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Office of the National Coordinator for Health Information Technology (ONC)
U.S Department of Health and Human Services
330 C Street SW, Floor 7
Washington, D.C. 20201

RE: *United States Core Data for Interoperability (USCDI) Draft version 3*

Submitted electronically via HealthIt.gov

Kaiser Permanente (KP) appreciates the opportunity to offer comments on the USCDI draft version 3. The Kaiser Permanente Medical Care Program is the largest private integrated health care delivery system in the U.S., delivering health care to over 12 million members in eight states and the District of Columbia[1] and is committed to providing the highest quality health care.

KP relies on standardized data to provide high-quality, equitable, and affordable care to our members. We appreciate ONC's leadership and support USCDI's role as a central mechanism to identify and implement a foundational set of electronic health information standards. A common set of data classes and elements is essential to achieving interoperability between providers, payers, community-based organizations, and consumers.

We offer the following comments in response to updates and requests for additional feedback.

Draft USCDI v3 Key Updates

NEW Health Status data class

This new data class includes four new data elements and two existing data elements that have been re-classified from their own classes in USCDI v2. It is intended to provide broader context, address inequities, and improve care.

Recommendation: While we support efforts to improve data collection to reduce disparities and improve patient outcomes, we are concerned that this data class and the functional status, disability status, mental function data elements, lack standardization and appropriate documentation in EHR systems, are redundant with existing clinical data, and are hard to capture discretely. For these reasons we do not support including these additional data elements at this time. They need further development, testing, and achievement of maturity before being adopted by the USCDI. Additional detail is provided below:

- Disability status: This data element is intended to represent assessments of an individual's physical, cognitive, intellectual, or psychiatric disabilities (e.g., vision, hearing, memory, activities of daily living).

[1] Kaiser Permanente comprises Kaiser Foundation Health Plan, Inc. and its health plan subsidiaries outside California and Hawaii; the not-for-profit Kaiser Foundation Hospitals, which operates 39 hospitals and over 720 other clinical facilities; and the Permanente Medical Groups, self-governed physician group practices that exclusively contract with Kaiser Foundation Health Plan and its health plan subsidiaries to meet the health needs of Kaiser Permanente's members.

As such, the data element is redundant and does not add value. Clinical assessment is already captured in diagnosis under Problems. If the intent is to allow raw patient responses for a standardized questionnaire to be exchanged, then the data should not be presented or equated to an assessment. Furthermore, as documented in the original submission of this data element, there is no applicable standard and this data element is not currently captured or accessed by organizations. This is a data element that, by its own assessment, ONC considers to be at a "Comment Level" of maturity.

- Mental function*:* This data element represents observations related to a patient's current level of cognitive functioning, including alertness, orientation, comprehension, concentration, and immediate memory for simple commands. As such, the data element is redundant and does not add value. This information is already captured for diagnosis/assessment under Problems and Assessment and Plan of Treatment. It is also captured for clinical observations under Clinical Notes. Further, the term "observations" is vague and discrete data elements are needed to capture this information and display it in a comprehensible manner, such as a score on a scale of observations.
- Functional status: This element represents assessments of a patient's capabilities or their risks of development or worsening of a condition. This information cannot be displayed in a way that is useful to the patient and many physicians are not familiar with the scales. Additionally, "assessment" as used in this data element conflates the provider's clinical assessment with raw patient responses on questionnaires. Clinical assessment is already captured in diagnosis under Problems and Assessment and Plan of Treatment. If the proposed data element intends to capture patient questionnaire responses it should be defined and presented separately to avoid confusion. Also, if patient questionnaires reveal confidential or sensitive information there needs to be thoughtful consideration of how the data will be shared or safeguarded.

Recommendation: We support including the pregnancy status and maintaining the health concerns and smoking status data elements in this new Health Status data class. This information is easy to capture and adds clinical value. However, special consideration must be given to these data elements to ensure that confidential or sensitive information is not subject to unauthorized disclosure in accordance with state and federal privacy and consent to medical treatment requirements.

NEW Health Insurance Information data class

This new class includes seven new elements and is intended to provide an opportunity to capture and exchange key elements of health care insurance coverage.

Recommendation: We support including this new data class and set of data elements because they will be helpful for coordinating benefits and care, particularly for patients with more than one type of coverage or who may be traveling/accessing services outside of their usual access points. We are concerned, however, about the possibility that this information will risk identifying a person without their consent. Requirements to share data with third parties becomes a critical consideration when the data will not be subject to HIPAA privacy and security controls. Data accuracy becomes a concern when data are obtained from different sources without full attribution or provenance. The new information being proposed under the health insurance information class is held by insurers or health plans. They should be the primary data sources, using the existing mechanisms to provide such information to consumers and others.

Patient Demographics Data Class

Several data elements have been added to this existing data class, including date of death, tribal affiliation, related person's name, related person's relationship, occupation, occupation industry. Most of these new data elements

are intended to support person-centered care, enable research to advance health equity and improve social determinants of health.

Recommendation**:** We support including these additional data elements to help improve care quality and patient chart/medical record accuracy. This information may be valuable to clinicians and aid in diagnosis and communication, especially when treating new patients or patients in the Emergency Department. We recommend adding contact information (e.g. email or phone number) for the related person data element to provide a contact for the patient.

Recommendation: The Occupation and Occupation Industry data elements are very similar and we are concerned that there may be risk of duplication in data capture. We recommend that USCDI focus on one of these two data elements instead of including both.

Laboratory Data Class

Adds two additional data elements, specimen type and result status, to this data class to address public health reporting priorities.

Recommendation: We support including the additional data elements because they provide clinical context for more accurate interpretating test results and may allow for improved decision support for imported data. This is particularly important for tests that may have preliminary status over the course of several days before finalizing (e.g. microbial culture results). We recommend that it is not required to share results until finalized (examples include: urine cultures, pathology reports, x-ray readings via teleradiology etc.)

Procedures data class

Adds a new data element, reason for referral, to the Procedures data class.

Recommendation: We support including this additional data element because it is helpful in ensuring that a patient receives proper follow-up referral and provides context for procedures and results. However, special consideration must be given to ensure that confidential or sensitive information is not subject to unauthorized disclosure in accordance with state and federal privacy and consent to medical treatment requirements

Requests for additional feedback

Sex (assigned at birth)

ONC seeks input on the USCDI concept of Sex Assigned at Birth, its associated vocabulary standards (value set), and specifically whether the term itself and its value set should align with Gender Harmony's definition for Recorded Sex or Gender.

Recommendation: We recognize that this can be an important element as part of a broader data set for accurate decision support, particularly for transgender patients, and may be helpful in making clinical determinations. This information would be best captured at the membership level instead of at the clinician level. We recommend that the standard terms be adopted and maintained to promote consistent, reliable, and accurate data capture. We do believe it will be important for ONC to align this data element "Sex (assigned at birth)", or to replace it, with the concept and definition of Recorded Sex developed by the HL7 Gender Harmony Project (https://confluence.hl7.org/display/VOC/The+Gender+Harmony+Project)

Gender Identity

ONC requests feedback on the most appropriate value set to represent Gender Identity for USCDI v3.

Recommendation: Gender identify reflects how individuals perceive themselves and it is important for clinicians to understand to respectfully connect with their patients. However, this data element does not provide clinicians with all information needed to best treat patients. We recommend that USCDI include additional gender inventory data elements that capture organ inventory and hormone treatment status. This will provide clinicians with information needed to provide clinically appropriate, respectful, and high-quality whole person care. We also recommend ONC align these data elements with the Gender Identity concepts defined by the HL7 Gender Harmony Project.

Patient Address

ONC seeks feedback on whether this specification should be the required standard for Current and Previous Address in USCDI v3 or a future USCDI version.

Recommendation: We recommend that the patient's previous address be required in a future USCDI version. The patient's previous address can be helpful in certain clinical scenarios, such as when there is an urgent clinical need to physically locate the patient. Additionally, the current USCDI standards do not differentiate between a patient's physical address and mailing address. We recommend adding an additional data field to differentiate between these two addresses.

Additional Updates needed for Draft USCDI v3

ONC seeks feedback on any additional or modifications needed to data classes and data elements.

Recommendation: We recommend adding a data element (Other) to capture the broad range of non-medication allergies such as food and environmental allergies (e.g. peanut allergies, bee venom allergies) to help clinicians quickly diagnose and treat patients.

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Thank you for considering our feedback. If you have questions or concerns, please contact me at Jamie.ferguson@kp.org or megan.a.lane@kp.org.

Sincerely,

Jamie Ferguson
Vice President, Health IT Strategy and Policy
Kaiser Foundation Health Plan, Inc.