Perspectives and Updates on
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By Tony Schueth, Editor-in-Chief

We say this every year, but the annual meeting of the Healthcare Information and Management Systems Society (HIMSS) is, hands down, the best place to catch up on vendors, clients, stakeholders and doings by the federal government in the area of health information technology (health IT). While attendance at HIMSS16 in Las Vegas was relatively flat, it sure didn't feel like it.

The Point-of-Care Partners team used its time productively through face-to-face consultations, attendance at presentations, discussions with exhibitors and investment of a lot of shoe leather.

Consequently, we feel compelled to break a cardinal rule: not all of what went on in Las Vegas is staying in Las Vegas. Here is what the POCP team heard at HIMSS16.

1. The little guys got invited to the table.
Historically, HIMSS has been dominated by large electronic health record (EHR) and revenue cycle vendors. HIMSS16 included two major exhibit halls featuring innovations by smaller companies and start-ups. The number of participants in these halls and the cool technology we saw shows there's plenty of room for innovation. We look forward to seeing more of these kinds of companies next year, as well as what kind of traction this year's innovators had achieved.

2. Telehealth hits the big time. We've been saying for several years that telehealth is poised for broad growth. We feel validated because developments in telehealth technologies were a major focus of HIMSS16. For example, WebMD is entering this burgeoning arena, while Teledoc and American Well are expanding their offerings.

3. Behavioral health is getting connected.

Vendors focused on behavioral health services were newly evident this year — and in a big way. We believe this prominence marks a growing overall interest in —and need for — technologies to address the high cost and disjointed care of patients with various behavioral health issues in communities, long-term care facilities, hospitals and installations caring for military personnel.

4. Expect more specialty-related EHRs.
Behavioral health EHRs are demonstrative of the growth in specialty-specific EHRs. These continue to gain in popularity and are benefiting from the robust replacement EHR market as specialists abandon "general purpose" EHRs for systems designed specifically to their unique work flows.

5. MU3 was MIA. We were surprised to see that meaningful use (MU) stage 3 was not on anyone's lips at this gigantic meeting of EHRs and provider organizations. This may be because many stakeholders believe it is dead and have moved on. Not so fast, though. MU's death has been greatly exaggerated, as MU3 has effectively been folded as a component of the new Medicare Incentive Payment System (MIPS). (For details, see our article in the February 2016 issue of HIT Perspectives). A quarter of MIPS incentives in 2019 will be based on "meaningfully using certified EHRs." The big catch is that 2019 incentives will be calculated based on 2017 provider activity. The government has yet to roll out any specifics as to what will be measured to demonstrate meaningful use. In the meantime, vendors and providers will need to pay attention to MU3 requirements to avoid potential lost incentives or even penalties.

6. There seemed to be fewer major announcements. HIMSS traditionally has been the

place for major announcements about new initiatives and products. There were some, but not as many as in the past. Maybe it's because the emphasis seemed to be less about new announcements and more about communicating with a big audience. Maybe it's because HIMSS has gotten so big and overwhelming that announcements tend to get overshadowed by the enormity of the event. An example is the annual Report to Congress on Health IT Progress by the Office of the National Coordinator for Health Information Technology (ONC). Its release always garners major trade press coverage, but not this year. We expect to see companies making up for lost time by rolling out their big announcements in the next few weeks, when they will get more attention from the media and audiences alike.

7. Yet some big announcements were made.
Despite the size of the meeting and the noise surrounding it, some big initiatives were unveiled. These primarily were from the federal government and included:

•Department of Health and Human Services (HHS) Secretary Sylvia Burwell announcing an industry initiative to further health data interoperability, information sharing, and patient engagement. More than a dozen professional organizations, the five largest health care systems in the country, and electronic health vendors representing a sizable percentage of the US EHR market have agreed to implement three core principles to: 1) reduce information blocking, 2) increase patient access to their own health data and 3) embrace national interoperability standards, including those related to privacy and security.

•The Medicaid program is making funding available to promote health information exchange (HIE) and encourage the adoption of certified EHR technology by Medicaid providers. "Seriously, this really is a B.F.D.," tweeted Jon White, MD, ONC's acting deputy director.

•The ONC and the HHS also made a variety of announcements: a Proposed Rule to Support the Reliability, Transparency, Accountability, and Safety of Certified Health IT; the availability of $625,000 to spur the development of market-ready, user-friendly software applications for consumers and health care providers; and a new model privacy notice.

8. There were no new buzzwords this year. HIMSS meetings usually have a dominant buzzword or two. Last year, they were "precision medicine" and "FHIR" (Fast Health Interoperability Resources), which was showcased as one of the newest in HL7's family of standards. Previous years' buzzwords were "interoperability," "transparency," "patient engagement," and "Big Data." Those catchphrases and concepts didn't disappear this year; there just wasn't one big, new one that took over the meeting. Rather, stakeholders spent a lot of time explaining how these concepts have emerged from the idea phase and are being translated into action.

9. Data analytics is still going strong. Hype around Big Data was the rage for awhile. The enthusiasm for the buzzword thankfully cooled, but the appetite for translating data into actionable information has not. This was evident at HIMSS16, where it was clear that the usual and not-so-usual suspects were turning their focus to clinical data rather than concentrating on selling software. Nontraditional health companies like Dell, Google and IBM are staking their claims. Others are reinventing themselves to make another run at this opportunity.

10. Nontraditional stakeholders had a bigger presence. Pharmacies, pharmaceutical manufacturers and biotechnology firms continued to have an expanded presence at HIMSS16. While these stakeholders did not understand the usefulness of HIMSS in earlier years, they have seen the light and their attendance has steadily increased. We saw them at HIMSS16 on a mission to learn and absorb the details and benefits of health IT.

See you next year in Orlando!

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2 **Part 2:** Integrating EHRs and PDMPs: How Vendors Can Get Ahead of the Curve

By Michael Burger, Senior Consultant

Prescription drug monitoring programs (PDMPs) were created in 2002 as a tool to help address the growing problems of prescription drug abuse and diversion. PDMPs are independent, state-run databases of controlled substance prescriptions operated using supplementary funding through the Bureau of Justice Assistance (BJA). Until recently, PDMPs existed in relatively unknown, little-used silos. Of late, three things happened: 1) prescription drug abuse has emerged as a national epidemic, 2) technology has advanced, and 3) lawmakers at the federal and state levels have seized on the improvements in usability and technology available to access PDMPs. This was done through legislation, regulation and political will.

Electronic health record (EHR) vendors should be aware of PDMP activities and regulations to ensure their products are compliant with rapidly emerging federal and state requirements. By being proactive, vendors reduce the risk of being caught short and potentially losing revenue and market share.

What's the fuss about? The root cause of these regulatory and legislative initiatives is that abuse and diversion of prescription drugs have reached epidemic proportions in the United States. Overdoses, in particular, are overwhelming police, health care workers and families in every state — inner cities and suburbs alike. The numbers are staggering and heartbreaking. The Centers for Disease Control and Prevention reports that roughly 47,000 Americans — or about 129 per day — died from a drug overdose in 2014. Two-thirds of the overdose deaths involved opioids or heroin. Overdoses are the number 1 accidental killer of Americans 25 to 64 years old, surpassing even traffic deaths.

Recognizing that threat, federal and state lawmakers have stepped up regulatory and legislative mandates. All states (except Missouri) have established a PDMP. PDMPs collect data from dispensers such as pharmacies, outpatient hospital pharmacies, outpatient clinics and other submitters regarding quantities of and to whom controlled substance medications have been dispensed. Each state controls access to the database based upon purpose of access (such as law enforcement) and "need to know."

In general, states encourage prescribers to check the PDMP before prescribing most controlled substances but do not impose a penalty for noncompliance. Some states, such as New York, require prescribers to check the database in advance before prescribing nearly all controlled substances.

The number of these mandates is growing. A challenge for prescribers is that PDMP access is typically via a standalone web portal, not a built-in feature of the EHR work flow. As demand for easier access grows due to regulatory requirements, EHRs should soon begin to be interoperable with individual states' PDMP databases to both meet customer demand and regulatory compliance.

Five things EHR vendors should do now. State and federal policy makers have begun to recognize that it's time to end the PDMP silos and make them more interoperable and useful in fighting the war against substance abuse. Here are five actions EHRs should take to prepare for integration with PDMPs.

1. **Know who's in charge.** Because PDMPs are

state sponsored, a variety of state agencies are responsible for their administration. They include state boards of pharmacy, departments of health, law enforcement agencies, professional licensing agencies and substance abuse agencies. These various entities will be handling technical aspects that could impact how EHRs interact with PDMPs. EHR vendors need to know who's in charge in the states where their products are used so they can keep abreast of the evolving regulatory requirements concerning PDMPs.

2. What about the PMIX? PDMPs were created in a different environment than EHRs. As unique state-based initiatives, PDMP systems are developed using disparate tools and software to manage data. Some states contract with private-sector service providers to host or maintain their systems while others are developed in house. That lack of consistency, plus the lack of uniformity among state laws and policies, creates significant interoperability and interstate data-sharing challenges. Also, PDMPs use the Prescription Drug Monitoring Program Information Exchange (PMIX), which is an architecture for data sharing that is different than what is traditionally used by EHRs. Created by the BJA and the Office of National Drug Control Policy, PMIX is a national, interoperable architecture that supports the sharing of PDMP data within and across states by various "hubs" (such as PMP InterConnect®, RxCheck and RxSentry). EHR vendors need to be mindful of how their products will integrate with the PMIX architecture and related standards until the federal government promulgates a national inoperability standard. This standard could include the standards typically used for electronic prescribing and related transactions from HL7 and NCPDP. A new standard could be created, as well. Either way, it could take many years before such overarching standards are created and put in place.

3. Keep up with harmonization efforts. There are inherent differences in PDMPs from state to state, including how they may be accessed and how each uses PMIX to share data. Recognizing these differences and the challenges they present, the federal government has initiated standards and harmonization efforts through the S&I Framework (see the web page for more information). Pilots are under way in several states to test the use of

NCPDP SCRIPT 10.6 and ASAP web services for supporting a PDMP/pharmacy hub. The results of these pilots will have implications for how EHRs integrate with PDMPs.

4. Check business agreements. As EHRs need to connect with PDMPs and share data, vendors may need to create or revisit business agreements with individual PDMPs and interstate data hubs. These agreements will need to address collection, use, privacy, disclosure, storage and other aspects of PDMP data exchange.

5. EPCS can help nip opioid abuse and doctor shopping in the bud. Electronic prescribing of controlled substances can be a useful tool to help prescribers identify potential substance abuse and doctor shopping — before the PDMP is checked and prescriptions are written electronically through the EHR. Medication history often will provide valuable information about previous controlled substance prescriptions paid for by insurance as well as where they were filled. Such information can be used by a physician to initiate the necessary conversation with a patient about substance abuse. This makes EHRs a powerful adjunct tool to help prevent substance abuse and save lives. It's definitely a value-add from EHRs that physicians can get behind.

Point-of-Care Partners can help you keep up with current events regarding PDMP, including state mandates and what needs to be done to integrate EHRs and PDMPs. For starters, check out our regulatory resource center, which makes it easy for you to stay current with state and federal regulatory actions.

③ **Part 3:** Alerting Prescribers for Biosimilar Substitution to Protect Patient Safety

By Pooja Babbrah, Senior Consultant

Biosimilars are starting to enter the market in the United States and are expected to quickly become mainstream in the near future because of their significant cost-savings and patient care implications. There are a number of issues the industry must address as biosimilars become more widespread. One that requires high-priority attention is how to indicate to the prescriber that a substitution has been made either for a biosimilar over another drug or one biosimilar over another. Why is this important? Patient safety is at stake.

This issue is taking on heightened importance now that nearly two-thirds of states have enacted — or are considering enacting — legislation requiring that physicians be notified when a biosimilar substitution is made. Biosimilars are made from living organisms and are different in chemical composition than conventional medications. They vary in how and where they are administered — most are infused in hospitals, special ambulatory centers and even patients' homes. The physician must have information about which specific product was dispensed to a patient to ensure care quality and to protect the patient's safety in case an adverse event occurs. Despite legislative efforts to ensure that the provider is notified of the substitution, such legislation is silent as to how such notification should be done.

There are four possible electronic transactions that could be used to indicate to a prescriber that a substitution was made and which biosimilar was dispensed. These transactions are used by electronic health record (EHR) systems to communicate between prescribers and pharmacies. NCPDP SCRIPT standard contains three transactions that might be used to indicate a biosimilar substitution: RxFill, RxChange and

medication history. The fourth possibility is consultation with state prescription drug monitoring programs (PDMPs), which are state-specific databases containing information about dispensed controlled substances.

What are the pros and cons of each? Is there one best option? Let's take a look.

RxFill or fill status notification. This transaction is sent to the prescriber from the pharmacy and indicates the status of the prescription (dispensed, partially dispensed or not dispensed).

> •Pros: This transaction is part of the suite of NCPDP electronic prescribing (ePrescribing) transactions. It is specially designed to alert prescribers when a medication was dispensed. The RxFill standard was modified in 2015 to accommodate biosimilars by the addition of an optional field for lot number. It also can indicate whether a prescription has been filled, partially filled or not filled. Fill status can help the physician monitor medication adherence — a care quality issue for all drugs but a patient safety issue for biosimilars if it becomes necessary to determine why an adverse event occurred.

> •Cons: The RxFill transaction is not widely utilized by pharmacy and EHR systems, although user demand may push that change in the near future.

RxChange. This transaction is sent by the pharmacy to the prescriber when the pharmacy would request approval to switch from a drug originally prescribed to something different. RxChange would typically be utilized in situations in which an insurer has a preferred alternative drug, if the drug is not covered

by the patient's insurer or if a quantity change from a 30- to 90-day supply has been requested. RxChange is a bidirectional transaction, involving a query from the pharmacy and a response by the prescriber.

•Pros: This transaction is part of the suite of NCPDP ePrescribing transactions.

•Cons: This transaction was not designed for pharmacy-to-prescriber notifications. It is a query-response transaction and would be adapted to use only the query portion to notify the prescriber of a biosimilar substitution. This does not fit in with pharmacy work flows, as the pharmacy system would be waiting for the response to be sent by the prescriber. RxChange is not widely utilized by EHRs and pharmacy systems.

Medication history. This NCPDP SCRIPT query transaction is sent from a doctor to an intermediary (such as Surescripts), which in turn requests a patient's medication history from various payers. The intermediary gathers the responses, which are then downloaded into a patient's medication history file in the EHR.

•Pros: This is part of the suite of ePrescribing standards. Responses give the provider a wide range of information about what was prescribed, where the prescription was filled and whether it was covered by insurance. Medication history is widely utilized by EHRs and pharmacy systems.

•Cons: Medication history requests are typically made when a patient visit is scheduled. Data latency is an issue because of the time lapse between patient visits, when the prescription information is downloaded. This means that each dispense of a biosimilar may not be included in the medication history if multiple dispenses were made between visits.

PDMPs. Prescription drug monitoring programs are state-run databases that contain information about all controlled substance prescriptions dispensed in each state (except Missouri, which lacks a PDMP). The information is supplied by pharmacies on varying timetables (such as daily, weekly or monthly). Most states encourage prescribers to check the database before prescribing a controlled substance to help address the epidemic problems of prescription drug

overdose and doctor shopping. New York mandates checking with the PDMP for nearly all controlled substance prescriptions and other states are expected to follow its lead. PDMP content, technical aspects and accessibility (such as who has access to the database and for what purpose) vary by state.

•Pros: PDMPs will capture details about biosimilar prescribing and substitution for biosimilars classified as controlled substances.

•Cons: Not every state has a PDMP. Information about manufacturer and product lot number are not explicitly tracked in PDMP databases today. PDMPs are not interoperable with EHRs or each other due to a variety of technical and legal issues. These issues will have to be addressed and resolved to handle biosimilar substitution. The lack of PDMP interstate interoperability is problematic in many metropolitan areas where patients may live in one state and get their prescriptions filled in another. As a result, a prescriber may not have complete information about a patient's controlled substance prescriptions or substitutions. Plus, consulting the PDMP for controlled substances (and, when available, biosimilar substitution) lies outside the ePrescribing work flow, which would serve as a barrier to use. These changes and work-flow integration could take years and may not result in consistent information being available to prescribers because of state-to-state variations.

What's our pick? The Point-of-Care Partners team has been heavily involved in issues involving ePrescribing and biosimilars. While all four options described here to notify prescribers of a biosimilar substitution have some appeal, we believe RxFill is the best option. This transaction was designed to do what we need it to do, is part of the ePrescribing process, and the standards infrastructure has been expanded to accommodate biosimilars. It is available for use now by EHRs in all states.

Let us know if we can help you understand the changes to standards.