

Perspectives and Updates on Health Care Information Technology

HIT Perspectives Biopharma Insights •

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About the newsletter

HIT Perspectives Biopharma Insights is published by Point-of-Care Partners. Individuals at the leading management consulting firm assist healthcare organizations in the evaluation, development and implementation of winning health information management strategies in a rapidly evolving electronic world. The team of accomplished healthcare consultants, core services and methodologies are focused on positioning organizations for success in the integrated, data-driven world of value-based care.

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February 2016

POINT-OF-CARE PARTNERS
Health IT Management Consultants

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By Tony Schueth, Editor-in-Chief

If 2015 was any indicator, 2016 will continue to be a year of innovation and change in health care and health information technology (health IT). We expect to see developments in how prescription drugs are prescribed, the organization and delivery of care, and requirements on the legislative and policy fronts. Some will be new while others will build on what has gone before. With that as a backdrop, here are the top 10 trends the Point-of-Care Partners (POCP) team foresee for 2016.

1. Alternative delivery and payment models. It seems like the world is awash in new value-based payment and delivery models aimed at improving outcomes and quality while lowering costs. The list includes integrated delivery networks, accountable care organizations and patient-centered medical homes (PCMHs). All rely on health IT — particularly electronic health records (EHRs) — to capture and exchange patient and administrative information, prescribe medications, coordinate care and develop and report on quality and payment metrics. The latter will be the criteria on which organizations will be paid and how they divvy up resulting savings. In 2016, we will see such organizations continue to try to integrate systemwide technology solutions as new providers are added to their networks. This will require more interoperability on the part of EHRs, better information exchange across disparate sites of care and more training on the part of users. Also in 2016, organizations will begin evaluations and pilots to assess the role of technology in improving patient outcomes and lowering costs.

2. Biosimilars. In 2016, we'll see more biosimilars introduced into the US health care market, driven by the lower price tag for these expensive pharmaceuticals. EHRs will take on new and expanded roles in coordinating patient care using biologics and biosimilars, and tracking therapies administered or dispensed to patients. For EHR developers, 2016 will be the year they start to see glimmers of interest for added functionality to track and trace batch and lot numbers of pharmaceuticals in the physician office because physicians are the major reporters of adverse drug events. EHRs increasingly will be called upon to build biosimilars into clinical decision support. At the same time, EHRs and pharmacy systems will need to

keep abreast of evolving state laws concerning biologic and biosimilar substitution. Even though biosimilars have just been approved for the US market, states have already begun addressing substitution. This is important because a dispensed biologic may be different than what was prescribed. According to the National Conference of State Legislatures, in 2013 and 2014 eight states enacted the first round of such biologics and biosimilars laws. As of January 4, 2016, bills or resolutions related to biologics and/or biosimilars were filed in 31 states.

3. Electronic prescribing of controlled substances (EPCS). EPCS will continue to grow steadily, and more states will take up the cause. It is now legal at the federal level and in all states and the District of Columbia. EHR vendors are ready for EPCS, as are most pharmacies. Many of the bigger barriers no longer exist; physicians simply need to get past having to use a second factor for authentication and start prescribing controlled substances electronically. We see them doing so in New York, where electronic prescribing (ePrescribing) is mandated. However, more policy levers may be needed. In Minnesota, ePrescribing is mandated but there are no penalties for nonuse. Will “toothless” legislation have an impact? As it pertains to ePrescribing of noncontrolled substances, it has, as Minnesota has ranked first in the past couple of Surescripts’ analyses. But that’s not the extent of it. Physicians will have to ePrescribe controlled substances if they are to meet ePrescribing, cost and quality targets set by public and private payers. And we expect other states to follow New York and Minnesota’s lead.

4. Electronic prior authorization (ePA). Vendors in 2016 will expand implementation of ePA and prescribers will increase adoption as we begin see the fruits of efforts started in previous years. Legislation that had 2015 deadlines pushed payers and providers to consider different options. In the short term, stakeholders opted for portals and solutions not integrated with work-flow or core operating systems, allowing each to “check the box.” However, everyone recognized these solutions as suboptimal. Building more integrated solutions, however, takes investments of time and resources that must be budgeted and prioritized. In 2016, we will see the results of

some efforts begun in 2015 and the start of others that will bear fruit later this year and into next.

5. Implementation of the Medicare Access and CHIP Reauthorization Act (MACRA). MACRA is a new acronym that physicians and EHR vendors will need to understand in 2016. This legislation did away with the sustainable growth rate formula for determining Medicare payments for health care providers' services. More importantly, MACRA rolls up the disparate quality reporting systems of the Centers for Medicare and Medicaid Services (CMS) into the Merit-Based Incentive Payment System (MIPS). Now the Medicare EHR incentive program (meaningful use) will be part of a single program based on quality, resource use, clinical practice improvement and use of certified EHR technology. What the requirements will be, as well as their timelines, incentives and possible noncompliance penalties, will be of immediate interest to providers, vendors and policy makers. It will be interesting to see what and how much gets locked into place by regulation before administrations change next January.

6. The "death" of meaningful use. A major topic of discussion in 2016 will be the "death" of meaningful use (MU) as a federal program and driver of EHR adoption and functionality. Physician groups told Congress and the CMS that MU is unworkable and needs to be replaced. The federal government got the message loud and clear. In January, CMS Acting Administrator Andy Slavitt announced the end of MU as we know it. However, MU is not dead, as some thought (or wished). Rather, it is being integrated as a component of MIPS, along with other elements. The details and implementation will consume a lot of attention in 2016. (For more about POCP's thoughts on what will happen, see the article in this edition of HIT Perspectives.)

7. Medication adherence. Greater attention will be focused on medication adherence in 2016, as everyone looks to reduce costs and improve the quality and safety of patient care. The cost of nonadherence has been estimated at \$100 billion to \$300 billion annually, including expenditures for avoidable hospitalizations, nursing home admissions, and premature deaths. Plus, half of the 3.2 billion annual prescriptions dispensed in the US are not taken as prescribed. Now that use of ePrescribing is becoming ubiquitous, pharmaceutical companies, payers and others are evaluating ways it can be leveraged to increase medication adherence. In fact, the opportunity to encourage patient adherence to prescribed therapies has long been discussed as a major potential benefit of ePrescribing technology. One early study showed ePrescribing increased first-fill rates by 11%, but this just scratches the surface of the opportunity. The Office of the National Coordinator for Health Information Technology has funded tests of this concept, and we expect more interest in 2016.

8. Continued automation of specialty medications. The industry will begin to look at ways to reduce the costs of

specialty medications leveraging health IT. Specialty drug spend alone is enough to get people's attention. Specialty medications represent the fastest-growing cost in US health care, expected to jump two-thirds in 2015 and account for half of all drug costs by 2018. Specialty medications can cost \$2,000 per month per patient, with those at the high end costing upward of \$100,000 to \$750,000 per year. 2016 will mark renewed interest in better automating specialty prescribing, which is ripe for process improvement and has spotty, partitioned computerization so far. Look for NCPDP to continue to address data elements that are critical to the safe, appropriate and timely ePrescribing of specialty medications.

9. Telemedicine. Telemedicine is here to stay. It will help alleviate the shortage of primary care physicians as well as improve outcomes, access and cost efficiencies. Other drivers include the growing demand for convenience, innovation and a personalized health care experience. Policy makers have been listening. According to one analysis, 29 states and Washington, DC have enacted legislation mandating that private insurers offer reimbursement for telemedicine at equivalent levels with in-person services, provided the care is deemed medically necessary. Many of the laws enacted in 2015 have taken effect in January. Medicare, Medicaid and the Department of Defense have expanded their coverage for telehealth services. The growing number of retail medical clinics and employers with on-site medical facilities also are looking to offer telemedicine services in 2016. Now health IT vendors will need to provide more and better interoperable systems to capture and exchange patient data related to telemedicine visits — within and across sites of care and payers.

10. War on drug abuse. America will continue the war on prescription drug abuse in 2016. According to new statistics from the American Society of Addiction Medicine, drug overdose is the leading cause of accidental death in the US, with 47,055 lethal drug overdoses in 2014. Opioid addiction is driving this epidemic, with 18,893 overdose deaths related to prescription pain relievers and 10,574 overdose deaths related to heroin in 2014. And the numbers are growing. Stemming this tide will be a priority in 2016. It will result in more state laws like New York's I-STOP (Internet System for Tracking Over-Prescribing), which requires ePrescribing of all medications and consultation by most prescribers of the state's prescription drug monitoring program (PDMP) registry when writing prescriptions for Schedule II, III and IV controlled substances. We expect other states will build on the New York precedent by requiring that providers and pharmacists consult the database before prescribing or dispensing a controlled substance. (PDMP consultation is optional in the vast majority of states.) The federal government is collaborating with stakeholders to see how PDMPs might be better able to exchange prescribing information within and across states. EHR developers will need to ensure their products contain features enabling their physician customers to be in compliance with state requirements for PDMP consultation.

2 Part 2: Getting Doctors Ready for New York's War on Opioid Abuse

By **Brian Bamberger**, *Life Sciences Practice Lead*

Many doctors in New York will need help to electronically send all prescriptions — including those for controlled substances — beginning March 27, 2016. The reason is New York's law known as I-STOP (Internet System for Tracking Over-Prescribing), which is a comprehensive program to combat rampant controlled substance diversion and abuse. I-STOP creates opportunities for pharmaceutical manufacturers in the near term to help prescribers navigate unfamiliar systems, resolve inevitable confusion when prescribing non-tablet products and provide patient education. This assistance can be replicated in the longer term as other states follow New York's lead.

Misuse and abuse of prescription drugs are reaching epidemic proportions in the United States. They are overwhelming police, health care workers and families in every state, — in inner cities and suburbs alike. The numbers are staggering and heartbreaking. The Centers for Disease Control and Prevention (CDC) reports that roughly 47,000 Americans — or about 129 per day — died from a drug overdose in 2014. That surpasses deaths from guns or automobiles. Two-thirds of those deaths involved opioids or heroin. Prescription painkiller abuse is now considered a gateway to the use of heroin, which is cheaper and becoming more readily available than opioids.

Recognizing the threat posed by opioid abuse and diversion, New York took action with I-STOP. It offers a multipronged approach, including:

- All prescriptions, both scheduled and nonscheduled, must be electronically prescribed (ePrescribed) by March 27, 2016. (The original date was moved out by a year because of readiness concerns by prescribers and vendors.
- ePrescribing system vendors must be certified to transmit scripts for controlled substances according to a strict process created by the Drug Enforcement Administration (DEA). Prescribers also must be registered to ePrescribe controlled substances and do so according to the DEA's stringent protocols, which include using two-factor identification when logging onto the system.
- Prescribers must complete a registration form with New York's Bureau of Narcotics that identifies their certified system vendor and software version number.
- Most prescribers of controlled substances are required to consult the New York's prescription drug monitoring program (PDMP) database before prescribing Schedule II, III and IV controlled substances. The database includes all controlled prescription drugs dispensed in the state. This advance consultation is expected to reduce doctor shopping, help identify rogue prescribers and pill mills and prevent the filling of bogus prescriptions for painkillers.
- Creation of safeguards for distribution of prescription drugs prone to abuse, medical

education courses, public awareness efforts and establishment of an unused medication disposal program.

- Stiff penalties for noncompliance. According to the New York Bureau of Narcotic Enforcement (BNE), noncompliance is punishable by a \$2,000 fine, imprisonment not exceeding one year or both. Furthermore, it is considered professional misconduct by the applicable professional boards and could lead to suspension or revocation of professional licenses.

Not surprisingly, this lengthy list of requirements means many providers will need all the help they can get to meet the March 27 deadline for ePrescribing and electronic prescribing of controlled substances (EPCS). Although many prescribers in New York have been ePrescribing for years, the majority were not ready when the first I-STOP deadline approached last March, which is why it was extended for a year. With the new deadline looming, a significant number of prescribers still are not ready — even through electronic health record (EHR) software vendors serving 96% of prescribers in New York are already certified for EPCS and all can handle regular ePrescribing. Similarly, nearly all pharmacies can process both kinds of electronic prescriptions. The problem lies in provider readiness. According to the latest Surescripts statistics, 27% of total prescribers are enabled for EPCS and 58% of prescribers are actively transmitting electronic prescriptions in general. That means a lot of prescribers will need to hustle, unless there is a large exceptions process or the deadline is extended again. We think there's at least even odds of that happening.

In the meantime, pharmaceutical manufacturers and their representatives have an unprecedented opportunity to help physicians before March 27 — and beyond — as they take up ePrescribing or EPCS. For example, I-STOP creates the opportunity for drug manufacturers to assist practices in creating

efficiencies with favorites and reducing pharmacy calls with correct prescriptions. Writing electronic prescriptions for non-tablet products — even familiar ones — can be confusing to new ePrescribers and can create a risk to patient safety. Practices need to understand how to use these unfamiliar systems for more difficult-to-prescribe products. Existing materials concerning drug abuse, addiction and patient safety can be leveraged by sales representatives to help physicians comply with I-STOP's educational requirements.

Learnings from their New York experience can help pharmaceutical manufacturers position themselves to help physicians in other states considering similar legislation. Going forward, it will be imperative to learn how to assist prescribers in adapting to the new ePrescribing technologies. Today, ePrescribing is primarily done via EHRs) instead of stand-alone systems.

The war on opioid abuse is far from over, but electronic tools show promise for fighting this deadly epidemic. Point-of-Care Partners (POCP) has been helping pharmaceutical companies prepare as well. We have ready-made seminars for New York sales teams that not only help them understand the regulations but also address the hurdles that new ePrescribing physicians may have in finding and prescribing their products. We also have developed webinars that sales representatives can offer to health care providers and practice staff to help resolve some of the mysteries of ePrescribing.

Let POCP position your firm and sales representatives to take advantage of this unprecedented opportunity to help physicians adapt to EHRs and ePrescribing.

3 Part 3: Meaningful Use: Not Entirely Gone But Certainly Not Forgotten

By Tony Schueth, Editor in Chief

There was high-fiving all around the provider and vendor communities when Andy Slavitt — acting administrator of the Centers for Medicare and Medicaid Services (CMS) — announced plans to phase out the meaningful use (MU) program as we know and love it. Not everyone heard all of that message. Many, in fact, reacted as though the program had a stake through its heart. You could almost hear the popping of champagne corks.

But a [closer look at his remarks](#) shows that CMS is not totally getting rid of the program. What remains is a monster mashup: some MU elements will stay but be combined with new statutory requirements created through the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). Needless to say, many technical and implementation details have yet to be determined.

What are we to make of this? Here's the initial take from the Point-of-Care Partners (POCP) team.

Some consider MU a success. On Wednesday, February 3, the National Coordinator for Health Information Technology, Karen DeSalvo, MD, called MU “successful” at the eHealth Initiative 2016 Annual Conference. We can see where she's coming from. The original goal was to encourage adoption of electronic health records (EHRs), and the EHR incentive component of the landmark American Recovery and Reinvestment Act of 2009 (ARRA) certainly did that. In 2014, three-quarters of office-based physicians had a certified EHR as compared with none in 2010, when ARRA's EHR adoption incentives kicked in. In addition to leading US efforts to leverage technology for better health, Dr. DeSalvo occupies a position from which she can evaluate how the US stacks up against the rest of the world and believes that we've jumped ahead in terms of adoption of EHRs by physicians and hospitals. At the same conference, Steven Stack, MD, president of the American Medical Association, noted that while physicians continue to be frustrated with EHRs, there's a positive trend toward their liking them.

We're not surprised by the changes. Mr. Slavitt's news was not unexpected. Meaningful use was running toward its statutory deadline and maxing out its incentive payment kitty, so we did not think it would be extended. Meanwhile, providers and others had been lobbying CMS and Congress very hard to either kill MU or replace it with something else. The logic was fairly compelling. Although the vast majority of providers are now using EHRs, at last count some 60% of hospitals and 90% of physicians had yet to attest to MU stage 2. And if stage 2 was unattainable, the more prescriptive requirements of stage 3 were perceived as totally beyond the realm of possibility. A significant number of providers are opting out of MU, frustrated by the work-flow challenges posed by regulatory requirements and willing to accept penalties rather than continue. Providers have said enough is enough; MU was adjusted but not killed entirely.

Provider concerns are only part of the issue, however. A bigger challenge is the sequencing of MACRA on top of the “final” rule for stage 3 and modifications to stage 2. MACRA rolls up CMS' quality reporting systems into the Merit-Based Incentive Payment System (MIPS). Now parts of the [Physician Quality Reporting System](#), the [Value Modifier \(or Value-based Payment Modifier\)](#) and the [Medicare Electronic Health Record](#) incentive program will become components of a single program based on quality, resource use, clinical practice improvement and meaningful use of certified EHR technology.

The result: MACRA ties EHR use to physician payment. Plus, because MACRA has clear elements of MU in it, CMS took the unusual step of asking for another round of comments on the MU3 final rule. Clearly, something needed to be done to get things synced up and simplified. That seems to be the intent of CMS' latest actions.

Here's What We Know. While many details have yet to be determined, there is still a lot we do know. For example:

• **MU isn't totally gone.** Meaningful use will still be

around despite agitated suggestions to the contrary in trade press. MACRA still has MU elements; specifically, meaningful use of certified electronic health records (MU of CEHRT), which will base physicians' Medicare Part B payments in 2019 on 2017 performance. MACRA states that EHR use will account for a quarter of physician performance scoring under the MIPS program. Doctors can receive penalties or bonuses of up to 4% starting in 2019, a number that grows to 9% by 2022, depending on how well they perform on MIPS. The idea is to focus more on quality and less on prescriptive EHR usage. The EHR certification program will survive in some form or another.

•**Penalties could be significant.** The failure to achieve MU of CEHRT could cost eligible providers a quarter of their maximum composite MIPS score. This could have a huge impact—far greater than the current payment adjustment under the regular MU program.

•**Bring on the apps.** The new program, as yet unnamed, is a push toward supporting a system of loosely coupled, best-of-breed program applications (apps). We've heard hints of this approach before, as in the [JASON Committee's report](#), which was released late in 2014.

So, how will it work? The vision is pretty rosy. For example, physician practices won't need to rip out their EHR because doctors can use an alternative app to document care or review gaps in care. Nurses can use something else that suits their work flow. Focused tools for care managers and other providers and administrators, up to and including management dashboards, are also available. Presumably, all of these apps will connect seamlessly. We remain cautiously optimistic that this rosy vision will come to fruition.

•**The door is opened for customization and innovation.** The app approach also will allow for customization and innovation. Providers might even choose their own suite of apps and tools and plug them in to the EHR platform of their current workplace. The same programming interfaces could also allow an innovative vendor to build software to export data from an old system, reducing the cost of migration. This would allow competition between platforms and the ability of users to switch, similar to moving from Apple to Android. Naturally, the big EHR vendors are in a race to see who can bring the most popular platform with the most apps.

•**MU actually did some good.** Despite its shortcomings, we agree with Dr. DeSalvo that MU has some good points. It provided \$30 billion in funding to push forward EHR adoption in the middle of the nation's recent financial crisis. That

money wouldn't have been available otherwise and it motivated a good number of providers to purchase EHRs, which they might not have done so otherwise. We didn't see anybody returning the money.

MU also established a floor of functionality, stimulated the creation of new health IT standards and created a certification system. Thanks to MU, EHRs are here to stay and will increasingly shape how medicine is practiced. Even at the most basic level, medical practices have technology that can document the current status of a patient and run some quality metrics. Implemented properly, EHRs can improve the patient experience and satisfaction. At the same time, they can capture patient and administrative data used to measure quality and outcomes.

•**A practice technology gap still exists.** Thanks to MU, large practices now have the tools to increase efficiency and quality and be rewarded for a quality improvement. Small practices continue to be at a disadvantage as a result of a "practice technology gap," which inhibits their ability to use their current technology. This gap is measurable. In fact, the Healthcare Information and Management Systems Society's analytics group has a technology gap scale that providers can use to determine where they rank.

What We Don't Know. There's probably more that we don't know at this point. We expect implementation details and regulations to dribble out over 2016 and maybe into 2017, if the next administration doesn't put a hold on things. (Whether the presidency stays in the hands of the Democrats or changes to the Republicans, our experience is that there are always changes.)

•**Which meaningful use measures will survive?** Nobody knows. Even the Medicare Payment Advisory Commission (MedPAC) — the federal advisory group on Medicare fiscal issues — said publicly it has no idea what CMS would require for EHR use measures, which would translate into MIPS payments or penalties. Mr. Slavitt gave some hints in his speech, saying CMS would move away from technology use and start rewarding outcomes. He also said providers would be able to customize their goals as opposed to the government dictating what must be done.

•**How many doctors will be subject to MIPS?** Those who have a certain percentage of their Medicare payments

tied to alternative payment models are excluded from the MIPS program. Who will make the cut is still a large question mark. The MIPS and alternative payment model tracks appeal to different groups of providers for different reasons. And as MedPAC commissioners noted, certain alternative payment models are targeted more squarely at primary care doctors.

•**What about standards?** Standards are a major issue to be addressed. The new program will be based on open source. Perhaps using open standards will help make apps portable rather than being locked to a particular platform/system. [See the SMART on FHIR \(Fast Healthcare Interoperability Resources\) app gallery](#) for a glimpse at what things might look like if this approach works. On the other hand, it strikes us that there is still a place for the various transaction and other standards that are now integral parts of EHRs and health data exchange. How will the various health care Standards Development Organizations work in an open-source world? Who will decide?

•**What about oversight?** Regardless of your opinion about them, oversight and governance issues still must be considered. App companies can discontinue or limit availability or features. Terms and conditions of use can change dramatically at any time. Prices can escalate. Companies offering apps can simply go out of business, leaving the user high and dry. The health IT landscape is changing so rapidly that an app that is necessary in today's world may not be needed tomorrow. In the worst case, what if a patient is harmed as a result of an app failure? The app company could cease to exist in a New York minute, so who will end up dealing with the liability? Somebody needs to be minding the store. Who gets the nod? Or, will we end up with a whole new gaggle of federal advisory groups whose opinions are more than just advisory?

•**What happens in 2017?** MIPS is planned to start in 2019 and, like meaningful use, will be based on performances two years prior. That means that whatever EHR measures are included in payment adjustments would come from performance in 2017 (and from 2018, in 2020). This means it is almost impossible for doctors to avoid MU stage 3 because CMS won't be able to replace the program with finalized MIPS measures by the end of 2016. As a result, measures won't be ready to be applied to the first year or two of MIPS.

Will this new program be workable? Will it be better or worse than the devil we know in MU? Will it be enough to win over the "hearts and minds" of providers, as Mr. Slavitt said in his address? Time will tell. In the meantime, POCP is closely monitoring the evolution of the program and its implementation. Let us help you understand where things are headed and help your organization capitalize on the changes that lie ahead.