

## Health Information Technology Advisory Committee

### HTI-1 Proposed Rule Task Force 2023 Virtual Meeting

#### Group 3: ONC Health IT Certification Program Updates- Insights Condition, Standards Updates, and Request for Information (RFI)

### Meeting Notes | May 25, 2023, 10:30 AM – 12 PM ET

---

#### Executive Summary

The focus of the Group 3 Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Proposed Rule Task Force session on May 25 was to review and discuss the Pharmacy Interoperability Functionality Within the ONC Health IT Certification Program Including Real-Time Prescription Benefit Capabilities RFI and the Clinical Decision Support Hooks RFI.

#### Agenda

10:30 AM	Call to Order/Roll Call
10:35 AM	HTI-1 Proposed Rule Task Force Charge
10:40 AM	Pharmacy Interoperability Functionality Within the ONC Health IT Certification Program Including Real-Time Prescription Benefit Capabilities RFI
11:15 AM	Clinical Decision Support (CDS) Hooks RFI
11:50 AM	Public Comment
12:00 PM	Adjourn

#### Call to Order

Mike Berry, Designated Federal Officer, Office of the National Coordinator for Health IT (ONC), called the meeting to order at 10:31 AM.

#### Roll Call

##### Members in Attendance

Steven Eichner, Texas Department of State Health Services, Co-Chair  
Steven Lane, Health Gorilla, Co-Chair  
Hung Luu, Children's Health, Group 3 Lead  
Hans Buitendijk, Oracle Health  
Clem McDonald, National Library of Medicine  
Fillipe Southerland, Yardi Systems, Inc

##### Members Not in Attendance

Naresh Sundar Rajan, CyncHealth



## ONC Staff

Alex Baker, ONC  
Mike Berry, Designated Federal Officer, ONC  
Dustin Charles, ONC  
Alex Kontur, ONC  
Carmen Smiley, ONC  
Maggie Zeng, ONC

## Key Points of Discussion

---

### HTI-1 Proposed Rule Task Force Charge

HTI-1 Proposed Rule Task Force (Task Force) Co-Chairs, Steven Eichner and Steven Lane, welcomed Group 3 attendees. Hung Luu, Group 3 Lead, reviewed the meeting agenda and Steven Lane recapped the charge detailed in the [May 25 meeting presentation materials](#).

### Pharmacy Interoperability Functionality Within the ONC Health IT Certification Program Including Real-Time Prescription Benefit Capabilities RFI

Alex Baker, ONC, provided an overview and background of the Real-Time Prescription Benefit Capabilities RFI.

Carmen Smiley, ONC, reviewed details of RFI, including Section 1: Real-Time Prescription Benefit Certification Criterion and Section 2: Health IT Ecosystems for Pharmacy Interoperability. Carmen noted ONC seeks comment on potential transactions and capabilities for testing, requirements for Extensible Markup Language (XML) or Electronic Data Interchange (EDI) format use, requirements for use of NDC (National Drug Code Directory) or RxNorm codes, International Classification of Diseases – 10<sup>th</sup> Edition – Clinical Modification (ICD-10-CM) and SNOMED-Clinical Terms (CT) in clinical segments, patient specific benefit information system integration, and prescription benefit certification scope. ONC also seeks comment on formulary and benefit management, electronic prior authorization, and certification approaches.

Margaret Weiker, National Council for Prescription Drug Programs (NCPDP), noted NCPDP will be formally responding to the RFI. She explained NCPDP is opposed to replacement or secondary status of ICD-10-CM codes. Margaret said NCPDP recommends that any certification must support both RxNorm and NDC.

Shelly Spiro, Pharmacy HIT Collaborative, recommended both RxNorm and NDC be supported because they report different information and are complimentary to each other. RxNorm is not as granular as NDC. Shelly also noted the proposed workflow in the RFI will reduce burden on the prescriber side.

Frank McKinney, Point-of-Care Partners, noted it will be key to consider purpose when looking at the use of the patient segment and script. Frank said Real-Time Benefit version 12 does not have any patient location information in it. However, Real-Time Benefit version 13 added city and state information that can be used for aspects of response. Frank also noted from a certification standpoint; the workflows have the most success when the workflow being tested is objective and standardized.

### Discussion:



- Steven Eichner said there are issues with inputting medications that are in clinical trials or being tested by the FDA into electronic health records (EHRs). Is there an opportunity to accommodate the exchange of those types of medications?
  - Carmen said these are the challenges ONC hopes to address. ONC hopes the Real-Time Prescription Benefit capabilities are the first step in solving this issue.
- Hung Luu agreed that it makes sense to use both RxNorm and NDC because they are complementary to each other. He also verified that version 13 has additional functionality and information provided than in version 12. Version 13 is more favorable.
  - Margaret said NCPDP submitted a comment on the use of version 13 over version 12.
    - Shelly agreed.
    - Frank noted version 13 still supports the XML and EDI formats. There is movement towards JISON in the next few years, so it may increase burden to change it again.

## Clinical Decision Support (CDS) Hooks RFI

Alex Kontur, ONC, provided background and context to the CDS Hooks Implementation Guide (IG). ONC requests comment on whether to add a certification criterion for the adoption of the Fast Healthcare Interoperability Resources (FHIR) CDS Hooks specification v1.0, on specific hooks for implementation, and the use of CDS Hooks for supporting workflow improvement and reducing provider burden. Alex mentioned during a clinical workflow, when a clinician tries to order a medication, the CDS client will call the CDS server, and it will request the appropriate service based on whatever that trigger condition was. However, CDS IGs do not define the triggers.

Bryn Rhodes, Co-Chair of CDS Hooks Workgroup, Smile Digital Health, noted this CDS specification is designed to support provider interaction, but there are specifications that are patient facing. He noted the workflow-specific nature of CDS Hooks ensures that the guidance an individual receives is relevant to the step of the workflow they are involved in. The specification does not publish Hook definitions, as they are not part of the specification. They are separate artifacts. Each Hook goes through a Hook maturity process, and he recommends calling those out specifically since use cases need to be identified.

Isaac Vetter, Co-Chair of CDS Hooks Workgroup, Epic, noted the CDS Hooks workgroup is making progress on the first normative release set for next year. He noted the CDS Hooks specification maturity model is used to evaluate how mature a given Hook is. For example, one of the Hooks published by HL7 includes an order signed by Hook, meaning an electronic health record (EHR) can call out to remote standards-based CDS service when the clinician is signing an order. Isaac recommended that ONC use the published objective maturity model to guide what Hooks are important and what use cases are valuable.

## Discussion:

- Hans Buitendijk noted CDS Hook standards are still maturing. If ONC focuses on certification for CDS Hooks, there are a variety of capabilities. There is a lot of support around the CDS Hook, but when it comes to certification and when it is used, there needs to be more clarification and guidance.
- Bryn Rhodes recommended ONC conduct studies on the impact of the proposed regulations. He worried ONC's proposal may burden providers by requiring a significant amount of documentation.
  - Clem McDonald cautioned that automatic reminders are not always welcomed and may burden providers.
- Steven Eichner noted it is difficult for patients to have information in multiple places. He envisions a CDS module that serves patients and is built similarly to an EHR but is a third-party tool.
  - Isaac said there is flexibility and possibility that a CDS Hook integration could cause alert fatigue for providers. It depends on the use case and quality of the implementation for how this happens.
- Steven Lane said there has been a lot of work on the local level for decision support and workflow.



Functionality allows for other market actors to develop and maintain CDS that can be pushed into EHRs.

- Steven Lane encouraged Task Force members to fill out the recommendations document with their comments.
- Clem McDonald emphasized ONC should study the effects of implementation.

## **PUBLIC COMMENT**

Mike Berry opened the meeting for public comments.

## **QUESTIONS AND COMMENTS RECEIVED VERBALLY**

No questions or comments were received verbally.

## **QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT**

Mike Berry (ONC): Welcome to the HTI-1 Proposed Rule Task Force. Please remember to tag "Everyone" when using Zoom chat.

Mike Berry (ONC): Meeting materials can be found here: <https://www.healthit.gov/hitac/events/hti-1-proposed-rule-task-force-2023-group-3-3>

Steven (Ike) Eichner: Are there impacts on prescription drug management programs that need to be accounted for?

Pooja Babbrah: +1 on shelly's comment. My concern about just using RxNorm only is the payer system may not return an accurate price for the patient

Hung S. Luu: When in the life cycle of a product is the unique ingredient identifier (UNII) assigned? Could that be used for compounded or clinical trial medications?

Margaret Weiker: NCPDP supportive of adoption of the RTPB standard and certification. We will be asking that Version 13 be adopted. Should have certification capability for both formats (EDI and XML). Support mandating ePA transactions in SCRIPT.

Margaret Weiker:  
<https://standards.ncdp.org/Standards/media/pdf/Correspondence/2021/NCPDPLettertoONConRxNorm.pdf>

Margaret Weiker:  
[https://standards.ncdp.org/Standards/media/pdf/Correspondence/2023/20230213\\_To\\_CMS\\_CMS\\_4201\\_P\\_NPRM.pdf](https://standards.ncdp.org/Standards/media/pdf/Correspondence/2023/20230213_To_CMS_CMS_4201_P_NPRM.pdf)

Margaret Weiker: Page 4 contains the information regarding Version 13

Carmen Smiley: Big thanks to all SMEs for their incredibly helpful feedback today and engagement in this process. We look forward to reviewing everyone's comments in response to the RFI.

Susan Clark: @Carmen - thank you for your presentation and the extra emphasis great on patient matching. You know that's also my passion. :)

Kim Boyd: Version 13 for RTPB would be the better version for adoption

Margaret Weiker: In regard to ICD-10 and SNOMED, ICD-10 is the preferred code set. It is also mandated under HIPAA.



Mark Savage: Are there existing or anticipated patient-facing API uses of CDS hooks? (So, not solely clinical workflows?) I'm thinking, for example, about shared care plans/planning among all care team members, including individual.

Clem McDonald: Will CDS hooks create a storm of interruptive reminders. The problem of excessive reminders has been noted in the literature.?

Steven Lane: EHRs today already provide clinical decision support based on proprietary solutions and logic. The CDS Hooks Standard provides a common method for delivering CDS content to users, which will support the standardized delivery of 3rd party decision support, lessening burden on provider organizations to develop and maintain this content themselves. The availability of this functionality will not, in and of itself, increase the number of alerts, except perhaps for providers whose systems do not provide robust functionality today.

Steven Lane: Does the specification include the ability to automatically prioritize alerts and deliver to end users a specified number or type of alert based on local/individual preferences?

Clem McDonald: I like Steven Lane's question

Isaac Vetter: The CDS Hooks specification doesn't specify an ability to accommodate end-user preferences, Rather, this should be accommodated by logic within the CDS Service and EHR configuration.

Bryn Rhodes: We recommend if the CDS Hook specification is named, that the latest version STU2 be named as the most recent version

Frank McKinney: Summarizing my comments related to RTPB to be included in the public record: Recommend naming of RTPB version 13 for certification because it supports content that will benefit migration from existing formats (e.g., Formulary Status and CoverageStatusMessage in the response, and patient address information in the request). Support including RxNorm in the request, in addition to the product-level NDC needed for pricing. Suggest caution when including certification rules related to prescriber workflows because they are by nature less objective and difficult to test consistently, and because workflow is typically configurable by practice/site--and so can differ from the configuration tested--reducing the value of certification. Recommend supporting both XML and EDI formats to ease migration for implementers.

Fil Southerland: Does the CDS IG consider how we surface evidence-based CDS vs predictive models? How does this interplay with new algorithmic transparency requirements?

Steven Lane: Good question Fil.

Bryn Rhodes: We recommend also naming specific hook definitions including patient-view, order-select, and order-sign

Pooja Babbrah: we are also using CDS Hooks in the REMS medication use case under the CodeX accelerator. pilots are starting next month

Kim Boyd: CDS Hooks has been challenging for some in oncology but is progressing - CodeX PA Use Case executing on pilot in early 2024

Kim Boyd: Yes @Steven it does - CodeX Prior Authorization in Oncology

Frank McKinney: Additional RTPB comment to included in the record... With respect to augmenting patient information in a real-time benefit request with that in the SCRIPT Patient segment: The RTPB responder typically bases member matching on insurance information (e.g., PBM Member ID, Cardholder ID) rather than demographics. However, the RTPB 13 request does include additional demographics (patient address information) that was not present in RTPB 12, which could potentially be used in patient matching. Mechanically, incorporating the SCRIPT Patient segment in an RTPB 12 or RTPB 13 request would require



the NCPDP RTPB message definition to be modified, which would result in a new version of the RTPB standard.

Mark Savage: +1 on Ike's suggestions about patient-facing applications for CDS Hooks!

Steven Lane: Time for public comment! Public participants with comments please raise your hand in Zoom.

Cathy Graeff: Isn't the RTPB responder typically the patient's health plan so that patient matching using identifiers related to the insured and their benefit plan are critical as well as the specific member under the plan?

Pooja Babbar: Patient facing CDS hook application is interesting concept. We could look into it for the REMS medication use case as there is often simple information need to be captured from the patient (e.g., yes/no received patient education materials, etc.)

Clem McDonald: +1 to Steves suggestion about where to direct the output of hooks

Steven Lane: Thank you everyone for your participation!

## **QUESTIONS AND COMMENTS RECEIVED VIA EMAIL**

No comments were received via email.

## **Resources**

[HTI-1 Proposed Rule Task Force 2023 Webpage](#)

[HTI-1 Proposed Rule Task Force 2023 – May 25, 2023 Meeting Webpage](#)

[HITAC Calendar Webpage](#)

## **Adjournment**

The meeting adjourned at 12:00 PM.