Perspectives and Updates on
Health Care Information Technology

HIT Perspectives

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1 Part 1: Five Health IT, Opioid-Related Trends Impacting Electronic Health Records

By Connie Sinclair, Director, Regulatory Resource Center

America is in the throes of an opioid epidemic, which is shattering lives nationwide with record-breaking overdose deaths and levels of addiction. The result: an onslaught of new state requirements forelectronic health record (EHR) vendors that are coming fast and furiously but which lack consistency. In addition, there are potential mandates from the federal government regarding meaningful use and the Medicare and CHIP Reauthorization Act (MACRA). All these laws and requirements create many challenges for EHR vendors, who must keep up or risk declining market share or even product survival.

Trends affecting opioids and EHRs. Five
trends related to the opioid epidemic directly affect EHRs: mandatory electronic prescribing (ePrescribing) of controlled substances (EPCS), mandatory use of prescription drug monitoring programs (PDMPs), EHR integration with PDMPs, interoperability and quantity limits on controlled substance prescriptions.

1. Mandatory EPCS. Many states are now requiring EPCS to fight the opioid epidemic. This trend began with New York's Internet System for Tracking Over-Prescribing (I-STOP) program in 2016. It is gathering steam as Maine now has a mandate for EPCS for opiates; several other states have passed legislation that become effective over the next couple of years.

The move toward mandatory EPCS at the federal level also is likely. HR 3528 was recently introduced in the US House of Representatives, which would require EPCS

for all such prescriptions covered by Medicare Part D. Consequently, EHR vendors will need to ensure their products are compliant with all federal and state requirements for EPCS, which could be a challenge due to lack of consistency.

2. Mandatory PDMP use. States are beginning to mandate the use of PDMPs, which are statewide databases of controlled substance prescriptions.This trend for requiring prescribers to review the PDMP before writing for controlled substances began in 2012 and has been slowly building. So far, more than 30 states have some form of required access; however, details vary greatly, creating challenges for EHR implementation.

An interesting aspect of this trend is that beyond simply requiring it, states are getting much more specific about the "who, what, when and how" of PDMP access. No consistent pattern is emerging. Access might be based upon the prescribed drug class, days' supply to be prescribed and/ or the maximum morphine equivalent (MME) of dosing. Requirements may also vary by type of pain, diagnosis, practice setting or prescriber type. Vendors may be pressured to incorporate these requirements into their ePrescribing modules, which will, again, be difficult as a result of significant differences among the states. EHR vendors are also being leaned upon to enable efficient and timely access to PDMPs to facilitate compliance.

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3. EHR Integration. PDMP use typically has been outside the provider's workflow, requiring a separate login to access the statewide controlled substance prescription information. Stakeholders agree this creates an inefficient, burdensome process that needs to be altered. Such changes are being implemented through guidance and statute. There are numerous examples on the policy side. For example, 43 governors signed the **Compact to Fight Opioid Addiction** in 2016, which included a commitment to build on their efforts to fight opioid addiction by integrating use of PDMPs into EHRs. On the legislative side, a growing number of states are facilitating integration of PDMP access with EHRs. Michigan is an example. Michigan's PDMP, the Michigan Automated Prescription System, will soon be connected with EHRs from such major vendors as Cerner, McKesson and Epic. That said, many states still have statutes barring the integration of PDMP data with EHRs and local medication profiles. Some are beginning to remove that barrier. EHR vendors must stay on their toes to keep abreast of such rapidly changing developments and ensure their products are compliant. They also will need to be on the lookout for guidance and related laws on the docket in state legislatures.

4. Interoperability. Stakeholders are calling for increased interoperability of EHRs and PDMPs to address the opioid crisis. This is important because of pressure for states to share data across state lines—especially in border areas where patients receive care in one state and fill prescriptions in another. Despite progress that has been made, work remains to make PDMPs and EHRs interoperable. For example, fewer than half of states are actively exchanging PDMP information with other states and such authorized users as hospitals and providers, according to **data from the National Alliance for Model State Drug Laws**. Again, some states prohibit data sharing by statute.

This means that pressure will be put on EHRs and PDMPs to become fully interoperable sooner rather than later—especially because high level recommendations often are translated into policy and legislation.

5. Limits on Controlled Substance Prescriptions. Controlled substance prescribing limits are quickly being enacted to guide prescribers to be more intentional about prescribing the minimum amount needed to address patient Examples include days' supply limits; MME limits; and non-opiate directive forms that must be documented in medical records. Again, there is no consistency in how the states are implementing these requirements. Prescribers will need new forms of decision support to guide them, which may need to be developed and

incorporated into EHR offerings. Prescriber patterns are being monitored by state boards and there are serious consequences for noncompliance. Provider organizations will likely look to their vendors to help facilitate compliance.

Keeping up with developments. We expect to see new legislation aimed at making PDMPs an even more valuable tool in fighting the opioid abuse epidemic. Point-of-Care Partners (POCP) is on top of those efforts. Our **ePrescribing State Law Review** service was created to keep companies up to date with federal and state regulatory changes so they can proactively identify opportunities and modifications that may be needed. Subscribers receive ongoing, in-depth analyses of relevant prescribing rules and have access to POCP regulatory experts. For a current, point-in-time summary of state laws, check out our recently launched **ePrescribing State Law On-Demand**. ●

To learn more, visit our Regulatory Resource Center or contact me at connie.sinclair@pocp.com.

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② Part 2: Interoperability and Standards Will Be Areas of Focus Through Year End

By *Michael Burger,* **Senior Consultant**

While there are many uncertainties in health care, interoperability and standards will undoubtedly be areas of focus through the end of the year. Everyone wants and needs health information technology (health IT) to be, well, more interoperable and useful. To that end, work will continue on refining existing standards to address interoperability challenges. That work includes federal policies and ongoing efforts by standards development organizations (SDOs) and electronic health record (EHR) vendors.

Federal policies. The Office of the National Co-ordinator for Health IT (ONC) will be active in this area. Although its fiscal year 2018 budget is likely to be considerably smaller than in previous years, the agency says it is committed to interoperability and standards as main areas of emphasis. As part of that commitment, ONC is putting the finishing touches on its **Proposed Interoperability Standards Measurement Framework,** the final document for which will be issued this fall. Results will inform the agency's **Interoperability Standards Advisory** and updates to its Health IT Certification Program.

The newly created **Health Information Technology Advisory Committee** will also be influential with regard to standards and interoperability. This committee will soon convene for the first time and it's pretty much a given that its recommendations to ONC will be translated into rule making and policy.

Industry Progress. The next few months also should see continued progress by SDOs in refining standards for interoperability with a focus on practical use cases by vendors.

One example is FHIR (Fast Health Interoperability Resources), which is one of the newest standards from Health Level 7 (HL7). Vendors are beginning to embrace the most recent iteration of the standard for various clinical use cases and FHIR is being used to extract relevant clinical data from EHRs. The goal is to facilitate data sharing among physicians, hospitals and payers, which in turn will improve patient care, enhance public health and hold down costs.

Also, the National Council for Prescription Drug Programs (NCPDP) is refining the SCRIPT standard to facilitate the transition to electronic prescribing of specialty medications. Today, specialty prescribing is largely a manual process, which isn't easily adapted to existing electronic prescribing workflows. An NCPDP task group is looking at ways in which new data elements could be added to the SCRIPT standard to handle enrollment for specialty medications, which accompanies the prior authorization that is required for nearly all such medications. The goal is to enable enrollment and electronic prior authorization (ePA) for specialty medications. Changes to the standard will enhance the ePA functionality, which EHR vendors have already built for non-specialty medications. (For more information on automating specialty enrollment, see the article in this issue of HIT Perspectives.)

Challenges. There are still obstacles that must be overcome to move health IT interoperability down the field. Three come to mind:

1. **Lack of a national patient identifier.** One of the biggest interoperability challenges is the lack of a national patient identifier (for a primer on the issue, **see the article** in the November 2016 issue of HIT Perspectives). Currently, there is no single way to identify individual patients within and across the health care system. While industry solutions are being developed, they are one-offs that are not totally standards based. True interoperability cannot be achieved unless this problem is solved.

2. **Business Models.** A second significant challenge is the lack of focus on the business model underlying health care delivery. Interoperability is not so much a technology challenge as a business one. The competitive nature of the business of health care delivery is primarily what prohibits the exchange of clinical information — competitors don't want to make it easy for patients to seek care outside of their networks. Making access to clinical data a cumbersome process is a compelling reason for patients to stay in network. It is a convenient red herring to point the finger at the "evil" EHR vendors for colluding to prevent systems from talking to one another, but the real issue is supply and demand. When there is demand among customers to connect systems, software vendors respond by building and selling connectivity solutions. The most successful of these solutions rely on standards that have been created and vetted through SDOs.

3. **Variations in Standards Implementation.** Other interoperability challenges are created by variations in how standards are used in application program interfaces (APIs) with EHRs. Sometimes these APIs rely on technology that is not standardized, thus adding to the complexity and inconsistency in how data are exchanged among EHR platforms. The goal of using standards to achieve interoperability can only be met when standards are interpreted, implemented and used consistently. The use of APIs is required under both the 21st Century Cures Act and the Medicare Access and CHIP Reauthorization Act (MACRA), which will accelerate the use of APIs and possibly exacerbate interoperability challenges. ●

The Point-of-Care Partners team are experts in standards and interoperability. If you are planning for pilots, software optimization or new initiatives, let us know so that we can discuss how POCP can be of assistance. You can reach me at michael.burger@pocp.com.

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3 **Part 3:** Automating Enrollment for Specialty Prescriptions

By *Jocelyn Keegan,* **Senior Consultant**

Millions of patients require expensive specialty medications. Before they can get these prescriptions filled, they must go through today's complex paper-phone-fax processes for enrollment using a specialty pharmacy or "hub" associated with the drug's manufacturer. Recognizing there must be a better way, the industry is taking steps to automate this process. These efforts build on standards and implementations for electronic prescribing (ePrescribing) as well as complement the work under way to automate other aspects of specialty pharmacy.

Enrollment today. Enrollment today for a specialty medication is a complex, manual process. Specialty pharmacies and hubs gather patient-specific demographic, clinical and other data to support the necessary close supervision and monitoring of the patient; the special handling of the drug that is often required; and various administrative processes, such as eligibility and payment. This primarily is done manually with paper forms, which lack consistency and stan-

dardization in the data elements required by either the specialty pharmacy or manufacturer. Information is gathered and shared by phone and fax. This creates time-consuming, frustrating, expensive, uncompensated work for a provider. Automating the process is expected to eliminate such issues as well as integrate enrollment into the electronic workflow of providers and pharmacies.

Currently, there are some business-to-business solutions that are filling this gap in lieu of having standards. Such proprietary solutions are valuable in the short term but, candidly, can be difficult to scale. They can also make it difficult for specialty pharmacies to be interoperable with the standards-based infrastructure used for ePrescribing.

Opportunities. While automating the specialty prescribing enrollment process is complicated, there are opportunities to accelerate the process. Many are already under way, including:

- **Eliminating standards gaps.** Stakeholders are coming together to identify additional or enhanced standards to support enrollment and other aspects of specialty pharmacy automation. Two standards development organizations are very active: Health Level 7 (HL7) and the National Council for Prescription Drug Programs (NCPDP).

  HL7's FHIR (Fast Healthcare Interoperability Resources) is likely to become the standard of choice to extract relevant patient administrative and clinical data from electronic health records. NCPDP is addressing the transition to electronic specialty prescribing through its Specialty Electronic Prescribing Task Group. It is looking into ways in which new data elements useful in the enrollment process can be incorporated in the SCRIPT standard. These include, for example, additional patient contact and demographic information, diagnosis, lab values, height and weight.

- **Building on ePrescribing.** Now that ePrescribing is the norm for most other medications, it increasingly is being viewed as a solution to reduce the costs and administrative burdens associated with specialty prescribing. Two ePrescribing transactions are particularly well suited to the requirements of specialty prescribing.

  1. **Electronic prior authorization.** Through use of the electronic prior authorization standard (ePA) in NCPDP SCRIPT, prospective PA has been automated for ePrescribing and is being adopted nationwide. It can help facilitate PAs that are needed for many specialty medications and get them approved more quickly. This reduces speed to therapy and expensive overhead for pharmacies and physician practices. Use of ePA for specialty medications also is expected to reduce extensive outlays by pharmaceutical companies for administrative assistance for prescribers and patients.

  2. **Real-time benefit inquiry.** There currently is no clear way for pharmacies and hubs to identify plans as well as formulary and benefits associated with individual patients. In addition, specialty drugs are often split across medical and pharmacy benefit plans, making it difficult and time consuming to figure out who pays. While benefit verification is being done retrospectively, an NCPDP Task Group is working to identify options to support a real-time benefit inquiry (RTBI). RTBI's value lies in its potential for providing real-time, patient-specific formulary and benefit information at the point of prescribing or enrollment. This includes patient-specific condition management programs (such as PA and step therapy), true out-of-pocket costs for a medication (specific co-pay/coinsurance amount) and specific deductible information.

- **Demonstration projects.** The ability of the industry to sponsor demonstration projects will yield realistic understanding of potential use cases and needed standards; priorities for tackling challenges; and creation of support from organizations to drive collaborative standards efforts. There is a need to move the ball down the field by helping stakeholders better understand the value of automating specialty pharmacy transactions. ●

Point-of-Care Partners is heavily involved in laying the groundwork for automating specialty prescribing. The NCPDP Task Group for Specialty Prescribing is chaired by our own Pooja Babbrah and a colleague, Laura Topor. For more information and a sense of the landscape, feel free to contact me (jocelyn.keegan@pocp.com) or Pooja Babbrah (pooja.babbrah@pocp.com).