes for EPCS do not always align well with normal e-prescribing workflows—often physicians must start new computer programs and windows each time they use EPCS. Cumbersome workflows and applications that do not take physician needs into account impede EPCS uptake. Finally, although EPCS reduces prescription fraud and diversion, it is less clear how it affects valid prescriptions for opioid analgesics. For example, does the prescriber using EPCS put in a dose and duration or are numbers suggested by the EPCS system and, if so, how are these amounts derived? These are among the questions the AMA has been asking from vendors and physicians.

To help resolve other barriers, the AMA and the President’s Commission on Combating Drug Addiction and the Opioid Crisis have recommended the DEA modify EPCS regulations in order to reduce barriers to EPCS adoption. The AMA asked DEA to reexamine the scope of technology that is compliant with EPCS requirements and allow use of lower-cost, high-performing biometric devices in two-factor authentication. The AMA also believes that there must be further study to evaluate the variations in how EPCS systems handle initial dosing, i.e., are opioid doses or durations auto-populated in EPCS systems and, if so, are the amounts appropriate.

A final point is that the AMA has made clear to the DEA that its 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. This and other rules contribute to cumbersome workflows and applications which are an impediment to physician EPCS uptake. 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. The AMA also continues its efforts in support of making PDMPs better clinical tools. The use of PDMPs continues to increase in states regardless of mandates—tied mainly to quality of the PDMP as a decision-support tool in those states without mandates. Important policies that have improved PDMP workflow and data reliability include delegate access, data input by pharmacists within 24 hours, and states sharing PDMP information. PDMP usability continues to improve, but usage in rural and other areas may be affected by lack of access to broadband and other technologies. Consistent, long-term funding of state PDMPs is also a concern—most states depend on federal grants for ongoing maintenance and improvements. The AMA also continues to try and identify best practices in designing PDMPs to identify risk including: distinguishing between uncoordinated care, misuse, and “doctor shopping,” identifying opportunities for referrals to specialized care; providing reports to prescribers to better inform prescribing decisions; and conducting public health surveillance activities.
One best practice is PDMP and EHR integration, but, as previously discussed, that goal remains largely elusive. It is not clear, for example, how many PDMPs are integrated into EHRs, which makes identification of best practices challenging given the variety of EHR systems in use. Each state PDMP may require a slightly different interface to connect to an EHR. With over 600 different EHRs on the market, the number of custom EHR/PDMP interfaces required can reach into the thousands. Custom software development is time-consuming and expensive—with costs being passed on to the physician. Without PDMP and EHR integration, physicians must use multiple usernames and passwords to shuttle between different systems, often having to re-enter login information if one system times out while they are using the other one. This results in increased time to enter information, decreased satisfaction with the technology, and potentially less use of the systems.

Furthermore, the AMA notes that one dominant PDMP developer is responsible for the PDMP platforms of more than 40 states. PDMP quality and uptake has improved and it is clear that the PDMP interface is moving toward greater integration through the use of more advanced tools offered by the developer. This development, along with the growing interstate interoperability has led, anecdotally, to physicians receiving a greater number of alerts about potentially dangerous drug combinations, multiple prescriber events, and other clinical issues. Yet, these advanced tools are not without costs, and it is not clear how these tools may be affecting patient care. The PDMP interface can help identify a patient’s prescription history, but that is only one component of effectively screening a patient for a potential substance use disorder or helping understand whether a patient’s pain is being effectively managed.

Similarly, while there are some positive examples with PDMP-EHR integration, EHRs are generally not interoperable between different organizations, making coordination between primary care physicians, pain medicine physicians, addiction medicine physicians and other providers much more difficult. When PDMP and EHR integration does exist (e.g., Oregon’s EDIE), the patient, public health and cost utilization benefits are extremely positive. This integration requires time and broad, institutional support. For example, the state of Washington’s integration project with the state Health Information Exchange (HIE) began in 2012. As of August 2017, more than 90 percent of emergency departments include PDMP data in the EHR using data through the HIE. The state’s major health systems still are working to accomplish this integration.

To help resolve some of these issues, the AMA advocates for consistent and sufficient appropriations to support a state’s ability to maintain and improve its PDMP, including broad state-based grants to improve statewide HIEs and the ability to integrate HIE data into the EHR of statewide emergency departments and other providers. The AMA also would support a U.S. Government Accountability Office study on best practices for small and large physician practices on using PDMPs to improve pain care as well as treatment for substance use disorders. This would include identifying how PDMPs can distinguish uncoordinated care from misuse or “doctor shopping” as well as help coordinate care for a patient with a substance use disorder or other condition requiring specialty care. In addition, a need exists to evaluate the variations in state-based PDMP technology and work with the health IT industry to discuss “common understanding” of how each PDMP works—providing transparency for EHR vendors to facilitate development of custom connections between their products and PDMP software. This could include funding for programs that pilot test low-cost technologies to better integrate EHRs and PDMPs as well as efforts to identify burdensome federal regulations that prevent EHRs from being designed and developed to support objective clinical decision-making.

The AMA also has been engaged in the SMART project to help EHR systems work better for physicians and patients. A key component of this effort is the development of a flexible
information infrastructure that allows for free, open development of plug and play applications (apps) to increase interoperability among health care technologies, including EHRs, in a more cost-effective way. The infrastructure development specific to PDMPs is part of both ongoing research as well as work by states working to achieve more comprehensive data integration. In addition, the Office of the National Coordinator for Health Information Technology has compiled multiple sources and pilot examples for PDMP and EHR integration. The pilot examples, not surprisingly, found that PDMPs were most helpful when they were integrated into physicians’ workflow as well as EHRs.

AMA POLICY

The AMA House of Delegates has provided strong guidance to the AMA that reflects the issues raised by the original resolution that is the subject of this report. Relevant policies include:

Policy H-120.957, “Prescription of Schedule II Medications by Fax and Electronic Data Transmission,” which “encourages the Drug Enforcement Administration to support two factor authentication that is easier to implement than the current DEA and EPCS security requirements; and because sufficient concerns exist about privacy and confidentiality, authenticity, and other security measures, 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.”

In addition, Policy H-95.928, “Model State Legislation Promoting the Use of Electronic Tools to Mitigate Risk with Prescription Opioid Prescribing,” provides that the AMA support multiple facets of PDMP development, including interoperability, assisting physicians and pharmacists in identifying “when their patients have received a prescription for controlled substances from multiple prescribers or multiple pharmacies within a short time frame.”

Policy D-478.972, “EHR Interoperability,” calls for the AMA to continue efforts in support of EHR interoperability standards, reducing excessive costs and generally reducing barriers to EHR adoption.

Finally, Policy D-478.994, “Health Information Technology,” broadly notes AMA support for “legislation and other appropriate initiatives that provide incentives for physicians to acquire health information technology,” which reasonably would include PDMP EPCS and EHR uptake.

RECOMMENDATIONS

The Board of Trust recommends that the following recommendations be adopted in lieu of Resolution 212-A-17, and the remainder of the report be filed:

1. That our American Medical Association (AMA) advocate for a federal study to evaluate the use of PDMPs to improve pain care as well as treatment for substance use disorders. This would include identifying whether PDMPs can distinguish team-based care from uncoordinated care, misuse, or “doctor shopping,” as well as help coordinate care for a patient with a substance use disorder or other condition requiring specialty care. (Directive to Take Action)

2. That our AMA urge EHR vendors to increase transparency of custom connections and costs for physicians to integrate their products in their practice. (Directive to Take Action)
3. That our AMA support state-based pilot studies of best practices to integrate EHRs, EPCS and PDMPs as well as efforts to identify burdensome state and federal regulations that prevent such integration from occurring. (New HOD Policy)

Fiscal Note: Less than $500
REFERENCES

6. Additional efforts in the commercial market to better integrate PDMP use into clinical workflow and integrate with EHRs include PMP Gateway from Appriss Health (https://apprisshealth.com/solutions/pmp-gateway/), web-based apps using SMART on FHIR protocols (https://apps.smarthealthit.org/app/rxorbit-inworkflow-app), a product from Allscripts (https://allscriptsstore.cloud.prod.iapps.com/applications/id-17010/LogiCoy_PDMP), to name a few.
15. PDMPConnect. Office of the National Coordinator for Health Information Technology. Available at https://www.healthit.gov/pdmp/PDMPConnect