The Office of the National Coordinator for Health Information Technology

Health IT Advisory Committee

U.S. Core Data for Interoperability Task Force

Christina Caraballo, Co-Chair
Terry O'Malley, Co-Chair

May 31, 2019

Agenda

- Call to Order/Roll Call
- Opening Remarks
- Promotion Model Timeline
- Promotion Model Guidelines
- Promotion Model Data Element Lifecycle
- Public Comment
- Next Steps and Adjourn

General Discussion About Promotion Model Timeline

- Including:
  - Speed/duration of promotion
  - Data elements of critical importance

Promotion Model Guidelines (1 of 3)

- Any individual or entity may submit a Data Element to the USCDI process as well as contribute to a Data Element's promotion.
- Stakeholders will submit Data Elements for consideration as part of the USCDI Promotion Model.
  - A Data Class with multiple Data Elements may be submitted, but each constituent Data Element will be individually evaluated for level placement (ADD: "and advancement").
  - A Data Class may have Data Elements at different classification "levels."
  - A single Data Element may be a Data Class in name as well (e.g., Immunizations).
- Task Force Discussion:
  - How many "data elements" get advanced at one time?
  - Is there a programming cost that may be difficult to estimate?

Promotion Model Guidelines (2 of 3)

- The Data Element information submitted for entry to the USCDI Promotion Process will determine whether the Data Element is classified as Level 1 or Level 2.
  - » Task Force Discussion: One task will be to define those criteria precisely both for initial level and advancement. Both should align.
- No Data Element can proceed directly into the USCDI. To promote transparency, planning, and predictability a Data Element would need to be in Level 2 for at least one process cycle before promotion to USCDI.
  - » Task Force Discussion: This raises the issue of "time-line". How long will it/should it take to advance? Are there ways to speed up this process, eg. engage SDOs early in process?

Promotion Model Guidelines (3 of 3)

- Data Elements that do not demonstrate advancement will be removed from the promotion process after specified periods of time.
  - » Task Force Discussion:
    - Define a “cycle time” that allows for the inherent speed of standards development and testing while trying to keep the pathway to USCDI as uncluttered as possible.
    - It is not clear what that timeline should be.
    - If a data element meets the criteria to get into a stage, what’s the harm of keeping it there? Does it remain in the que as “inactive”?
    - If implementing this type of a process, should we consider a demotion process rather than removal?
- The USCDI Promotion Process guidelines and criteria will be transparent to the public.

Promotion Model Lifecycle for Submitted Data Elements (1 of 3)

- A “submission cycle” begins when ONC announces a new version of the USCDI, which marks the beginning of a new Data Element submission period. A submission cycle ends at the end of the calendar year when the Data Element submission period closes.
- Submitted Data Elements exist as “Comments” until they are classified into Level 1 or Level 2.
  - » Task Force Discussion:
    - This approach allows anyone to submit a “comment” which ONC will advance based on internal criteria.
    - Should we advise about what those criteria should be?
    - Would it calling these data elements “Unclassified Proposals” simplify and more accurately describe this tier?

Promotion Model Lifecycle for Submitted Data Elements (2 of 3)

- Data Elements not classified into Level 1 or Level 2 have three submission cycles from the ONC final decision period to remain at the comment level before they are removed.
  - Data Element submissions may be (TF: add "modified/")updated and resubmitted to be reviewed again. If the submitter updates and resubmits the Data Element, the three-year cycle restarts.
  - ONC will make the level classification decisions for each new submission.
- Task Force Discussion:
  - Is 3 years the appropriate timeline from initial submission?
  - How should proposals be re-submitted? And how does this adapt as industry readiness changes.
  - Should modification should be a requirement? The original submission may be viable due to shifts in the industry.

Promotion Model Lifecycle for Submitted Data Elements (3 of 3)

- Once classified into Level 1 or Level 2 by ONC, a Data Element has up to three submission cycles to be promoted to its (TF: replace "its" with "the") next level (from Level 1 to Level 2, or Level 2 to USCDI). ONC retains discretion to keep a Data Element in Level 2 for longer than three submission cycles.
  - » Task Force Discussion: How are related proposals grouped and/or split?
- When a Data Element is removed from the process due to lack of progress, it will be archived in a separate section on the USCDI webpage. To be reinserted (TF: change reinserted to reintroduced) into the promotion process, the Data Element must be resubmitted.
- After a Data Element's level classification has been published, a submitter may request to be debriefed on the classification decision.
  - » Task Force Discussion:
    - This should be public.
    - Would it be reasonable to expect ONC to provide/publish/post a write-up regarding each such decision so as to make more transparent to all stakeholders the logic behind their decisions? Why make a submitter submit an individual request?

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

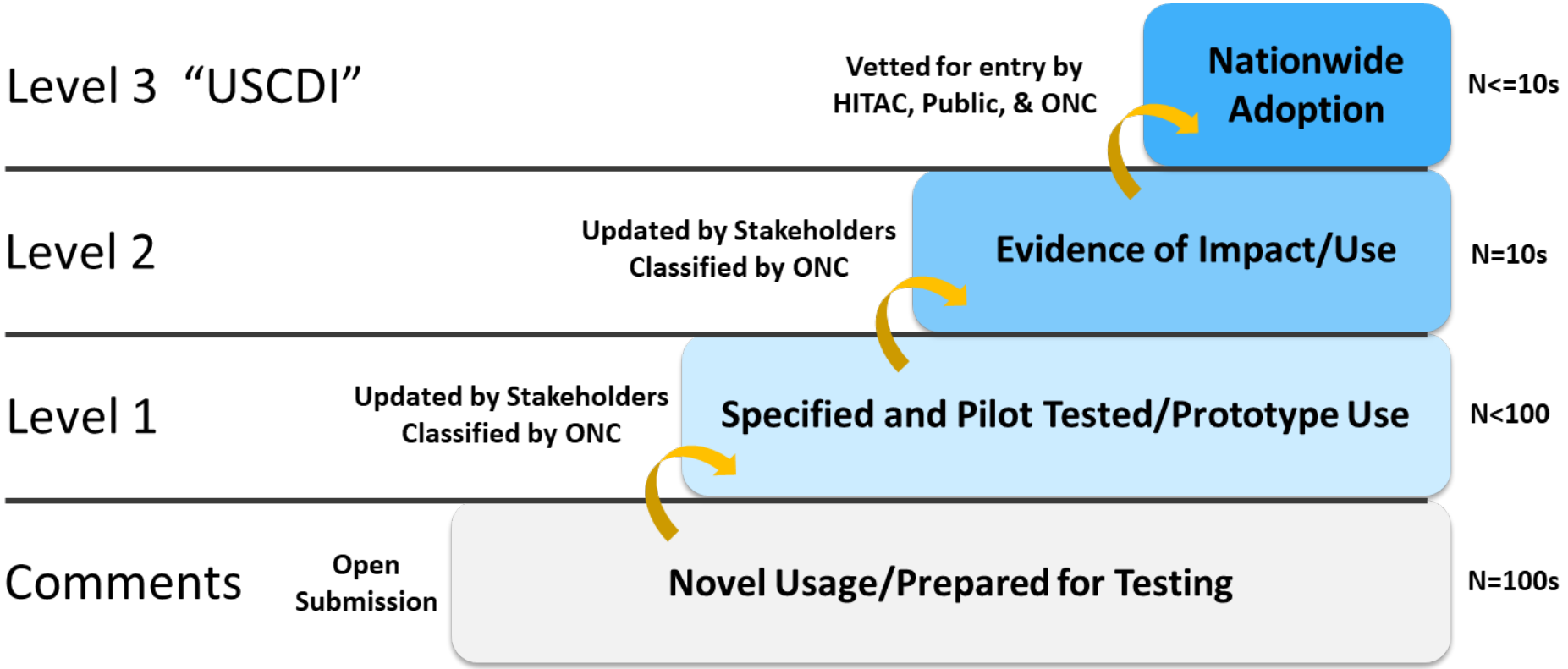
Meeting Adjourned

@ONC_HealthIT @HHSONC HealthIT.gov

USCDI Task Force Charge: Data Element Promotion Model

- **Overarching Charge:** Review and provide feedback on the U.S. Core Data for Interoperability (USCDI) Data Element Promotion Model.
- **Specific Charge:** Provide recommendations on the following:
  - » Promotion Model Lifecycle for Submitted Data Elements
  - » Data Element Submission Information
  - » Data Element Promotion Criteria
- **Supplemental:** Discuss additional defining criteria as needed

USCDI Promotion Model – Annual Promotion/Status



Promotion Model Guidelines

- Any individual or entity may submit a Data Element to the USCDI process and contribute to a Data Element's promotion.
- The USCDI Promotion Process guidelines and criteria will be transparent to the public.
- The Data Element information submitted for entry to the USCDI Promotion Process will determine whether the Data Element enters Level 1, Level 2, or requires more development before entering the Process.
- No newly-proposed Data Element can proceed directly into the USCDI.
- Data Elements that do not demonstrate technical development activities will be removed from the promotion process after specified periods of time.

Promotion Model Lifecycle for Submitted Data Elements

- Submitted Data Elements exist as “Comments” and are then classified by ONC.
- Data Elements not classified into Level 1 or Level 2 have three submission cycles from the ONC final decision period before they are removed. Data Element submissions may be updated and resubmitted to be reviewed again.
- Once classified into Level 1 or Level 2, a Data Element has up to three submission cycles to be promoted to its next level (from Level 1 to Level 2, or Level 2 to USCDI).
- When a Data Element is removed from the process due to lack of progress, it is archived in the Comments section.
- After a Data Element’s classification has been published a submitter will have an opportunity to ask for a debrief on the classification decision.

Data Element Promotion Criteria: From "Comment" to Level 1 classification

- A new Data Element submission must include the following information:
  - Data Element name and description
  - Why should this Data Element be captured and exchanged nationwide?
  - Do systems currently capture this Data Element?
  - Do standards exist to represent and exchange this Data Element?
  - Please describe any testing, pilots, or production use of the Data Element.

- To be formally entered into the Promotion Process at Level 1, a Data Element must meet the following requirements:
  - Identify at least one developed use case, including its relevance to nationwide exchange
  - Identify at least one content standard (or implementation guide) with which it can be used
  - Demonstrate that it has been tested for exchange

Data Element Promotion Criteria
To move from Level 1 to Level 2 classification

- To be eligible to move to Level 2, a Data Element must demonstrate that it has achieved sufficient technical development to be tested at scale:
  - » Have a definition for the Data Element, including technical representation (structured or unstructured) in at least one content standard (or implementation guide) and, if applicable, vocabulary or value set binding; and
  - » Has been tested successfully in at least two independent systems.

Data Element Promotion Criteria
To move from Level 2 to the USCDI (1/2)

1. Technical Maturity – The Data Element must demonstrate that it:
   - Has been tested successfully in at least four independent systems.
   - Has formal, published documentation for its representation and exchange.

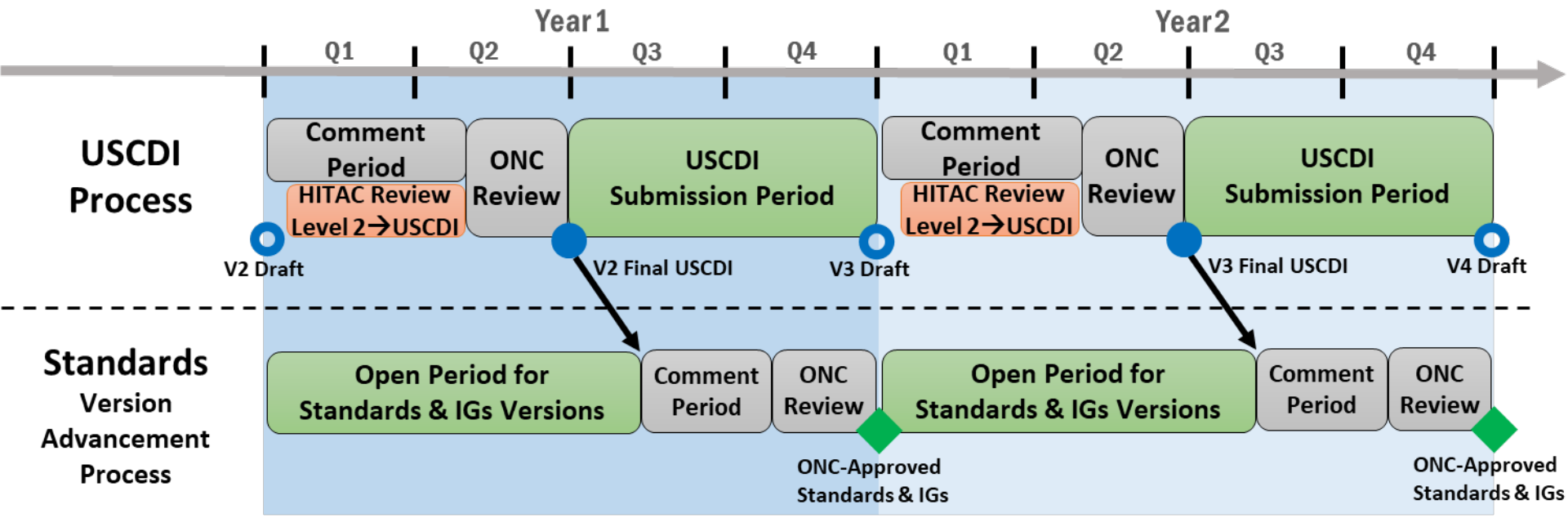
2. Nationwide Applicability – The Data Element submission must include the following information:
   - How it impacts healthcare costs for individuals and populations
   - Estimated number of providers who would use this Data Element
   - Whether there are any restrictions to the Data Element's standardization
   - Estimated industry burden to implement the Data Element

Data Element Promotion Criteria
To move from Level 2 to the USCDI (2/2)

- The Health IT Advisory Committee (HITAC) would be charged to review Level 2 Data Elements that seek to move into the USCDI, including
  - » Assess the cumulative impact of USCDI-recommended Data Elements; and
  - » Provide recommendations to the National Coordinator on an annual basis.

- A Data Element would be added to the USCDI when the National Coordinator approves its promotion, weighing feedback from public comment and HITAC recommendations.

USCDI and Standards Versions Advancement Process Annual Relationship (Example Post-Final Rule)



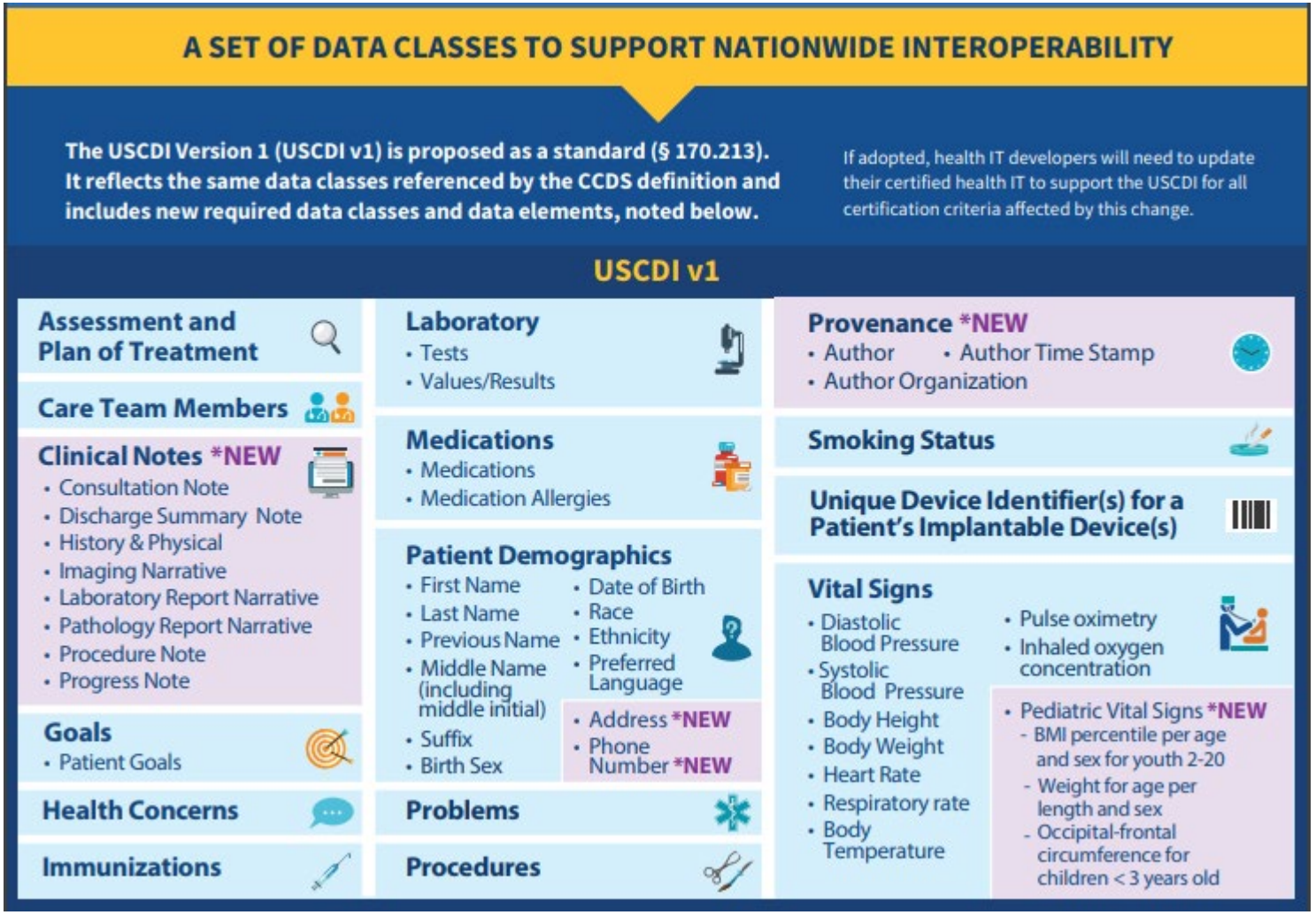
Work Plan – Phase 2

Meeting Date	Potential Discussion Items
May 17, 2019	• Phase 2 Kickoff • Discuss Promotion Model Guidelines
May 31, 2019	• Discuss Promotion Model Lifecycle
June 14, 2019	• Discuss Data Element Submission Criteria
June 28, 2019	• Discuss Level 1 Classification
July 12, 2019	• Discuss Level 2 Classification
July 26, 2019	• Discuss USCDI Classification • Draft recommendations
August 9, 2019	• Update and refine recommendations
August, 2019	• Present draft recommendations

Task Force Members

First Name	Last Name	Organization	Organization Type
		CO-CHAIRS	
Christina	Caraballo	Audacious Inquiry	Consultant/Patient Advocacy
Terrence	O'Malley	Massachusetts General Hospital	Health & Hospital Organization
		MEMBERS	
Tina	Esposito	Advocate Aurora Health	Health & Hospital Organization
Valerie	Grey	New York eHealth Collaborative	Health IT Organization
Kensaku	Kawamoto	University of Utah Health	Health & Hospital Organization
Steven	Lane	Sutter Health	Health & Hospital Organization
Leslie	Lenert	Medical University of South Carolina	Health & Hospital Organization
Clem	McDonald	National Library of Medicine (NLM)	Federal
Brett	Oliver	Baptist Health	Health & Hospital Organization
Steve	Ready	Norton Healthcare	Health & Hospital Organization
Mark	Roche	Centers for Medicare & Medicaid Services (CMS)	Federal
Sasha	TerMaat	Epic	EHR Vendor
Sheryl	Turney	Anthem Blue Cross Blue Shield	Health IT Technology
		ONC STAFF	
Al	Taylor	ONC	Federal
Adam	Wong	ONC	Federal

USCDI v1

Data Elements in blue are already included in the 2015 Common Clinical Data Set (CCDS).

Data Elements in pink are those for which ONC seeks recommendations in the Phase 1 charge.