

October 16, 2019

Donald Rucker, MD  
National Coordinator for Health Information Technology  
U.S. Department of Health and Human Services  
330 C Street, SW  
Washington, DC 20201

Dear Dr. Rucker,

The Health Information Technology Advisory Committee (HITAC) asked the U.S. Core Data for Interoperability Task Force (USCDI TF) to review and provide feedback on the U.S. Core Data for Interoperability Data Element Promotion Model. This transmittal letter offers these recommendations, which are informed by deliberations among the Task Force and HITAC subject matter experts.

### USCDI Task Force Charge

The USCDI TF was tasked to review and provide feedback on the U.S. Core Data for Interoperability (USCDI) Data Element Promotion Model. Specifically, it was tasked to provide recommendations on:

- Promotion Model Lifecycle for Submitted Data Elements
- Data Element Submission Information
- Data Element Promotion Criteria

Additionally, the TF was given the supplemental charge to discuss additional defining criteria as needed. Early in the process, the TF identified the need to provide details to ONC's Draft USCDI Data Element Promotion Model and think through the process from the "user's" perspective.

### 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
<a href="#">Kensaku</a>	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	<a href="#">TerMaat</a>	Epic	EHR Vendor
Sheryl	Turney	Anthem Blue Cross Blue Shield	Health IT Technology
ONC STAFF			
Al	Taylor	ONC	Federal
Adam	Wong	ONC	Federal

# ONC Draft U.S. Core Data for Interoperability Data Element Promotion Model

ONC's Draft USCDI Data Element Promotion Model included the following language for the specified components of the TF charge:

## Promotion Model Lifecycle for Submitted Data Elements

- 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.
- 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 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.
- Once classified into Level 1 or Level 2 by ONC, 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). ONC retains discretion to keep a Data Element in Level 2 for longer than three submission cycles.
- 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 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.

## Data Element Submission Information

The following fields would need to be addressed for a Data Element submission to be considered for level classification (submitter contact information would be collected separately):

1. Data Element name and description.
2. Why should this Data Element be captured and available for exchange nationwide? Provide applicable use case(s) with a focus on the following: specific setting (e.g., outpatient/ambulatory or inpatient), specialty area, and/or federal/state/local regulatory requirement.
3. Do systems currently capture this Data Element? If yes, please provide details.
4. Do standards exist to represent and exchange this Data Element? If yes, please provide.
5. Please describe any connect-a-thon testing, pilots, or production use of the Data Element.
6. (Not factored into classification) Is there any other information you would like to provide? For example, do you have partners to support development of this Data Element? Are you providing resources to ensure the Data Element will be implemented?

## Data Element Promotion Criteria

### Level 1

To be formally entered into the USCDI Promotion Process at Level 1 a Data Element must have a complete Data Element Submission and 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; and
- Demonstrate that it has been tested for exchange.

## **Level 2**

To be eligible to be promoted to Level 2, a Data Element must have a complete Data Element Submission, meet the Level 1 requirements, and 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.

## **USCDI**

To be eligible to be promoted into the USCDI a Level 2 Data Element must address the following two dimensions prior to the start of its public comment cycle and be assessed by the Health IT Advisory Committee (HITAC):

1. Technical Maturity – The Data Element must meet the Level 2 Requirements and 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 (include published literature or evidence).
  - Estimated number of providers who would use this Data Element.
  - Whether there are any restrictions to the Data Element’s standardization and use (e.g., licensing and fees).
  - Estimated industry burden to implement the Data Element (e.g., clinician data capture, patient data submission, health IT upgrade costs).

## **HITAC Role in the USCDI Promotion Process**

Once a Data Element has been promoted to Level 2 by ONC, it will be on track to be assessed by the HITAC for recommended promotion to the USCDI. As part of the annual promotion process, the HITAC would be provided a period of time at the beginning of each calendar year to assess the cumulative impact of USCDI-recommended Data Elements and provide recommendations to the National Coordinator regarding which Data Elements it believes are ready for promotion to the USCDI.

## **HITAC Commentary and Recommendations**

The HITAC overwhelmingly endorses the spirit, direction and emphasis of the ONC draft USCDI Promotion Model. Our comments and recommendations are made in response to issues raised by the HITAC and by TF members and participants. The most significant change that we propose is the timeline of the promotion model because the feedback was strongly in favor of a more rapid process. Two other substantial recommendations are to institute an annual review of the overall USCDI process and to create a detailed users' guide for data element submission and advancement. The remainder of our recommendations focus on the details of the promotion model and concerns raised during our two year deliberation.

### **Overarching Goals of USCDI Promotion Model (6)**

- Open, public, and transparent submission and promotion processes that enables and encourages diverse stakeholders and communities of interest to propose and provide supporting evidence to promote new data elements/classes
- Establish lowest possible barriers for data element submission
- Establish a high bar of technical specification and testing for promotion
- Establish clear requirements for promotion enabling submitters and communities of interest to plan appropriately
- Establish clear requirements for promotion enabling ONC to appropriately place elements/classes for inclusion in USCDI
- Provide opportunities for feedback
- Provide advance notice to industry
- Ensure that newly adopted data elements are ready for implementation, adoption and use

### **Key Components of Data Element Promotion Process Proposed by the HITAC (7)**

- Four Data Element Classifications: Comment, Level 1, Level 2, and USCDI
- The process to submit data elements for promotion to USCDI is open to everyone
- Searchable, public-facing work space maintained by ONC to enable and encourage submission of additional information required for data element(s) promotion
- Data Element Promotion based on meeting specific milestones rather than specific timelines
- Ongoing review by ONC to determine the appropriate level for each data element
- Frequent communication with data element stakeholders regarding level changes and feedback regarding promotion
- Final evaluation by ONC with recommendations from HITAC to assess strategic priority and burden to implement

### **Recommendation 1 - Promotion Model Based on Meeting Milestones**

HITAC members have indicated that the proposed promotion process is too slow. In the ONC proposed model, advancement from one level to the next level requires a minimum of one year. The HITAC believes that progress through Level 2 should be shortened as much as possible and recommends:

- a) Promotion occurs solely on the basis of meeting the required milestones without a minimum required promotion cycle time. (See Promotion Process Milestones slides)
- b) Decouple the promotion process from the Standards Advancement Process
- c) Publish status of all data elements in the Data Element Promotion Process quarterly in conjunction with a public comment period (See Public/Submitter Feedback slide)

## **Introduction to the Promotion Model Milestones**

The HITAC discussed specific criteria that would need to be met to advance a data element through the promotion process. Once all criteria are met for each “milestone”, the data element advances. The milestones would serve as guidance to data element sponsors. The milestones are discussed in the following sections:

- Administrative requirements
- Promotion from Comment to Level 1
- Promotion from Level 1 to Level 2
- Promotion from Level 2 to USCDI

## **Recommendation 2 - Promotion Model Milestones- Administrative Requirements**

The HITAC recommends the following administrative expectations for data element sponsors:

- a) Complete submission form
- b) Adhere to guidance regarding acceptable standards, code sets and value sets
- c) Provide sufficient additional information to inform re-leveling
- d) Respond to ONC feedback regarding submissions required for further promotion

## **Recommendation 3 - Promotion Model Milestones-Comment to Level 1**

The HITAC recommends the following criteria must be met to move from Comment to Level 1:

- a) Justification exists for data element capture and national exchange
- b) There are applicable use cases(s) involving this data element
- c) There are projects currently underway using this data element
- d) This data element is currently captured discreetly in one or more electronic systems with preliminary understanding of how often and how the data element is collected (e.g., free text, coded data element)
- e) A content standard exists for this data element
- f) This standard is supported by an established SDO that uses a public balloting process
- g) An implementation guide exists that contains this data element with stability
- h) There have been pilots, “Connect-a-thon”® testing, and/or production use of this data element

## **Recommendation 4 - Promotion Model Milestones-Level 1 to Level 2**

The HITAC recommends the following criteria must be met to move from Level 1 to Level 2:

- a) The exchange of the data element(s) has been successfully tested at scale among several distinct/different EHR platforms/systems in a production environment using the previously cited content and transport standards
- b) Sufficient testing to satisfactorily meet the requirements of the proposed use case(s) in applicable settings
- c) There has been sufficient testing to satisfactorily meet the requirements of the proposed use case(s) in a “several” applicable settings move to Level 1 to 2

## **Recommendation 5 - Promotion Model Milestones-Level 2 to USCDI**

The HITAC recommends the following criteria must be met to move from Level 2 to USCDI:

- a) Technical Maturity - The exchange of the data element(s) has been successfully tested at scale between distinct/different EHR platforms/systems in a production environment sufficient to establish feasibility for the majority of anticipated users
- b) National Applicability
  - i. Evidence that the data element(s) supports the quadruple aim
  - ii. Estimated number of stakeholders who would use this data element/class
  - iii. All known restrictions potentially limiting the standardization of this data element (e.g. proprietary codes, value sets) have been addressed
  - iv. All known restrictions potentially limiting the use of this data element (e.g. licensing and fees) have been addressed
  - v. There is an estimate of the overall burden to implement (e.g., clinician data capture, patient data submission, health IT upgrade costs)
    - Supporting multiple, complex use cases may present significant challenges to implementers

## **Recommendation 6 - Final Review of Data Elements Proposed for USCDI**

The HITAC discussed the process for the final review of data elements that have met all of the milestones for advancement into USCDI. The HITAC recommends:

- a) Review data elements for:
  - i. Technical maturity
  - ii. Barriers to implementation, adoption and use
  - iii. Alignment with identified national priorities
  - iv. Industry readiness

- b) Process:
  - i. ONC provides the HITAC with a proposed draft of data elements that meet the criteria for promotion into USCDI
  - ii. HITAC provides ONC with recommendations regarding the proposed draft
  - iii. ONC publishes final decisions taking into consideration public comment and HITAC recommendations

### **Recommendation 7 - Public/Submitter Feedback in Promotion Model**

The HITAC was concerned that there was not an explicit process and timeline for obtaining public and data-element-submitter feedback on the readiness, applicability, or prioritization of a proposed data elements/classes. The HITAC recommends:

- a) Solicit public comment quarterly to coincide with updating the status of each data element in the process
- b) Specifically seek comments on the maturity, adequacy, and adoption levels of a proposed data class/element
- c) Specifically seek comments on the maturity and applicability of use cases, workflows, and value propositions which may be more broadly applicable for a particular data class/element

### **Recommendation 8 - Annual Review**

The HITAC raised the concern that there is still significant uncertainty regarding the model and process, and recommends the following issues for specific attention during an annual review:

- a) Does the process work?
- b) Does the process need a “prioritization” function?
- c) Does the process need a “harmonization” function?
- d) Does the process need a “stalled data element” function?
- e) Are the standards development business models adequate to support the required promotion work?
- f) Is there a role for ONC to identify and promote high priority data elements?

#### **8 a) - Does the process work?**

Once experience has been gained with the process it should be possible to assess whether the public finds it easy to use, whether the leveling criteria are appropriate, whether data elements advance as anticipated, and whether the process results in submission and advancement of high priority data elements. The HITAC recommends monitoring the following items as part of an initial assessment:

- i. Volume of submissions

- ii. Number of submissions placed directly into Level 1 or Level 2
- iii. Number of data elements by level
- iv. Number of advancements by level
- v. Number of failures to advance by level
- vi. Time for advancement to next level
- vii. Aggregate time from submission to USCDI
- viii. Are there high priority data elements that are missing?
- ix. Are there high priority data elements that failed to advance?

### **8 b) - Is a prioritization function needed?**

The HITAC was concerned about the potential need for a “data element prioritization” step before promotion to USCDI. The HITAC makes the following recommendations:

- i. If in its annual review of the Data Element Promotion Model ONC finds that there are too many data elements eligible for simultaneous promotion to USCDI, ONC should establish a prioritization process to reduce the likelihood of overwhelming both providers and the vendor community with new requirements
- ii. The prioritization process should consider, among other issues, the following:
  - Relevance to meet the Quadruple Aim
  - Extent of applicability
  - Presence of clearly defined use cases and workflows associated with the data class/element
  - Clear value propositions for adopting the data class/element

### **8 c) - Is a harmonization function needed?**

The HITAC discussed the risks and benefits of harmonization and recognized the benefits of reducing variability to enable interoperability. The HITAC makes the following recommendations:

- i. Develop a process for reviewing submitted data elements to identify those that express similar concepts
- ii. Develop a process to determine whether the elements should be merged or remain separate
- iii. Achieve consensus when multiple approaches exist

### **8 d) - Stalled Data Elements**

The HITAC concurred with ONC that data elements that have neither advanced nor received additional submissions for an extended period of time should be removed from Level 1 and/or Level 2. Because the promotion process advanced by the HITAC differs from the process initially proposed by ONC, the HITAC recommends that ONC institute the following process:



- i. Provide a warning to submitter(s)/sponsor(s) indicating that data element(s) that have not advanced to the next level AND have not received additional submissions during the expected advancement time are at risk for reassignment to a “stalled” category
- ii. Place data elements that have neither advanced NOR received additional submissions in twice the average advancement time into the “Stalled Data Element” category
- iii. Re-introduce the data element following submission of new information that indicates that the element is more likely to advance

### **8 e) - Is the upfront work being done?**

The HITAC has raised concerns about the sustainability of the different business models that underpin creation, testing, and maintenance of standards and value sets which underlie the USCDI Data Element Promotion Process.

The HITAC recommends:

- i. As part of the Annual Review of the Promotion Process, ONC assess the adequacy of financial support for entities that create, support, test, and maintain important interoperability standards, code sets and value sets.
- ii. If ONC finds gaps that may delay or imperil activities that are essential for nationwide interoperability, it will address these gaps using available remedies.

### **8 f) - Are high priority data elements being introduced?**

The HITAC raised a concern that a promotion process that relies heavily on the private sector to identify and advance data elements of value may not necessarily identify and advance data elements that address national priorities such as the Quadruple Aim.

The HITAC recommends that if, as part of its annual review of the Promotion Process,

- i. ONC identifies that one or more high priority data elements are missing from the Promotion Process then it will use the tools at its disposal to facilitate the submission of missing priority data elements
- ii. ONC identifies that high priority data elements are not advancing that it will use the tools at its disposal to facilitate promotion

## **Recommendation 9 - Creation of a Submission and Advancement Users’ Guide**

The HITAC discussed the need to provide guidance to submitters and communities of interests to help them adequately provide relevant information to fulfill required criteria and meet milestones to advance through the promotion process.

The HITAC recommends that ONC create a Submission and Advancement Users’ Guide to assist

submitters and communities of interest. The HITAC drafted a Users' Guide as a base for ONC to expand upon. The draft Users' Guide consists of the following key sections:

- I. Identification of Data Element
- II. Justification for Data Element promotion
- III. Extent of use and technical specification
- IV. Potential impact
- V. Potential barriers

The HITAC also recommends that as part of the guide ONC provides examples of successful applications and subsequent submissions.

## **Submission and Advancement Users' Guide**

### **Section I: Identification of Data Element**

- a) Name of Submitter
- b) Contact Information of Submitter
- c) Data Element Name
- d) Data Element Description
- e) Related data elements
- f) Proposed Data Class (Optional)
- g) Do similar data elements currently reside in the UDA? Y/N/UNK
  - i. If yes, please explain why this data element should be considered separately

### **Section II: Justification for Data Element Promotion**

- a) Explain why this data element should be captured and available for national exchange
- b) Briefly describe a representative use case

### **Section III: Extent of Use and Technical Specification**

- a) Is this data element currently captured discreetly in any electronic system?
  - i. If yes, please cite known systems that capture this data element and briefly describe the format and frequency of capture
- b) Does a content standard exist for citing this data element?
  - i. If yes, please cite the applicable standard

### **Section III: Extent of Use and Technical Specification continued**

- a) Does an implementation guide exist that contains this data element?
  - i. If yes, please cite the IG
- b) Has there been any "Connect-a-thon"<sup>®</sup> testing, pilots, or production use of the data element?
  - i. If yes, please cite artifacts describing its use
- c) Has the exchange of this data element been successfully tested between several different platforms in a production environment?

- i. If yes, please cite supporting artifacts
- d) Has the exchange of this data element been successfully tested at scale between multiple different platforms in a production environment sufficient to establish feasibility for the majority of anticipated users?
  - i. If yes, please cite supporting artifacts

**Section IV: Potential Impact**

- a) Is there evidence that the data element(s) supports the quadruple aim?
  - i. If yes, please provide supporting data
- b) Please provide an estimate of number of stakeholders who would use this data element/class

**Section V: Potential Barriers**

- a) Are there any restrictions on the standardization of this data element (e.g. proprietary code)?
- b) Are there any restrictions on the use of this data element (e.g. licensing, user fees)?
- c) Please provide an overall estimate of burden to implement

**Recommendation 10 - Proposed “Pilot” Use Case to Test the USCDI Model**

Considering the unknowns regarding the USCDI Data Element Promotion Process, the HITAC recommends that ONC pilot data elements through the promotion process to identify any issues and create early examples for the Users’ Guide. The HITAC identified the following data elements for consideration because of their importance, broad stakeholder support and complexity:

- a) Such as, Social Determinants of Health
  - i. Data class with data elements at multiple levels of specificity
  - ii. IG in preparation
  - iii. Identified by the HITAC as a high priority use case for future consideration
- b) Or a well specified data class

We appreciate the opportunity to summarize the work of the HITAC and provide it to you for consideration.

Respectfully submitted,

*Carolyn Petersen*

/s/

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