

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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1 Part 1: 10 Trends to Watch in 2017

By **Tony Schueth**, Chief Executive Officer

It's traditional this time of year to look ahead at the trends that will be shaping health care and health information technology (health IT) in particular. We haven't seen as many prognostications as we usually do. We suspect folks are waiting to see what happens with the fate of the Affordable Care Act (ACA), which will be all-consuming in many ways. In the meantime, the business of health care will go on 24/7, with health IT as both a driver and enabler. With that in mind, here's our take (in alphabetical order) on 10 trends to watch in 2017.

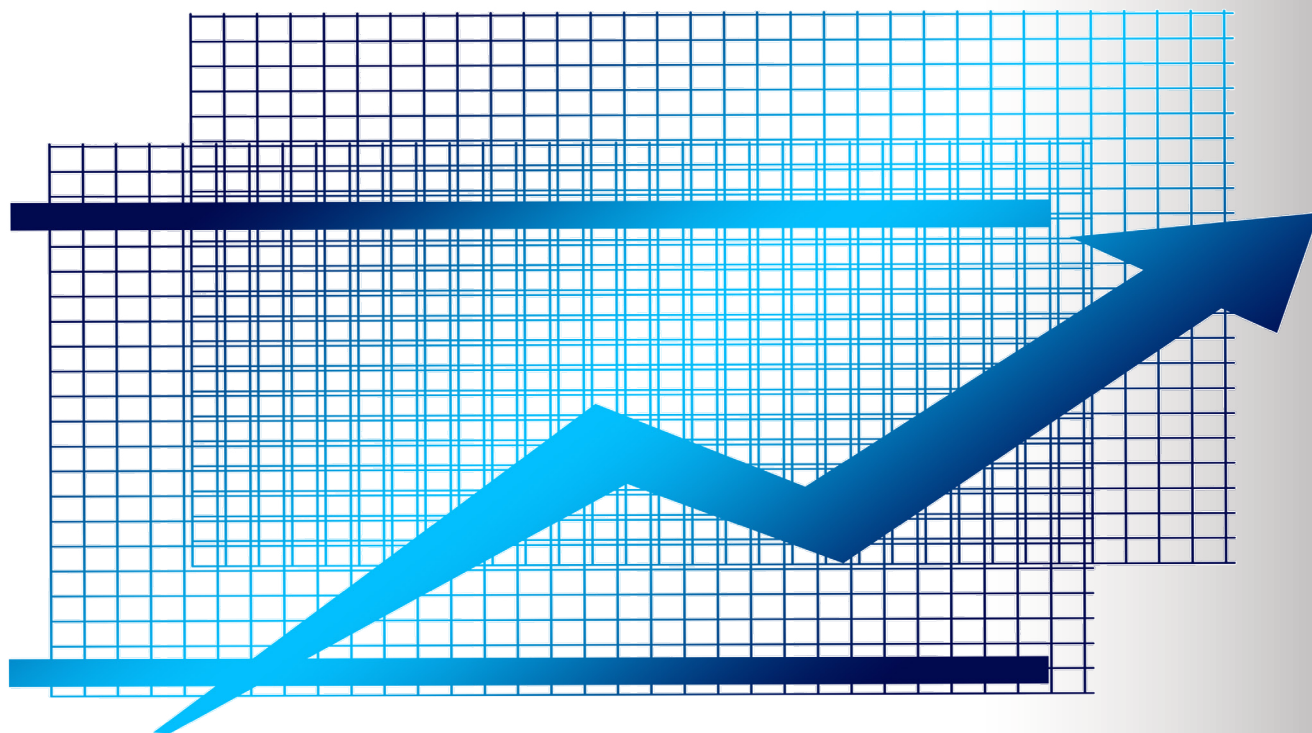
1. Biosimilars. In 2017, we will see the federal government and states continue their efforts to establish the needed infrastructure for approval and adoption of biologics and biosimilars. For example, the Food and Drug Administration recently **issued a final rule** on naming conventions. This is part of establishing necessary regulatory and pharmacovigilance frameworks. States are moving ahead with legislation on product substitution.

2. Consumer-directed health information exchange. The power of consumerism will play a large role in 2017. Patient engagement is picking up traction. A related topic is consumer-directed health information exchange (HIE). In fact, many participants in private- and public-sector initiatives — including the Medlist Effort from the Office of the National Coordinator for Health IT (ONC) and the federal Precision Medicine initiative — are beginning to share information using consumer-directed exchange. To be sure, giving consumers the ability to direct the flow of their personal health information will require changes to technology and infrastructure. However, we'll start to see that getting off the ground in 2017. For example, the

creation of a trusted data exchange framework will begin as part of the 21st Century Cures Act. Private-sector initiatives already are under way. Developers will continue to create and support safe exchange with consumer-authorized thirdparty applications and systems. Expect to see innovation and growth in these areas in 2017.

3. Electronic prescribing (ePrescribing). 2017 should be an active year for ePrescribing. We expect to see growth in automating specialty prescribing, with costs and volume of specialty medications fueling the trend. The ePrescribing infrastructure is in place and use cases have emerged that will facilitate adoption. Canada and other countries are looking to the United States for ways to implement ePrescribing; we should hear more about that in the next few months. Electronic prescribing of controlled substances (EPCS) also should experience an uptick in adoption, continuing the rapid acceleration in controlled substance prescription volume seen over the past couple years. Providers are finally beginning to invest in and use EPCS infrastructure — because it's time; it will help them meet required quality reporting targets. Also, an increasing number of states are requiring that all such prescriptions be sent electronically as a tool to fight the opioid epidemic.

4. Electronic prior authorization (ePA). The ePA standard is maturing. As an example, the National Council for Prescription Drug Programs (NCPDP) ePA Task Group, led by Point-of-Care Partners (POCP), has received no requests for tweaks to the standard because payers and others are moving toward adoption. We're seeing implementation involving the ability of many electronic health



records (EHRs) and pharmacy benefit managers to accept and exchange basic information for prior authorizations (PAs). Expect that to increase in 2017, but also look for adoption to start moving to the next level. Other indicators are also signaling that ePA is poised to take off. For example, CoverMyMeds — a large ePA platform that uses the NCPDP ePA standard to help automate and accelerate PA requests and approvals — recently was bought for \$1.4 billion by McKesson. This shows market recognition of the value and opportunities inherent in ePA. New use cases are emerging, such as in pharmacy-initiated ePA in the long-term care (LTC) arena. Pharmacists already have information to process PAs in that environment, and others still. As pharmacy moves to become instrumental in the care process, we expect to see efforts to facilitate ways pharmacists can become involved in ePA for LTC patients.

5. Fast Healthcare Interoperability Resources (FHIR).

FHIR is one of the latest in the HL7 family of standards. It underpins the movement toward open, standardized application programming interfaces (APIs), which are

getting a further boost under the 21st Century Cures Act. Providers and pharmaceutical companies are considering how to use innovative APIs to communicate with patients and partners. Increased adoption of FHIR-based APIs is expected in 2017. FHIR also is becoming key to Internet-based information exchange networks. Its accelerating momentum continues with public backing. For example, Anthem joins Independence Blue Cross in using the FHIR standard to build out value-based data exchange work flows with providers.

6. Health information exchanges (HIEs). States will continue to step up efforts to initiate and improve HIEs in 2017. This will be fueled in part by funding and **guidance from ONC**. Since 2010, 56 states, eligible territories, and qualified state-designated entities received awards totaling \$547.7 million. The agency is making additional funding available through its **HIE Challenge Grants**. The exchange of health information is key to cutting costs, improving quality and giving patients better access to their health information. It also is central to value-based health care. Moreover, the “interconnectedness of con-

nectors” will be important in a couple of years if insurance is sold across state lines and if millions of people potentially move off “Obamacare” and on to new insurance plans. That said, connecting individual physicians is still a challenge and essentially taking place one at a time. There are opportunities for consolidating provider-to-provider connectivity and easing the onramps to data exchange.

7. Interoperability. Interoperability is no longer a buzzword but a concept that is being put in place. Drivers for 2017 include requirements of the Medicare Access and CHIP Reauthorization Act (MACRA) and existing ONC programs. There also will be downstream impetus from the 21st Century Cures Act. [According to a recent survey](#), interoperability projects on which health care organizations will be working in 2017 include connecting to external databases, such as HIEs (65%), connecting applications within the organization (58%) and adding connections from medical devices to existing systems (37%). Emphasis also will be placed on greater integration of EHRs and provider work flows.

8. Prescription drug monitoring programs (PDMPs). Sadly, the opioid epidemic will show few signs of abating in 2017. In response, states will continue to enact legislation mandating that prescribers and pharmacists consult PDMPs. These are independent, state-run databases of controlled substance prescriptions that exist in all states except Missouri. Research by the [Pew Charitable Trusts](#) and others indicate that consultation of PDMPs before controlled substances are prescribed or dispensed can be effective in reducing overdose-related deaths. Emphasis also will be placed on making PDMPs more interoperable — both with each other and with EHRs by integrating access into prescriber work flows. For more information, see [the related article](#) in the February issue of *HIT Perspectives*.

9. Telehealth. [Telehealth seems to be everywhere these days](#). It has many benefits, including filling gaps in care transcending geographic barriers to care and reducing costs. Legislators are working to remove such barriers as

licensing. There are efforts to expand its use in Medicare and Medicaid, not to mention increasing coverage by employers and private insurers. [During his campaign](#), telehealth was cited as a key piece of President Trump’s plans to reform the Department of Veterans Affairs. That marker is likely to be cashed in. [According to one expert](#), telehealth is fast becoming a major focus of the annual meeting of the Healthcare Information and Management Systems Society, as well as a key business initiative among health care leaders. All in all, we expect to see a lot more about telehealth in 2017.

10. Value-based care. The shift from volume to value will continue in 2017, with a growing emphasis on consumers. This will be driven in part by MACRA and the 21st Century Cures Act. EHRs will be essential in supporting the data collection and analyses needed to support increased population health, quality initiatives and improved patient outcomes. In order to compete and comply with federal mandates, health care organizations must increase access to consumer-friendly services while decreasing costs. Also, expect to see high-level interest in addressing drug costs.

There’s no doubt about it: 2017 will be a year of change, but also a year of continued hard work on previous initiatives. Many of the trends covered in this article are explored in detail in previous issues of *HIT Perspectives* and blogs. We also closely monitor regulatory trends. To learn more, visit our [Regulatory Resource Center](#) or contact its director, Connie Sinclair, at connie.sinclair@pocp.com. ●

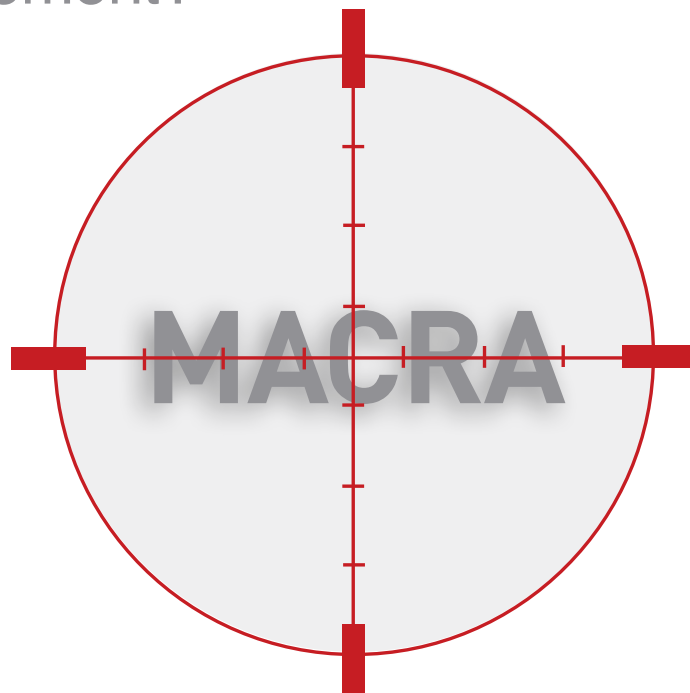
2 Part 2: Will MACRA Be In the Crosshairs for Repeal and Replacement?

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

A lot of energy and angst is being expended, both inside and outside the Washington Beltway, about the future of the Affordable Care Act (ACA), the **Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)** and many other regulations.

So far, it looks as though groundwork is being laid to address the repeal and replacement of “Obamacare.” However, we’ve also been hearing that many across the health care community are hopeful MACRA will be in the crosshairs as well. While we caution that it’s too soon to tell, we believe congressional action affecting MACRA is unlikely. Any such action is apt to be placed on the back burner and would materialize slowly — if ever. Here’s why.

- The fate of the ACA will occupy Congress, the Department of Health and Human Services (HHS) and the Centers for Medicare and Medicaid Services (CMS) for most of 2017. That in itself will be a gigantic undertaking — almost to the exclusion of everything else. There’s only so much bandwidth to go around.
- MACRA is a statute. MACRA and its two payment tracks for physicians participating in Medicare were passed with overwhelming bipartisan support in Congress. As a result, it is unlikely there will be much



appetite to repeal or replace this law anytime soon. Besides, Congress and HHS will have bigger fish to fry in the near future with the planned repeal and replacement of the ACA, not to mention the activity that will ensue if rumored changes are brought forward for Medicaid and Medicare.

- This brings us to speculation that CMS’ Center for Medicare and Medicaid Innovation (CMMI) will come under fire. Created by the ACA, the CMMI is charged with creating most of the alternative payment models that form the foundation of MACRA’s alternative payment model track. Even if the CMMI is changed or dismantled, policy experts believe that MACRA’s core provisions will remain.

- Although there may be some delays in implementation, it is nonetheless inevitable, which would not be unusual. In fact, implementation slowdowns are bound to happen and are commonplace with large federal regulations. ICD-10 is the poster child for this scenario. For MACRA, policy makers are likely to respond to stakeholders' vocal concerns over such issues as an aggressive implementation deadline and the gap between the time when data must be reported in 2017 and when they will actually be used in 2019 to compute physician payments. Additionally, the new administration may want to put its own stamp on some requirements, which could result in a good deal of tweaking down the road. It may, for example, want to simplify some of the statute's complicated requirements. Again, that would not be unusual but is unlikely to result in a whole new law.

Physician Compare website. Many of the new accountable care organizations — and large integrated delivery networks — publish physician quality scores internally. We hear that some plan to make them available to the public as well. Quality reporting is the way of today's world, which is increasingly focusing on value-based care and pay-for-performance. Making provider performance data available to the public is viewed as a way to bring better quality alignment for providers and reduce costs. It also could help inform physician hiring by hospitals and health systems.

While 2017 will be a year of change, providers should not sit back and wait to see what happens with MACRA. Over the years, we have watched providers sit on their hands, hoping against hope that statutory and regulatory changes will be made, and then playing a costly game of catch up. The MACRA clock started ticking January 1, 2017. Deci-

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- Frankly, the genie is out of the bottle regarding quality and pay-for-performance. MACRA represents the latest in a string of such requirements for Medicare and public payers. Providers who chafe at CMS' plans to publish performance data from the Merit-Based Incentive Payment System payment track have short memories. CMS has been publishing provider data for years, such as on its

sions about contracts, risk management, hiring and infrastructure will need to be made soon — and they could have far-reaching implications for the future. •

3 Part 3: What the 21st Century Cures Act Means for Health IT

By **Tony Schueth**, Chief Executive Officer

In one of his last official acts, President Obama signed the 21st Century Cures Act into law on December 16, 2016. The health information technology (health IT) community may have overlooked this bipartisan, \$6.3 billion piece of legislation. The name doesn't sound like it involves health IT and large portions are devoted to more mainstream health issues, such as expanding medical research, speeding approval of new drugs and medical devices, addressing the opioid epidemic and expanding access to mental health services. Many people may recognize the act due to considerable press coverage of its \$1.8 billion in funding for the cancer research "moonshot" championed by former Vice President Joe Biden.

What many health IT stakeholders may have missed is Title IV of the act, which is devoted almost exclusively to health IT. [Our blog](#) summarizes the numerous relevant sections of Title IV. Here's our take on some of the provisions.

- **Electronic health records (EHRs).** EHR vendors will have their hands full meeting the legislation's requirements. They will have to ensure their products meet new certification requirements concerning interoperability, such as the free and secure exchange of patient information. These undoubtedly will be dealt with through notice and comments rule making, so vendors will need to stay tuned for these draft regulations.



Vendors ultimately will have to address requirements for developing products for pediatrics, other specialties and sites of services "for which no such technology is available or where more technological advancement or integration is needed." The law requires the Secretary of the Department of Health and Human Services (DHHS) to consult with stakeholders and make recommendations within the next 18 months for voluntary certification of health IT that meets the requirements of pediatricians across various sites of care. The statutory language is vague as to whether this applies to all EHRs or some subsets. Does it mean that those EHRs not offering a pediatric-specific version of their software would be required to build one? In terms of voluntary certification, pediatric-focused products certainly will have to meet specific criteria

— such as a meaningful use (MU)-like certification for a specialty. This indeed would be uncharted territory, which could pave the way for future certifications for other specialties down the road. That said, specialties have discrete requirements, so one size will not fit all. It also remains to be seen whether there would be penalties for vendors who choose to ignore ensuing voluntary certification requirements.

It also is unclear whether the statutory language means only EHRs or includes various modalities, such as mobile health, depending on how DHHS interprets the statute. Health IT is a broad term, after all. To ensure their voices are heard, we recommend that vendors monitor and participate in the stakeholder group that will be convened to address those requirements for pediatric health IT. These recommendations undoubtedly will form the basis of future rule making, which will lock down requirements to which the industry will have to conform.

The act's requirements could hasten further consolidation of the EHR market with additional functional and certification requirements, over and above those required for MU and the Medicare Access and CHIP Reauthorization Act (MACRA). Piling on these 21st Century Cures Act requirements might prove too burdensome for smaller vendors.

- **Interoperability.** The law makes it clear that interoperability is not going away as an issue and will continue to be a policy driver in the world of health IT. The act approaches interoperability from several different directions. Among the most significant is creation of a framework for a trusted exchange network for health IT. This will be spearheaded by the Office of the National Coordinator for Health IT (ONC) in conjunction with the National Institute of Standards (NIST) and stakeholders. The law also calls for the development and certification of patient-centered EHRs. Expect to see rulemaking further down the line to flesh out implementation and adoption details and timelines. In addition, application program interfaces (APIs) also figure into the picture, following a grow-

ing trend in legislation and policy making over the past few years. The act requires them to be part of ONC's Health IT Certification Program.

In an unusual move, this legislation creates “teeth” for enforcement against information blocking. It establishes authority for the DHHS' Office of the Inspector General to investigate claims of information blocking and fine those found to be in violation. That appears to include developers, networks and exchanges. Those fines can be substantial — up to \$1 million per violation. It also appears that enforcement actions also may be taken against noncompliant providers; forthcoming notice and comment rule making will provide details. All of this is rare, indeed. Stakeholders have been put on notice.

- **Office of the National Coordinator (ONC).** The act further enhances the value of ONC in terms of its expertise, oversight, accountability and interoperability of health IT. For example, it expands the role of ONC as a certifier of health IT and establishes it as a resource to help providers select appropriate health IT. The agency also could be involved in pilot testing various solutions. As mentioned previously, it will work with NIST and stakeholders to develop a framework for the trusted exchange of health information.

That said, ONC-related regulations for 21st Century Cures Act implementation currently are on hold due to an across-the-board freeze placed in effect by the Trump administration. One would have created authority for ONC to oversee health IT certification, the EHR reporting program and the newly created Health IT advisory committee. A second was to begin the process of renewing the contract for ONC's approved accreditor. That job of overseeing the EHR certification program currently is held by the American National Standards Institute (ANSI), whose three-year term expires in June.

- **Patients.** The act clearly emphasizes the patient perspective and experience, suggesting these will continue to be important to regulators going forward. It carries on the patient focus seen over the past few years with



requirements for MU, the creation of value-based reimbursement based on patient-centered care models (think patient-centered medical homes) and new requirements under MACRA. With respect to health IT, the 21st Century Cures Act contains requirements to make EHRs more patient friendly and more readily able to exchange patient information. EHRs will be required to exchange information with registries, although harmonization of these provisions and similar ones in MACRA may be in order. These and other patient-centered provisions clearly signal that patient empowerment and patient-centric care should be considered by payers, providers and health IT vendors must continue in the future.

The new law also requires the General Accountability Office to study challenges related to patient access to health information. These include barriers to access, complications health care providers experience when providing access and methods patients may use for requesting their personal health information. If the past is prologue, this study will be used as the basis for future rules making to address issues that haven't been covered.

- **Standards.** Standards clearly were on the minds of the drafters of the 21st Century Cures Act. For example, it clearly spells out that various activities, such as development of a trusted exchange network, must use standards created by recognized standards development organizations. It also sunsets and combines existing Health IT policy and standards advisory committees to create a new Health IT advisory committee that will engage stakeholders to identify priorities for standards adoption. Standards harmonization and implementation are also part of its portfolio, as well as pilot testing certain standards. The committee will also specifically address issues related to interoperability, privacy and security. In sum, it will be very influential. Its recommendations are likely to be translated into rules making and policy. As a result, its membership and deliberations will be of critical importance to the health IT community.

- **Telehealth.** Telehealth is an under-the-radar trend that has been quietly gaining traction over the past several years. The act clearly aims to expand Medicare adoption of telehealth services. It calls for Medicare to identify which beneficiaries might find telehealth useful, which high-volume health care services would be amenable to this approach and barriers to adoption. MedPac is to weigh in on related financial matters. Further adoption of —and payment for — telehealth services by Medicare will push the private sector to follow suit. This will create opportunities for EHRs and APIs to facilitate the capture and exchange of patient data.

This article only touches the surface of what the 21st Century Cures Act means for health IT. Point-of-Care Partners can help you perform a deeper dive of its provisions and their impacts on various stakeholders. Drop us an email or give us a call. •