Call to Order/Roll Call

Mike Berry, Designated Federal Officer, ONC
# Interoperability Standards Workgroup Roster

<table>
<thead>
<tr>
<th>Name</th>
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<tbody>
<tr>
<td>Steven Lane (Co-Chair)</td>
<td>Sutter Health</td>
<td>Kensaku Kawamoto</td>
<td>University of Utah Health</td>
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<td>Arien Malec (Co-Chair)</td>
<td>Change Healthcare</td>
<td>Leslie Lenert</td>
<td>Medical University of South Carolina</td>
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<td>Kelly Aldrich</td>
<td>Vanderbilt University</td>
<td>Hung S. Luu</td>
<td>Children’s Health</td>
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<td>Hans Buitendijk</td>
<td>Cerner</td>
<td>David McCallie</td>
<td>Individual</td>
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<td>Thomas Cantilina</td>
<td>DOD</td>
<td>Clem McDonald</td>
<td>National Library of Medicine</td>
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<td>Christina Caraballo</td>
<td>HIMSS</td>
<td>Aaron Miri</td>
<td>Baptist Health</td>
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<td>Grace Cordovano</td>
<td>Enlightening Results</td>
<td>Mark Savage</td>
<td>Savage &amp; Savage LLC</td>
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<td>Steven Eichner</td>
<td>Texas Dept. of State Health Services</td>
<td>Michelle Schreiber</td>
<td>CMS</td>
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<td>Adi Gundlapalli</td>
<td>CDC</td>
<td>Abby Sears</td>
<td>OCHIN</td>
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<td>Rajesh Godavarthi</td>
<td>MCG Health</td>
<td>Ram Sriram</td>
<td>NIST</td>
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<td>Jim Jirjis</td>
<td>HCA Healthcare</td>
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Agenda

10:30 a.m. Call to Order/Roll Call
  • Mike Berry, Designated Federal Officer, ONC

10:35 a.m. USCDI Process Review
  • Al Taylor, ONC

10:55 a.m. Workgroup Work Planning
  • Steven Lane, Co-Chair
  • Arien Malec, Co-Chair

11:05 a.m. Charge 1a – Draft USCDI v3 New Data Classes and Elements
  • Steven Lane, Co-Chair
  • Arien Malec, Co-Chair

11:55 a.m. Public Comment
  • Mike Berry, Designated Federal Officer, ONC

12:00 p.m. Adjourn
USCDI Process Review

Al Taylor, Office of Technology, ONC
Why USCDI Matters? (aka, USCDI Version 1 in Regulation)

• Adopted as a new standard in the ONC Cures Act Final Rule (2020)
• Sets the foundation for broader sharing of electronic health information to support patient care and patient access to their data.
• Required part of new health IT certification criteria for standardized application programming interface (API) for patient and population services.
• Replaces the Common Clinical Data Set (CCDS) in these Certification Criteria:
  • Transitions of Care document (C-CDA) create, send, and receive
  • Clinical Information (C-CDA) reconciliation and incorporation
  • Patient View, download, and transmit to 3rd party
  • Electronic case reporting transmission to public health agencies
  • Create quality C-CDA document
  • Access to data via APIs
USCDI Core Principles

• Comprises a **core set** of structured and unstructured data needed to support patient care and facilitate patient access using health IT

• Establishes a **consistent baseline** of harmonized data elements that can be broadly reused across use cases, including those outside of patient care and patient access

• **Expands over time** via predictable, transparent, and collaborative **public** process, weighing both anticipated benefits and industry-wide impacts
USCDI, EHI and Information Blocking

Certification

- Specific Compliance Requirements Start for Several Conditions of Certification, Including Information Blocking, Assurances, APIs: 4/5/2021
- General Effective Date, including Cures Update Certification Criteria: 6/30/2020
- Health IT Developers Prohibited From Restricting Certain Communications: 4/5/2021
- Submit Initial Real World Testing Plans: 12/15/2021
- New HL7® FHIR® API Capability and Other Cures Update Criteria Must Be Made Available: 12/31/2022
- First Attestation to Conditions of Certification Required: 4/1/2022
- By 12/31/2023
- EHI Export Capability Must be Made Available
- 3/15/2023
- Submit Initial Real World Testing Results

Information Blocking

- Applicability date for Information Blocking Provisions: 4/5/2021
- 4/5/2021 through 10/5/2022
- EHI definition is limited to the EHI identified by the data elements represented in the USCDI

EHI = Electronic Health Information
USCDI = United States Core Data for Interoperability
USCDI, EHI and Information Blocking

**Certification**
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- **3/15/2023**: Submit Initial Real World Testing Results
- **By 12/31/2023**: EHI Export Capability Must be Made Available

**Information Blocking**
- **4/5/2021**: Applicability date for Information Blocking Provisions
- **4/5/2021 through 10/5/2022**: EHI definition is limited to the EHI identified by the data elements represented in the USCDI
- **On and after 10/6/2022**: EHI definition is no longer limited to the EHI identified by the data elements represented in the USCDI
USCDI, EHI and Information Blocking

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EHI = Electronic Health Information  USCDI = United States Core Data for Interoperability
USCDI Version Update Process
Standards Version Advancement Process

• SVAP allows health IT developers in the ONC Health IT Certification Program to voluntarily update their products to include National Coordinator-approved, newer versions standards.

• Limited to the standards adopted in these certification criteria
  • Care Coordination
  • Quality Measure Reporting
  • Patient Engagement
  • Public Health
  • Data Transport

• ONC established a public comment process to identify versions of the standards or implementation specifications that are ready for use in the Certification Program.
  • The first list of Approved Standards was published January 2021
  • HealthIT.gov/SVAP
SVAP – Timeline Adjustment

- USCDI v2 will be considered in the current SVAP cycle.
  - This would allow health IT developers to update their systems to USCDI v2 and provide these updates to their customers.

- SVAP Comment Period extended to accommodate the HL7® FHIR US Core and C-CDA implementation guides.
  - These IGs implement exchange of USCDI data elements under the applicable certification criteria.
HL7® FHIR® US Core Release Cycle

- US FHIR Core ballot 2021
- US FHIR Core will ballot every January starting in 2022
- This ballot will reflect HL7 update requests (JIRA) and response to USCDI v+1
- Connect-a-thons/pilot testing precede US FHIR Core Update Ballot

| Jan 2020 | USCDI Final v1 | Industry testing/piloting prior to and feeding into US FHIR Core Ballot |
| May 2020 | US FHIR Core 3.1.1 Published |
| July 2020 | Industry testing/piloting prior to and feeding into US FHIR Core Ballot |
| Dec 2020 | SVAP USCDI Final v2 |

| Jan 2021 | USCDI Draft v2 |
| Comment Period |
| Review and Response |
| US FHIR Core Ballot Publication |
| Ballot Resolution |
| Industry testing/piloting prior to and feeding into US FHIR Core Ballot – Not Limited to USCDI |
| (Continuous build updated) |
| *Early Ballot? |
| SVAP USCDI Final v2 |
| SVAP US Core Jan 2021 Pub |

| Jan 2022 | USCDI Draft v3 |
| Comment Period |
| Review and Response |
| US FHIR Core Ballot Publication |
| Ballot Resolution |
| Industry testing/piloting prior to and feeding into US FHIR Core Ballot – Not Limited to USCDI |
| (Continuous build updated) |
| *Early Ballot? |
| SVAP USCDI Final v3 |
| SVAP US Core U*F2 Publish |
USCDI and USCDI +

- USCDI is a **core set** of supporting broad use cases of patient care and facilitating patient access.
- USCDI sets a **consistent baseline** on which additional use cases can be built.
- USCDI + Buzz Blog
- USCDI+ Landing Page
Workgroup Work Planning

Steven Lane, Co-Chair
Arien Malec, Co-Chair
Interoperability Standards Workgroup Charge

**Overarching charge:** Review and provide recommendations on the Draft USCDI Version 3 and other interoperability standards

**Specific charges:**

1. Evaluate Draft USCDI v3 and provide HITAC with recommendations for:
   - 1a - New data classes and elements from Draft USCDI v3
   - 1b - Level 2 data classes and elements not included in Draft USCDI v3

   **Due:** April 13, 2022

2. Identify opportunities to update the ONC Interoperability Standards Advisory (ISA) to address the HITAC priority uses of health IT, including related standards and implementation specifications.

   **Due:** June 16, 2022
Charge 1a
Draft USCDI v3 New Data Classes and Elements

Steven Lane, Co-Chair
Arien Malec, Co-Chair
Interoperability Standards Workgroup Charge

Discussion of Specific Charges

1. Evaluate Draft USCDI v3 and provide HITAC with recommendations for:
   1a - New data classes and elements from Draft USCDI v3
   1b - Level 2 data classes and elements not included in Draft USCDI v3

Potential areas of focus-
ONC called for general feedback on Draft USCDI v3 content

1. Are there any improvements needed in the data classes or elements included in Draft USCDI v3, including:
   a) Appropriate and meaningful data class and element names and definitions?
   b) Representative examples or value sets used by health IT developers and implementers to fully understand the intent of the data element?

2. Should other data elements classified as Level 2 be added to USCDI v3 instead, or in addition to those included in Draft USCDI v3? If so, why?

3. Are there significant barriers to development, implementation, or use of any of the Draft USCDI v3 data elements that would warrant not including them in USCDI v3?
Interoperability Standards Workgroup Charge

Discussion of Specific Charges

2 Identify opportunities to update the ONC Interoperability Standards Advisory (ISA) to address the HITAC priority uses of health IT, including related standards and implementation specifications.

Potential areas of focus-
1. TEFCA standards enablement
   • FHIR roadmap, standards from FAST, patient access leveraging QHINs for national access
   • Additional exchange purposes that are contemplated in CURES but not perfectly enabled via initial TEFCA
   • Contemplate standards/IG for potential HIE certification
2. SDOH Standards
   • Gravity Standards
   • CDC Race/Ethnicity vocabulary subsets
3. Lab Orders/Results
   • SHIELD/LIVD, LIS to EHR/PH SYSTEMS
4. CDC
   • PH Data Systems Certification
   • eCR Standards

Due
June 16, 2022
Questions?
Upcoming Meetings

- February 8, 2022
- February 15, 2022
- February 22, 2022
- March 1, 2022
- March 8, 2022
- March 15, 2022
- March 22, 2022
- March 29, 2022
- April 5, 2022
Public Comment

To make a comment please

Use the Hand Raise Function

If you are on the phone only, press "*9" to raise your hand

(Once called upon, press "*6" to mute/unmute your line)

All public comments will be limited to three minutes

You may also 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 Committee and made part of the public record.
Adjourn