April 14, 2023

Steven Posnack, Deputy National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology (ONC)
U.S. Department of Health and Human Services
330 C St SW
Floor 7
Washington, DC 20201

Re: USCDI Draft Version 4

Dear Mr. Posnack,

The Medical Imaging & Technology Alliance (MITA) is the leading trade association representing the manufacturers of medical imaging equipment and radiopharmaceuticals. We are encouraged to see the Office of the National Coordinator for Health Information Technology (ONC) continue its work to improve USCDI and enhance interoperability in healthcare—a goal MITA members share. We submit these comments in support of that shared goal.

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On New Proposed Elements for USCDI v4

Allergies and Intolerances

MITA supports the proposed addition of "Allergies and Intolerances" to USCDI v4. Non-medication allergies are important risk factors related to intravenous contrast administration for imaging devices. Inclusion of this information would reduce risk to patients.

Encounter Identifier

MITA commends ONC on incorporating Encounter Time, Encounter Diagnosis, and Encounter Type in USCDI v4. To further strengthen Encounter Information, we support the proposed addition of "Encounter Identifier" to USCDI v4. This data element is key to being able to link associated information to the appropriate Encounter. The use of the FHIR element "Encounter.identifier.system", as profiled in US Core[1], is also key to successfully sharing related information between institutions. For imaging procedures the identifier would likely be the DICOM Accession Number and the system would be the

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[1] https://hl7.org/fhir/us/core/StructureDefinition-us-core-encounter.html

Issuer of Accession Number. If the intention is that the encounter identifier for an ordered imaging procedure is to be something other than the imaging accession number, then additional guidance is needed.

As a caveat, note that encounters are typically considered to be hierarchical (e.g., an encounter with a physician within an encounter with a department within an encounter with a hospital). Encounter identifiers, on their own, will not be sufficient to navigate this hierarchical structure. Profiling will be needed in the future to further address the issue.

Time of Procedure

We support the proposed addition of "Time of Procedure" to USCDI v4. The element better enables clinicians to track infection, which can occur parallel to some imaging procedures (such as interventional radiology).

Facility Information

We support the proposed addition of "Facility Information" to USCDI v4. The element is critical for cross-enterprise exchange and would improve patient information availability. Further, it corresponds to the Enterprise Identity Option in section 34.2.10 of Scheduled Workflow.b (SWF.b), an IHE profile[2] with wide adoption.

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On Prior Proposed Elements

Diagnostic Imaging Group

We continue to advocate the promotion of the elements "Imaging Reference", "Requested Procedure Identifier", and "Accession Number" within the "Diagnostic Imaging" Data Class from Level 2 to USCDI v4. These elements are central to the handling of diagnostic imaging information. Maturity and breadth of these elements are consistent with the ONC prioritization criteria for being considered a USCDI data element.

Clinical Tests

We continue to advocate the addition of ECG procedure types to the "Clinical Test" element in USCDI v4. We support ONC usage of up-to-date versions of the LOINC codes for clinical tests. DICOM is working with LOINC to supplement the list of codes for ECGs acquired in an imaging context.

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[2] https://www.ihe.net/uploadedFiles/Documents/Radiology/IHE_RAD_TF_Vol1.pdf

MITA commends the ONC for its continued work towards healthcare interoperability and the development of the USCDI. If you have any further questions, please do not hesitate to contact Zack Hornberger, Director of Cybersecurity & Informatics at zhornberger@medicalimaging.org or by phone at 703-841-3285.

Sincerely,

Patrick Hope
Executive Director, MITA

MITA is the collective voice of medical imaging equipment and radiopharmaceutical manufacturers, innovators, and product developers. It represents companies whose sales comprise more than 90 percent of the global market for medical imaging technology. These technologies include: magnetic resonance imaging (MRI), medical X-Ray equipment, computed tomography (CT) scanners, ultrasound, nuclear imaging, radiopharmaceuticals, radiation therapy equipment, and imaging information systems. Advancements in medical imaging are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. The industry is extremely important to American healthcare and noted for its continual drive for innovation, fast-as-possible product introduction cycles, complex technologies, and multifaceted supply chains. Individually and collectively, these attributes result in unique concerns as the industry strives toward the goal of providing patients with the safest, most advanced medical imaging currently available.