

# Perspectives and Updates on Health Care Information Technology

# HIT Perspectives

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## About the Newsletter

*HIT Perspectives* 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: CARIN Alliance - Multisector Coalition Strives to Connect Patients to Medication Costs



By **Pooja Babbar**, Practice Lead, PBM Services



“We’ve been working now since 2015...”

Connecting patients with information about the costs of their medications is part of the growing movements toward consumer-directed care and drug price transparency. Price transparency is important because it can help reduce abandoned prescriptions and medication nonadherence, which often result from sticker shock at the pharmacy and **cost the American health care system** between \$100 billion and \$289 billion a year. Now a nonpartisan, multisector stakeholder coalition, the **CARIN Alliance**, is working on an up close and personal

way to help consumers understand their out-of-pocket prescription costs before they arrive at the pharmacy. CARIN’s vision is to rapidly advance the ability of consumers and their authorized caregivers to easily get, use and share their digital health information whenever, wherever and however they want.

This new method is the consumer-facing, real-time pharmacy benefit check (RTPBC). It will use technology — application programming interfaces (APIs) — to enable consumers to look up the costs of their prescriptions, as well as what their insurance will

cover and pay for, on a smart phone, tablet or other electronic device. This has been a black box for most people. The consumer-facing RTPBC also will give the cash price for a medication and apply the costs of coupons and other kinds of financial assistance, as well as indicate whether prior authorization (PA) is needed, which can also be a barrier to access.

To be sure, some drug pricing and PA information is posted on payers' patient portals. However, consumers often don't know about this resource or don't use it, in part because it doesn't include prices for cash purchases or financial assistance. Those who do use their payer's portal often use it solely to look up claims or better understand their benefit parameters and options for new regimens.

Having personalized drug information at their fingertips will enable consumers to find treatment options and alternatives that meet their needs. **A recent study found** that 40% or more of Americans have difficulty affording their prescription drugs, despite having insurance coverage. Roughly a fifth said they have had trouble paying for such basic necessities as food or housing due to the cost of their medication, and a similar percentage have borrowed money from friends or family, taken out a loan or even declared bankruptcy for that reason. Additionally, benefits are always changing, so certain medications may no longer be covered and consumers will be on the hunt for alternatives.

Work on the patient-facing RTPBC continues to gain speed through a CARIN-sponsored workgroup convened in November 2018. Over the next few quarters, it will be putting together API implementation guides that will leverage transactions using standards from Health Level Seven International and the National Council for Prescription Drug Programs. These will be key for vendors to use in their development work. These guides will also assist health plans in knowing when their member went off formulary and paid cash, thus improving their medication adherence quality scores. Implementation of the API would follow the **Patient Right to Know Drug Prices Act** of October 2018 and the proposed **real-time benefit tool rule for Medicare Part D** published in November 2018. Development of the patient-facing RTPBC also will align with the newly issued proposed



*Aneesh Chopra and Pooja Babbarah at CARIN Alliance RTBC Workgroup held during HIMSS19*

**regulation on interoperability** and information blocking from the Office of the National Coordinator for Health Information Technology and the **new proposal** on making patient data available through APIs from the Centers for Medicare and Medicaid Services. •

*Point-of-Care Partners is working closely with the CARIN Alliance to advance consumer-facing RTPBC. Want to know more or join the Workgroup? Reach out to me at [pooja.babbarah@pocp.com](mailto:pooja.babbarah@pocp.com).*

# 2

## Part 2: 8 Impressions from HIMSS 2019



By **Tony Schueth**, Editor-in-Chief



The book is closed on this year's annual meeting of the Healthcare and Information Management Systems Society (HIMSS) in Orlando, the go-to meeting for health information technology (health IT). We understand that attendance was down slightly, but there still were more than 40,000 people who spent a lot of time and money to attend, exhibit and make presentations. With its notable focus on real-world efforts to improve the patient journey and noticeable C-suite attendance, the conference lived up to its theme, "Champions of Health Unite." This makes HIMSS — without a doubt — the best place to catch

up on the latest from vendors, clients and various stakeholders. The Point-of-Care Partners (POCP) team used its time productively through face-to-face discussions, attendance at sessions and presentations, discussions with exhibitors and investment of a lot of shoe leather.

There are plenty of reports in the media on various aspects of HIMSS 2019. Instead of a meeting summary, we offer insights on what we learned in Orlando and how they might impact the health IT industry going forward. Here are our top eight takeaways from HIMSS 2019.



## 1. The feds' regulations drop overshadowed the published agenda.

Normally, we provide thoughts on the buzz generated by the keynotes and major announcements at the meeting. This year the buzz was about announcements of new proposed regulations from the Office of the National Coordinator for Health Information Technology (ONC) and the Centers for Medicare and Medicaid Services (CMS). They rolled out unexpectedly at the meeting, grabbing attention away from just about everything else. **ONC's proposed regulation** on interoperability and information blocking has been in the works for quite a while. It was long overdue, so we really weren't surprised when it debuted at HIMSS. Everyone had speculated for months about the details. We heard rumors that some vendors put activities on hold in their app store until the proposed regulation was issued. If that weren't enough, attendees were really caught off guard by **CMS' long-anticipated proposal** that notably would require qualified health plans to give Medicare beneficiaries access to their claims data through FHIR-based open application programming interfaces (APIs). This "proposal" essentially mandates that this must be done by 2020 by all health plans doing business with Medicare and Medicaid and through the federally facilitated exchanges. The announcements were a major focus. It appeared everyone spent most of their time discussing the proposals and guessing about their contents and impacts, since nobody had the documents in advance or the time to read them at the meeting. The rules drop also overshadowed other big announcements that were made. An example is the Department of Veterans Affairs (VA) joining forces with Apple to make health records available via iPhones to more than 9 million patients in the VA system by this summer. [\(Click here for our thoughts on the two proposals and their impacts.\)](#)

## 2. Accessibility and control of patient data were prominent topics.

This continues a theme launched last year by the federal government when Seema Verma, who heads CMS, used her 2018 keynote to announce two initiatives: **MyHealthEData** and Blue Button 2.0. This year, she introduced the proposed regulation on sharing patient data through APIs, as described above. This continues the administration's ongoing emphasis on providing data and technology to patients so they can control and direct their own health care. (As an aside, this message, delivered by the keynote panel speakers as what some perceived as a scolding to the electronic health record vendors was received incredulously by the au-

dience of health IT vendors, who were focused more on their provider client base and less on patients.) Also, many technical possibilities for providing data to patients were showcased at sessions and exhibits. There also were calls by the American Medical Association and others for making such information useful and understandable to patients, who cannot act on information they don't understand.

## 3. Artificial intelligence (AI) replaced big data.

We heard a lot at HIMSS about AI. It has replaced big data – not apparently a dead term – as a HIMSS buzzword, subsumed as a concept under AI, which has evolved as an umbrella term having multiple meanings to many people. For example, people talk about good, old-fashioned decision support but are coating it with an AI overlay. It seems like something new but is still clinical decision support (albeit more precise) at the end of the day.

## 4. APIs took center stage. The new regulations from ONC and CMS have turned 2019 into the year of the API.

Through regulations, standards and technology, there is the expectation that a (free!) API ecosystem will be created for health care. There was a lot of hype at HIMSS about that and the problems it could potentially solve. That said, APIs are not the end all and be all. There are still many details to be thrashed out to make them available and useful including how vendors will recoup their costs while not placing themselves at risk for information blocking. While an API is a recipe for ways to interact, developers still must go through a certification process before their apps can be connected to an electronic health record (EHR). Still to be determined is how developers of certified health IT will "recover costs reasonably incurred" with implementing APIs.

## 5. A focus on the practical. Aside from the hype surrounding APIs and AI, practicality was the focus of many sessions and exhibits.

Problem solving is the name of the game. We saw that with the Health



Level 7 (HL7) Da Vinci Project's emphasis on use cases that solve real business problems. Other sessions, such as Humana's "Payer Insights to the Provider at the Point of Care," focused on blocking and tackling opportunities to use health IT to deliver data through EHRs to mitigate provider frustrations and make clinical data actionable.

**6. Fast Healthcare Interoperability Resources (FHIR). FHIR was everywhere at HIMSS. It's required under the ONC and CMS regulations mentioned previously.** The ONC rule looks to promote the adoption of APIs using FHIR, while the CMS rule will hold qualified health plans accountable for using FHIR-based APIs to give Medicare beneficiaries access to their claims data. FHIR also was the basis of many innovations in the exhibit hall and "Interoperability Showcase." A couple of other announcements slipped under the radar. The first is the set of 15 FHIR resources that health IT modules must support for ONC certification. These are known as the **API Resource Collection in Health (ARCH)**. CMS' Verma also **announced** a FHIR-based bulk data access draft specification project but didn't offer details. The project is aimed at making it easier for accountable care organizations to retrieve Medicare Parts A, B, and D claims data for their beneficiaries. It's clear that FHIR isn't a flash in the pan and the obvious government backing of the standard will further drive its accelerated adoption. As a result, stakeholders will need to scale their FHIR knowledge and expertise quickly to meet surge in demand. This also means that other standards development organizations (SDOs) will have to collaborate with HL7, FHIR's parent SDO, to align standards as use cases evolve for various kinds of health data exchange.

**7. Da Vinci made its mark. The Da Vinci Project for which POCP is the project management organization, really had a big showing at HIMSS.**

This new private-sector initiative is developing a rapid multi-stakeholder process using FHIR to address value-based care data exchange use cases between payers and providers. Da Vinci's use cases address real business problems and interoperability, as highlighted in demonstrations at the Interoperability Showcase. Different payers were rotated through to show how transactions can flow successfully among different stakeholders. Da Vinci also was highlighted by payers, providers, and ONC and CMS representatives at various sessions, including sessions moderated by POCP's **Jocelyn Keegan, Da Vinci project manager.**

However, Da Vinci's momentum is best exemplified by being singled out by name in the **proposed CMS rule** including specific mention of Da Vinci's *Coverage Requirements and Documentation Rules Discovery* use case and a direct statement that encourages all payers to align with the Da Vinci Project "to build an ecosystem that will allow providers to connect their EHRs or practice management systems and efficient work flows with up-to-date information on which items and services require prior authorization and what the documentation requirements are for various items and services under that patient's current plan enrollment."

**8. There were few new EHR vendors. Normally, HIMSS is a place for new EHR vendors to strut their stuff.** The cheap seats on the fringes of the exhibit halls are usually chock full of new entrants into the EHR market. Not so much this year. We wonder if this is indicative of the consolidation that has occurred in that market, the expense of attending HIMSS or both. We also wonder if it's because the grab for EHR customers is over, so vendors are focusing on how to optimize revenue and provide more value to users.

That said, we saw some vendors focused on the long-term and postacute care market. These sites of care have their own specific health IT needs and challenges. Addressing them is an emerging area that we can expect to see more about as 2019 rolls on. •

*The POCP team was actively engaged at HIMSS and it was our best year yet. What we have reported here is a drop in the bucket. Want to know more? Reach out to me at [tonys@pocp.com](mailto:tonys@pocp.com).*

# 3 Part 3: 10 Thoughts About the New Proposed Rules from ONC and CMS

By *Point-of-Care Partners Team*



The federal government surprised most of us with the launch of two major proposed rules the day before the recent annual meeting of the Healthcare and Information Management Systems Society (HIMSS) in Orlando.

The Office of the National Coordinator for Health Information Technology (ONC) issued a **proposed regulation** on interoperability and information blocking. Many provisions were in response to requirements from the 21st Century Cures Act. The Centers for Medicare and Medicaid Services (CMS) issued a **related pro-**

**posal** concerning various aspects of interoperability. Both carry out the administration's goals of promoting patient-centric care and helping patients become more informed consumers of health care through access to their data. The proposals are far-reaching and will have significant impacts on all sectors of health care when they are implemented.

There are several reviews of the regulations out there. Here are 10 thoughts we have:



## 1. The real question on information blocking is

**“How will it be enforced?”** Publicly, we have **made the point** that if there’s a will to share information, we can find a way. In a free market society, that means having a business case. That is apart from us/patients, of course, who should have access to our own data as we either own it or are paying for it in our co-payments and premiums.

We’re starting to hear ONC talk about business case; however, in the 21st Century Cures Act, Congress charged ONC with addressing “information blocking” and it is meeting that challenge. The ability to exchange information will be part of the certification process for electronic health records (EHRs). ONC will publish the names of violators and a \$1 million fine will be imposed by the Office of the Inspector General. That said, ONC recognizes there are legitimate reasons to block information and lists **seven exceptions**. Some stakeholders are concerned about the definitions, however, arguing that they could cause more harm than good.

It will be interesting to see how this is enforced. Like most violations, it’ll probably come down to someone turning in an offending company.

**2. Payers must make data available through FHIR APIs.** Both proposed rules call for use of open application programming interfaces (APIs) based on the Health Level 7 (HL7) FHIR (Fast Healthcare Interoperability Resources) standard. Many EHRs already have developed APIs using FHIR, but it’s now part of the certification process. Interestingly, by 2020, payers (doing business with Medicare and Medicaid and through the federally sponsored health exchanges) must make data available to patients, providers and other payers (with approval from the patient), building on the myhealthdata initiative and BlueButton 2.0.

It’s worth noting that EHRs that have developed APIs have entire programs and app stores, meaning they certify those to whom they grant access and in many cases charge them a fee. While patients should surely have access to their data – and be able to direct it to a provider – one has to wonder how payers will grant this access.

**3. If you’re not involved in HL7, you’re missing out.** We’ve noticed more and more ONCers at HL7,

including the National Coordinator for Health Information Technology, Dr. Rucker, himself. CMS also got on the HL7 bandwagon by specifically mentioning the **Da Vinci Project** in its proposed rule, so it’s no surprise to us that ONC’s proposed rule requires an expanded list of standards that must be used and which vendors (technology suppliers) will have to accommodate to achieve ONC certification. These mostly HL7 standards include:

- **FHIR.** This is the standard for APIs. The proposed rule mandates use of Release 2 (aka **FHIR DSTU2**), which is five years old. That’s the “floor.” The proposed rule acknowledges the recent rollout of FHIR Release 4 and says that it may be used by agreement. There’s also a **Standards Version Advancement Process** that allows developers to choose from among the versions of standards and implementation specifications listed in the regulation or ONC-approved newer versions.
  - **ARCH.** This new government acronym (as if there aren’t enough) is the set of 15 FHIR resources that health information technology (health IT) modules must support for ONC certification. These are known as the API Resource Collection in Health or **ARCH**.
  - **The Argonaut Data Query Implementation Guide.** **The Argonaut Data Query Implementation Guide** is based on **FHIR DSTU2**. It documents security and authorization, data element query of the ONC Common Clinical Data Set, and document query of static documents.
  - **SMART.** **SMART** is one of the suites of FHIR standards. The SMART App Launch Framework connects third-party applications to EHR data, allowing apps to launch from inside or outside the user interface of an EHR system.
  - **United States Core Data for Interoperability (USCDI).** As the country moves toward value-based care, data beyond those included in the **Common Clinical Data Set (CCDS)** are needed. ONC proposes replacing CCDS with the USCDI standard for certification purposes. The USCDI has a wider number of data classes and elements than the CCDS. Examples include a number of clinical notes, pediatric vital signs and patient phone numbers and addresses.
- 4. Focus on standards but not versions.** The notice of proposed rulemaking (NPRM) specifies a myriad of required standards, some of which are listed above. But ONC



stops short of specifying standards to be used for certain requirements, such as the mandated Export Format. ONC also does not specify a version of FHIR to be supported by APIs. The proposal is to allow technology suppliers flexibility to evolve versions as the technology advances. Not mandating a particular version makes sense because that would require ongoing rules making as versions change. The unintended consequence, however, could be a free-for-all with different vendors supporting different versions. It will be challenging enough for technology suppliers to support the mandated APIs and standards. That challenge will be multiplied if multiple versions of standards need to be supported as well.

We believe the required support of all these standards and versions perpetuates the need for clearinghouses. Not everyone

The proposed rules focus on EHI, which is a wider umbrella than the “protected health information” we’ve used for years in implementing provisions under HIPAA. Encounters data, adjudicated claims, directory information and clinical data can now be added.

Another part of the proposal focuses on encryption of authentication credentials and multifactorial authentication, while another updates certification criteria for data segmentation and consent management. Data security and privacy remain top of mind for ONC; as the scope of data widens to EHI, granularity of consent management increases proportionally.

- 7. The rules for certification could change in some key ways.** ONC’s proposed rule would update the existing 2015 edition certification criteria to ensure certified health

Even seemingly small things like replacing the CCDS with the USCDI is not an insignificant task.

will be able to transition to new standards at once due to the breadth of such an undertaking and the large number of distributed systems. There will be a need for translation by clearinghouses for some time into the future.

- 5. Scope of electronic health information (EHI).** The NPRM defines the data required to be available via interface and for export as “the health IT’s entire database, including but not limited to clinical, administrative and claims/billing data.” This dramatically increases the scope of data to be exposed to APIs. Within many health IT systems, administrative and billing data are managed by a separate practice management system, sometimes from a different health IT vendor. The intent of the NPRM is clear, but is the requirement to include administrative and billing data out of scope for rules focused on clinical data?
- 6. We have a window into HIPAA 2.0.** For years, we’ve been awaiting anticipated changes to Health Insurance Portability and Accountability Act (HIPAA) privacy and security provisions and we know they’re working on them.

IT systems can: (1) send and receive EHI in a structured format, (2) make that EHI available without “special effort” through the use of APIs, and (3) export a single patient’s or multiple patients’ EHI from the health IT system to a location designated by the patient(s). This will be accomplished largely through use of new standards (see above). EHR certification will be an ongoing process, but technology suppliers can update their software more freely (instead of waiting for new regulations). ONC also proposes updating the 2015 edition by not only identifying a **number of criteria** for removal but by revising and adding new certification criteria that would establish the capabilities and related standards and implementation specifications for the certification of health IT. This may seem like a positive move, but any necessary changes to be made will require technology suppliers to modify software, seek recertification and then upgrade customers. Even seemingly small things like replacing the CCDS with the USCDI is not an insignificant task.

**8. Who pays for the data?** Many entities are naturally interested in the **fees that might be charged** by API technology suppliers and data providers. The proposed rule places a strong focus on patients' ability to access all their EHI (structured and/or unstructured) at no cost. While it sounds straightforward, there are some gray areas.

THE NPRM proposes that "API technology suppliers can recover the full range of reasonable costs associated with developing, deploying and upgrading API technology" and that "API technology suppliers be able to recover these costs and earn a reasonable return... so that they have adequate incentives to make continued investments in these technologies." The NPRM is not entirely clear as to what technology suppliers may charge. Most will need to readjust their business model to comply with the proposed rules, similarly as for payers and other data sources. We look forward to the final rule to provide greater clarity – and hope that API activity doesn't stall while we await the final rule.

**9. Admissions, Discharge and Transfer notification gets codified.** CMS is proposing that Medicare-participating psychiatric and critical access hospitals be required to send electronic notifications to providers and other facilities whenever a patient is admitted, discharged or transferred. This requirement will be important to EHRs serving hospitals. The requirement also would be included in Medicare's conditions of participation, which have met strong opposition from the hospital industry and some who feel it doesn't go far enough and should also include emergency visits.

**10. Food and Drug Administration (FDA) Digital Software Precertification Program.** The NPRM proposes that software certification from this FDA program could be used to satisfy requirements for 2015 Edition certification. We agree there are efficiencies to be gained by not having two certifications with similar requirements.

This clause does give us pause, however. The complexity of FDA certification for IT products is strict and arduous. FDA certification of EHRs has been long talked about and dreaded by EHR vendors. We wonder if this move to harmonize the FDA program with the ONC program could be a precursor of things to come?

**Our initial take-away.** We applaud ONC and CMS for their thoughtful and diligent work in developing these proposed regulations. The amount of detail is mind-numbing and the industry has much to absorb. ONC, in particular, has been challenged in trying to implement the many provisions of the 21st Century Cures Act in a real-world manner. We hope that ONC and CMS will take into account the intended and unintended real-world consequences of the proposed rule to technology suppliers.

The short-term impact will be industry pushback — and a lot of it. There's a mountain of work to be done in a short while, which won't make a lot of folks very happy. At a minimum, we expect the proposed 2020 implementation date for many requirements to be a bone of contention, although some of the compliance dates have been extended to 24 months. We almost wonder if the NPRM isn't a starting point for negotiation, meaning the feds are asking for way more than they expect to get.

On the other hand, ONC recognizes the scope of lift required by the proposed changes for technology suppliers. The agency noted in a **recent blog** that about a third of certified health IT developers have published via the Certified Health Products List that they are using FHIR Release 2, as of mid-September 2018. Additionally, 51% of health IT developers appear to be using a version of FHIR and OAuth 2.0 together. It's been too soon since the two proposed rules were rolled out to fully gauge industry reaction and provide a guesstimate as to what may be eliminated or changed in the final rule based on comments.

In the longer term, we think the depth and breadth of implementing these proposals may be too much for many of the smaller EHRs in the market. In fact, Table 7 in ONC's Impact Analysis noted a 23% drop in EHRs being certified between 2011 and 2014. This proposed rule could increase market consolidation. •

*We'd be happy to help you understand the impact of the proposed regulations to your business and assist in developing comments. Comments are due by close of business on May 3rd. Reach out to me at [tonys@pocp.com](mailto:tonys@pocp.com).*