



Accessing the data we need to get the medications right: What new health IT requirements mean for you—and for consumers

Nearly three years after the 21st Century Cures Act was signed into law, multiple government and industry-led initiatives are underway to implement key provisions designed to facilitate the interoperability of electronic health information.

Two soon-to-be-finalized rules—one from The Centers for Medicare and Medicaid Services (CMS), the other from The Office of the National Coordinator for Health IT (ONC)—will transform how providers and payers share data and how patients access it.

These efforts are foundational for those working towards a more comprehensive, person-centered approach to optimizing medication management. Beyond complying with new regulations, everyone who pays for or delivers care will transform how they capture, exchange, use and apply data so that

individuals may access their personal health information where and when they need it.

New Rules for a New Era of Interoperability

In February 2019, CMS and the ONC put out two significant proposed regulations. They are intended to drive increased efficiency and transparency through an array of measures, including preventing information blocking and expanding how patients can access their health care information.

Once finalized, the proposed ONC and CMS rules will significantly advance interoperability and patient access to data. That will have a profound impact on comprehensive medication management (CMM).

“Comprehensive medication management will become more

CHEAT SHEET

- **APIs**, or Application Programming Interfaces, govern how applications communicate and interact with one another. In health care, they will allow patients, providers and other stakeholders to use third-party software (like a mobile app) to access secure information in a standardized format.
- **HL7** is a set of international standards for the transfer of clinical and administrative data between software applications used by various health care providers.
- **FHIR (pronounced “fire”)** is a health care-specific standards framework for the same kind of APIs that underlie most internet commerce. FHIR-based apps can be plugged into any FHIR-capable EHR.

viable and easier to achieve with interoperability and the availability of information across health care organizations,” says Deb Gage, MBA, president and CEO at Medecision and GTMRx Institute board member. “We must also empower consumers and put them in a position to have access to their own health data.”

The rules will likely be finalized by the end of 2019, and the impact on the industry cannot be overstated. Unfortunately, these proposed rules seem to have flown under the radar of many organizations.¹

Three years after the 21st Century Cures Act became law with new regulations designed to help drive increased efficiency and transparency, many health care executives are not yet focused on the law and its potential impact on their organization and their customers.

An October 2019 Accenture survey found only 18% of health care executives surveyed are “very familiar” with anticipated requirements for organizations handling patient medical records, while 17% are “completely unaware” of the requirements.

That cannot stand, says Gage. “Supporting the empowered consumer starts with understanding these regulations and the industry initiatives underway to help all stakeholders apply them to the patient journey.”

¹ “Federal Requirements for Sharing Patient Medical Records Pose Major Challenges and Opportunities for Healthcare Organizations,” Accenture, Oct. 2019

CMS proposed rule: Data on FHIR

The CMS Interoperability and Patient Access Proposed Rule introduces policies that will expand access to health information and improve the seamless exchange of data in health care, according to CMS. “This will enable better care coordination, better patient outcomes and reduced costs. The proposals will help to break down existing barriers to interoperability and empower patients by giving them access to their health information,” says Lisa Bari, MBA, MPH, consultant and former health IT and interoperability lead at the CMS Innovation Center.

The policies in this proposed rule touch on all aspects of health care, involving, among others, patients, providers, payers and researchers.

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While the rules generally apply to health plans and payers, such as those offering Medicare Advantage and Medicaid Managed Care plans, the longer-term impact will be widespread.

Perhaps most notably, it requires payers and health plans to make patient health information available electronically through a standardized, open application programming interface—an API based on the FHIR standard.

“This is a big deal because the government has never before said ‘You have to exchange data this way,’” Bari says. Neither has it ever embraced a specific standard. Now it has.

Health Level 7 (HL7) Fast Healthcare Interoperability Resources (FHIR, pronounced *fire*) is a health care-specific standards framework for the same kind of APIs that underlie most internet commerce. FHIR-based apps can be plugged into any FHIR-capable EHR.

CMS has indicated it would like private payers and other stakeholders to adopt similar requirements for access to information and interoperability.

Other aspects of the proposed rules include

- Making the payer’s provider directories available through APIs—and keeping them updated. Having a centralized directory of providers that

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contains electronic addresses would be an important step in fostering communications across the patient continuum of care.

- Knowing other organizations’ digital addresses and how to find them when you exchange information with them.
- Requiring hospitals to send admission, discharge and transfer (ADT) alerts to other providers as a condition of participation in Medicare.
- Publicly reporting providers and hospitals that engage in information blocking.

The proposed rule accelerates work on patient matching strategies, promoting wider adoption of interoperable health IT systems in long-term, post-acute care, behavioral health and home care services.

This is just the beginning, Bari says. “The current regulatory landscape for interoperability is robust. The administration has demonstrated strong commitment to regulations that advance interoperability and patient access to data.”

She expects to see more activity in this area. “This is the first one that CMS is creating, and it brings together as much authority as possible to really move interoperability forward using the things that CMS is actually able to regulate.”

ONC’s rules: Freeing access to data

The ONC-proposed Interoperability, Information Blocking and their Health IT Certification Program Proposed Rule detail proposals that further advance interoperability and patient access to health information. It implements certain provisions of the 21st Century Cures Act, including definitions for activities that do not constitute information blocking.

The impetus for the ONC rule was the 21st Century Cures Act of 2016 which required the Office of the National Coordinator for Health IT to act in a variety of areas, including defining interoperability.

The ONC proposes that interoperability, with respect to health IT:

- enables the secure exchange of electronic health information with, and use of EHI from, other health IT without special effort on the part of the user;

- allows for complete access, exchange and use of all electronically accessible health information for authorized use under applicable state or federal law; and
- does not constitute information blocking.

This is key, as is their definition of data blocking as a practice “by a health care provider, health IT developer, health information exchange or health information network that ... [with certain exceptions] is likely to interfere with, prevent or materially discourage access, exchange or use of electronic health information.”

Intent will matter, Bari says. But we don’t know how much. What we do know is that ONC and CMS have made stopping data blocking a top priority, introducing a variety of financial penalties, “but there’s also a big question mark around penalties and enforcement for organizations who are not directly health IT vendors,” she warns.

She added, “We’ll have to see what’s in the final rule to understand more about how to avoid being an information blocker or partnering with information blockers, but it’s clear that organizations will have to adjust their business practices to ensure they are in no way connected to information blocking.”

Implications Across Health Care

Among other things, the proposed rules make it possible for the individual to access *all* their health

information in the form and format that they want and aggregate it into a third-party app into any type of device. It's a sea change.

But these proposed regulations are just the first step. Bari says more are in the pipeline. For the short term, it's important to look closely at the final regs—especially the timelines.

"It's important that you keep an eye on the space and understand what the requirements will be," Bari says. Timelines will be critical, she says; accelerated timelines could pose a

real challenge to payers, providers and health IT vendors. The comments and feedback ONC and CMS received reflected these concerns.

Some of the proposed deadlines are as early as the end of 2020 and the beginning of 2021. She expects the administration to make some concessions on the timelines, but it remains unclear what those will be.

Another outstanding issue is how these changes around information blocking and individual data rights will apply to pharmacy benefits

managers (PBMs). "We will know more once the ONC rules are finalized," she says. It may ultimately boil down to how regulators answer the question, "What *is* the health information network?"

Also up in the air is the question of who pays for what and how they pay for it. One aspect of that is certain: The ONC and CMS proposed rules require that providers and health plans not charge individuals to access their own health information. How individual companies are paying and/or charging for the

CARIN Alliance offers building blocks

■ **CARIN Blue Button 2.0 API:** In 2018 CMS launched Blue Button® 2.0 which allows all Medicare fee-for-service beneficiaries digital access to download claims information on an app of their choice. The private sector took this and ran with it. In 2019, CARIN debuted the CARIN Blue Button 2.0 API, providing a data model and draft implementation guide for commercial plans. The guide includes more than 240 claim data elements that have been agreed upon by multiple regional and national health plans. CARIN mapped those data elements to HL7 FHIR resources to ease implementation of the CMS Interoperability and Patient Access proposed rule.

"This will allow all the health plans as well as CMS to essentially be on the same API standard so that everyone is exchanging data in a similar way. This reduces transaction costs and actually provides significant benefit to the industry."

■ **Trust Framework and Code of Conduct:** Because the industry is now starting to send protected health

information outside of HIPAA for the first time, CARIN has developed a data-sharing code of conduct for third-party entities not covered by HIPAA." This is important because we need to protect that data no matter where it sits or who has it."

He hopes it will become the industry's de facto standard. The Department of Veterans Affairs is already using it, and some health information networks are also looking to put it in production. In addition, many EHR vendors are doing something similar.

■ **Real-time pharmacy benefit check:** As the name suggests, this will allow consumers to obtain in real-time formulary and benefit information, out of pocket cost, therapeutic alternatives and the cash price. All of that information is actually going to come into a third-party app of the consumer's choice, allowing them to make much more informed decisions.

Meanwhile, the National Council for Prescription Drug Programs and HL7 have signed a joint memorandum of understanding to co-publish the consumer-facing, real-time pharmacy benefit check FHIR API implementation guide in 2020. "Both are actively participating and aware of the work we are doing within the CARIN Alliance," says Howells.

development of their APIs vary greatly across the health care ecosystem, observes Ryan Howells, MHA, PMP, principal at Leavitt Partners and lead at the CARIN Alliance.

Perhaps the biggest question is this: How will those who hold the data make it easily available for consumers to access their own data? That remains to be seen, but some models are already being tested.

Modeling the future

The new regulations are just one aspect of what's needed to answer that question. Bari stresses that the work the ONC and CMS are doing to facilitate interoperability goes far beyond regulatory.

For instance. The CMS Innovation Center will be launching advanced interoperability pilots. "This is an opportunity to be on the cutting edge of interoperability and help shape future programs and policy," says Bari.

It's here we'll see more efforts around comprehensive medication management. "What I can tell you for sure is that primary care models like CPC+, and the forthcoming Primary Care First (PCF) models, emphasize CMM as part of care delivery requirements designed to improve comprehensiveness and coordination. And they could certainly use more input."

Opportunities abound. She encourages organizations and individuals to get involved and learn about the new models being tested.

Bari notes that CMS announced that the PCF initiative is open for applications. It's a new 26 state and region model for advanced primary care which, she says, "is highly relevant" to CMM as CMM is a care delivery principle in PCF.

The Innovation Center—and for that matter, the ONC and CMS—all need more information from what's actually happening in the field. "I really recommend getting involved and reading about them and commenting and providing feedback. Ask for meetings with the Innovation Center and other parts of CMS and with the ONC to give feedback on CMM and interoperability."

These government regulations and innovative models are advancing interoperability and transparency—essential foundations to giving consumers the ability to control, manage and take hold of their health and well-being, says Gage. But the government agencies aren't alone, she notes. Private sector initiatives are also driving change, and it's essential that they keep moving forward. In describing the role of health IT companies specifically, Gage says there is value to be gained, "even by doing simple things, like using APIs to connect care teams across the health-care ecosystem so they can share credible, real-time information."

Private sector: Building the framework

Howells notes that the development of APIs has been a collaborative public/private sector process for the last few years. The private sector

has led those efforts with the public sector supporting what the private sector has agreed to do.

Leavitt Partners helped set up one such private sector effort—the CARIN Alliance. Formed just prior to enactment of the 21st Century Cures Act, CARIN comprises payers, providers, hospitals, EHR vendors, patient and caregiver advocacy groups, associations, pharmacies and others who are focused on giving consumers and their caregivers real time access to their digital health information.

"CARIN's vision is to rapidly advance the ability for consumers and their authorized caregivers to easily get, use and share their digital health information when, where and how they want to achieve their goals," he says.

He emphasizes that these efforts are truly collaborative. It started with one question: "What could we do in a very bipartisan way to really improve health care and move the needle to achieve the triple aim or quadruple aim?"

The answers that came back were remarkably similar and boiled down to this: "We've got to get the data moving, and we've got to get more person-centered data across the systems to be interoperable. We can move toward value-based care and achieve all that we've wanted to achieve for quite some time."

It's the right time for a number of reasons, not the least of which is the

fact that at least 95% of provider organizations have EHRs, providing at least a rudimentary digital infrastructure.

“Now we have APIs, which is the way data is moved across the internet economy today. As a result, health data can start to move at the speed of the internet economy,” he says.

Soon, an individual will be able to aggregate all their data and share it with whomever they want to share it with. “We have been solely focused on the business policy and technical barriers associated with making this happen.” One important consideration is this: Third-party consumer apps are not governed by HIPAA; that falls to the FTC.

“This is the first time at scale it’s ever happened. We really want to ensure that we effectively balance the need for individuals to get access to their clinical and claims data while ensuring both the public and private sectors effectively secure and keep private the individual’s health information based on that individual’s consent and personal preferences. That’s what CMS, the ONC and the CARIN Alliance are all working on together.”

He doesn’t see real or perceived HIPAA concerns getting in the way. “HIPAA’s individual right of access provision is the driving catalyst for why patients will be able to access more of their digital health information than ever before. There will be multiple ways to share and protect the information once

the data can be aggregated with the individual.”

Bringing it back to CMM

GTMRx is committed to ensuring that data standards, technology systems and analytical tools provide a single view of patient care and incorporate those medical and pharmaceutical management practices consistent with a personalized, person-centered, team-based systematic approach to optimizing medication use.

But all of this represents only a beginning and—especially in terms of CMM—much work remains. For instance, there appears to be no seamless way to add pharmacogenomics test results into the EHR and make them downloadable.

“Nearly all of the open standard APIs that are being developed today are ‘read-only’ APIs. For ‘write’ capability that integrates directly into the EHR, you would need to talk to the individual EHR vendor who may have a proprietary way to integrate into their system,” says Howells. More broadly, he encourages third-party vendors with CMM-related solutions, such as pharmacogenomic testing, to become more involved with HL7 and the FHIR community.

To get the medications right, it’s essential to get the data right.

“We need to put the power of information about medications and treatment and outcomes in the hands of care teams who are working collaboratively across

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the specialties and systems that exist today,” Gage says.

Information architecture and digital health experiences will enable more comprehensive medication management throughout health systems. “What an exciting time it is to be in health care and addressing these issues of interoperability and transparency,” Gage says. “All of this provides a firm foundation for getting medications right and creating a comprehensive team-based approach to lowering health care costs and improving the experience of care for all Americans.” **GTMR**

About the Experts



Lisa Bari, health IT consultant and former health IT and interoperability lead at the Centers for Medicare and Medicaid Services' (CMS) Innovation Center

Lisa Bari advises diverse organizations on health IT and interoperability policy and regulatory strategy as an independent consultant at www.healthcareitpolicy.com. She recently served as the Health IT and Interoperability lead at the Centers for Medicare and Medicaid Services' (CMS) Innovation Center and helped author the groundbreaking CMS Interoperability and Patient Access Proposed Rule.

She also led health IT strategy for the Comprehensive Primary Care Plus model, the largest test of primary care payment and delivery system reform in the U.S. As the senior technical advisor on artificial intelligence and emerging technology to the U.S. Department of Health and Human Services (HHS) Value-Based Transformation Initiative, Lisa designed and launched the CMS Artificial Intelligence Health Outcomes Challenge, a \$1.65M prize competition that spurred the use of CMS data to build AI-driven

solutions to predict health outcomes in Medicare beneficiaries.

Prior to her federal government service at HHS and CMS, Lisa was the associate vice president of marketing and growth at Practice Fusion, a primary care-focused electronic health records platform. Lisa began her career in digital marketing and communications for consumer and enterprise technology firms and has worked in the U.S., Germany, Mexico and the United Kingdom.

Lisa earned a master of public health with a concentration in health policy and public health leadership from the Harvard T.H. Chan School of Public Health, an MBA from Purdue University's Krannert School of Management and a B.A. in cognitive science from the University of California, Berkeley.



Deborah M. Gage, MBA, president and CEO at Medecision and GTMRx Institute board member

Deb Gage is a proven business transformer, having built her career as an entrepreneur

founding and leading health care technology companies, including operational and leadership experience in start-up and growth businesses in the analytics, financial and clinical sectors of health care IT.

She was an early team member at Truven Healthcare (then MEDSTAT), and then became CEO of several venture-backed health-care IT firms including Solution-Point®, Inc., a provider of database management and decision support software products for hospitals and integrated delivery systems; GTESS Corporation, a SaaS-provider of claims automation solutions for health care payers; and RosettaMed (acquired by Kryptiq), an electronic medical record patient intake application.

Now, as president and CEO at Medecision, Deb oversees the company's mission to lead the digital transformation of health care through consumer engagement solutions that help health plans and care delivery organizations manage and care for their members, patients and caregivers.

Under her leadership, Medecision has transformed from its beginnings as a powerful care management workflow engine

continued

About the Experts (Continued)

for health plans, into a market-leading provider of big data, visualization, workflow and engagement solutions, as noted by Gartner and IDC. Recently, Medecision acquired GSI Health, a SaaS provider of workflow, engagement and compliance solutions and related services.

The company's Health Coordinator platform is used by some of the nation's leading health systems to coordinate and optimize value-based care for more than one million beneficiaries, often operating under Delivery System Reform Incentive Payment (DSRIP) programs. In 2017, the company acquired a boutique consulting business (Aveus) to help the company's clients transform their own

models and operations. The same year, Medecision acquired the AxisPoint Health platform business, including more than 50 new clients.

Deb is a proud graduate of the University of Michigan Ross School of Business.



Ryan Howells, M.H.A., PMP,
principal at Leavitt Partners and lead at the CARIN Alliance

Ryan Howells is a principal at Leavitt Partners. Ryan has worked with the White House,

VA, CMS, CCIIO, ONC and OCR on health care issues and is a frequent speaker at major industry events.

Ryan currently helps lead the CARIN Alliance, a multi-sector, public-private alliance focused on providing consumers digital access to their health information. Ryan is also a member of CMS' Medicaid Information Technology Architecture (MITA) Governance Board and board observer for a major technology company.

Ryan received his master's in health administration from USC where he was a Dean's Merit Scholar and bachelor's degree in English from BYU.



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Our **VISION** is to enhance life by ensuring appropriate and personalized use of medication and gene therapies.

Our **MISSION** is to bring critical stakeholders together, bound by the urgent need to optimize outcomes and reduce costs by *getting the medications right*.

About the GTMRx Institute The GTMRx Institute is a catalyst for change that brings critical stakeholders together, bound by the urgent need to get the medications right. We are physicians, pharmacists, caregivers health IT innovators, drug and diagnostics companies, consumer groups, employers, payers and health systems—aligned to save lives and save money through comprehensive medication management, or CMM. By showcasing evidence and innovation, we motivate practice transformation and push payment and policy reform. Together, we ACT to champion appropriate, effective, safe and precise use of medication and gene therapies. Learn more at gtmr.org.