EHRA
HIMSS ELECTRONIC HEALTH RECORD ASSOCIATION

550 W Van Buren Street, Suite S1110
Chicago, IL 60607

@EHRAssociation | ehra.org

April 14, 2025

Steven Posnack, MS, MHS
Acting Assistant Secretary for Technology Policy,
Acting National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C St SW
Washington, DC 20416

Dear Acting Assistant Secretary Posnack,

On behalf of the 27 member companies of the HIMSS Electronic Health Record (EHR) Association, we are pleased to provide feedback to ASTP/ONC on its Draft USCDI v6.

As the national trade association of EHR developers, our member companies serve most hospital, post-acute, specialty-specific, and ambulatory healthcare providers using EHRs and other health IT across the United States. Together, we work to improve the quality and efficiency of care through the adoption and use of innovative, interoperable, and secure health information technology.

As communicated previously, we fully support the growth of USCDI and its continued expansion toward encompassing all EHI. While we find many of the proposed changes to USCDI reasonable, we nonetheless have several concerns, which we discuss in detail in the following comments.

As always, we stand ready to continue collaborating with ASTP/ONC and other relevant stakeholders on expanding USCDI and other issues of importance to advancing safe, interoperable, standards-based health IT.

Sincerely,

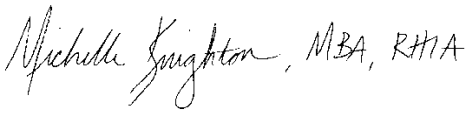
Leigh Burchell
Chair, EHR Association
Altera Digital Health

Stephanie Jamison
Vice Chair, EHR Association
Greenway Health

HIMSS EHR Association Executive Committee

David J. Bucciferro
Foothold Technology

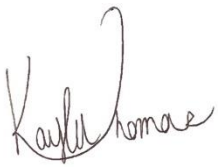
Danielle Friend
Epic



Michelle Knighton
NextGen Healthcare

Ida Mantashi
Modernizing Medicine

Shari Medina, MD
Harris Healthcare



Kayla Thomas
Oracle Health

Established in 2004, the Electronic Health Record (EHR) Association is comprised of 27 companies that supply the vast majority of EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families. The EHR Association is a partner of HIMSS. For more information, visit www.ehra.org.

Medical Devices: Unique Device Identifier

Numeric or alphanumeric code that uniquely identifies a medical device.
Usage note: Contains a device identifier (DI) and one or more production identifiers (PI).

The concerns of the EHR Association center on the lack of clarity on the full implications of the proposed expansion of UDI requirements beyond implantable devices. For example, is a UDI required for every diagnostic device even when the originating system does not provide, support transmission of, or sufficiently communicate one, as is the case with laboratory information systems (LIS) and point-of-care (PoC) devices used directly with electronic health record (EHR) systems? This also raises questions about what would be considered reasonable next steps for UDI adoption beyond implantable devices.

While we support greater interoperability in medical device data, management of much of this information happens in non-EHR systems. Consequently, a considerable expansion of the UDI requirement to encompass devices beyond implantable ones could impose substantial workflow challenges and necessitate manual data entry on the part of end users. Therefore, we propose that this requirement be paused or withdrawn until broader industry adoption by source systems and instruments has advanced to a level that ensures its maturity and readiness for inclusion in the USCDI.

Orders: Portable Medical Orders

Provider-authored request for end-of-life or life-sustaining care for a person who has a serious life-limiting medical condition.
Usage note: These are meant to follow a person regardless of when and where such an order might be needed (e.g., hospital, care facility, community, home). There are variations in requirements and names for portable medical orders based on jurisdiction.
Examples include but are not limited to POLST (Portable Medical Order for Life-Sustaining Treatment), MOLST (Medical Orders for Life-Sustaining Treatment), and out-of-hospital DNR (do-not-resuscitate).

The proposal to include Physician Orders for Life-Sustaining Treatment (POLST or Portable Medical Orders) is a reasonable inclusion if scoped to existing submission standards (e.g., FHIR US Core ServiceRequest). However, further industry maturation is needed before further expansion. The included references do not mention that the Clinical Documentation Architecture (CDA)-based POLST Implementation Guide has already been recognized as insufficient. Further, the PACIO Implementation Guide that includes guidance on communicating POLST – which is more complex than a simple ServiceRequest – has not yet been balloted, much less published.

Because these standards are immature, the EHR Association suggests a more limited scope that aligns the PMO definition with Advance Directive Interoperability (ADI) by indicating the presence, type, and location of a POLST document rather than requiring a fully structured format. Specifically, we suggest an alternate definition of PMO:

Definition: Information about a provider-authored PMO document indicating its location, content, type, and verification status.

Usage note: This may include structured or unstructured data, whether a person has one or more PMO documents, the type of PMO, location of the document, and its verification status. Such documents, which often also include care goals, may be used during an emergency or health crisis when a person is unable to communicate to a treating provider their preferences for CPR and/or life-sustaining treatment interventions.

Examples include but are not limited to an indication that a POLST, MOLST, DNR or similar document is on file, a reference to the location of the PMO document, and the validating provider.

This recommended approach ensures current feasibility while allowing future expansion as standards mature.

Facility Information: Facility Address

Physical location of available services or resources.

The EHR Association supports the inclusion of Facility Address but seeks clarification on the specific address type that will be required, e.g., physical location, billing address, or mailing address. A clear definition is needed to ensure consistency and appropriate use across implementations. We further recommend that USCDI clarify the data classes for which Facility Information is generally relevant and suggest it clarify its scope as what is currently implemented in HL7 FHIR US Core and HL7 CDA C-CDA.

Patient Summary and Plan: Care Plan

Shared plan informed by members of a coordinated care team that details conditions, needs, and goals along with strategies for addressing them.
Usage notes: Includes prioritized problems, health concerns, assessments, goals, and interventions from across care settings.
Examples include nursing care plan, diabetic care plan, multiple chronic conditions care plan, and long term services and support care plan.

The EHR Association supports expanding patient summary and plan data. However, because care plans vary by setting (e.g., cancer treatment vs. inpatient care), we do not support requiring that all care plans include every proposed element. Mandating elements like goals in all cases would not align with real-world workflows.

It is also unclear whether “prioritized problems” refers to problem list conditions, health concerns, plan elements, or something else. For clarity, we recommend removing the word “prioritized.” Doing so acknowledges that while every plan needs to identify a presence, they do not need to identify a problem.

Finally, it is unclear how USCDI "Patient Summary and Plan" elements overlap with or differ from the "Assessment and Plan of Treatment" data class; we recommend clearly defining scope to avoid redundancy and misalignment.

Problems

Date of Onset

Date or estimated date when signs or symptoms of a condition began.
Usage note: This may be a specific day, week, month, or year, or it may be an estimate.

The EHR Association supports the addition of Date of Onset.

Family Health History

Family members' health conditions that are relevant to a patient's care.
Applicable Vocabulary Standard(s)

- *SNOMED Clinical Terms (SNOMED CT) U.S. Edition, September 2024 Release*
- *International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) 2025*

The EHR Association generally supports incorporating Family Health History as a data class. Nevertheless, we recommend explicitly defining its scope and the relevant code sets. This data class encompasses more than the documentation of "problems," as it necessitates the inclusion of additional information, such as the individual's familial relationship to the patient. Therefore, clarification is essential regarding the specific data elements to be captured and the required structuring of these elements to promote standardization and minimize undue complexity.

Procedure: Performance Time

The EHR Association reiterates its concerns with the use of examples that are not considered Procedures in the supporting implementation guides and are therefore not included in those guides. For example, medication administration is not managed as a procedure and is not included in HL7 FHIR US Core nor HL7 CDA C-CDA. In addition to such examples, Procedure data elements like Performance Time should also not be used to expect that the various laboratory-specific times, e.g., specimen collection date/time or test result date/time, are assumed to be covered by Procedure rather than in the Laboratory data class.

We strongly urge ASTP/ONC to include relevant times in the specific data classes already established. This includes Laboratory data and additional classes that are not explicitly categorized as Procedures (e.g., Medication Administration). Furthermore, remove any examples that seem to imply they are supported by the respective implementation guide, particularly regarding medication administration. This will further reduce ambiguity and maintain consistency with the primary interoperability implementation guides that everyone should adhere to when automating their data access, exchange, and utilization processes.