Health Information Technology Advisory Committee

Electronic Prior Authorization RFI Task Force 2022 Virtual Meeting

Meeting Notes | February 10, 2022, 10:00 a.m. – 11:30 a.m. ET

Executive Summary

The focus of the Electronic Prior Authorization RFI Task Force 2022 (ePA RFI TF 2022) was to continue the work of the task force. The TF reviewed its work plan and the Request for Information (RFI) on Electronic Prior Authorization Standards, Implementation Specifications, and Certification Criteria published by ONC on January 24, 2022. The Da Vinci Project presented its implementation guides (IGs). Members reviewed comments on a working document and provided feedback.

There were no public comments submitted by phone, but there were several comments submitted via the chat feature in Zoom Webinar.

Agenda

10:00 a.m.	Call to Order/Roll Call
10:05 a.m.	Welcome Remarks, Review of Plan
10:15 a.m.	Da Vinci Project IG Presentation
10:35 a.m.	Working Document Review and Discussion
11:20 a.m.	Public Comment
11:25 a.m.	Homework and Next Steps
11:30 a.m.	Adjourn

Call to Order

Mike Berry, Designated Federal Officer, Office of the National Coordinator for Health IT (ONC), called the meeting to order at 10:01 a.m. and welcomed members to the meeting of the ePA RFI TF 2022.

Roll Call

MEMBERS IN ATTENDANCE

Sheryl Turney, Anthem, Inc., Co-Chair
Tammy Banks, Individual, Co-Chair
Hans Buitendijk, Cerner
Dave DeGandi, Cambia Health Solutions
Rajesh Godavarthi, MCG Health
Jim Jirjis, HCA Healthcare
Rich Landen, NCVHS
Heather McComas, AMA
Patrick Murta, Humana
Eliel Oliveira, Dell Medical School, University of Texas at Austin
Debra Strickland, NCVHS

MEMBERS NOT IN ATTENDANCE

Aaron Miri, Baptist Health

ONC STAFF

Mike Berry, Designated Federal Officer
Alex Baker, Federal Policy Branch Chief
Michael Wittie, Policy Analyst

Key Specific Points of Discussion

TOPIC: WELCOME REMARKS, REVIEW OF PLAN

Sheryl Turney and Tammy Banks, ePA RFI TF co-chairs, welcomed everyone and invited new TF members to introduce themselves:

- Patrick Murta is the Chief Interoperability Architect and Fellow at Humana. He provides strategy architecture to achieve integrated care delivery. Patrick has more than 22 years in healthcare IT and has served as co-chief architect of the National Coordinator's FHIR at Scale Task Force (FAST), a leader of the Da Vinci operating committee and architecture team, and others.
- Dave DeGandi is the Senior Interoperability Strategist at Cambia Health Solutions, and his technical expertise is in the design and implementation of distributed applications and systems integration. He has been engaged in the HL7 Da Vinci project since its beginning.

Sheryl reviewed the work plan for the TF and encouraged TF members to focus on offline work. She reviewed the agenda for the meeting and explained that the TF would present a progress report to the HITAC at its February 17, 2022, meeting. Tammy thanked everyone for attending and welcomed the presenter.

TOPIC: DA VINCI PROJECT IG PRESENTATION

Viet Nguyen, Technical Director of the HL7 Da Vinci Project, presented an overview of the HL7® Da Vinci Project Burden Reduction (CRD/DTR/PAS) and Clinical Data Exchange (CDex) Implementation Guides (IGs). He briefly shared the Da Vinci 2021 multi-stakeholder membership, which includes providers, payers, vendors, electronic health records (EHRs), deployment, and industry partners. This information was detailed in the Da Vinci Project presentation slides. He described the use case readiness of a variety of Da Vinci's IGs in terms of maturity and if they were referenced in/supporting Federal Regulation or aligned with expected Federal Regulation. Also, he explained the ongoing balloting process for these guides.

Viet presented three use cases (Coverage Requirements Discovery, Document Templates and Rules, Prior-Authorization Support) related to the business challenge of reducing the burden of prior authorization (PA). He described the status for each and their core capabilities, regulatory impacts, and implementer progress and stated that CMS will likely rerelease new regulatory information for these IGs this year. He detailed how the Coverage Requirements Discovery IG utilizes a Fast Healthcare Interoperability Resources (FHIR) technology called Clinical Decision Support (CDS) Hooks, which are initiated during the workflow for EHRs and provider back-office systems to reach out to payers. He also described how Documentation Templates and Coverage Rules IG utilizes FHIR application programming interfaces (APIs) in workflows programmatically. Anything that is missing from this process can be highlighted. Then, he explained how the functionality outlined in the PA Support IG supports the gathering of data around either X12 278 or X12 275 transactions, so data can be submitted as a FHIR operation at the endpoint (payers, another vendor, providers). This provides the opportunity to submit the FHIR application and real-time transactions, as well as to query if the education and response is not an immediate response from the payer. This improves transparency, reduces the effort for PA, leverages available clinical content, and increases automation.

Viet presented a description of a workflow depicting the example of PA for durable medical equipment (DME) and described how CDS Hooks support the steps in the flow. He defined the base FHIR technologies that support and can be leveraged by each of the three IGs discussed previously, and he described work Da Vinci has done on them during recent Hackathons. He added that they will soon publish the Clinical Data Exchange

(CDex) IG to automate processes for provider-payer and provider-provider clinical data exchange. These were all detailed in the presentation slides. He presented a depiction of the CDex workflow and defined the base FHIR technologies that support it, which were detailed in the presentation slides.

Viet provided an overview of Da Vinci's upcoming activities, including the balloting process that will occur in quarter one of 2022 and anticipated reconciliation and publication by quarter four of 2022. He stated that Da Vinci also plans to publish CDex in quarter 2022, including ongoing testing and feedback. A list of Da Vinci and FHIR-related references were included at the end of the presentation, and Viet invited TF members to review them and submit feedback/questions.

Discussion:

- Tammy stated that, though the workflows laid out by Da Vinci simplified the process, the activities they depict also occur in a variety of software packages beyond the EHR. She highlighted the following comments from the public Zoom chat:
  - Hans stated that though the slides imply that the EHR back-office systems directly interact with the payer, they do not indicate how this will flow with a SMART app or how intermediaries may fulfill certain capabilities, thus yielding a different configuration of interactions between EHR and payers. On the provider side, multiple health IT (HIT) applications beyond EHRs likely evolved from back-office systems from different HIT suppliers. How should we get the clarity to avoid certification taking too much of a monolithic or one model approach, rather than enabling a more flexible configuration approach reflecting the current environment?
    - Viet stated that Da Vinci recognizes that the term "EHR" is ambiguous, and they will need to create additional terminology modules within the EHR component that support the ability to send and receive the X12 and CPT codes and other PA activities.
    - Hans commented that a potential step could be better recognizing the boundaries between the components/interactions across HIT. Though the IGs have been working, greater specification is needed for certification. He discussed various examples.
    - Viet thanked him for his comments and invited EHR developers to bring feedback on configurations and challenges to Da Vinci to improve the IGs.
  - A TF member sent a question to Tammy to share that asked if Viet would address delegating the FHIR questionnaire completion from clinician to other practice staff, putting in the work queue to store initiated PA request for later completion? Do the IGs address that type of role-based workflow (non-provider versus clinician workflows)?
    - Viet responded that they are working on this with the EHR vendors and are trying to better understand delegation in the workflows.
    - Tammy asked if there is production implementation of the approaches Viet described, and he described a presentation in which Da Vinci members demonstrated their production-level capabilities to the community during a roundtable in January. Jocelyn shared a link in the public Zoom chat.
  - John asked Viet to comment on whether certification requirements for EHRs to support CDS Hooks and CQL might eliminate the need for EMR vendors to support multiple SMART on FHIR apps for every Payer/UM vendor.
    - Viet stated that this would facilitate the ability for the EHRs to do the functionality that is embedded in SMART on FHIR.
  - Hans commented that DTR does not clearly address how SMART on FHIR would gather the data from the source system. There has been consensus that FHIR US Core would be a starting point, beyond which various other techniques could be deployed until FHIR incorporates the data. The source system need not support CQL or Questionnaire responses rather have FHIR US Core-based to enable the SMART app to gather the data.

Will that be clarified in an upcoming version?

- Viet stated that US Core is already built into the expected functionality of EHRs and should be able to retrieve data using standardized US Core codes, terminology, and queries that are inherent in Observations or Medications.
- Hans stated that if the system is certified, it will retrieve data using SMART on FHIR, but if it is not certified, guidance will be needed.

- A TF member sent a series of questions to Tammy to share that asked about the use cases when supplemental data would be used and for clarification around when CDS is not meant for use within DTR to gather the supplemental data where the initial data is incomplete.
  - Viet responded that the "happy path" for DTR/the FHIR Questionnaire is that the central relationship of the provider-payer that defines the data needs is defined in advance via structured data, adjudication rules, and real-time response. He described how CDex is used to allow the payer to define any additional missing/supplemental data via FHIR queries. He described how CDex can be used to support a related use case, opportunities, and quality measures.
  - Tammy asked for more information on the scalability of the CDex model, and Viet described the relationships and support for PA, qualified health information networks (QHINs), health information exchanges (HIEs), and others, though he stated that generalizations would not be as accurate as evaluating a specific workflow.
  - Tammy summarized a variety of questions that were submitted that asked about the timeline to maturity for the IGs, and Viet responded that CDex is already being implemented (published content is ready for production/pilots, draft content can work), though further testing is needed. The same situation stands for the other IGs, though they are constantly being balloted and improved/matured incrementally. He encouraged everyone to help expedite the maturation process by participating in implementations and testing events.

- Rich submitted two comments:
  - The comments Hans shared regarding complexities in provider systems also apply on the payer side, in combination with the in-house and external business associate vendor systems.
  - Given that testing has been done, are there any very high-level preliminary results and particular categories of PA that work better than other categories?
  - Viet responded that situations in which the following are true go more smoothly: where the data are well structured and supported by US Core, vendors have maturity around CQL, and data can be used for adjudication for vendors and payers. More work must be done to automate traditionally "human-readable" beneficiary roles. He described some examples of an ideal future state that will use artificial intelligence (AI) and machine learning.
- Heather McComas thanked Viet for the presentation and new information and submitted several comments:
  - Providers/clinicians might be anxious that their administrative burden will increase due to the IGs. How can the new process closely match the current process in a physician's office?
    - Viet responded that he could sympathize with the concerns of clinicians, as he has been a practicing one. There may be a small burden around ensuring that documentation is available, but the goal for PA is to reduce the overall burden on the provider at the office and to reduce delays for patients.
  - Have Da Vinci workgroups discussed the delegation capacity and how transient data will be stored in the EHRs (or elsewhere) until a PA request is triggered?
    - Viet stated that EHR vendors must be brought together to define these needs and to do more testing.

- Tammy commented that the TF would forward any additional questions to Viet and asked him to expand on how the CDex IG could support attachments or alternative approaches.
  - Viet responded that CDex could be a viable approach to providing clinical data as attachments (referrals, FHIR bundles as attachments to claims) that are well structured in FHIR. They will allow the payer to receive them purely as FHIR resources in the workflow.
  - Tammy asked if this would be in an external database, and Viet responded that data elements would be defined in advance between all parties.

TOPIC: WORKING DOCUMENT REVIEW AND DISCUSSION

Tammy reviewed the most recent ePA RFI TF member comments from the TF's shared Google working document and described updates to the document. She invited members to share any missing comments, caveats, or information and to provide any necessary corrections to the text. TF members discussed the comments.

DISCUSSION:

- Tammy shared a summary of comments and topics that were centered around readiness for adoption of the IGs as part of certification criteria, timelines for the use of the IGs in production for PA transactions, and any potential changes to the PA that are necessary prior to adoption as certification for health IT.
  - Patrick commented that IGs are already implemented, so the blanket statement that they are not ready for adoption is not accurate.
  - Raj agreed with Patrick and stated that the TF should consider which pieces in the workflows add the most value. He shared potential questions:
    - Can the IG help answer when PA is required?
    - Can the status of PA be found and shared with patients?
    - How does the level of maturity of the IG factor in?
  - Sheryl agreed that gradation should be added to the wording, as there are different levels of maturity and implementation of the IGs.
  - Hans agreed but also highlighted the differences between how the IGs and workflows were originally developed and how what has been developed could be used for certification. Though the guides are ready to get people on the path to certification, they are not ready. He highlighted several comments Rich made in the chat.
- Tammy asked TF members to comment on the statements that were made around the timeline in the working document.
  - Heather commented that the TF has a limited time frame to make recommendations right now and suggested that they indicate that things are in flux while the IGs are in the balloting and reconciliation process. Perhaps they should wait a year to make this recommendation, and, though the guides are ready to use for production, they are not ready for certification.
  - Tammy suggested that the TF could define three separate timelines and volunteered to add them to the working document.
  - Raj highlighted his previous comments about determining what provides the most value in the IGs and offered to draft that timeline.
  - Sheryl stated that the TF should provide some context around the scope relative to what will be required for the adoption and timelines.
- Tammy reviewed TF members' comments on the second point in the working document, which asked if the IGs are not ready, should ONC still propose certification criteria?
  - Dave asked if there is a timeframe for enforcement of certification and suggested that an incremental approach would allow for a smoother path to full automation. He asked about options to do an iterative certification.
  - Raj suggested that ONC guidance is needed, and he and Sheryl voiced their agreement for the iterative option with a defined timeline to foster EHR system adoption.

- Hans offered several cautions around ensuring stakeholder adoption and discussed challenges related to different levels of certification criteria and complex workflows. He stated that, in the absence of a monolithic approach, a functional requirement might complicate matters. He added that he would like to add comments, but guidance is needed.
- Dave asked about the scope of the certification requirements, and Tammy described the payer certification module and prerequisites to submitting a PA request. Sheryl commented that the text asks about payer certifications but noted that she could not speak to how that certification criterion is applied now. Alex commented that the Health IT Certification Program is not specific to one type of vendor or product, though it has historically focused on EHR. He clarified the intent of the questions.
- Hans described the potential of the entire ePA workflow to be supported by HIT (including payers) and how this would relate to certification. TF members were reminded that the ONC Certification Program is voluntary, and they were asked to consider levers available to require the certification across parties that have not typically adopted certified health IT (based on previous policy mandates).
- Heather asked other members for feedback on the CMS requirement that will be under consideration this year that payers adopt the three IGs discussed at the current meeting. She asked if the TF needs to recommend a payer certification if a different policy would mandate that payers use specific technology. Dave asked what would require that payers adopt the IGs?
- Raj, Patrick, and other TF members emphasized the need for CMS and ONC to coordinate efforts and suggested that CMS be invited to share with the TF at a future meeting. Patrick stated that support, certification, and regulations for payers and providers must be in lockstep.

Action Items and Next Steps

The ePA RFI TF co-chair captured comments and suggestions submitted by ePA RFI TF members in a Google document, which was then shared with TF members, who will capture their thoughts and recommendations between meetings to better inform the TF's recommendations and streamline conversations. Members should share a Google email address with ONC's logistics contractor at onc-hitac@accelsolutionsllc.com to be set up with access to the document.

Before next week's meeting, ePA RFI TF members were asked to:

- Review the extracted RFI questions in the TF's Google document, and add comments to the space next to each question.
- Focus in on the functional capabilities in your priority topic areas to create consensus comments for all TF members to react to in the document
  - Topic 1: Certified Health IT Functionality – ALL, note specific wording assignments in 2/3 call summary document
  - Topic 2: Implementation Specifications for Prior Authorization - All
  - Topic 3: Healthcare Attachment Standards – SME's Identified
  - Topic 4: Impact on Patients, Heather McComas, ALL
  - Topic 5: Impact on Providers - Jim Jirjis, Aaron Miri, Eliel Oliveira, Heather McComas
  - Topic 6: Impact on Developers - Hans Buitendijk, Rajesh Godavarthi, Deb Strickland
  - Topic 7: Payer Implementation – Patrick Murta
- Make sure that any previous comments in the notes are properly reflected, or add clarifications if necessary. TF members will discuss the comments at the next meeting and begin formulating them into recommendations.
- If you have additional supporting information (e.g., costs and burden of PA), please send it to the co-chairs and onc-hitac@accelsolutionsllc.com so it can be added to the discussion.

Public Comment

QUESTIONS AND COMMENTS RECEIVED VIA PHONE

The public comment period was delayed by five minutes. There were no public comments received via phone.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR

Rich Landen: Glad that HHS granted the exemption for direct FHIR to FHIR.

Jocelyn Keegan: To clarify the Exception is only for testing purpose at this time, and members must work closely with HHS to gain approval for their partners to test for a specific time period. It is not a general exception for all. Creating burden and barriers to more full-fledged testing in the industry.

john kelly: Can Viet elaborate on whether or not certification requirements for EMR's to support CDS Hooks and CQL might eliminate the need for EMR vendors to support multiple Smart on FHIR apps for every Payer/UM vendor? I believe this has been an issue for the model of needing the SoF app to mediate between the Guides and the EMR/Provider workflow.

Pooja Babbrah: Do we know how widespread adoption is for CDS Hooks in EHRs currently?

Jocelyn Keegan: https://confluence.hl7.org/display/DVP/Da+Vinci+Implementation+Guide+Dashboard

john kelly: To what degree is it reasonable to view standards to be somewhat aspirational? i.e., standardize a process to which all parties need to invest to integrate with a standard process as opposed to expecting the published standard to integrate with every existent capability in the market. The recent Patient API defined an aspirational state to which everybody had to build onramps to a process.

Jocelyn Keegan: https://confluence.hl7.org/display/DVP/Da+Vinci+Video+Presentations

Jocelyn Keegan: The January Roundtable

Jocelyn Keegan: We'll also have some of the EHR members discussing their progress with FHIR and DV guides on this month's CR meeting. https://confluence.hl7.org/display/DVP/Da+Vinci+2021+Calendar to watch, or sign up for listserv to be notified.

Sheryl Turney: 👍 thankyou Jocelyn for the update and link.

Jocelyn Keegan: Hans point is important as non EHR vendors participate.

Jim Jirjis: I am so sorry I have an unavoidable conflict for which I must drop off this call

Hans Buitendijk: @john Kelly: The challenge is how in a certification program that needs to be based on unambiguous requirements and testing procedures to be aspirational. It's a pass/fail paradigm. Given the variety of configurations we want to avoid that in that paradigm HIT is not asked to do more than they need, but certainly also not less. Even if the certification criterion initially focuses on the functionality as was done with the first API round, or with Case Reporting, etc. But then still the question would be what each party is expected as a minimum to satisfy that in varying configurations.

Alexander Baker: Just want to clarify that there is actually a reference to the CDex IG in the attachments background section of the RFI and questions about how this or other approaches could support attachments, so comments very welcome on this as well.

Jocelyn Keegan: I think a better understanding on the usability of HL7 FHIR guides ahead of normative status is worthwhile to address "readiness". Goal at core of the move from STU1-STU2-Normative is to actively use the guides through the maturation process. Part of why we added add'l color coding to show guides in blue

and green are actively being used and deployed, but to Viet's point as we see more and more use, scenarios expand and guides and the resources around them expand as a package and within each guide.

john kelly: @ Hans. Total agreement. My comment/observation is predicated on an assumption that the standard process and tech requirments definition is very clear. That was not true of the CMS and ONC rules on patient API. Learn from the past or repeat our mistakes. 🙂

Hans Buitendijk: @John: Agreed, if very clear it would help. Current guides the sub-module boundaries are not as clear (unless you have been part of the journey to date) that have to be made visible and understand to appreciate and reference the building bocks a particular HIT will provide, thus "dependent"/"collaborating" with other HIT to enable the full ePA flow.

John Travis: As a public comment on how any criteria for ePA may be developed, ONC should develop criteria that matches to what Hans highlighted - meaning, providers adopt HIT from different sources to cover the waterfront for what is represented by the Da Vinci guides and the functional capabilities outlined in ONC's RFI. ONC should support a modular approach to allow HIT developers to certify to a scope of capability that fits the way their products are deployed - whether being able to cover the full scope or only the clinical or financial/administrative aspects of ePA.

John Travis: Also, given CMS is likely to develop rulemaking alongside any ONC effort for ePA certification criteria, these criteria should not be adopted into the definition of CEHRT for sometime until their utility has been proven through vendor certification and market adoption experience.

john kelly: Within the context of the CURES Act, are comments about what providers and payers and EMR vendors can do is perhaps less important that what is it going to take to reduce consumer burden???

John Travis: And then there is the question of the USCDI - especially with version 3 - expanding into administrative data and whether the USCDI specification can remain a monolith - expansion into health plan and subscriber/beneficiary data really challenges the USCDI remaining a whole as what historically has been mainly a core clinical data set. Time to begin to segment it!

john kelly: One observation about iterative mandates is that if we look at Meaningful Use 1 through 3, by the time we got to Meaningful Use 3, there was not much left.

Jocelyn Keegan: Hans is spot on, you need alignment with payer and provider (and their vendors) to put the capability in workflow with enough "all payer" capability so it actually works for providers. We learned that on the ePA SCRIPT adoption to improve 1st. Transparency of coverage and benefits 2nd requirements, documentation, steps 3rd actual automate, remove need for PA if 1 and 2 work.

John Travis: Amen - moving too quickly here for payer or provider risks outflanking market readiness - that was a complaint payers had about CMS's approach with their rulemaking last year - and the same is a risk if the push is too much on advanced capabilities on the provider side without realistic payer cooperation

Hans Buitendijk: If ePA is considered being supported by HIT, are then all actor's IT involved in the ePA considered HIT, thus SMART Apps, intermediaries, payers contributing to this have HIT for this purpose, thus subject to CHIT?

Hans Buitendijk: A streamlined certification process that could be based on automated test harnesses that one can attest having passed with supporting reporting from those test tools would be very helpful.

Heather McComas: Thanks all and thanks Viet!

QUESTIONS AND COMMENTS RECEIVED VIA EMAIL

There were no public comments received via email.

Resources

ePA RFI Webpage
ePA RFI – February 10, 2022 Meeting Webpage
ePA RFI – February 10, 2022 Meeting Agenda
ePA RFI – February 10, 2022 Meeting Slides
HITAC Calendar Webpage

Meeting Schedule and Adjournment

Sheryl and Tammy thanked everyone for their participation.

The meeting was adjourned at 11:27 a.m. E.T.