Meeting Notes
Health Information Technology Advisory Committee
Interoperability Standards Priorities Task Force
June 11, 2019, 10:00 a.m. – 11:30 a.m. ET
Virtual

The June 11, 2019, meeting of the Interoperability Standards Priorities (ISP) Task Force of the Health IT Advisory Committee (HITAC) was called to order at 10:00 a.m. ET by Lauren Richie, Designated Federal Officer, Office of the National Coordinator for Health IT (ONC).

Lauren Richie conducted roll call.

Roll Call

MEMBERS IN ATTENDANCE

Kensaku Kawamoto, co-chair, University of Utah Health
Steven Lane, co-chair, Sutter Health
Tamer Fakhouri, Member, One Medical
Cynthia Fisher, Member, WaterRev, LLC
Valerie Grey, Member, New York eHealth Collaborative
Victor Lee, Member, Clinical Architecture
Leslie Lenert, Member, Medical University of South Carolina
David McCallie, Jr., Member, Individual
Clement McDonald, Member, National Library of Medicine
Terrence O'Malley, Member, Massachusetts General Hospital
Ming Jack Po, Member, Google
Ram Sriram, Member, National Institute of Standards and Technology
Sasha TerMaat, Member, Epic

MEMBERS NOT IN ATTENDANCE

Ricky Bloomfield, Member, Apple
Tina Esposito, Member, Advocate Health Care
Anil Jain, Member, IBM Watson Health
Edward Juhn, Member, Blue Shield of California
Arien Malec, Member, Change Healthcare
Raj Ratwani, Member, MedStar Health
Mark Roche, Federal Representative, Centers for Medicare and Medicaid Services (CMS)
Sheryl Turney, Member, Anthem Blue Cross Blue Shield
Andrew Truscott, Member, Accenture

Scott Weingarten, Member, Cedars-Sinai Health System

ONC STAFF

Denise Joseph, Public Health Analyst, ONC ISP Task Force Lead
Lauren Richie, Branch Chief, Coordination, Designated Federal Officer

Call to Order

Lauren Richie turned the meeting over to the co-chairs.

Review of Agenda

Steven Lane reviewed the robust agenda and noted that several presenters have been asked to share their expertise during today's discussion. He turned the meeting over to the first presenter, Margaret Weiker.

Current and Anticipated Standards Challenges

Margaret Weiker, National Council for Prescription Drug Programs (NCPDP)

Margaret Weiker, Director of Standards Development, provided an overview of NCPDP. NCPDP has a formulary and benefit standard that is widely used and is mandated for use under Medicare. The formulary and benefit standard provides a means to communicate benefit information to prescribers via technology vendor systems.

A formulary is a list of products that are eligible for prescription by the payer. Products are given a formulary status and preference level. Each product is assigned the following:
- Formulary Status
- Preference Level
- Coverage Information
- Copay Information
- Therapeutic Alternatives

Margaret Weiker noted that each of these categories is complex; for example, co-pay information, which describes the cost to the patient, provides multiple ways to describe this (e.g., flat co-pay, percent, combination, tier, min/max, days supplied, minimum allowances, quantity-based co-pay). Formulary and benefits data is typically sent as a flat file by the payer to vendor partners for incorporation into their systems, e.g., EHRs.

She also shared that there is a telecommunication standard that is widely used.
- It is the standard format for transactions between a pharmacy and insurance carrier. It incudes patient pay amount, prior authorization and information reporting.
- The telecommunication standard version D.0 can provide information regarding provider networks and coverage gaps.
- The telecommunication standard version F2 is in the queue to be adopted. This will require an NPRM from HHS.

- o Additional patient pay components are added into this version, due to the changing landscape of products and offerings.

NCPDP is bringing the Real-time Prescription Benefit Standard to ballot in August.
- o It was developed to facilitate the ability for the pharmacy benefit managers (PBM) to communicate patient-specific formulary and benefit information to providers in real time.
- o It contains coverage indicators, alternate pharmacies, maximum age, and detailed alternative product information.

Margaret Weiker identified regulatory challenges regarding the following rules:
- Centers for Medicare and Medicaid Services (CMS) 4180 Final Rule
  - o In the proposed rule, CMS encouraged plans to promote full drug cost transparency by showing each drug's full negotiated price, in addition to the beneficiary's out-of-pocket cost information. Ultimately, CMS did not mandate in the final rule as the majority of commenters opposed inclusion.
  - o NCPDP has decided to include this information conditionally; therefore, the field will be available, even though it was not mandated by CMS.
- Office of the Inspector General (OIG) HHS Proposed Rule (file code OIG–0936–P)
  - o OIG has recommended the removal of the safe harbor protecting rebates. NCPDP is waiting on the final rule

Consumer-Facing Real-time Pharmacy Benefit Check
Ryan Howells, Creating Access to Real-Time Information Now (CARIN)

Ryan Howells noted that he helps lead the CARIN alliance which is a group of 50 multi-sector organizations working to make sure that patients can have digital access to their health information via application programming interfaces (APIs) using third-party applications (apps).

He noted that the CARIN Alliance is working on creating a Fast Healthcare Interoperability Resources (FHIR) implementation guide (IG) that allows for a consumer-facing real-time benefit checks leveraging the NCPDP standard.

He referenced the Patient Right to Know Drug Prices Act, which provides the ability for a patient to be told whether the formulary or cash price is less. He noted that historically there had not been a way to operationalize this, but they are leveraging the NCPDP real-time prescription standard work. This standard will be mapped to a FHIR API standard so that third-party apps can aggregate information at the point of prescribing and dispensing. CARIN is hoping that patients and providers will be able to have the same information simultaneously via their HIT in order to make informed decisions about prescribing. This also includes the ability for patients to see their cash price alternative.

Ryan noted that CARIN is using an open API from GoodRx. There are currently 10M individuals on this platform. 50% of the time the cash price proves to be less than the formulary price.

He also noted that CARIN had received approval from Health Level Seven (HL7) to move this work to ballot, likely in February. This work leverages the work that NCPDP has done.

Current and Future Functionality; Standards Needs
Andrew Mellin And Ryan Hess, Surescripts

Andrew Mellin provided an overview of Surescripts and then reviewed the process Surescripts uses to support prescribers. He noted that multiple sets of data come together to support the provider at the point of care, including the following:

- Eligibility and formulary information
- Real-time prescription check that is focused on giving the provider as precise information as possible.

Ryan Hess reviewed the real-time prescription benefit which:

- Does outreach to relevant PBM or health plan
- Provides details for prescribing in real-time
- Aims to display results within two seconds which provides an opportunity for a discussion with the patient at the point of prescribing

Ryan Hess reviewed the data Surescripts delivers to the provider that includes:

- Coverage alerts
  - Channel options (e.g., retail, mail order, and specialty
- Member pay details
- Alternative drugs (with a price associated with it)

Ryan Hess reviewed the features Surescripts has in development, which includes:

- Real-time benefit checks
  - Rolling out for additional PBMs and health plans
  - Real-time to other market segments (e.g., pharmacist)
  - Integration of additional price information
- Patient matching and medical drug matching
- Electronic prior authorization
  - Clinical data extraction from the EHR
  - Expansion into medical drug prior authorization

Current and Future Use Cases; Standards Needs
Viet Nguyen, Da Vinci Project

Viet Nguyen noted that his role with Da Vinci is to help shepherd use cases through the HL7 process. The Da Vinci project was formed under HL7 and includes major payers (including CMS), providers, and health IT vendors. The community identifies use cases to support payer-provider data exchange in support of value-based care.

He noted that Da Vinci develops project scope statements and brings them through the HL7 process for FHIR implementation guides. He provided an updated to the ISP TF regarding current progress.

- He noted work on the FHIR representation of drug formulary data. The use case has taken the formularies released through the qualified health plans and represented through FHIR resources for use by APIs.

Discussion

Steven Lane asked each presenter what is needed to move to the next level.

- **Margaret Weiker** commented that having the final rule come out soon would be helpful especially if CMS commits to naming the real-time benefit standard in the rule.
- **Ryan Howells** noted his support for Margaret Weiker's comments. He commented that the CARIN Alliance would also like to see the patient named in the real-time benefit final rule. He expressed hope that, as the standard is finalized, there will be opportunities to incorporate the patient's right of access, ensuring receipt of the same information as the provider. He noted that he was concerned with losing the idea of the cash price component, but there is a need to find opportunities to work together with industry and public sector partners.
- **Surescripts** stated that there is a need to reinforce the utilization of standards by health plans, PBMs and providers. There needs to be broad adoption of the NPDP standards as well as inclusion of the Medical Drug Coverage as a part of pharmacy benefits.
- **Viet Nguyen** agreed with the previous speakers around shared standards that use open APIs. He noted a need for additional controlled medical vocabulary. He noted that some concepts are not consistent across plans (e.g., 30 days vs. a month dispense, retail vs. mail order pharmacies, co-pay options) and there is a need to have information directly comparable.

Steven Lane asked each of the presenters to share their wish list, including specifics (e.g., standards, names of appropriate rules, implementation guides).

Sasha TerMaat asked about the work being done by HL7 FHIR, and she questioned if the resource is patient specific or just general plan information.

- **Viet Nguyen** responded that he believed it was general plan information, but he noted he is not the author.

David McCallie asked for a diagram depicting the sources and controls of the data and how the standards are used to help that data flow. He noted that it isn't that there are missing standards, but instead, there seem to be overlapping standards and unclear data flows. He commented that there are blockers based on regulatory language and that is something that can be brought back to HITAC, but he suspected that what hasn't been heard are the business blockers. He questioned whether market failures are prohibiting progress and asked who will host the FHIR APIs.

- **Viet Nguyen** commented that the DaVinci work is intended to be used by insurers and there will need to be implementation considerations around architecture.
- **David McCallie** commented that GoodRx seems to have done this very well and may be a good presenter in the future to understand how they get their data and how they solved some of these problems.

Terry O'Malley thanked the presenters for the informative discussion. He noted that there is an issue around coordination. He questioned if there is an understanding of the end goal and questioned what is in place to get there.

- **Margaret Weiker** noted that there is coordination across organizations:
  - NCPDP coordinates with the CARIN Alliance
  - NCPDP is participating in the DaVinci project around formulary and API
  - Surescripts participates in NCPDP's task groups

- **Ryan Howells** echoed Margaret's comments noting that they are all working closely to do work together and not overlapping. While it appears that some of this work is overlapping, there are individual workstreams.
- **Ryan Hess** volunteered to create a diagram.

Cynthia Fisher noted her support for hearing from GoodRx to help catapult things further, from an innovation angle, this would be helpful. She commented that creating open standardized architecture is important so innovators can have access to the data. She questioned how HITAC makes sure that the data flows are accessible without restriction. She also asked Margaret Weiker to clarify regarding safe harbor.

- **Margaret Weiker** commented that OIG issued the *Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees* (file code OIG–0936–P). She noted that the goal of the proposed rule is to have rebates be more consumer facing and be applied to the consumer's out of pocket expense versus the pharmacy or payer.
- **Ryan Howells** noted that Da Vinci and CARIN are trying to do their work using open APIs which anyone can use. When a patient goes to the pharmacy and pay cash the problem exists that payers don't know if there is medication adherence. It is difficult to capture some of the information. He noted that regarding GoodRx, they have PBMs to access the information, but this information has been around for quite some time. There are health plans that have put this into production already. NCPDP is balloting the standard so that it is more formalized. The hope is that there will be broad adoption of an open standard.

David McCallie noted that an API could be open, but the service that hosts it can charge. He commented that the real question is what are the business blockers keeping this information from flowing. He also commented that if no one is willing to serve the data for a reasonable price, it won't be useful. He noted the need to understand where incentives could possibly help increase the flow of information.

- **Ryan Howells** commented that ONC and CMS have made it clear through recent rules that patient access to their information should be free and available.
- **Cynthia Fisher** agreed that it would be helpful to understand what is preventing data from flowing.

Terry O'Malley asked if there are additional information needs that would be helpful.

- **Viet Nguyen** noted there are controlled terminology needs, e.g., increased specificity around drug classes. He commented that a lot of terminology is healthcare focused, and patients need to understand how to interpret this information. He volunteered to write this up and share with the ISP TF.

Ken Kawamoto asked what the market/business issues are.

- **Margaret Weiker** responded that regarding standards, NCPDP provides the highway. She noted that she could not answer why this isn't being populated by payers and PBMs. Also there is regional variation.
- **Ryan Hess** responded that the biggest driver is that health plans and PBMs have different goals. He noted that some are focused on total spend, others prior authorization avoidance, others on drug utilization review; it is not one size fits all. He commented that it is difficult to find agreement on what information is most important to the patient.

Lauren Richie opened the lines for public comment.

Public Comment

Shelly Spiro commented that she is the director of the Pharmacy Health IT Collaborative, which is an active member of NCPDP. Her organization worked on several projects, in collaboration with NCPDP and HL7, especially around the Pharmacist Electronic Care Plan. She noted these are important for pharmacists, especially those involved in value-based payment models. She wanted to make the ISP TF aware that pharmacists provide clinical services and are working on standards to make sure that information is codified to measure outcomes from pharmacist encounters. This also includes information to make sure that the patient can afford the medications they are taking and the patient's social determinants of health are taken into account when caring for the patient.

COMMENTS IN THE PUBLIC CHAT FEATURE OF ADOBE

Sasha TerMaat: Is the FHIR resource a patient-specific check or just general plan info? David, do you think that what GoodRx has done is significantly different from what EHRs have done incorporating the features Surescripts offers? It seems similar to me, except with different users and focusing on cash prices rather than insurance prices.

David McCallie: I'm thinking of the consumer-facing services - finding best local price, sometimes where cash is less than co-pay, etc.

Sasha TerMaat: Yes, okay, that makes sense. I didn't want to under-value the other work that's also going on.

Next Steps and Adjourn

Steven Lane thanked all of the presenters and noted that the next meeting will be on June 25, 2019 at 10:00 a.m. ET.

The meeting was adjourned at 11:30 a.m. ET