The Office of the National Coordinator for Health Information Technology

Health IT Advisory Committee

Health IT for the Care Continuum Task Force

Carolyn Petersen, co-chair
Chris Lehmann, co-chair

April 19, 2019

Agenda

- Call to Order/Roll Call
- Welcome Remarks
- Privacy Considerations Presentation
- Neonatal Abstinence Syndrome (NAS) Presentation
- Recap Discussion - Opioid Use Disorder (OUD) Request for Information (RFI) & HITAC Feedback
- Public Comment
- Next Steps and Adjourn

Privacy Considerations:
21st Century Cures Act Proposed Rule

ONC Health IT for the Care Continuum Task Force

Hannah K. Galvin, MD, FAAP
Medical Director of Informatics
Lahey Health

19 April 2019

Beth Israel Lahey Health

Disclosures

Beth Israel Lahey Health

No financial conflicts to disclose.

Currently working with the AAP Council on Clinical Information Technology and collaborating with HIMSS to develop multidisciplinary national workgroup to address the challenge of industry-wide adoption and implementation of granular tagging of sensitive data to support patient privacy preferences while promoting interoperability.

AGENDA

Beth Israel Lahey Health

Thoughts on proposed rule

- New DS4P-send and DS4P-receive criteria (§170.315(b)(12) and § 170.315(b)(13))
- FHIR v3-based Consent2Share resource

Implementation considerations for pediatric use cases

Implementation considerations for opioid use disorder cases

New DS4P Criteria

Beth Israel Lahey Health

- Applaud ONC's response to request for more granular tagging standard to meet clinical use cases.
- Tagging available at the following levels:

CDA R2 Documents: Discharge, Encounter, Operative Note, Procedure, and Interval Documents

CDA R2 Sections:

- Advance Directives Section (entries optional)
- Advance Directives Section (entries required)
- Allergies Section (entries optional)
- Allergies Section (entries required)
- Anesthesia Section
- Assessment and Plan Section
- Assessment Section
- Chief Complaint and Reason for Visit Section
- Chief Complaint Section
- Complications Section
- DICOM Object Catalog Section - DCM 121181
- Discharge Diet Section
- Encounters Section (entries optional)
- Encounters Section (entries required)
- Family History Section
- Fetus Subject Context
- Findings Section (DIR)
- Functional Status Section
- General Status Section
- History of Past Illness Section
- History of Present Illness Section
- Hospital Admission Diagnosis Section
- Hospital Admission Medications Section (entries optional)
- Hospital Consultations Section
- Hospital Course Section
- Hospital Discharge Diagnosis Section
- Hospital Discharge Instructions Section
- Hospital Discharge Medications Section (entries optional)
- Hospital Discharge Medications Section (entries required)
- Hospital Discharge Physical Section
- Hospital Discharge Studies Summary Section
- Immunizations Section (entries optional)
- Immunizations Section (entries required)
- Implants Section
- Instructions Section
- Interventions Section
- Medical (General) History Section

CDA R2 Entries:

- Admission Medication
- Advance Directive Observation
- Age Observation
- Allergy Observation
- Allergy Problem Act
- Allergy Status Observation
- Boundary Observation
- Code Observations
- Comment Activity
- Coverage Activity
- Discharge Medication
- Drug Vehicle
- Encounter Activities
- Estimated Date of Delivery
- Family History Death Observation
- Family History Observation
- Family History Organizer
- Health Status Observation
- Hospital Admission Diagnosis
- Hospital Discharge Diagnosis
- Immunization Activity
- Immunization Medication Information
- Immunization Refusal Reason
- Indication
- Instructions
- Medication Activity
- Medication Dispense
- Medication Information
- Medication Supply Order
- Medication Use - None Known (deprecated)
- Non-Medicinal Supply Activity
- Plan of Care Activity Act
- Plan of Care Activity Encounter

Workgroup for Electronic Data Interchange: www.wedi.org

DS4P: Disclosure & Rediscosure

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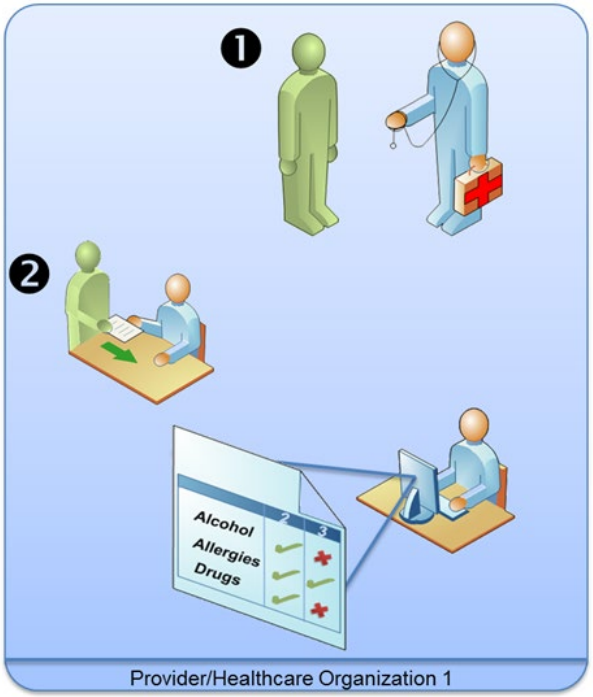

❶ The Patient receives care at their local hospital for a variety of conditions, including substance abuse as part of an Alcohol/Drug Abuse Treatment Program (ADATP).

❷ Data requiring additional protection and consent directive are captured and recorded. The patient is advised that the protected information will not be shared without their consent.

Slides courtesy of Johnathan Coleman, CISSP – DS4P Initiative Coordinator, S&I Framework, OCPO/OST/ONC/HHS (CTR)

DS4P: Disclosure & Rediscosure

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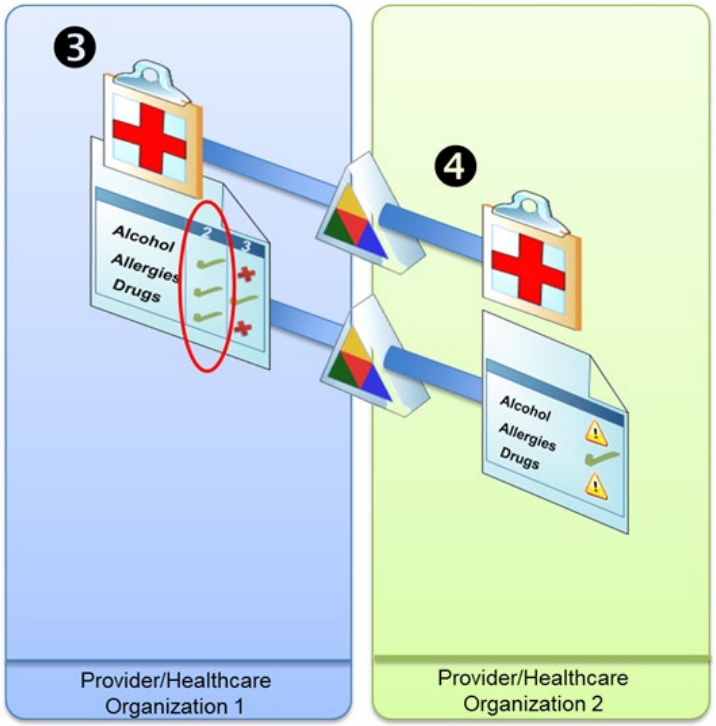


❸ A clinical workflow event triggers additional data to be sent to Provider/Organization 2. This disclosure has been authorized by the patient, so the data requiring heightened protection is sent along with a prohibition on redisclosure.

❹ Provider/ Organization 2 electronically receives and incorporates patient additionally protected data, data annotations, and prohibition on redisclosure.

Slides courtesy of Johnathan Coleman, CISSP – DS4P Initiative Coordinator, S&I Framework, OCPO/OST/ONC/HHS (CTR)

DS4P: Challenges with Vendor Adoption

Beth Israel Lahey Health

- Document-level standard less of an issue than prioritization and lack of a business case.
- Pediatric certification good first step.
- Caveats:
  - Broad definitions open to vendor interpretation, difficult to measure success.
  - Degree of standardization is needed to promote interoperability
  - C-CDA is not the only data exchange standard (see use cases)

DS4P: High-Level Recommendations

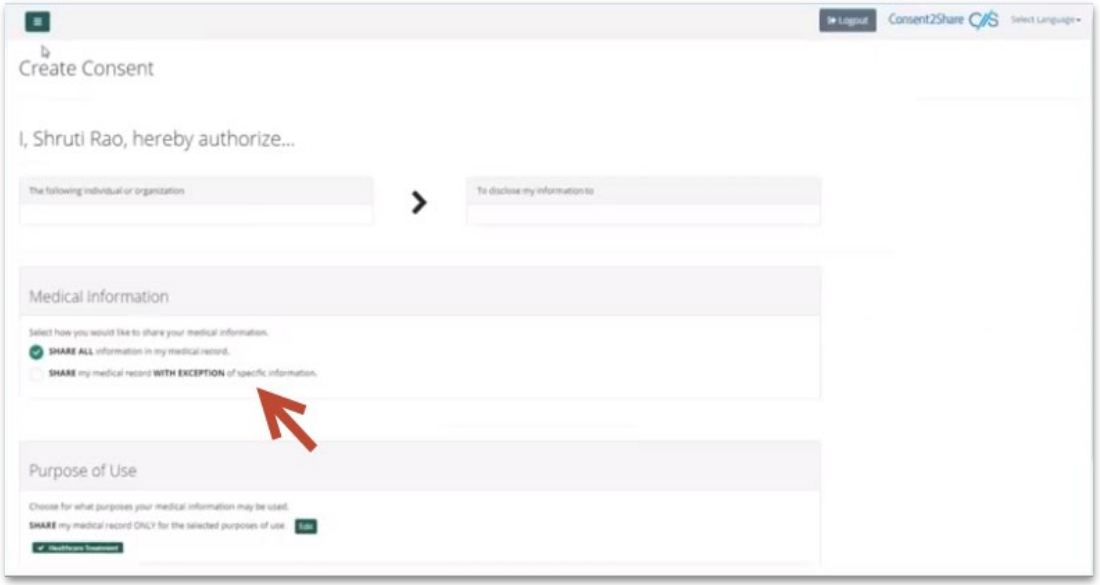
Beth Israel Lahey Health

- Include as a requirement for 2015 Edition Certification to encourage vendor prioritization.
- Require discrete metric(s) for certification.
- Sponsor workgroup to develop broader, standardized implementation framework.

Consent2Share Resource

Beth Israel Lahey Health

- Applaud ONC's efforts toward proposing consent management standard.
- C2S compatible with DS4P; allows for consent initiation, management, and redaction.
- Caveat:
  Vendor/organization must evaluate value sets to define "sensitive data" - requires alignment with granular data tagging by DS4P.



Pediatric Use Cases

Beth Israel Lahey Health

We believe these criteria could, for example, help enable providers to:

- Limit the sharing of reproductive and sexual health data from an EHR in order to protect the minor's privacy;
- Prevent disclosure of an emancipated minor's sensitive health information, while also permitting a parent or legal guardian to provide consent for treatment; and
- Segment child abuse information based on jurisdictional laws, which may have varying information sharing requirements for parents, guardians, and/or other possible legal representatives.

(Proposed rule, page 142)

Pediatric Use Cases

Beth Israel Lahey Health

Limit sharing of reproductive/sexual health data from EHR to protect minor's privacy

- Inter-organizational:
  - -Vendor-specific privacy functionality leveraged; generally not granular
- Between organizations:
  - -C-CDA most commonly utilized
- Integrated systems for clinical care: HL7, NCPDP, DICOM
- **Payors: ASCX12 EDI 1550**
- **Printed materials:** C-CDA for SCR, school note separate
- **Patient Portal & tethered PHR:** *some* C-CDA
  - **OpenNotes**: not C-CDA
- BlueButton, next generation PHR's and apps: FHIR; can parse C-CDA's

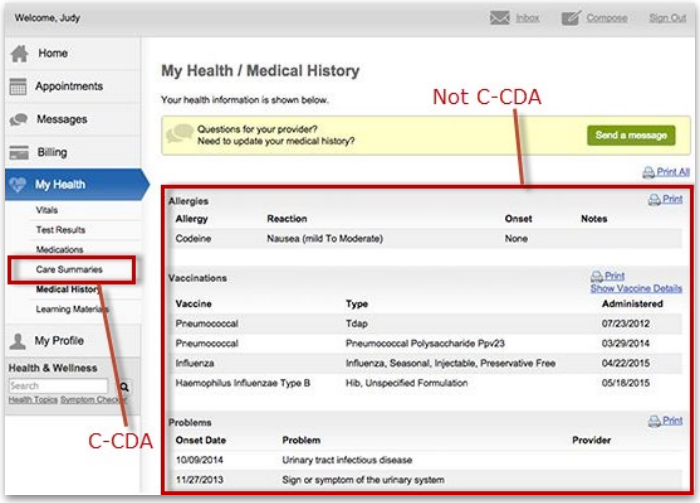


Image from www/dahlclinic.org

Pediatric Use Cases

Beth Israel Lahey Health

Prevent disclosure of emancipated minor's sensitive health information, while permitting parent/guardian to provide consent for treatment

If obtaining consent for treatment:

- At institution: C-CDA not involved; sensitive health information redacted from consent via vendor-specific functionality.
- Via Portal proxy access: sensitive health information not limited to C-CDA.

Pediatric Use Cases

Beth Israel Lahey Health

Segment child abuse information based on jurisdictional laws

Data sharing modalities similar to reproductive/sexual health use case.

Role definitions and security are needed around non-disclosure of specific information (diagnoses, notes, lab/imaging orders/results) to specific individual(s).

OUD Use Cases

Beth Israel Lahey Health

We believe this proposal would offer functionality that is more valuable to providers and patients, especially given the complexities of the privacy law landscape for multiple care and specialty settings. We also believe this proposal could lead to more complete records, contribute to patient safety, and enhance care coordination. Additionally, we believe this proposal may support a more usable display of OUD information at the request of patients within an EHR and we invite input on best practices, including the processes and methods by which OUD information should be displayed.

(Proposed rule, pages 150-151)

OUD Use Cases

Beth Israel Lahey Health

OUD Across Care and Specialty Settings for Care Coordination

- DS4P mostly useful re: sharing of data *between* organizations; less useful inter-organization
- Common practices:
  - Limit data sharing for patients with “sensitive conditions” (i.e. HIV, OUD)
  - Segregated BH EHR
- Limitations:
  - As per reproductive/sexual health slide
  - Opiate-related patient-level documents (Opiate Agreement, Voluntary Non-Opioid Directive) not C-CDA; interoperability frameworks working on ways to share Advanced Directives

Best Practices on Usable Display

Beth Israel Lahey Health

Data Visualization at Point of Care

Guidance needed from ONC and/or industry consensus.

Some organizations may feel the need for emergency access.

Ideal state: dynamic interaction with C2S application allowing real-time patient consent and display of data.

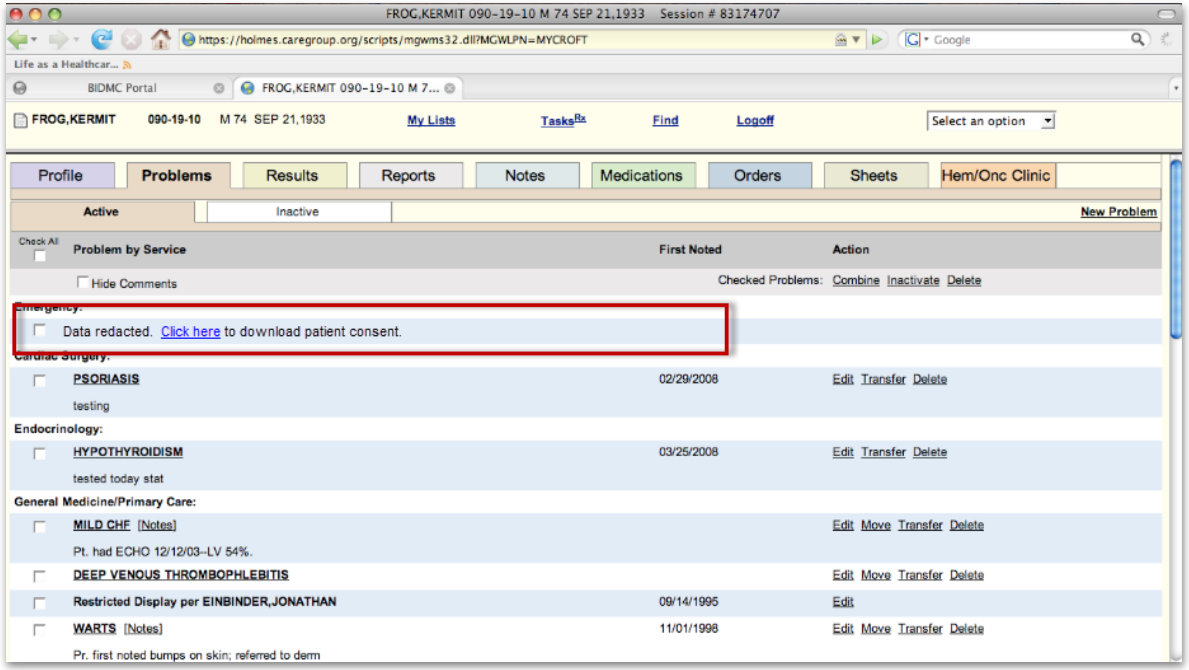


Image adapted from Dr. John Halamka: geekdoctor.blogspot.com

Data Availability for Clinical Decision Support

Beth Israel Lahey Health

- CDS logic has been built throughout systems without regard for potentially sensitive data.
- If implemented properly, CDS fires to right user in right workflow at right time - should not be firing to users who do not need information for clinical care.
- CDS algorithms pull from many areas of the record not necessarily included in C-CDA elements.
- Patient safety concerns if CDS altered due to non-disclosed sensitive data.

Recommendation: guidance from ONC/industry consensus that all patient data be available for CDS, but that CDS tools continue to be implemented according to the '5 Rights' with awareness of potential patient privacy concerns.

Image from www.careinnovations.org

Summary of Recommendations

Beth Israel Lahey Health

- Consider including DS4P as a broader requirement (perhaps to support OUD prevention & treatment) for 2015 Edition criteria to encourage vendor prioritization.
- Recommend requiring discrete metric(s) to focus vendor direction.
- Recognize that data exchange is complex and DS4P and C2S alone will not fully address proposed pediatric and OUD use cases.
- Consider ONC sponsorship of multidisciplinary workgroup forming to develop broader implementation framework, including consensus recommendations around:
    - Industry-wide adoption of these and potentially additional standards to protect privacy while promoting interoperability.
    - Data visualization at the point of care and availability for CDSS.

Image from www.careinnovations.org

Beth Israel Lahey Health

Discussion

Data Segmentation for Privacy (DS4P) and Consent Management for APIs Certification Criteria Discussion

- **Specific Charge:** Provide recommendations on the following:
  - 2015 Edition "DS4P" and "consent management for APIs" certification criteria
    - DS4P Certification Criteria Preamble
    - DS4P Certification Criteria Regulation Text
    - Consent management for APIs Preamble
    - Consent management for APIs Regulation Text
- Recap/summarized comments from 4/12 TF Meeting on DS4P:
  - Member acknowledged DS4P would help for opioid management and provide greater confidence in sharing of OUD information; the FHIR and API proposal also would further the exchange of information and is important to this part of the provision
  - Member raised question regarding the feasibility for the receiving entity to process and maintain the confidential markings; ONC indicated that the standard proposal contains both send and receive criteria though the receiving entity would need procedures for proper handling of such markings

Neonatal Abstinence Syndrome (NAS) Presentation

Neonatal Abstinence Syndrome (NAS) Discussion Questions

1. Neonatal Abstinence Syndrome (NAS)

- What are some health IT policies, functionalities and standards to support the NAS use case?
- Are there any ONC pediatric recommendations that are particularly relevant to the NAS use case?

Opioid Use Disorder (OUD) Recap from 4/12

- **General Sense/Value:**
  - » Health IT can further clinical priorities and also public health goals while offering more systematic, coordinated approaches for OUD prevention and treatment
  - » Health IT can support clinician's ability to access and use community resource information and to make referrals for individuals with or at risk for OUD
  - » Medication history in PDMPs should be available "as a single point of entry" for clinicians to access w/o burden of having to log in to and use many portals
    - ONC notes regarding this comment, the updated 2017071 NCPDP SCIPT open standard provides the capability to integrate data from a PDMP into an EHR or other electronic prescribing systems, as do other open standards outlined in the ONC ISA; this can support the access of PDMP information from within the EHR to the extent that the technology exists to allow for data integration between EHRs and PDMPs, and state-level regulation allows for data integration
    - The Task Force may offer additional comment on any perceived gaps as pertains to this standard or other existing, new, or proposed standards/certification for OUD prevention/treatment

Opioid Use Disorder (OUD) Recap from 4/12 cont'd

- **CDS:**
  - The members acknowledge the value of CDS tools, including CDS Hooks, for the OUD use case.
  - Member explored issues of burden, usability, and "trigger" for CDS Hooks from clinician's perspective as pertains to workflow considerations
  - Member inquired as to how the TF may support CDS, and for CDS Hooks identified from presenter's response the importance of having underlying data available and of the USCDI
  - Member noted that implementation should be made simple as possible (possibly one click) – easier to track and monitor the desirable outcome

- **Public Comment:**
  - Public comment from Pew indicated ONC should explore other aspects of its NPRM for advancing pediatric care and health by indicating, as examples, clarification that end users and test cases include pediatricians and pediatric practice settings.

HITAC Meeting 4/10 Feedback Summary

- **Logistical Comments & Questions:**
  - HITAC members sought clarification on framing for recommendations for which they are voting on
  - Members sought clarification on ONC pediatric recommendations as pertains to supporting certain settings and/or universal setting
  - HITAC sought a listing of functionalities that should be included in technology and reference each standard (if time permits)
    - Note – ONC will develop a visual table based upon the correlated items in the technical worksheet
  - Comment to limit certification requirements because it may cause regulatory burden
    - Caution to avoid creating redundant certification criteria or requirements

HITAC Meeting 4/10 Feedback Summary cont'd

- **Recommendation 8 (Associate maternal health information and demographics with newborn)**
  - One comment of disagreement on the statement that there are no standard nomenclature available
  - Question on what process has been used to look at the certification criteria in the pediatric setting and if there has been input from consumers
    - Separate question on if there was any discussion about newborns and/or adults who are privately adopted; should be able to link to birth maternal info crucial for the care of child
  - Suggestion to look where we can push out and allow the consumer to be able to transfer and be able to determine privacy and control

HITAC Meeting 4/10 Feedback Summary cont'd

- **Recommendation 4 Supplemental (Problem-specific age of consent)**
  - Comment that removing this Children's EHR Format requirement to the main recommendation could be a red flag. Agrees that it is not vendor responsibility to know all state/local laws but they should be required to provide certified technology that fits into their customer's practice
- **Recommendation 5 Supplemental (Synchronize immunization histories with registries)**
  - Noted that there are school forms in certain states/local areas that cannot be digitized
- **General Comments:**
  - Encouraged TF and Chairs to listen in on USCDI meetings for their discussion on pediatric vital signs – commented that there are substantial overlaps and that our task forces should stay in sync
  - Suggestion to keep in mind FHIR based apps as we move towards app economy. Note to make sure there is nothing specific in regulations to prohibit
  - Commended TF for taking on complex issues

Workplan

Meeting Date	Draft Discussion Items
	• TF Kick-off Meeting • Review of charge, discussion
	• TF Meeting • Discussion/early draft recommendations
	• TF Meeting • Discussion/early draft recommendations
	• Present draft recommendations to HITAC
	• TF Meeting • Discussion, update and/or revise recommendations
	• TF Meeting • Discussion, update and/or revise recommendations
	• TF Meeting • Discussion, update and/or revise recommendations
	• Present progress on draft recommendations to HITAC
	• TF Meeting • Discussion, update and/or revise recommendations
	• **TF Meeting** • **Update and revise recommendations**
April 23	
April 25	• Present final recommendations to HITAC
April 29 – May 2	• ONC prepares final transmittal letter from HITAC
May 3, 2019	

Public Comment

To make a comment please call:

Dial: 1-877-407-7192

*(once connected, press "*1" to speak)*

All public comments will be limited to three minutes.

You may enter a comment in the
"Public Comment" field below this presentation.

Or, email your public comment to onc-hitac@accelsolutionsllc.com.

Written comments will not be read at this time, but they will be delivered to members of the Workgroup and made part of the Public Record.

The Office of the National Coordinator for Health Information Technology

Health IT Advisory Committee

Meeting Adjourned

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OUD RFI Appendix

- *In the proposed rule, we summarize some of these 2015 Edition certification criteria identified and indicate how they support care coordination, the prevention of OUD and overdose, and the detection of opioid misuse, abuse, and diversion. We have also identified the proposals for revised or new 2015 Edition criteria within this proposed rule that we believe can support clinical priorities, advance interoperability for OUD (including care coordination and also the effective use of health IT for the treatment and prevention of OUD). We welcome input from stakeholders specifically on these criteria within the context of OUD prevention and treatment, as well as input on the identification of other criteria included either in the 2015 Edition and/or that are proposed in other parts of this rule that may be considered a clinical and interoperability priority for supporting OUD treatment and prevention.*

OUD RFI Appendix – CDS Hooks

- *Improving how opioids are prescribed through evidence-based guidelines can ensure patients have access to safer, more effective chronic pain treatment while reducing the risk of opioid misuse, abuse, or overdose from these drugs. In response to the critical need for consistent and current opioid prescribing guidelines, the Centers for Disease Control and Prevention (CDC) released the Guideline for Prescribing Opioids for Chronic Pain. While progress has been made in training prescribers and fostering the adoption of the CDC guideline, the President's Opioid Commission acknowledged that "not all states have adopted the guideline, not all physicians are aware of them, and sound opioid prescribing guidelines are far from universally followed." Clinical decision support (CDS) Hooks is a health IT specification that has the potential to positively affect prescriber adoption of evidence-based prescribing guidelines by invoking patient-specific clinical support from within the clinician's EHR workflow. ONC is currently collaborating with CDC on a project to translate the CDC guideline into standardized, shareable, computable decision support artifacts using CDS Hooks. We recognize that CDS Hooks is still an emerging technology and seek input on the adoption of the CDS Hooks specification for opioid prescribing and OUD prevention and treatment. We also request public comment on other health IT solutions and effective approaches to improve opioid prescription practices and clinical decision support for OUD.*

- Guideline for Prescribing Opioids for Chronic Pain: https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm

- President's Opioid Commission: https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf