

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: Legislation, Proposed Rules and Part D Guidance to Affect Electronic Prescribing and EHRs



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

Congress, the Department of Health and Human Services (HHS) and the Centers for Medicare and Medicaid Services (CMS) were busy toward the end of 2018 in issuing guidance that will affect electronic prescribing (ePrescribing) and electronic health records (EHRs). The requirements were put forth as legislation, proposed rules or as a memorandum to Medicare Part D plan sponsors. We also understand that two additional regulations are waiting in the wings: one concerning electronic prior authorization (ePA) and the other concerning perceived information blocking by EHRs. In case you missed it, let's review.

**1. Legislation mandating ePrescribing and improved interoperability for prescription drug monitoring programs (PDMPs).** These are part of the bipartisan SUPPORT for Patients and Communities Act (also known as **HR6**). The bill mandates ePrescribing for controlled substances covered under Medicare Part D and ePA for all covered Part D drugs requiring prior authorization, effective January 1, 2021. Of note is that facsimiles, proprietary payer portals and electronic forms no longer comply with the law. The act also provides grant support to promote PDMP interoperability ([Click here](#) for our take on the legislation and how it impacts ePrescribing and PDMPs).

**2. Proposed rule to require use of the real-time benefit check for Part D by January 1, 2020.** CMS recently issued a proposed Part D rule under which plan sponsors must adopt a "real-time benefit check (RTBC) tool" by January 1, 2020. The draft regulation also indicates that if an RTBC standard is available in a year or so, it could be adopted by Part D for 2021. Point-of-Care Partners submitted extensive comments on the proposed rule, including the timeline, adoption of standards and other implementation issues. ([Click here](#) to read our comment letter.)

**3. Part D sponsors to provide an indication-based formulary design beginning contract year (CY) 2020.** According to **CMS**, indication-based formulary design is a formulary management tool that allows health plans to tailor on-formulary coverage of drugs predicated on specific indications. CMS says this gives health plans the ability to negotiate formulary coverage based on specific indications. That sounds promising, but there are many details to be fleshed out by stakeholders such as CMS, EHR vendors and standards organizations. Some of these unknowns may be addressed in the final rule:

- How will indication-based formulary information be displayed in EHRs?
- Will vendors have enough time to meet this implementation date?
- Are standards needed?
- How will payers develop the information?
- Will physicians understand it?
- And will physicians be required to use the data?

**4. Proposed rule to rescind two HIPAA administrative simplification standards.** HHS issued a proposed rule that would rescind the required use of the standard unique health plan identifier (HPID) and other entity identifier (OEID), which are part of the suite of standards named under the Health Insurance Portability and Accountability Act (HIPAA). These two standards are really oriented toward claims but payers and physicians have resisted using them. In fact, HHS has never taken enforcement actions for noncompliance with these two standards.



HHS’ action to rescind the two standards was taken in response to recommendations by the National Committee on Vital and Health Statistics in 2014 and follow-up input by stakeholders. According to HHS, the identifiers do not add value to electronic health care transactions and would be “costly, complicated and burdensome” to implement. In addition, the industry already has moved on, developing other ways to route claims and other HIPAA transactions using existing payer IDs. Comments are due February 19, so the final rule should be out in early summer. Payers and providers should be happy with HHS’ action, as they have opposed use of the standards for decades. In particular, providers were unhappy about the prospect of using HPIDs, noting that their health information technology systems were programmed to identify payers rather than plans. We wonder whether CMS’ action signals the need for HHS to update HIPAA standards and operating rules to reflect regulatory and market developments. Such a reboot would definitely have implications for ePrescribing as well as EHRs.

Speaking of HIPAA, the proposed rule does not address the elephant in the room: development of an electronic claims attachment standard under HIPAA, which has not

gained any real traction since 1996. Because of the inaction, the Affordable Care Act — passed in 2010 — included a provision requiring the federal government to issue a final rule by January 1, 2014 on standardizing electronic claims attachments. Needless to say, we’re still waiting but not holding our breath. The world has since moved on by creating standards to be used for certain types of attachments and incorporating information into EHRs. In addition, meaningful use requires 12 types of structured documents. It will be interesting to see if CMS takes up the challenge any time soon.

**5. Coming Soon.** As mentioned previously, we expect there will be a proposed rule from CMS for implementing ePA provisions of the SUPPORT for Patients and Communities Act. The Office of the National Coordinator for Health Information Technology has been expected to issue a rule on interoperability and information blocking as required by the 21st Century Cures Act. We will be writing about provisions and potential impacts, so stay tuned. •

*Point-of-Care Partners is closely monitoring these and other legislative developments. We’d be happy to walk you through them and help you with comment submission. Drop me a line at [tonys@pocp.com](mailto:tonys@pocp.com).*

# 2

## Part 2: 14 Health IT Game Changers



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

Every January, we publish our take on trends that will influence health information technology (health IT) in the coming year. For 2019, we are leaving it to others to prognosticate on the big ones, such as interoperability. Instead, we are taking a deeper dive into three areas where we see significant numbers of activities that will affect health IT in both the short and long term: electronic prior authorization (ePA), specialty pharmacy automation and value-based care.

### ePrior Authorization to Improve Medication Access

A growing number of medications require prior authorization (PA) before they can be dispensed. This is causing friction among providers, who are very concerned about the impact. In response, the industry has ramped up an electronic process to make PA submissions and responses faster and easier, prevent delays in treatment and find affordable therapies. Although the industry has been working on this since passage of the Health Insurance Portability and Accountability Act (HIPAA) in 1996, not much progress has been made. That should change in 2019. Here are six predictions for ePA:

**1. The industry will settle on a standard for the real-time pharmacy benefit check (RTPBC).** We include the RTPBC in the ePA section because our research shows that payers care about its ability to indicate the need for PA. ([Click here](#) to learn more about our study findings.) The RTPBC is a transaction that can be used in the ePrescribing process to provide patient-level formulary benefit details, such as patient out-of-pocket cost, drug alternatives and flags indicating that PA is required. It enables providers to make better informed medication choices at the point of prescribing and helps connect patients with the costs of their care. There



are currently three ways to facilitate an RTPBC: 1) proprietary or, via one of two standards, 2) National Council for Prescription Drug Programs (NCPDP) SCRIPT (ePrescription) or 3) Telecomm (the pharmacy claim). The industry won't be able to settle on one transaction standard; instead, it will be a compromise between the two.

**2. The implementation deadline for adoption of the RTPBC by Medicare Part D will be moved back from January 1, 2020.** The 2020 date was recently proposed under a regulation from the Centers for Medicare and Medicaid Services (CMS) entitled *Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses*, [CMS-4180-P](#). A one-year preparation period doesn't provide enough time for electronic health record (EHR) vendors and others to incorporate the transaction into their prod-

ucts and workflows. That's why we think the implementation date will be moved back. Regardless of when Part D adopts the RTPBC, it will drive adoption by the industry. ([Click here](#) to read our comment letter on the proposed rule).

**3. Substantial progress will be made on electronic medical prior authorization (eMPA),** a standardized electronic method for handling PAs for drugs, devices and procedures covered under a patient's medical benefit. We are participating in and tracking no fewer than a half-dozen separate, industry-led conversations to reduce or remove PA and provider burden.

**4. There will be experimentation and innovation regarding removing PA as a requirement.** Payers will publish more policies indicating that if certain conditions are relevant, PA *isn't* required. Others will try more "gold carding" where payers allow certain specialists that meet quality criteria to proceed with expensive procedures without PA. Payers' engines will get smarter, not requiring PA when it's a completely unnecessary action.

**5. We will see incremental progress to standardize and automate delegated ePA.** Delegated ePA is when payers and providers send prescription drug ePA requests to a third-party for processing; some vendors also manage PA for the drugs, devices and procedures covered under the patient's medical benefit. We think other rapidly evolving efforts in ePA will push stakeholders to get off the dime. So far, they have not been interested in stepping up.

**6. There will be greater integration of ePA in EHRs.** **Research** indicates that 73% of the EHR market in 2018 had already integrated an ePA solution. There are various flavors of these implementations, which will begin to coalesce around federal and state requirements. The recently enacted federal **opioid legislation** mandates ePA for Part D covered drugs by January 1, 2021. A standard was not named, but we predict CMS soon will name one. A growing number of states are creating and enacting ePA mandates. (Learn more about state ePA laws from our [Regulatory Resource Center](#).)

## Specialty Pharmacy Automation Will Improve Speed to Therapy

Specialty medications are high-cost, complex drugs with special handling and delivery requirements. They are primarily used to treat rare or chronic conditions. While retail pharmacies are highly computerized and most noncontrolled substances are prescribed electronically, specialty pharmacy has lagged behind and is ripe for automation. Specialty medications are generally still being prescribed using antiquated paper-phone-fax methods. This results in significant delays in getting needed medication to the patient. The speed-to-therapy lag is a major pain point for both patients and providers, which also has implications for the quality and safety of care. Here are four predictions for specialty:

- 1. Automated methods for enrolling patients in specialty programs will emerge.** NCPDP will draft a standard to automate patient enrollment forms, and other proprietary methods will emerge. This component of specialty pharmacy is key to ensuring that patients start off on the right foot and provide the payer and provider with the information needed to process and dispense/administer a specialty medication. Key stakeholders and standards development organizations are stepping up to make this happen.
- 2. Stakeholders will accelerate automating various facets of specialty prescribing,** such as patient outcomes reporting and requirements associated with Risk Evaluation and Mitigation Strategies (REMS). The Food and Drug Administration (FDA) requires REMS for specific high-risk medications. They include complex processes for educating patients and physicians about a drug's safety and various criteria prescribers must meet to ensure safe use, such as physician certification in order to prescribe the drug, patient enrollment in a central registry and restricted distribution of the drug to certain specialty pharmacies. Assessments and reports must be done periodically and provided to the FDA and the drug's manufacturer. Currently, this involves time-consuming, labor-intensive, paper-phone-fax based processes, which are ripe for automation.

- 3. The industry will finally grapple with solutions to definitively identify who owns coverage for a patient at the point of prescribing.** Currently, prescription drugs may be covered under the patient's pharmacy benefit, medical benefit or both. This also has implications concerning which pharmacy may fill the order. The lack of clarity results in frustration and expands time to therapy, which has implications for patient safety and quality of care.
- 4. A baseline study of speed to therapy will be conducted.** Key stakeholders who understand specialty prescribing will conduct a definitive, scientific baseline study of the speed-to-therapy lags associated with specialty prescribing. It will measure timeframes for prescribing, processing and receipt of medications as well as target areas for improvement.

## Value-Based Care Solutions Will Become Available in EHRs

How we pay for health care is undergoing a disruptive, fundamental shift. We rapidly are moving away from the traditional fee-for-service, pay-for-volume approach to one that pays for demonstrated value. EHRs and automated processes are the tools powering this change. Here are four predictions for value-based care.

- 1. The industry will double down on real-world solutions to help patients understand the true costs of their therapies.** The RTPBC is a start by exposing many facets of a therapy's actual costs to the provider and patient.
- 2. EHRs will increase availability of clinical decision support to better merge patient orders against real-world options.** This will help the physician make the proper choice for the appropriate patient at the correct time, thus improving speed to therapy and quality of care. It also will tell the clinician what documentation is needed, which will expedite the reimbursement process.
- 3. There will be an acceleration of efforts to shift the collection of quality-related information needed for value-based care into provider workflows in EHRs.** Ensuring that information is captured in workflow will be one way the industry will focus on

reducing burden. Another will be continued collaboration to ensure that better measurement is integrated and automated (prospective) for providers and payers powered by collaborations, like Da Vinci, funding Data Exchange for Quality Measures. Moving from large structured documents to discrete data points using Fast Healthcare Interoperability Resources (FHIR) will reduce work and increase trust in provider-sourced content for such issues as data provenance.

- 4. Payers will unleash patient health records, which will give clinicians a fuller picture of their patients' health and treatments across providers and sites of care.** Health plan records are an untapped silo of valuable information, the availability of which can improve care and outcomes by creating a more complete picture of a patient's care across all care providers. Work began in earnest in fall 2018 to begin to unleash payer claims and clinical data to care providers via eHealth record exchange.

**Looking Ahead.** Standards development and multi-stakeholder initiatives are key to advancing ePA, RTPBC, real-time medical benefit check and value-based care. NCPDP is actively working to refine and develop standards to advance widespread industry adoption of ePA and RTPBC while Health Level 7, through the **Da Vinci Project**, is actively rolling out use cases in support of value-based care data exchange. An example is **Coverage Requirements Discovery**, for which an implementation guide will be published Q419. This use case will enable providers with a FHIR-based application program interface to discover in real time specific payer requirements that may affect the ability to have certain services or devices covered by the responsible payer. •

**Conclusion.** *The Point-of-Care Partners team is actively engaged in all of these areas. What we have reported is a drop in the bucket compared to what is planned, what is in progress and what is to come. Want to know more or become involved? Reach out to me at [tonys@pocp.com](mailto:tonys@pocp.com).*

# 3 Part 3: What Version 4 of FHIR Standard Means for Adoption and Innovation



By **Jocelyn Keegan**,  
Payer Practice Lead



FHIR's adoption is snowballing... Approximately one-third of certified health IT vendors are using FHIR and nearly half of related developers appear to be using a version of FHIR in combination with another standard. The availability of R4 is expected to accelerate and increase adoption.

Updates of standards underlying health information technology (health IT) happen all the time and usually are not newsworthy events outside of the technical community. However, there are exceptions to the rule. Now comes the latest version, or release, of the FHIR (Fast Healthcare Interoperability Resources) standard from Health Level 7 (HL7). It's a big deal because of what **Release 4 (R4)** does and what it is expected to do. In short, R4 will deliver greater stability, a broader range of maturity and ensure a more stable shelf life for organizations implementing it. This translates to more certainty, confidence on the specification and a wider range of organizations willing to adopt it.

**What is FHIR?** FHIR burst on the scene almost 5 years ago as a draft standard that leveraged existing, well-established Web-based standard concepts with a tilt toward support for clinical data exchange. It empowers organizations to leverage agreed upon, consistent data formats and attributes (known as resources) to build an **application programming interface (API)** to power data exchange across systems. FHIR found its initial home as the standard leveraged by electronic health record vendors to share clinical data required by meaningful use. FHIR can be and is used as a stand-alone data exchange standard as well as in partnership with existing, widely used standards.

FHIR's adoption is snowballing. The Office of the National Coordinator for Health IT - **is tracking progress**. Approximately one-third of certified **health IT vendors** are using FHIR and nearly half of related developers appear to be using a version of FHIR in combination with another standard. The availability of R4 is expected to accelerate and increase adoption.

This rapid growth is powered by the simplicity it brings to bridge long-standing interoperability gaps across the many disparate systems used today to exchange clinical data between payers and providers and providers and providers. We see the R4 release as the engine to drive the data exchange needed for value-based care.

**The Da Vinci Project** — a collaborative stakeholder group of which I am co-lead—is an example. The group has developed a rapid-cycle, multistakeholder process to leverage FHIR's resources and technological frameworks to unleash the data needed for value-based care delivery to succeed on a national scale.

**A dive into the details.** So, what's new about R4? FHIR Release 4 and the base platform of the standard have passed a normative ballot submitted to the American National Standards Institute (a national accrediting body) for the “normative” designation. What does this mean? On the technical side, this means that future changes should be backward compatible so applications that implement the normative sections of R4 can stay conformant with the standard and not have to reinvent products and services. Translation: if you write to this, future updates and improvements won't break your code. Significant parts of the standard were changing before being designated as normative. In fact, more than 3,000 edits and updates were made to this most recent version alone.

A significant portion of R4's elements have received the normative designation. They include the resources that determine how to use terminologies, how to build APIs, as well as data formats and elements that define how to recognize a patient and record patient observations. For the more technical among us, those fully baked aspects are:

- The RESTful API, the XML and JSON formats, and the basic datatypes
- The Terminology layer (CodeSystem and ValueSet)
- The Conformance Framework (StructureDefinition and CapabilityStatement)
- The key resources Patient and Observation

**The impact of R4.** In short, R4 will ensure a longer-lasting, more stable platform and greater interoperability. It allows vendors and health IT users to create and implement FHIR-based applications more consistently and uniformly, without worries of near-term obsolescence due to a major change in the standard. Many players will maintain software across the early versions, such as version 2, as they migrate new and existing assets up to this normative version.

Industry experts are waiting to see if the normative designation will be one more step in making FHIR the go-to building block for new and existing clinical workflows. This will dovetail with efforts to improve interoperability as required by the 21st Century Cures Act.

**Moving forward.** To be sure, all aspects of FHIR R4 will evolve and other elements will be added to the normative designation. HL7's **FHIR Maturity Model** helps implementers understand how the various parts of the standard are advancing through the standards development life cycle. •

*Want to know more? I'd be happy to help. Reach out to me at [Jocelyn.keegan@pocp.com](mailto:Jocelyn.keegan@pocp.com).*