May 13, 2025

Submitted Electronically

Steve Posnack
Principal Deputy National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C St SW, Floor 7
Washington, DC 20201

Re: Draft USCDI Version 6

Dear Mr. Posnack:

Thank you for the opportunity to provide comments on ONC's draft of the United States Core Data for Interoperability Version 6 (USCDI v6).

As a leading developer of interoperable health information technology, we support ONC's goal of aligning the industry's efforts and thoughtfully adopting standards to improve health information exchange. Consensus on standards like the USCDI contributes to enhanced data exchange in nationwide interoperability networks like the Trusted Exchange Framework and Common Agreement.

We have provided some general feedback on the USCDI, as well as more detailed recommendations on areas of ambiguity in the Draft USCDI v6 that should be resolved before it is published and adopted by the industry. We support ONC's approach to prioritize new data elements that, when combined, are a "modest aggregate" lift for developers and implementers. Modest inclusions create a manageable scope for health IT developers and make it easier for them to quickly adopt updated versions of the USCDI in their products.

We would be happy to answer any questions you might have on our feedback and to continue to work with ONC and standards development organizations to improve standards-based data exchange in healthcare.

Thank you for your consideration.

Sincerely,

Dave Fuhrmann
Research and Development
Epic

Feedback on Specific Data Classes and Data Elements

Addition of the Facility Address Data Element

The same healthcare facility might make use of multiple addresses depending on the context:

- The address provided to patients to direct them to the correct location for an appointment (e.g., the facility's reception area or front desk)
- The address used for mailed correspondence
- The address used to meet requirements of health plans' claims submission/processing requirements

Any of these are reasonable to include, but the final USCDI v6 should specify which to use by default for consistent interpretation by the industry. Alternatively, the USCDI could include multiple address types as distinct data elements.

Addition of the Care Plan Data Element

The patient's care plan and future care objectives are often informed by the patient's condition when they reach a given point (e.g., based on the patient's lab values in six months after attempting a given therapy). For example, a care team might order a therapy, and measure its impact using lab orders, then subsequently decide in conjunction with the patient what an appropriate next course of action will be. Care plans often involve specific protocols defined by the care team's organization.

This results in two key challenges when it comes to the interoperable exchange of Care Plan information as contemplated in the Draft USCDI v6. First, it is challenging to model and enable documentation for changes in a Care Plan that might take place in the future. Doing so could impose significant clinician burden, since many of the potential options might not be pursued, depending on the outcomes of the therapies ordered and subsequent changes to the patient's goals. Any Care Plan data element would need to enable flexible documentation approaches that are additive and modifiable over time—which can be challenging when exchanged data elements are "snapshots."

The second challenge stems from the fact that Care Plans are often dictated by organization-developed protocols. This makes it challenging for recipients of the Care Plan data element to receive the information and reconcile it in a discrete manner into their local health IT systems. The receiving organization may have different practices or protocols that are not mappable to the received Care Plan. This makes the received data less interactive for users.

Finally, aspects of the Care Plan data element appear to be redundant with the Assessment and Plan of Treatment data element. For example, a clinician's "conclusions and working assumptions" would be mutually informed by details of the patient's "conditions, needs, and goals along with strategies for addressing them." Many of the components of an Assessment and Plan of Treatment (e.g., the health concern it is intended to address, clinical tests, labs, procedures and medications ordered to address it) are included elsewhere in the USCDI and/or the patient's chart. The final version of the USCDI v6 should specify how the intended use of the Care Plan differs from those other data classes and elements to avoid the exchange of duplicative data within a single patient's record. This is especially important given that the standards development community has already mapped the CarePlan FHIR resource to the Assessment and Plan of Treatment data element.

ASTP will need to address these challenges within the structure of the USCDI before incorporating the Care Plan data element into a version of the USCDI. Specifically, it should clarify how the Care Plan differs in intended use from the existing Assessment and Plan of Treatment data element and reconcile and describe how the components that make up a Care Plan should be modeled for the purposes of the USCDI data element to minimize the exchange of duplicative information within a CCDA or set of FHIR resources. It should adopt an approach that focuses on exchange of historical and current information about the Care Plan without requiring exhaustive documentation of potential future paths within the Care Plan.

Addition of the Portable Medical Order Data Element

There is no industry consensus on the discrete POLST data elements that should be interoperable; they are not widely interoperated today. ASTP can begin to make progress on exchanging this type of data by encouraging the exchange of documents, including pdfs, containing human-readable information. Epic's software has long had the capability to exchange pdfs alongside structured data.

The intended use of the existing data element for Treatment Intervention Preference within the Goals and Preferences data class overlaps to a significant degree with how Portable Medical Order for Life-Sustaining Treatment (POLST) is understood within the industry.

Treatment Intervention Preference Data Element	**POLST (https://polst.org/)**
Person's goals, preferences, and priorities for care and treatment in case that person is unable to make medical decisions because of a serious illness or injury. Examples include but are not limited to thoughts on cardiopulmonary resuscitation, mental health treatment preferences, and thoughts on pain management.	The POLST form is how patients who are seriously ill or have advanced frailty tell all health care providers what they want during an emergency and what their goals of care are given their current medical condition. Orders on a POLST form include: • Whether you want cardiopulmonary resuscitation (CPR) attempted • Whether you want to go to the hospital or stay where you are • Whether you want to receive care in an intensive care unit and be on a breathing machine, if needed The POLST form is also a way to share your general goals of treatment. These help providers make sure any other medical treatments you may need that aren't covered on the POLST match your goals.

A data class dedicated to Advance Care Planning related activities could more effectively group these data elements together for exchange and promote consistency in how they are expressed in standards used for exchange. Although there can be different degrees of formality between a patient's expressed Treatment Intervention Preferences as communicated in a conversation compared to those documented formally as part of a POLST or Advance Directive, the content often has similarities or overlaps. Such an approach also aligns with our previous feedback recommending that the USCDI adopt an approach that positions the data elements in the Orders data class in data classes that better match their intended use.

Unique Device Identifier Request for Feedback

ASTP solicits input on whether Unique Device Identifier should be a single data element or two—one for implantable devices and another for non-implantable devices. Although both approaches could be supported in standards and facilitate effective information exchange, we recommend the approach with two data elements. The industry is broadening its use of Unique Device Identifiers to enhance visibility into the usage of different types of medical devices. As different types of medical devices proliferate, it could become increasingly important that clinicians and health IT systems can quickly distinguish between those that are implanted and those that are not implantable but still used by an individual patient.

Care Plan Request for Feedback

As ASTP incorporates the Care Plan data element into the USCDI, it should harmonize its use with other, similar data elements in the USCDI. The components of the Care Plan data element identified by ASTP align with those commonly understood as included in a Care Plan, but they overlap with many of the data classes and elements elsewhere in the

USCDI. For example, ASTP suggests that Prioritized Problems would be a component of the Care Plan data element. However, there is already a Problems data class and data element. ASTP should work with the standards development community to incorporate a "prioritized" concept into the standards used to represent and exchange the existing Problem data class/element. Health Concerns, Assessments, Goals, and Interventions are similarly already included in other data classes in the USCDI. ASTP should evaluate whether it is feasible for standards to represent that a given Health Concern (or Assessment, Goal, Intervention, etc.) has a Care Plan associated with it and vice versa (i.e., that one Care Plan covers multiple Health Concerns). This could enhance the ability to consume exchanged data and reduce redundancy.

Diagnostic Imaging Request for Feedback

We strongly support ASTP's efforts to enhance the exchange of medical images and related data. More efficient access and exchange of imaging data can significantly reduce the wasteful duplication of orders for imaging studies. It would also reduce the administrative burden on nurses and physicians, who often need to jump through several hoops before they can review imaging studies. Together, these will improve patients' healthcare access and experience.

Historically, it has been highly atypical for healthcare providers to use their EHR system to store diagnostic images. Instead, they implement specialized Picture Archiving and Communication Systems (PACS) and Vendor Neutral Archiving (VNA) systems. These systems are often specifically designed to integrate with the imaging modalities (e.g., X-Ray, MRI, and CT imaging machines) in use at the organization. This presents unique challenges to the ability to access and exchange this information, because these systems do not follow the same interoperability standards and specifications as certified health IT. This has led to a variety of strategies for incorporating access to this data into clinical workflows:

- Some PACS and VNA systems provide a viewer or portal that can be embedded into EHR screens in users' workflows.
- Other approaches require users to launch a separate application outside of the EHR to view imaging data, even within a single health system.

The blend of equipment and system/application strategy that the healthcare provider organization has adopted will inform what options it has for granting access for users outside of the organization to access or view the imaging data or for the organization to have the capability to directly exchange the medical image in question.

Although a hyperlink could in theory be used to direct a user to the right imaging data, operationalizing such an approach introduces challenges related to authentication and security. In order for a user outside of the organization to use an imaging link, the link-providing organization would need to be willing to expose their imaging repository to the public internet for unauthenticated users to access the system. This would be a significant security risk because it exposes the imaging repository to multiple security threats, including attempts to brute force access the system by attempting to generate valid URLs. Alternatively, provider organizations could require authentication methods such as log-ins and passwords to view the linked images, but this would be impractical for ASTP's intended use because organizations would not be able to credential every potential user outside of their organization.

The lack of authentication and cross-organizational user identity management will make it infeasible for organizations to account for disclosures of Protected Health Information (PHI), and therefore infeasible to comply with their obligations under the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule. It would also create compliance concerns at the receiving organization whose doctors are accessing the images. Because the images themselves might not be transferred (because the doctor might use a viewer of the sender's PACS), it would often be impossible to add it to the patient's Designated Record Set (DRS), a necessary compliance requirement if the images are to be used for medical decision making. Additionally, medical images accessed in this manner might "disappear" for several reasons, including chart corrections, patient consent revocation, or IT system reconfiguration, meaning that

the images would not be available after-the-fact to justify medical decision making, resulting in increased liability for medical malpractice.

Instead of the hyperlink-based approach proposed in recent rulemaking, ASTP could pursue the following strategies for enhancing access to medical images:

- Encourage PACs, VNAs, and others to offer patient viewing capabilities. This could include promoting their adoption of technologies that would enable image viewers to be embedded in the patient portals offered by certified health IT.
- Promote the adoption of interoperability standards by PACs and VNAs that would enable images to be exchanged amongst healthcare provider organizations. This ensures that providers that rely on imaging data will receive a copy of it for their own record keeping purposes, and would eliminate the need to do cross-organization credential management.