Transcript

HTI-1 PROPOSED RULE TASK FORCE 2023 MEETING

GROUP 3: ONC HEALTH IT CERTIFICATION PROGRAM UPDATES – INSIGHTS CONDITION, STANDARDS UPDATES, AND RFIS

May 25, 2023 10:30 AM – 12 PM ET

VIRTUAL

Speakers

Name	Organization	Role
Steven Eichner	**Texas Department of State Health Services**	**Co-Chair**
Steven Lane	**Health Gorilla**	**Co-Chair**
Hung S. Luu	**Children's Health**	**Group Lead**
Hans Buitendijk	Oracle Health	Member
Clem McDonald	National Library of Medicine	Member
Naresh Sundar Rajan	CyncHealth	Member
Fillipe Southerland	Yardi Systems, Inc.	Member
Michael Berry	Office of the National Coordinator for Health Information Technology	Designated Federal Officer
Dustin Charles	Office of the National Coordinator for Health Information Technology	ONC Program Co-Lead
Michael Wittie	Office of the National Coordinator for Health Information Technology	ONC Program Co-Lead
Alex Baker	Office of the National Coordinator for Health Information Technology	Presenter
Carmen Smiley	Office of the National Coordinator for Health Information Technology	Presenter
Shelly Spiro	Pharmacy HIT Collaborative	Presenter
Margaret Weiker	National Council for Prescription Drug Programs	Presenter
Frank McKinney	Point-of Care Partners	Presenter
Alex Kontur	Office of the National Coordinator for Health Information Technology	Presenter
Issac Vetter	Epic	Presenter
Bryn Rhodes	Smile Digital Health	Presenter

Call to Order/Roll Call (00:00:00)

Michael Berry
Good morning, everyone, and welcome to the HTI-1 Proposed Rule Task force. I am Mike Berry with ONC, and I would like to thank you for joining us today. I would also like to send a special thanks to our guest presenters today, that being the several ONC program leads we have with us today, and also some external SMEs that have joined us, and we are looking forward to hearing from them. All of our task force meetings are open to the public, and your feedback is welcomed, which can be typed in the Zoom chat feature throughout the meeting or can be made verbally during the public comment period that is scheduled toward the end of our meeting. I would like to begin rollcall of our task force members, so when I call your name, please let us know that you are here, and I will start with our cochairs and Group 3 lead. Steven Lane?

Steven Lane
Good morning, and welcome, everyone.

Michael Berry
Steve Eichner?

Steven Eichner
Good morning, and welcome.

Michael Berry
Hung Luu?

Hung S. Luu
Good morning.

Michael Berry
Hans Buitendijk will be joining us a little bit later. Clem McDonald? Naresh Sundar Rajan? Fil Southerland?

Fillipe Southerland
Good morning.

Michael Berry
Good morning to all. Now, please join me in welcoming Steven Lane, Steve Eichner, and Hung Luu for their opening remarks.

HTI-1 Proposed Rule Task Force Charge (00:01:18)

Steven Lane
Hung, do you want to take it from here?

Hung S. Luu
Sure. Welcome, everyone, to the final stretch of our work, gathering and reviewing the requests for information for the ONC published rule, and I am really excited about this session because we have a full slate of speakers that will be educating everyone on pharmacy interoperability functionality, and I think we

will get a lot of good information that we can incorporate into the recommendation. Also, we have some speakers from the ONC as well as outside speakers to speak on the clinical decision support, CDS Hooks, and finally, we hope to have some public comment from you to help inform us on how best to move forward with the recommendations for this. Over to you, Steven or Ike.

Steven Lane
Well, thank you so much, Hung. So, again, we are looking forward to these presentations and do not want to dilly-dally in getting to them. It sounds like we might be missing Alex Baker for the moment, so, Carmen, I do not know if you can tag-team and switch things with him. Hopefully, he will show up here in the next couple minutes. Let's go to the next slide and quickly review the charge of our task force. These next two slides outline that that charge. Most of you have seen this before, but essentially, we are here to provide feedback on the various components of the HTI-1 proposed rule. On the next slide, you can see that today, we are focusing on soliciting feedback on requests for information related to program standards. That is where we will go with the decision support discussion. Next slide. These are the specific topics that were assigned to Group 3. As you can see, we are at the bottom of our list, having worked through the upper bullets, so we will proceed. Next slide. That brings us to the first presentation, which we are very excited about. Alex, are you here, or Carmen, can you start?

Alex Baker
Yes, this is Alex Baker.

Steven Lane
Oh, wonderful, you are here. Great.

Pharmacy Interoperability Functionality Within the ONC Health IT Certification Program Including Real-Time Prescription Benefit Capabilities RFI (00:04:00)

Alex Baker
All right. Hi, everyone. Thanks for having us. Let's go to the next slide. This is Alex Baker. I am a federal policy branch chief in the Regulatory and Policy Affairs Division in the Office of Policy, and am joined here by Carmen Smiley to talk about the pharmacy interoperability RFI that we included in HTI-1. Here is some of the basic disclaimer and public comment guidance information. Next slide. So, as folks may have seen, I have included a pretty significant RFI in this proposed rule around pharmacy interoperability within the health IT certification program. I just want to lay out the thinking behind how this is organized, and then we will turn it over to Carmen to review in a little bit more detail some of the questions that are in here.

So, this RFI has two sections. The first is questions related to a real-time prescription benefit certification criterion that we say that we are considering as something for the health IT certification program, and just to recap for folks, and this background is in the rule also, the immediate driver for this is a provision in the Consolidated Appropriations Act of 2021. This provision in the law required Part D to include real-time benefit tools as a requirement for those plans, which is something that Part D actually had already done in regulation in the 2019 rule, but the CAA reiterated that and then specified that the secretary must adopt a standard for real-time benefit tools as a part of those requirements.

Specific to ONC, this provision also amended the definition of "qualified electronic health record" in the Public Health Service Act to say that a qualified electronic health record must include or be capable of including a real-time benefit tool, and as folks may know, this is important because the qualified electronic health record in the Public Health Service Act is the original statutory provision that the current base EHR definition in regulation is based on, so when ONC defines the base EHR definition, that is how we continue to implement this original qualified electronic health record provision from the Public Health Service Act, and that means that, based on this new statutory provision, we need to look at how we could include this real-time benefit tool functionality within what we define as the base EHR definition, and thus need to think about a certification criterion in the program that could be included there. So, that is really the immediate motivation to do this, that we have this statutory provision that we need to figure out how we are going to implement in coordination with the CMS folks in Part D that are also covered by this.

So, the first part of this RFI is really focused on that concept and questions about how ONC should go about creating a criterion that could fulfill this. It specifically looks at an NCPDP standard, the Real-Time Prescription Benefit Standard, Version 12, as a standard that could serve as a basis for this criterion, and that is also the standard that the Part D folks have proposed to adopt in their program in their rule at the end of last year. This first section, in which Carmen will go into a little more detail, really looks at the specifics of that and asks questions about the standard and application of that so that we can hopefully better understand the public's views on these issues as we potentially develop such criterion under future rulemaking.

The second section of this RFI… So, I wanted to really focus on this criterion and how we can potentially implement this, but I think adding this criterion, potentially, to the certification program raises some other questions about the broader workflow around different pharmacy transactions and other issues around pharmacy and interoperability that are not necessarily already addressed in the certification program or where we have done certain things, but have not fully implemented it, and I think in questions about this criterion for us, we wanted to prepare this with additional questions about related workflows, to what extent we should also consider including those within the program, and then, to what extent potentially including this real-time prescription benefit education criterion would raise the need to implement complementary policies to cover related transactions within the program. So, those are the two big sections of this that you will see in the proposed rule and a little bit of the background for why we need to do this to implement the provision of the statute, and with that, I will turn it over to Carmen Smiley to go through some more of the details of these two sections.

Carmen Smiley
Perfect, Alex, thank you so much. Next slide, please. My name is Carmen Smiley, I am a senior health IT specialist in the Office of Technology at ONC, and I am the technical lead for all of our pharmacy interoperability efforts, and I get to work with Alex on many of those, so I really appreciate the intro. We are going to go into a little bit more detail on the specific questions that are asked throughout the RFI, and I am not going to read the questions to you per se, but I will touch on them and invite a little bit more context. As you will see, as we pose each of the questions and cover some of the major sections, we have done a great deal of research in this area before preparing the RFI, but there is a lot we still do not know, so we really look forward to receiving comments from this group and from the public so that we are better informed and educated as to how best to potentially implement such criterion.

I will start off with the potential transactions. In the RFI, of course, there is a great deal more detail, and I encourage everybody to read over the detail, but we provided a set of testing scenarios, and we are wondering if that initial set of testing scenarios that we have drafted would be really appropriate for a potential real-time prescription benefit criterion. Should we also cover other testing scenarios, or are there other testing considerations that we should take into account as we are considering moving forward? Finally, within this set of questions, we also are seeking more information on the value of negotiated price.

The value of negotiated price was included in the appropriations language that Alex referred to earlier, but it is not currently supported by the NCPDP real-time prescription benefit standard, and so, we are curious if it would bring value to patients and prescribers or if there are other opinions or insights that the public could provide on that particular subject. We are also asking about the use of XML or EDI format. Because the standard that we are considering supports both formats, we want to hear from you if we should also require both formats or one or the other, simply acknowledging that there are various areas across the industry that are more up to date, perhaps, on XML, while perhaps other legacy systems are still actively using EDI formats for various purposes. Next slide, please. Thank you.

We then go into a little bit more of the segment-based analysis of the standard and any capabilities that we should otherwise consider for the potential criterion. So, again, as the NCPDP real-time prescription benefit standard supports both NDC and RxNorm, within the clinical segment, we are curious as to if we were to require both, if that would support the improved adoption, maintenance, and harmonization between these two very different code sets, as we have heard concerns from the public and through the comment collection process and from the HITAC on concerns regarding that harmonization alignment, not just for real-time prescription benefit, but for other areas that may affect pharmacy interoperability, including electronic prescribing. From the certification perspective, what we do is develop requirements, so that requires health IT developers to demonstrate their capacity to support certain areas or certain aspects of the standard and acknowledging that the standard itself was developed to allow for situational support should that information be available.

So, would requiring this for the potential criterion we are discussing today bring other benefits to healthcare providers or any other participants that support the transactions across the ecosystem, would requiring both also impose undue burden on developers or others, anybody who may be seeking certification to the potential criterion, or would each independently provide sufficient information for various applications and various exchange partners to be able to process and exchange all of the information that they are sending and receiving, or what would be the consequences of establishing, as recommended by the HITAC, RxNorm as the single source? This was a previous recommendation by the HITAC. There may be more updated recommendations, but I think this is an area of interest to many on the call, and we really look forward to receiving comment on these, and we would love to hear more about real-world experience in both. Next slide, please.

Also in the clinical segment, which we are moving on to, we are curious if we should require the clinical segment, which is currently optional within the standard, and within that clinical segment, should we require a demonstration of both ICD-10 and SNOMED CT as part of the certification criteria, partially to support more seamless transition between ICD-10 and ICD-11 when that time arrives, or perhaps there are other benefits to requiring both. Of course, we are always interested if any requirements may impose any undue

burden on developers, and we are really looking for in what ways we can bring the greatest value to patients and prescribers through implementation of our certification program. Next slide, please. Thank you.

I am also an ONC subject matter expert in patient identity and matching, and so, I cannot help but see through that lens in almost all of my work, and I think it is widely known that the success of any patient-matching and record-linkage implementation for real-time prescription benefit is incredibly critical because without that patient-specific information, as I am stressing, that we really need to be successful, many times, that matching is occurring both within the health IT plus across exchange partners, and this has been an ongoing challenge for many years. There have been great successes, but additional work is certainly welcome, so what we are curious about, what we would like to hear from the public on specifically, what about the potential of expanding the number of patient demographics that would otherwise map to would be NCPDP SCRIPT standard, which is a far more comprehensive list of demographics that could potentially be leveraged for patient matching, both within and between systems.

Currently, the NCPDP real-time prescription benefit standard contains a much more condensed version of the available demographics that may be relied on, and we realize also that more information does not necessarily translate to greater success, but it could help in ways that we may not exactly foresee, so we would love to hear any other insights or suggestions on how we could support accurate matching throughout the ecosystem, and especially to ensure that the proposed criterion makes the greatest impact. Next slide, please.

System and workflow integration: So, I think as we continue to consider the larger ecosystem of pharmacy interoperability, we want to ensure that as there may be potentially additional modules developed in the future and there may be additional criteria within the pharmacy interoperability space, those would ideally work in tandem with each other in a way that supports each other and a way that is really seamless, and we hope to see also that all pharmacy interoperability-related criteria are always happening within the clinical workflow for prescribers so that prescribers never have to leave the application that they are already using, they do not have to log into separate web-based platforms or other applications that might be tacked onto the system that they are accustomed to, but rather, the seamless interchange of that data across applications so that that experience for prescribers is also seamless. Next slide, please.

We are also considering, and would love to receive additional comment on this, regarding the scope of real-time prescription benefits and the potential criterion, and so, the standard itself actually supports the exchange of medications, vaccines, devices, and supplies, but for an initial introduction of the potential criterion, should we limit that scope or should we expand it and really start off with the full potential coming out of the gate as the criterion may be introduced to the certification program? We are also curious to hear about any additional burden that the full scope may impose on developers or if additional development is needed within the standard to better support these various types of codified entries. Next slide, please.

This is actually more about the scope, really specific to devices or supplies, and as I am sure many of you have observed over the years, there are times when criteria will also evolve over time as the industry evolves or as standards evolve, and so, if you feel that an iterative approach may be more prudent, we would also love to hear from you on that matter. What additional opportunities might arise from requiring conformance to the NCPDP formulary and benefits standard, which is an additional standard that could be used to significantly support real-time prescription benefit?

Now, ONC previously had a drug formulary criterion within certification program, but a specific standard was not named at that time. That particular criterion was removed from the certification program after years because drug formulary management was so ubiquitous across the industry and we did not see that it really brought any great value to requiring developers to test to something that they do every day. This is actually a much more advanced application of the formulary and benefit standard for this specific use case, much more advanced and perhaps much more supportive to the standard we are also considering. Next slide, please.

I then go into a little bit more detail about formulary and benefit management, as I mentioned, and we really want to hear about some key benefits that providers may experience by having that standard available to them, and what processes that standard or additional processes that are currently under consideration or could be considered in the future through adoption of the formulary and benefits standard in conjunction with the real-time prescription benefit standard. Next slide, please.

We also asked about the potential of incorporating electronic prior authorization transactions within the electronic prescribing certification criterion, and so, this is slightly different in that the majority of questions we are asking you are about a potential criterion for real-time prescription benefits, though as I am sure you already know, we already have an electronic prescribing criterion that is at B3 within the certification program, but we are wondering if we should update that criterion by requiring electronic prior authorization transactions. Those transactions are currently optional within the program, and so, we do have the capacity to test for them already, though we do not require conformance to them yet. I know electronic prior authorization has been a hot topic on many of these discussions and across the industry. ONC is very interested in seeking ways in which we can better support this capability.

And then, there are other certification approaches that are slightly more programmatic in nature and, as we consider expanding pharmacy interoperability criteria within the program for additional capabilities and functionalities, potentially additional standards, could we provide a bundled approach to testing more than one criterion within a single testing event?

And so, if you were a health IT developer and you were seeking certification to both electronic prescribing and any other potential criterion that could be introduced, ideally, we would be able to knock them all out within one testing event because many of those processes work in tandem or are interchangeable, or much of the same data is used, and many of the standards that we are considering are already aligned and easily mapped to each other because of the work done from standards development organizations like NCPDP over the years. Or, if we were to propose any sort of an alternative testing approach that may support developers and may streamline the testing experience, we are interested in hearing about any additional opportunities to use testing resources especially. Next slide, please. I believe this is the discussion area. I really appreciate the opportunity to present more about our RFI today, and we look forward to your questions.

Steven Eichner
This is Ike. I am looking over our task force group to see if there are any questions from the group. Steven, do you have anything?

Steven Lane
No. I really appreciate those presentations. Carmen, as always, you are very clear and succinct. I really appreciate that. As soon as we can, I would like to get into the SME presentations with a focus on developing specific recommendations. I have been drafting some member recommendations in our spreadsheet, Tab 3, Row 8, Column G, and I invite the workgroup members to do the same. If you have anything to add there, again, we want to come out of this with any specific recommendations that you think would be valuable. I personally think these are warranted, so, in my case, it is very supportive of the changes that Carmen laid out as possibilities.

Steven Eichner
Carmen, this is Steve Eichner. I do have one question. One of the perpetual or long-term issues to me with prescriptions, medication lists, and the like in EHRs seem to be issues related to medications that do not have NDC numbers, such as new medications, not repurposed medications, that are in FDA clinical trials or many medications that are being processed as compounded drugs which are used for treating rare diseases or patients' particular circumstances. I am kind of wondering if there is an opportunity in the space of the questions ONC is asking or the data tools that are available in the proposal to do a better job of accommodating the exchange of those types of medications because it is challenging for everybody.

Providers do not always end up with a list of medications that patients are actually taking, patients do not end up with a consolidated list of drugs they are actually taking, and pharmacies do not end up with a comprehensive list of medications that a patient may be taking, and that, of course, runs into a bunch of issues looking at contraindications and things like that because there is not a consolidated list of everything that a patient may be consuming.

Carmen Smiley
This is Carmen. Thank you so much for providing insight, and these are exactly the challenges we hope to address. Currently, for electronic prescribing criteria, you may use codes other than RxNorm if that medication does not contain an RxNorm, so those codes could include NDC, but we really want to hear from the industry on whether or not this additional potential criterion for real-time prescription benefit would better support some of the challenges that you are describing.

Steven Eichner
Thank you.

Steven Lane
Hung, are you comfortable moving forward?

Hung S. Luu
Yes, I would agree with moving forward with the subject matter expert presentations.

Margaret Weiker
Hi, this is Margaret Weiker. I am Vice President of Standards Development at NCPDP, and I thought I would go first if Frank and Shelly do not mind.

Shelly Spiro
I do not mind, Margaret. This is Shelly. Go ahead.

Frank McKinney
Absolutely.

Margaret Weiker
So, my first comment is NCPDP is obviously in support of adoption of our real-time prescription benefit standard and the certification program that is being proposed and associated with that. We currently have one for the SCRIPT standard, the e-prescribing, and feel that it is useful for that particular business function, and RTPP would be beneficial as well. The NCPDP Foundation sponsored a grant in Johns Hopkins medical, actually put the standard in place, ran it through its paces, and found that, on average, it saved a patient $20.41, and in the instance of one patient, it saved them over $1,000.00, so this is a tool that is implemented that has proven to be cost-effective for the patient.

So, in response to a CMS Medicare Part D rule that was naming the real-time prescription benefit standard Version 12, we asked that Version 13 be adopted, which is the latest version of the standard, and gave our reasons why we wanted Version 13 adopted, so we will be providing those comments to the RFI. In regard to RxNorm and NDC codes, we sent a letter to HITAC, and I know we carbon copied ONC, but NCPDP is opposed to the replacement or the secondary status of using NDC codes versus RxNorm. If you all would like, I can put the link of that letter in the chat and you can have that to review, so we will be providing information, obviously, in the response to the RFI. In regard to ePA, we support the mandatory use of that.

In the SCRIPT e-prescribing certification, as Carmen mentioned, it is optional. The tool supports all of those transactions today, and we do have some companies' entities that have tested those transactions, but obviously, not all, because it was not mandatory that they do that, but the tool exists today. With XML versus EDI and supporting one or both, when we first put up the certification criteria for e-prescribing, it was the SCRIPT standard, and the version that was adopted, which would be Version 10.6, had both the EDI syntax and the XML syntax, and we had criteria that supported both, so I believe our recommendation will be that any kind of certification would need to support both in regard to that because we have entities, some of which have implemented XML and some of which have implemented the EDI piece of it, so I think the certification should be both at this time. In the interests of time, I will turn it over to Frank and Shelly, and then I may come back on if we have some more time.

Shelly Spiro
This is Shelly. I can go next. I just have a couple of comments, more from the clinical standpoint. The reason for NDC and RxNorm to both be used is RxNorm is a higher level, similar to what you would see with a medication order or physician order. When you get to the NDC level, you are actually getting down to the product level, which was what was actually dispensed or what is actually priced out from a particular manufacturer, so it is important that we support both RxNorm and NDC, as Margaret had stated. Also, in the bidirectional type of communication, this is really important, that the systems are able to understand the NDC as well as RxNorm because, as an example, if a medication is recalled, then you would have to know the actual NDC number of that particular medication.

In terms of the products that do not have a code or might not have even a unique product identifier, there are processes that can be used to use a code that might represent it. I know that Ike had mentioned compounded types of items, and we try to get down to the actual products within those compounded items in terms of clinical trials and other areas. You are not really seeing electronic prescribing of investigational drugs or some others. I agree with Ike in terms of the medication lists that this could be a potential problem, but these are somewhat unique situations. They might be more common in situations in hematology, oncology, or some of the other areas, but I think it is still important. It is my opinion that we need to support both NDC and RxNorm, and there can be some mapping that can be done between the two, realizing that RxNorm is not as granular as NDC, and there are reasons for the use of NDC numbers, even in identifying which product has caused an adverse drug reaction.

In terms of the workflow in real-time pharmacy benefit leading to prior authorization, we believe that this can reduce burden both on the prescriber side as well as on the pharmacy dispensing side. If we know that the medication is in the formulary and what the patient will actually be taking, it can lead to a reduction in prior authorizations, phone calls, faxes, and such, so we believe that it is important to move forward with using these standards that are out there, such as real-time pharmacy benefit, and also for prior authorizations. I will turn it over to Frank.

Frank McKinney
Great, thanks, Shelly. I can bring maybe more of an implementer's perspective to points that both Shelly and Margaret brought up, and then maybe a couple others. To finish the NDC versus RxNorm conversation, just from testing and creating rule around this perspective, in the standard, both are available and compatible, so they both can be populated. NDC is required because typically, for pharmacy benefit management systems, they operate at that level of a product. They are pricing out or determining the patient's responsibility for a given product that will be dispensed for them, so that is kind of the main frame of reference, but it is definitely possible to additionally send an RxNorm code, and so, if the determination was that to support downstream compatibility or other purposes, a certification rule could be added that does not conflict with any requirements of the standard itself, it would just add a certification requirement that further defines what a submitter would need to populate.

With regard to one of the points that I do not think was brought up by Shelly or Margaret, the use of the patient segment in SCRIPT, maybe in addition to or instead of what is in Real-Time Benefit, looking at the content of those, I think the purpose would be key to consider when it comes to the patient content. So, the Real-Time Benefit transaction really uses the patient information simply to identify the patient characteristics in addition to their member information, which is really primary in the process. So, a pharmacy benefit manager responding to the request will typically have member identification information that serves to pull up the right record to determine their plan details more so than doing demographic matching based on patient characteristics or their address, and so, if the aim is to tighten up that matching process, additional demographics may not have much of an effect toward that.

I do not know if we have talked about the Real-Time Benefit Version 13, which has come out since the time when I think initial recommendations for Version 12 were made, but it has some additional features that I think are really beneficial to those that are migrating from their current proprietary built-in benefit methods, and some additional things that would be helpful to support features in a response that a PBM might return. So, when it comes to patient information, Real-Time Benefit 12 does not have any patient address or

location content in it, but Version 13 added the city, state, and ZIP code of the patient, which, while unlikely to be used for matching, can help to determine aspects of the response. So, for example, if Medicaid or some other state-based program is at play, that state helps characterize that, and so, the response can be consistent with the state the patient is in, and it can also be used to identify alternative pharmacy locations, for example, so that kind of information in the patient might be useful.

And then, just to wrap up the patient aspect, looking at what is in the SCRIPT message versus Real-Time Benefit, neither of them have in-depth condition information or that sort of thing, and what would really be different comparing Real-Time Benefit 13 and SCRIPT is that SCRIPT has former name. It does have a street address, which Real-Time Benefit does not, alternative contact, and gestational age, so, some elements which may or may not be useful or pertinent in this exchange, so those would be things to consider when further pursuing the idea of expanding the patient content. Just to continue highlighting the benefits I see of focusing on Real-Time Benefit 13, some of the scenarios that we identified in the proposed rules really would only be able to be supported using the newer version of Real-Time Benefit. So, for example, having information that can support formulary information coming back to the patient is not something that was in Real-Time Benefit 12, but has been added to 13.

Also, many of the systems that will be migrating to a new standard version of Real-Time Benefit will be able to provide additional benefit detail or constraint benefit restriction details at a pharmacy and drug level, and Real-Time Benefit 12 lacks a field that can contain free text additional details, but that was added to Real-Time Benefit 13, and having done a fair amount of mapping between these different real-time benefit standard formats that are used today, many of them proprietary, that is content that is often very useful and does not have a home in the Real-Time Benefit 12 version, but 13 does have that, so that would be another consideration.

And then, just briefly, I have an additional point around workflow testing, and I also definitely have heard providers' comments with regard to workflow considerations and things that are more onerous versus less onerous. I guess my thought to introduce into that discussion is that from a certifying standpoint, and I did a fair amount of work helping with some of the initial Meaningful Use certification with NIST, because those processes are conducted by multiple parties, both in terms of testing entities but also individuals who are performing tests, to be most consistently applied across system vendors or systems, it is best and most reliable if the rules being tested are very objective, if this field is present or if this format is being met.

Typically, they do not go far into user experience, but when they do, it is usually the safest and gets the most consistent results if that test is still pretty objective, so this information is visible at this step of the process or a flag is presented in the context of some other information. Every tester can gauge that without bringing in additional interpretation: "Yes, this field is here, I can see it, whether not it is an efficient method of displaying it or if this would be preferable to something else." We do not have to consider that; I can just answer, "Yes, this is here." So, by getting into workflow characteristics, I think it is more difficult to have individuals consistently interpret and gauge whether or not a system is meeting the criteria, so that is one aspect of a challenge related to workflow testing.

Another is that I believe typically, most EHRs and prescribing systems offer a fair amount of configurability that a given customer or site practice that uses that system has available to them. So, in my practice, I might configure my workflow in a certain way, which is one of several options that that EHR makes available,

and so, even testing at that EHR product level that something is possible does not necessarily ensure that the providers at each practice are going to experience it the same way, so that would just be another consideration when pursuing workflow or user experience tests, that systems often have a range of options available, and there would still be need to be consistent implementation or choices, which are sort of outside the control of the EHR vendor. I think that is about the extent of my additional comments.

Steven Lane
Hung, do you want to move us along?

Hung S. Luu
I wanted to summarize to make sure that we capture the information provided from the subject matter experts. What we are gleaning is that it does make sense to use the NDC and RxNorm because they are both pervasive, but also because they can be complementary to each other, and right now, there is the ability to display both, so it would not be one or the other choice, but they could actually be used together. Is that correct?

Shelly Spiro
Yes.

Margaret Weiker
Yes.

Hung S. Luu
Okay. The other is consideration of using Version 13 versus Version 12 because there is additional functionality and information that is provided, including patient demographic, which may assist with matching, and also additional functionalities, such as free text fields, that may be more user-friendly than what is available in Version 12. Is there consensus on that, or is that still an area of debate?

Margaret Weiker
From an NCPDP perspective, it is not an area of debate, it is consensus. We have submitted comments to the CMS proposed rule, and in one of my postings in the chat, I posted a link to that letter, and I believe on Page 4, it talks about why you should adopt Version 13 versus 12.

Shelly Spiro
This is Shelly from the Pharmacy HIT Collaborative. We would agree with that from the professional standpoint also.

Frank McKinney
This is Frank. One thing to add with regard to the migration and the different formats, XML and EDI, is that Version 13 does still support both the XML and EDI formats, and I would agree with Margaret that to aid those that are already on one or the other of those formats, supporting both in certification would be important, and an additional point to that is these implementers will additionally, in the next 5 to 10 years or so, likely be migrating with NCPDP to an adjacent format, and requiring an interim change of format for this Version 13 of Real-Time Benefit to be followed by another format change feels like it would be an extra burden that would not be beneficial, and would just increase their obstacles or steps toward the future, so,

going with the status quo of the choice between XML and EDI at this point removes one step on their eventual path toward more consistent JSON format at NCPDP.

Hung S. Luu
Thank you for that. That was very helpful. If there are no other comments, we can proceed to our next topic.

Alex Kontur
Hi, should I just jump in?

Hung S. Luu
Yes, please.

Clinical Decision Support Hooks RFI (00:53:48)

Alex Kontur
All right, thanks. You can run to the next slide. I will start from there. Good morning, everyone. My name is Alex Kontur. I appreciate you guys inviting me here to speak a bit about some of the FHIR-related requests for information that are in HTI-1. Specifically today, I am going to be talking about the clinical decision support, or CDS Hooks, request for information. To get us started, I just wanted to do some quick technical level-setting for folks that are not familiar with the CDS Hooks implementation guide. I know that we have a couple of SMEs that are on the line as well, and hopefully they can steer me in the right direction with their remarks if I do mischaracterize anything, but anyway, the CDS Hooks implementation guide itself describes the technical interactions between two high-level system actors.

One is the system or software that hosts CDS services and actually performs the clinical decision support, and we will call that the CDS server, and the second is the system or software that actually interacts with the CDS server, requests CDS services, and then consumes the output of any clinical decision support, and I will call this the CDS client. Both of these actors can actually be functions of the electronic health record, or they could be third-party systems. I tend to think of the client typically as the EHR, and then the server as either a function of the EHR or a third party, but it does not particularly matter for our purposes today. So, the CDS server will provide CDS services, and it defines these services as hooks. Hooks provide some of the basic information about a service, things like the name like the client would use to call the service, where the service might be used in a specific workflow, and then, importantly, any information that the service might require as input for making a decision or making a recommendation, and in the implementation guide, this input is referred to as context.

So, during a clinical workflow, some triggering condition is met. An easy example is a clinician trying to order a medication. When that happens, the CDS client will call the CDS server, and it is going to request the appropriate service based on whatever that triggering condition was. I will note here that the CDS Hooks implementation guide does not actually define what these triggers are, and it does not require clients or servers to support any specific hooks. It does define a few hooks, but those are more examples than requirements, but anyway, the CDS client is going to be interacting with the server over HTTP, pretty standard protocols, and it can provide any of the contextual information that the CDS server needs for the service that the client is calling.

For example, it can pass FHIR resources, so maybe it will tap a patient resource or some information about the patient, or it can actually give the CDS server the ability to search for relevant information using the client FHIR APIs. Then, the CDS server goes and processes any of this contextual information, actually runs the service, and generates a response, which is in the form of what is known as a card, as defined by the implementation guide. These cards are a JSON object. Although they are not specifically FHIR resources, they are the same general-format approach, but they provide information that the client can use to, for example, render on the user interface or the screen to provide some information to the user in clinical decision making. It can do things like provide a set of suggestions or actions that the user can take, it might have links to information resources, or information about how the CDS service derived its recommendations or outputs.

So, these cards are returned by the server, using HTTP again, and then, in some cases, depending on how things are set up, the client might be able to actually respond to indicate to the server what it did with the information that it was given, but again, that kind of depends on how the server is set up and the way it defines its services. So, that is really the basic workflow that the CDS Hooks implementation guide describes. I do want to move to the next slide just to summarize at a very high level. The CDS Hooks implementation guide describes the RESTful APIs and the interactions to integrate clinical decision support between the CDS clients and CDS services. It standardizes an approach for calling CDS services from within a workflow as well as for returning output from a service, and it provides a consistent set of capabilities around which CDS developers can design their CDS services. Given what we know about clinical decision support and how it can help address some of the complexities of clinical decision making and the fact that CDS systems are not necessarily standardized today, we request information under HTI-1 about a few things.

One of those is the maturity of the CDS Hooks standard and whether it is something that we would consider adding in certification criteria for health IT modules to adopt specific to the CDS Hooks implementation guide, and then, recognizing that the implementation guide itself does not describe specific hooks, triggering conditions, or things like that, we are also asking for comment about whether there are specific hooks that make sense to include in any future certification criteria. Finally, we are looking for general feedback about whether and how the CDS Hooks implementation guide can help improve workflow, reduce provider burden, and then, any use cases that we should bear in mind when considering the role of CDS Hooks in future certification criteria. So, that is pretty much all I have. It is short and sweet, and I am happy to turn it into our discussion session now.

Hung S. Luu
Thank you, Alex. Go ahead.

Hans Buitendijk
Sorry, I am only on the phone, so I cannot raise a hand. I apologize for that. I really appreciate the background from Alex, and the opportunity. We talked about that within the EHRA community in particular, and I think the primary discussion was there, and CURES on other perspectives as well, is that the CDS Hooks standard, if you will, is very much maturing and there is a lot of use starting to be around, and that is quite good, but when the question comes of whether it should be considered for certification, it starts to become a similar question, like should you certify to the base standards or to the implementation guides in the context of the use case, and this will be a good example where how CDS context of what is needed for

a particular context, where it fits in the flow, what, therefore, the hooks are, and as Alex indicated, these are also examples, generally, the sense is that where particular workflows and capabilities are being looked at to be certifiable, that is the place to then incorporate and include the use of CDS Hooks, and you will see that in the various implementation guides, that CDS Hooks is being incorporated there, and then there is clear understanding on how to use it. If you are only going to focus on certification of the plain CDS Hooks, the base standard, then there is a potential large variety of capabilities that are out there, but they are not necessarily going to hook up in the right context for a particular workflow where it is going to be intended to be used.

So, prior authorization, appropriate use criteria, and others are all the kinds of things where that trigger in ordering, scheduling, or whatever is going to be very helpful, but we need to clearly understand what the data is to be exchanged. So, the general census is a lot of support, interest, and maturation around the CDS Hooks itself, but when it comes to certification, the context in which it is supposed to be used is going to be critically important to understand what data, where, and which hook, and therefore, you know exactly what to do.

Hung S. Luu
So, we do have additional comments or questions in the chat as well. From Mark Savage, "Are there existing or anticipated patient-facing API uses of CDS Hooks?"

Bryn Rhodes
This is Bryn Rhodes. I am a cochair of CDS, have been involved with the CDS specification since the beginning, and have been involved in a number of pilot implementations and usage of that specification. The specification itself is designed to support provider interaction, so it is focused on that workflow, but there are uses of CDS Hooks that are patient-facing. The specification itself does not preclude that possibility, it just focuses on the provider support. So, yes, there are known uses of the specification itself and its focus on that. Regarding the question about if it will create a significant number of messages to providers, increasing the number of alerts, that is a concern that has been part of the CDS Hook specification development from the very beginning. That is something that we provide a lot of guidance within the specification about how to ensure that does not happen. In addition, institutions are in control, obviously, of the services that they enable for their systems to come out, and the workflow-specific nature of CDS Hooks ensures that the guidance that you are receiving is relevant to the step of the workflow you are involved in.

As Alex noted, the specification does not publish the hook definitions. They are not part of the specification, they are actually separate artifacts, and the way that works is we have a hook maturity model that is very similar to FHIR resource maturity, if you are familiar with that, and as Hans was noting, the use cases need to be identified, and the data exchanged on those use cases is specific to the hook definition, and so, it is part of each hook definition to say exactly what information is exchanged as part of that, and each of those hooks then goes through a hook maturity process. We are currently balloting a maturity for patient view, order select, and order sign, and those are the ones that, in addition to the CDS Hooks specification, we would recommend calling out those hooks specifically because the use cases need to be identified. The hook maturity goes through to make sure that there is implementation testing in the same way that the FHIR specification does with implementation guides.

Hung S. Luu
Whoever is controlling the slide deck, can we go to the previous slide, please? The previous slide of the CDS Hooks presentation, sorry. There were specific questions posed by the ONC team on Slide 24 that I am hoping that we can address. Could I have our subject matter experts focus on the request for comments?

Issac Vetter
Hey, everybody. This is Issac Vetter. I work at Epic. Along with Bryn, I am a cochair of the HL7 Clinical Decision Support Working Group, along with the infrastructure and messaging. I am also chair of the CDs Hooks Project Management Committee. So, first, you guys should be looking at Version 2 of CDS Hooks, not Version 1. There was a recent publication, is an additional iteration, and has some small improvements and medium-sized new features in CDS Hooks, STU-2, as published by HL7. As Bryn mentioned, we are also actively beginning to work on our first normative release. That will happen sometime probably next year. We are talking about specific hooks for implementation, and I think Alex and Bryn touched on this. Most of the content in the CDS Hooks-based specification is optional, and as Bryn commented on, the CDS Hook specification defines an objective maturity model for evaluating how mature a given hook is. So, for example, one of the hooks that is published by HL7 is the order signed hook. The idea is that the EHR can call out to a remote standards-based CDS service at the moment when a clinician is signing an order, for example, prescribing a med.

That order sign workflow step is standardized and described by HL7 alongside the CDS Hook specification with the types of information that will always be present when that happens, as well as the types of responses that the external CDS service can provide to help guide that prescriber. So, there is an objective maturity model, so I would recommend that the ONC use that published objective maturity model to help guide what hooks are important, as well as what use cases are valuable. So, again, doubling down on what Hans said, a lot of this requires use case specificity to be implementable. It does not make a lot of sense just to say, “Hey, EHRs, support CDS Hooks.” Rather, we need to be a little bit more specific, both in terms of what features that means, as well as which should be driven by what use cases we want to enable.

Steven Lane
But the standard supports that local specificity, right?

Issac Vetter
Yes.

Steven Lane
That is the key point.

Issac Vetter
Yes. And then, in terms of the actual use cases, I think Hans also referenced the two obvious ones. Those are the Da Vinci coverage requirements discovery work, that prior auth coverage determination work, which is one use case that exists in the industry, and the other is appropriate use criteria for imaging orders. In both of those cases, the standards community has already done some to a lot of work to try to figure out how that could use CDS Hooks in work. Thanks, Pooja. And then, any specific questions on that? Clem? I

think Bryn wants to cover some of the specific feedback that the HL7 Clinical Decision Support Working Group is also drafting on this RFI as well.

Bryn Rhodes
Yes, I have put some of that in direct chat in response to some of the questions here and tried to summarize what we are recommending here, but in regard to the question about how this interplays with algorithmic transparency requirements, the CDS Working Group has had a number of sessions where we have discussed this topic and have prepared some feedback on that. While we applaud the ONC for prioritizing equity in healthcare, prior to mandating national regulation in this area, we recommend studies to evaluate the impact of proposed regulations when implemented.

The proposed criteria for transparency potentially represent a significant burden on health IT vendors and clinical practices by requiring a significant amount of documentation that is not typically present or available, so they would then be responsible for producing that documentation when, to our knowledge, there is no literature that supports the positive impact of having computer-generated reminders with citations and supporting evidence, so it is not clear that there is actually benefit, and we recommend studies in that direction.

Hung S. Luu
Clem, you have your hand up.

Clem McDonald
Yes. I strongly support Bryn's suggestion, but it is not clear to me who actually controls the content of the CDS Hooks. Is it the receiving physician, the institution, or some godlike creature up above? That makes a difference in how they can be tweaked if they cause problems.

Bryn Rhodes
So, the CDS Hooks specification talks about separation of concerns. The content of the decision support rule logic that it runs in the service is owned by the CDS service, and they are the ones that determine what the algorithm should be, what data is involved, and how that runs, but the display and workflow interaction of the response of the CDS service is in the purview of the EHR and the implementing system. To address another of the questions about prioritization, which is related to that, the specification does not automatically prioritize, but it does provide a way for the CDS service to indicate a relative priority of the guidance that is giving back, and then, the EHR, the CDS client, has the responsibility for how that priority is then surfaced in the user interface in the clinical workflow.

So, the service can say this is just informational, this is a warning, or this is a critical alert, and then the user interface and the implementing system have the responsibility for how that is incorporated. In the implementations of CDS clients we have seen thus far, there is a tremendous amount of care and attention paid to how that is presented to the clinicians to make sure that we are not enabling inadvertently or increasing alert fatigue and provider burden.

Clem McDonald

There is literature about the problems with automatic reminders and the lack of attention or welcomeness of them in some circumstances. I think something like 15% are actually attended to, so I think we have to be very conscious of our enthusiasm for computers not ruining the physician's workday.

Hung S. Luu
Ike, you have your hand up.

Steven Eichner
I will jump in. I am not sure if this is a question, an observation, or a comment for the task force, so bear with me. Most of the area for the rule is focused on pretty technical specifications, which is good and necessary. I do want to make sure or help encourage ONC that, as the final rule gets published, there is a good explanation as to what this kind of change means for patients. At the same point, is there information or material within the RFI specifications to support connectivity with the hooks between things other than EHRs, such as patient apps or other components, and have we looped in some of those same types of elements on a patient tool that might be a service offered through an HIT module? Because I could easily see that there may be questionnaires or decision support tools that are presented for patients to contribute information, but are we applying the same standards in that space?

Bryn Rhodes
I personally have been involved in several projects related to shared decision making, and CDS Hooks, as a specification, is a component of a shared decision-making solution, and could potentially be used to support patient-facing decision support in that context, but what we typically see currently is more the use of existing patient portal functionality to deliver pre-visit questionnaires that then, the answers to those questionnaires are available to the patient and physician through SMART on FHIR and CDS Hooks during the visit, and so, it is a component of it, and certainly can be used to help facilitate that shared decision making.

Steven Eichner
Right, but I guess what I am thinking is that down the line, as we are looking at further integration of other systems and thinking about social determinants of health, community-based providers, and greater data integration, as a patient, I would like to be able to put my information in one place and have it be used where it is needed rather than constantly filling out the same type of data, so I could easily see a CDS module that serves patients' needs that is not quite built into an EHR, but is a third-party tool, basically the exact same kind of thing that a physician's CDS tool would look like, except a different consumer. I just want to think ahead about whether we have the right support here to support that kind of functionality.

Hung S. Luu
Ike, I hate to interrupt, but we need to go to public comment. I think we will have time to revisit your question once we get back from public comment.

Public Comment (01:22:08)

Michael Berry
Great. Thank you, Hung. We are going to open up our meeting for verbal public comment. If you are on Zoom and would like to make a comment, please use the hand raise function located on the Zoom toolbar at the bottom of your screen. If you are on the phone only, press *9 to raise your hand, and once called

upon, press *6 to mute and unmute your line. So, let's pause for a moment to see if anybody raises their hand. I am not seeing any hands raised, so we can resume our conversation for the next few minutes. Thank you.

Hung S. Luu
Thank you, Mike. Ike, continue.

Steven Eichner
I think I am done with my question/observation. Thinking about task force members or other folks, is this something that we should think about commenting on, and is it relevant?

Steven Lane
I think you make a good point, that we want to be able to use CDS and direct the recommendations to any sort of user, a nurse, physician, patient, administrative staff, etc., so it is certainly a good idea to craft a recommendation in that regard if our experts feel that makes sense, just given the state of the technology. As sort of a question to our SMEs, is CDS Hooks also the right tool to use when directing recommendations to software? Let's say I have a bot that is sending messages to patients. Do CDS alerts exclusively go to cognizant human beings, or can they be used in other steps in the workflow?

Issac Vetter
That is a great question. As part of that STU-2 version of CDS Hooks, we did introduce the concept of a background suggestion, what you would call a system action. It is seeing some uptake, and actually is part of the Da Vinci coverage requirements discovery project, where some implementers within that project have really focused on ensuring that the clinician need not always be interrupted with a card from a payer system saying prior auth is not needed or this big long form needs to be completed, and one of the ways that that project is helping to control the cases when information is put in front of the provider versus not is by using this recommendation to the system instead of to the actual end user.

I think there is a lot of flexibility, and as Clem was saying, there is real possibility here that a CDS service developer integrating with a healthcare organization can… The end result of a CDS Hooks integration could be increased provider burden based on alerts and alert fatigue, and the opposite is also true. Good use of this standard and these capabilities can also reduce provider burden, put more information in a nice way into the workflow, and it is entirely dependent on the use case and the quality of the implementation as to which of those two things actually will happen, and we are learning that, I think, from the Da Vinci Project.

Hung S. Luu
Steven, you have your hand up.

Steven Lane
I just want to say that having been building and using EHRs for well over 20 years now and having implemented what I think was probably the first CDS implementation within a commercial EHR 20 years ago, I think so much work has been done at the local level to design and implement workflow decision support, and certainly, the capabilities of different EHR vendors have varied over time. I think one of the real benefits of this functionality is that it allows other market actors to develop, support, and maintain CDS that can then be pushed into EHR systems without the need for either large, well-resourced vendors

providing that or large, well-resourced provider groups supporting that. You could just subscribe. I love the idea of companies or academic institutions competing on the demonstrable value of their CDS services, and then providers being able to just plug those in, so I see this as a key component of that and, as such, really support this going forward.

Hung S. Luu
We are almost at the hour, so I think this might be a good time to review our… Sorry, Clem? You have your hand up.

Clem McDonald
I thought I had been muted, sorry. I would like to reemphasize what others have said, that we really should study the effect of this stuff to see what is good, what is bad, and how to tweak it to make it good and make it bad. I also have done reminders for many decades of my life, and they are not always happily received, so that is just a final message.

Hung S. Luu
Thank you, Clem. And so, just to review our future meetings, we have one last meeting on June 1st as a separate task force workgroup, where we will be looking at FHIR subscriptions RFI, and then, after that is our final sprint, where we will be meeting as a sole task force to develop the final recommendations and transmittal letters in a presentation to HITAC for a final vote in the middle of June. And so, I encourage everyone who is interested to attend those meetings and provide your input either through verbal comments or through the chat. With that, I think we adjourned. Thank you, everyone.

Adjourn (01:29:39)