STATE OF WASHINGTON
HEALTH CARE AUTHORITY
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October 4, 2023

The Honorable Micky Tripathi, Ph.D., M.P.P.
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C Street SW, Floor 7
Washington, D.C. 20201

Dear Honorable Micky Tripathi:

SUBJECT: Annual Comment Period for the Interoperability Standards Advisory (ISA), United States Core Data for Interoperability Standard (USCDI), Washington State Health Care Authority Comments

The Office of the National Coordinator for Health IT (ONC) opened the comment period for the public to offer comments, suggest revisions, and propose additions to the Interoperability Standards Advisory (ISA) before ONC publishes the 10th Annual ISA Reference Edition in January 2024.[1] ONC also requested comments on the United States Core Data for Interoperability (USCDI). Comments submitted at this time on the USCDI will be considered for USCDI v6.[2]

The Washington State Medicaid Agency, the Health Care Authority (HCA), submits the comments below on the ISA and USCDI. Comments are submitted on the following topics:

- Advance Directives/Mental Health Advance Directives
- Patient Demographic Record Matching and Patient Identity/Identification Management
- Patient Preference/Consent
- Race/Ethnicity
- Publish and Subscribe Message Exchange

Interoperability Standards Advisory (ISA) and United States Core Data for Interoperability (USCDI) Advance Directives

Background:

The ISA is organized and structured into four sections, one of which is "Content/Structure Standards and Implementation Specifications". This section includes "Care Coordination"

[1] Interoperability Standards Advisory (ISA) | Interoperability Standards Advisory (ISA) (healthit.gov)
[2] United States Core Data for Interoperability (USCDI) | Interoperability Standards Advisory (ISA) (healthit.gov)

which includes Advance Care Planning information[3]. The Advanced Care Planning page identifies as a developing standard for Advance Care Planning a specific instance of the HL7 Clinical Document Architecture (CDA) Release 2[4]. The website also indicates that feedback is requested.

Post-Acute Care Interoperability Project: Beginning in 2019, the PACIO (Post-Acute Care Interoperability) Project, supported collaborative efforts between industry, government, and others, with the goal of establishing a framework for the development of FHIR implementation guides to facilitate health information exchange related to advance directive content.

The PACIO Project has:

- worked to include advance directive data elements in the USCDIv4; and
- collaborated with the Health Level 7 (HL7) Patient Empowerment Workgroup to develop the emerging Fast Healthcare Interoperability Resources (FHIR) implementation Guide to support the exchange of patient generated advance directive documents.

HL7 Patient Empowerment Workgroup: The HL7 Patient Empowerment Workgroup, in collaboration with the PACIO Project, is developing a FHIR Implementation Guide (IG), entitled "Advance Directive Interoperability"[5]. The IG notes that:

(i) Advance Directives can be categorized into three types of information: Type I: Person-Authored Advance Directive Information; Type 2: Encounter-Centric Instructions; and Type 3: Portable Medical Order for Life-Sustaining Treatment; and

(ii) the FHIR is initially focusing on patient-authored documents.

USCDI: The USCDI includes Advance Directives as a "level 2 data element" and defines Advance Directives as follows:

> "Advance Directives - legal document that states a person's wishes about receiving medical care if that person is no longer able to make medical decisions because of a serious illness or injury. An advance directive may also give a person (such as a spouse, relative, or friend) the authority to make medical decisions for another person when that person can no longer make decisions. There are different types of advance directives, including a living will, durable power of attorney (DPA) for healthcare, and do not resuscitate (DNR) orders. In the United States, the laws for advance directives may be different for each state, and each state may allow only certain types of advance directives. Other forms of advanced directives include medical orders for life-sustaining treatment (MOLST).
> 1. https://www.cancer.gov/publications/dictionaries/cancer-terms/def/advance-directive[6]

[3] Care Coordination | Interoperability Standards Advisory (ISA) (healthit.gov)
[4] https://confluence.hl7.org/display/SD/POLST+CDA+IG
[5] HL7.FHIR.US.PACIO-ADI\Home - FHIR v4.0.1
[6] | Interoperability Standards Advisory (ISA) (healthit.gov)

USCDI and PACIO Project: In April 2023, the PACIO Project recommended that the "Advance Directives" data class and the "Advance Directive Observation" data element under this class be included in USCDIv4.
The rationale for this recommendation included:

- "the Advance Directive Data Class provides context to the information exchanged"; and
- the "Advance Directive Observation" data element would enable clinical ""confirmation" that what is wanted by the person has been validated by a clinician as being authentic for that person" and that certain jurisdictions/organizations may require this clinical confirmation.

Mental Health Advance Directives: As is the case with advance directives, Mental Health Advance Directives are legal documents through which individuals may express their care preferences in anticipation of times when individuals may not be able to express their care preferences. For example, in Washington state see: Chapter 71.32 RCW: MENTAL HEALTH ADVANCE DIRECTIVES (wa.gov). Other states and jurisdictions also have requirements for and support the use of Mental Health Advance Directives (e.g., TX, LA, DC).

Mental Health Advance Directives are developed by individuals and are critical documents that express care preferences on behalf of individuals in the event of future incapacity. For example, individuals with a history of mental health (MH) conditions and/or substance disorders (SUDs) may anticipate future circumstances where they find themselves in crisis because of their MH condition and/or SUD and are unable to express their preferences for treatment to the entities responding to the crisis events.

WA State Health Care Authority (HCA) Comments and Recommendations: Advance Directives/Mental Health Advance Directives
The HCA submits the following recommendations to ONC related to the USCDI and the ISA on Advance Directives/Mental Health Advance Directives. These recommendations align with and are supportive of ONC USCDI prioritization criteria (i.e., focus on behavioral health) and the U.S. Department of Health and Human Services (HHS) Roadmap For Behavioral Health Integration[7].

1. The HCA applauds the leadership role that the PACIO Project has played in advancing content and exchange standards for advanced directives. Advance directives are critical documents that enable individuals to express their care preference at times when they may not otherwise be able to do so.

2. USCDI: The HCA recommends that the definition of Advance Directives be modified in USCDIv6 to include Mental Health Advance Directives. Specifically, HCA recommends that the definition in the USCDI of Advance Directives be modified as follows:

[7] HHS Roadmap for Behavioral Health Integration Issue Brief

A legal document that states a person's wishes about receiving medical care, including behavioral health services, if that person is no longer able to make medical and/or behavioral health care decisions because of a serious illness, injury, or mental incapacity. An advance directive may also give a person (such as a spouse, relative, or friend) the authority to make medical or behavioral health decisions for another person when that person can no longer make decisions. There are different types of advance directives, including a living will, durable power of attorney (DPA) for healthcare, do not resuscitate (DNR) orders, and Mental Health Advance Directives. In the United States, the laws for advance directives may be different for each state, and each state may allow only certain types of advance directives. Other forms of advanced directives include medical orders for life-sustaining treatment (MOLST).

1. https://www.cancer.gov/publications/dictionaries/cancer-terms/def/advance-directive[8]

3. USCDI: The HCA supports the PACIO Project recommendation to include in USCDIv4: (i) "Advance Directives" as a data class; and (ii) "Advance Directive Observation" as a data element.

   We agree with the importance of having an "Advance Directives" data class and support the inclusion of an "Advance Directive Observation" data element. An advance directive data class would support the multiple advance directive document types (e.g., physical health advance directive documents, DNR orders, MOLST, other advance directive document types, including Mental Health Advance Directives).

   We understand that in some instances there may be a need for/value to having clinical confirmation of the creation of various advance directive document types and that "certain jurisdictions/organizations *may* require this clinical confirmation" (emphasis added). Based on this description, we interpret this data element would be permitted, not required, in implementation guides regarding advance directives.

   The HCA supports the permissive use of an "Advance Directive Observation" data element.

   We note that in the case of Mental Health Advance Directives, Washington State law does not require clinical confirmation of the creation of Mental Health Advance Directives.

   HCA recommends that a data class for "Advance Directives" be created in the new version of USCDI promoting the existing Level 2 data class.

   HCA supports the creation of an Advance Directive Observation as a data element that could be optionally used.

[8] | Interoperability Standards Advisory (ISA) (healthit.gov)

4. ISA: The HCA recommends the following changes to the 2023 Interoperability Standards Advisory Reference Edition:

   HCA recommends that the "Advance Care Planning" section in the Care Coordination section of the ISA be renamed to "Advance Directives". Replacing "Advance Care Planning" with "Advance Directives" will align the naming convention in the ISA with the recommendations being made for the USCDI (see recommendation #3 above).

   HCA recommends that on the newly named Advanced Directive page, include a link to the following emerging/developing implementation specification: HL7.FHIR.US.PACIO-ADI\Home - FHIR v4.0.1.

5. Federal Support to Advance Mental Health Advance Directives at HL7.
   In support of and in alignment with the HHS Roadmap For Behavioral Health Integration, HCA recommends that ONC, SAMHSA, and CMS support engagement with the HL7 Patient Empowerment Workgroup to:

   a. modify the FHIR IG for Type I: Person-Authored Advance Directive Information to include Mental Health Advance Directive content created by individuals; and

   b. develop an IG for Type 2: Encounter-Centric Instructions that supports Mental Health Advance Directive content created as a result of collaborations between individuals and clinicians.

   HCA believes that modest modifications to the HL7 FHIR IG for Type I: Person-Authored Advance Directive Information would support person-authored Mental Health Advance Directives.

Interoperability Standards Advisory (ISA): Patient Demographic Record Matching and Patient Identity/Identification Management

Background

The ISA is organized and structured into four sections, as noted above, one of which is "Content/Structure Standards and Implementation Specifications". The ISA section on Content/Structure Standards and Implementation Specifications includes standards and implementation specifications for Patient Identity/Identification Management including Patient Demographic Record Matching[9]. Another section of the ISA is "Services and Exchange" the Services and Exchange section includes standards and implementation specifications for "Patient

[9] https://www.healthit.gov/isa/section/patient-identityidentification-management

Identity/Identification Management"[10], including "Exchanging Patient Identification Within and Between Communities"[11].

The sections on Patient Demographic Record Matching and Exchanging Patient Identification Within and Between Communities include among the listed standards and implementation specifications an emerging standard/implementation specification the "HL7 Interoperable Digital Identity & Patient Matching Implementation Guide"[12],[13].

ONC requests feedback on this standard.

WA State Health Care Authority (HCA) Comments and Recommendations on Digital Identity & Patient Matching Implementation Guide

We support the inclusion of the HL7 Interoperable Digital Identity & Patient Matching Implementation Guide as an Emerging Implementation Specification in the ISA sections Patient Demographic Record Matching and Exchanging Patient Identification Within and Between Communities due to its utility to both categories. We note this is consistent with the HL7 recommendation in August 2022.[14]

Interoperability Standards Advisory (ISA): Patient Preference/Consent

<u>Background</u>

As noted above, the ISA is organized and structured into four sections, one of which is "Content/Structure Standards and Implementation Specifications". The ISA section on Content/Structure Standards and Implementation Specifications includes standards and implementation specifications for Patient Preference/Consent[15].

The standards and implementation specifications for "Recording Patient Preferences for Electronic Consent to Access and/or Share their Health Information with Other Care Providers" references the HL7 FHIR Consent Resource for exchanging Patient consents[16]. We note that this FHIR implementation specification is in trial use and is at a maturity level 2.

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[10] Section III: Standards and Implementation Specifications for Services | Interoperability Standards Advisory (ISA) (healthit.gov)
[11] Exchanging Patient Identification Within and Between Communities | Interoperability Standards Advisory (ISA) (healthit.gov)
[12] Exchanging Patient Identification Within and Between Communities | Interoperability Standards Advisory (ISA) (healthit.gov)
[13] HL7.FHIR.US.IDENTITY-MATCHING\Home - FHIR v4.0.1
[14] Exchanging Patient Identification Within and Between Communities | Interoperability Standards Advisory (ISA) (healthit.gov)
[15] Section II: Content/Structure Standards and Implementation Specifications | Interoperability Standards Advisory (ISA) (healthit.gov)
[16] https://www.hl7.org/fhir/consent.html

WA State Health Care Authority (HCA) Comments and Recommendations on Patient Preference/Consent
We recommend continued adoption of the HL7 FHIR Consent Resource for exchanging Patient consents.

Interoperability Standards Advisory (ISA): Race and Ethnicity

Background

The ISA is organized and structured into four sections, one of which is "Vocabulary/Code Sets/Terminology Standards and Implementation Specifications (i.e., "semantics")." The section includes code sets/terminology standards and implementation specifications for race and ethnicity[17]. As depicted below, a link to the referenced CDC (Center for Disease Control) race and ethnicity codes is broken.

WA State Health Care Authority (HCA) Comments and Recommendations on Race and Ethnicity Codes
The HCA recommends that ONC replace the broken link circled in red below with a functioning link to the 1.0 version of the CDC Race and Ethnicity coding system.

[17] Representing Patient Race and Ethnicity | Interoperability Standards Advisory (ISA) (healthit.gov)

Representing Patient Race and Ethnicity

Type	Standard / Implementation Specification	Standards Process Maturity	Impler Maturi
Standard	OMB standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, Oct 30, 1997	Final	Produc
Standard	CDC Race and Ethnicity Code Set Version 1.0	Final	Produc
Standard	CDC Race and Ethnicity Code Set Version 1.2	Final	Produc

Limitations, Dependencies, and Preconditions for Consideration

- The CDC Race and Ethnicity Code Set Version 1.0, which expands upon and can be rolled up to the OMB standards may help to further define race and ethnicity for this interoperability need as it allows for multiple races and ethnicities to be chosen for the same patient.
- The CDC Race and Ethnicity Code Set Version 1.2 is minor update to Version 1.0 and is the current version for CDC reporting requirements.
- The high-level race/ethnicity categories in the OMB Standard may be suitable for some statistical or epidemiologic or public health reporting purposes but may not be adequate for other uses such as in the pursuit of precision medicine and enhancing therapy or clinical decisions.
- LOINC® provides observation codes for use in the observation/observation value pattern for communicating race and ethnicity. LOINC is used to capture race and/or ethnicity in multiple coded panels; some of these align with the OMB race and ethnicity codes (e.g., 46463-6, 32624-9).

Interoperability Standards Advisory (ISA): Services and Exchange: Publish and Subscribe Message Exchange

Background

As noted above, the ISA is organized and structured into four sections, one of which is "Services and Exchange" and includes standards and implementation specifications to "Publish and Subscribe"[18]. The Publish and Subscribe Message Exchange references use of FHIRr4 Subscription Resource[19].

[18] Publish and Subscribe | Interoperability Standards Advisory (ISA) (healthit.gov)
[19] Publish and Subscribe Message Exchange | Interoperability Standards Advisory (ISA) (healthit.gov)

WA State Health Care Authority (HCA) Comments and Recommendations on Services and Exchange/ Publish and Subscribe Message Exchange
We recommend that the HL7 FHIR R4 Subscription Resource be updated to FHIR R5.

We thank HHS/ONC for its consideration of our comments. If you have any questions, please contact Jennie Harvell, Senior Federal Project Consultant, via email at jennie.havell@hca.wa.gov and Michael Barabe, IT Architecture Expert, via email at mike.barabe@hca.wa.gov.

Sincerely,

Vishal Chaudhry
Chief Data Officer
Clinical Quality and Care Transformation

By email

cc: Christine Nolan, Deputy Chief Information Officer, Medicaid Services ETS, HCA