EMORY
HEALTHCARE

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Delivered Electronically via: https://isp.healthit.gov/united-states-core-data-interoperability-uscdi#draft-uscdi-v7

Re: Draft United States Core Data for Interoperability (USCDI) Version 7 (v7)

Emory Healthcare, part of Emory University, is an integrated academic health care system committed to providing the best care for our patients; educating health professionals and leaders for the future; pursuing discovery in all of its forms, including basic, clinical and population-based research; and serving our community. As the clinical enterprise of the Robert W. Woodruff Health Sciences Center of Emory University, Emory Healthcare remains the most comprehensive health care system in Georgia, providing extensive inpatient and outpatient services to a diverse patient population.

Emory Healthcare applauds the Office of the National Coordinator for Health Information Technology's (ONC) consideration of public comments in the standards advancement process for the USCDI. We appreciate the opportunity to be a part of this process.

Interoperability is foundational to our ability to fulfill our purpose. At Emory Healthcare, we leverage electronic health data interoperability to support bedside care, research, and our partners in public health at the state, tribal, local, territorial and federal levels. To continue advancing our aligned yet adjacent missions, we must all depend on data standardization and the exciting modernization efforts that are being championed by the ONC and its federal partners. Emory Healthcare particularly looks forward to developments like the increasing landscape of systems that leverage the Fast Healthcare Interoperability Resources (FHIR) data standard, the continued evolution of the Trusted Exchange Framework and Common Agreement (TEFCA), and investments in artificial intelligence (AI)-related governance and tools. With reliable, high-quality and appropriate exchange of data between interested parties, we can collectively seize these opportunities to elevate our local and global communities.

In support of our comments on the Draft USCDI v7, Emory Healthcare assembled leaders, clinicians, pharmacists, transfusion specialists, medical ethicists, physician and clinical informaticists, security and regulatory specialists to review and offer feedback on the data elements and data classes proposed for inclusion in version 7. This is the sixth time Emory Healthcare has assembled to thoughtfully collaborate on comments. We appreciate the opportunity to respond to ONC's questions regarding suggestions for improving the Draft USCDI v7 as well as recommendations for other data elements to include. We submit our

perspectives, provided below, and strongly believe in the capacity that the USCDI has for positive impact.

If you have any questions regarding our comments, please feel free to contact our Assistant Vice President for Federal Affairs, Jessica Davis, at jessica.ann.davis@emory.edu. We look forward to continuing to participate in the development of the USCDI.

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Data Class: Allergies and Intolerances

Allergy Intolerance Criticality

EHC strongly supports the proposed addition of Allergy Intolerance Criticality as a data element within the United States Core Data for Interoperability (USCDI). However, we also recommend further differentiation within the 'Allergy and Intolerance' section, which currently aggregates allergic reactions, non-allergic adverse drug reactions, side effects, and intolerances. We recommend segmenting drug reactions from the following classifications:

Drug Allergies: We see a clear and significant use case for criticality in specific scenarios, particularly with drug allergies where cross-reactivity and severe systemic reactions are well-documented. A standardized criticality here is invaluable for immediate patient safety.

Foods and Other Agents: For food allergies, environmental allergies, or other agents that may have less significant cross-reactivity or direct disease-food interactions, the utility of a "criticality" classification can be less pronounced. The clinical impact often varies widely, and a blanket application might not always be beneficial.

We also note that Provenance of these data is vital, as what patients might perceive as severe discomfort or significant impact on their quality of life might not necessarily equate to a high-risk medical event. This inherent subjectivity makes it difficult to consistently apply a standardized criticality. Despite these challenges, we strongly agree with the need for a national standard to classify criticality. A simplified, standardized approach, such as classifying criticality into low, high, and unable to assess risk, would greatly simplify the classification process and improve consistency across systems. This approach could provide actionable information while acknowledging the complexities of certain reactions and data input. We recommend that the ONC continue to emphasize and potentially further define the requirements for capturing and exchanging Allergy and Intolerance Criticality, while also providing clear guidance on its appropriate application and the need for a simplified, nationally standardized classification system (e.g., low, high, unable to assess risk).

Data Class: Biologically Derived Product

EHC strongly recommends inclusion of the L1 and L2 data elements proposed within this data class, including Biologically Derived Product, Biologically Derived Product Information,

Biologically Derived Product Storage Information, Product Code, Unique Identifier, Source Identifier, Division and Processing Facility. We reiterate the comments on the use case and utility of these data as written by Barbee Whitaker in the submission details.

Data Class: Care Team Members

Healthcare Agent

EHC appreciates the comprehensive proposal and strongly supports interoperable exchange of advance directive information, including appointment of a Healthcare Agent. Enabling access to patient goals, preferences, and designated decision-makers across care settings is foundational to person-centered care.

However, we recommend the proposed data element more clearly distinguish between representation of patient-authored preferences (e.g., PACP content) and representation of legally validated decision-making authority. In many jurisdictions, including Georgia, the authority of a Healthcare Agent depends upon the existence of a properly executed and legally valid advance directive or medical power of attorney. Identification of an individual as "Healthcare Agent" without linkage to and verification of the underlying legal instrument may create false legal certainty, inappropriate reliance in clinical decision-making, or improper disclosure of protected health information.

While the HL7 PACP specification appropriately emphasizes preservation of context and avoidance of converting narrative preferences into computable orders, designation of legal authority is distinct from expression of treatment preferences. To safely support interoperability, the Healthcare Agent element should: 1) Distinguish among a formally appointed Healthcare Agent, a court-appointed guardian, and a statutory surrogate under state law; 2) Be structurally linked to the governing advance directive or power of attorney document; 3) Include document provenance and verification status (e.g., on file, verified, revoked, expired); 4) Capture governing jurisdiction (state law); and 5) Support successor or alternate agent designation.

Absent these safeguards, exchange of agent identity alone may not meaningfully support transitions of care and may introduce legal and regulatory risk, particularly in emergency care, interfacility transfers, and interstate information exchange. We strongly support advancement of interoperable advance directive exchange and believe that a structured, provenance-aware, and jurisdiction-sensitive representation of Healthcare Agent authority will better align federal health information technology policy with state decision-making statutes and HIPAA personal representative requirements.

Data Class: Clinical Notes

Airway Management Note

EHC recommends that Airway Management be moved from Level 1 to Level 2 within this data class to better reflect adoption and exchanges in place today.

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Data Class: Diagnostic Imaging

Diagnostic Imaging Reference

EHC strongly supports the inclusion of Diagnostic Imaging Reference and data elements that support the exchange of diagnostic imaging tests and results. Weblinks for images are an important part of efficient patient-facing image sharing which allows patients to access their own radiology images, on-demand.

Data Class: Facility Information

Facility Telecom

EHC supports the inclusion of this data element to improve availability of contact details. We encourage ONC to consider separating phone and email contact points at the facility level.

Data Class: Health Status Assessments

Tobacco Use (Modified)

EHC appreciates the efforts by ONC to build core data elements that recognize the use of smokeless tobacco, chewing tobacco, and vapes. We appreciate the need to balance the alignment of historical data with incorporating new data relevant for clinical and public health work, especially given the different pathways of biological harm. We support the modification of this data element.

Data Class: Immunizations

Immunization Record Source

We support detailed and specific provenance of data and strongly support the inclusion of Immunization Record Source in USCDI v7.

Data Class: Medical Device

Device Type

EHC appreciates the need to and utility of specifying device types, but we have concerns about the ambiguity of certain devices. For example, an intrauterine device is considered both a medical device and a medication. We seek clarity from ONC on how devices like those might be best documented.

Data Class: Medications

For all data elements within this data class, EHC notes the importance of differentiating between care contexts (e.g., inpatient, ambulatory, retail dispense), as dispensing can vary across care areas. We also recommend including standardized unit(s) of measurement.

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Medication Dispense Quantity

EHC requests additional clarity beyond the data element definition of "The amount of medication dispensed or to be dispensed", as dispensing can vary across care areas. For instance, does this data element refer to retail dispense? If so, EHC notes that this is a standard field in ambulatory prescriptions, but that dispense quantity is, at times, a calculated value. The definition which would provide greatest value would be the actual count of units dispensed with unit of measure included. That will support calculation of total dose, which is especially useful in the prescription of opioids and calculation of MEDD, for example.

Data Class: Travel Information

EHC submits its support for the inclusion of Travel History Location and Travel History Dates in the USCDI v7 under a Travel Information data class. Please see EHC's comments from 2023-09-30 (https://www.healthit.gov/isa/comment/13510) and note the alignment of inclusion of these data elements with the recently updated Administration for Strategic Preparedness and Response's 2026-2029 strategy of preparedness for disasters and emergencies.