MITA
MEDICAL IMAGING
& TECHNOLOGY ALLIANCE
A DIVISION OF NEMA

1300 North 17th Street ▪ Suite 900
Arlington, Virginia 22209
Tel: 703.841.3200
Fax: 703.841.3392
www.medicalimaging.org

April 15, 2021

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: U.S. Core Data Interoperability (USCDI) Draft Version 2

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 Current Level 2 Data Classes and Data Elements Proposed by ONC for the USCDI v2

Diagnostic Imaging Order

MITA strongly supports the proposed addition of "Diagnostic Imaging Order" to USCDI v2 and believe that it is consistent with the ONC prioritization criteria for moving Level 2 data elements to the USCDI v2: it addresses a gap, is widely used, and poses minimal burden to intra-organizational API workflow.

In addition, we propose the following revisions to the "Additional Information" table regarding the Diagnostic Imaging Order data element:

1. **Use Case Description**
   The following language should be added within the Use Case Description field: "The Diagnostic Imaging Order contains demographics and procedure details pertaining to the imaging service request. The order also acts as a trigger within imaging scheduled workflow, leading to patient and imaging resource scheduling, retrieval of relevant prior studies, and population of the reading worklist. Upon patient registration, patient demographic and procedure information from the

order are made available to the imaging resource through the DICOM Modality Worklist and used to populate DICOM information objects created by the imaging modality."

2. **Applicable Standard(s)**
   The list of Standards should also include:
   a. HL7 v2.5.1: ADT, OMG, OMI, ORM
   b. DICOM 3.0
   c. FHIR R4 ImagingStudy resource

3. **Estimated number of participants capturing, accessing, using, or exchanging**
   The table should reflect that there are just under 550 million medical imaging procedures performed annually in the U.S (Source: IMV 2019 Global Imaging Market Outlook Report). According to ISO 21860:2020, product adoption and site deployment of IHE Scheduled Workflow and its associated Standards is High.

We also suggest promoting the current Level 2 data element, "Types of orders for medical care/services," for inclusion in USCDI v2. Orders and order notifications contain useful information across multiple healthcare technologies. Inclusion of the element addresses a gap, is widely used, and poses minimal burden to intra-organizational API workflow.

Diagnostic Imaging Report

MITA strongly supports the proposed addition of "Diagnostic Imaging Report" to USCDI v2.

"Diagnostic Imaging Narrative", a USCDI v1 element, is typically structured within a Diagnostic Imaging Report. ONC should consider removing "Diagnostic Imaging Narrative" as an element or include a clarification that the "Diagnostic Imaging Report" is likely to contain a "Diagnostic Imaging Narrative."

In addition, we propose the following revisions to the "Additional Information" table regarding the Diagnostic Imaging Order data element:

- **Use Case Description**:
  The following language should be added within the Use Case Description field: "An imaging report is a clinical document that provides an interpretation and description of an imaging procedure. Imaging reports include clinical context, examination technique, contrast medium administered, radiation dose summary, comparison studies reviewed, image quality, recommended follow-up procedures and diagnostic impression. Imaging reports contain structured information, a narrative, and a conclusion. Reports may be complimented with chart, graphs, key images, or numeric reports. Reports are available for consultation by the patient's care team, follow-up procedures and shared cross-enterprise for referrals and second opinions."

- **Applicable Standard(s)**
  The list of Standards should also include:
  a. DICOM 3.0 PS 18: DICOMweb (retrieve and search), Key Objects (KOS), Radiation Dose Summary (RDSR), DICOM controlled terminology, Structured Reports (SR)
  b. CDA® Release 2, Imaging Reports Template 1.2.840.10008.9.1, as described in the DICOM 3.0 PS 20 SR to CDA Imaging Report Transformation Guide
  c. SNOMED International, Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) U.S. Edition, September 2020 Release
  d. FHIR R4 ImagingStudy resource

- **Estimated number of participants capturing, accessing, using, or exchanging**
  The table should reflect that there are just under 550 million medical imaging procedures performed annually in the U.S (Source: IMV 2019 Global Imaging Market Outlook Report). According to ISO 21860:2020, product adoption and site deployment of HL7 CDA and DICOM Structured Reports is Moderate.

Encounter Diagnosis, Time, Type, and Location

We strongly support the proposed addition of these three new data elements for the USCDI v2:

- Encounter Diagnosis
- Encounter Time
- Encounter Type

We also propose that the current Level 2 data element, "Encounter Location," be included in USCDI v2 Level 1 as this data element facilitates care-coordination inter- and intra-enterprise. The FHIR R4 Encounter resource already includes these Level 1 and Level 2 Elements, imposing minimal new development burden.

Patient Administration Data Elements

Patient administration data elements (orders, admissions, bed requests, discharge, and transfers) are necessary to establish a comprehensive API-based workflow when using applications that connect multiple health IT workflows. Administrative notifications are relied upon as triggers to prompt other elements of clinical workflow, and/or queries of patient clinical data. As such, ONC should consider including patient administration elements consisting of admissions, bed requests, discharges, and transfers within Encounter Information for Level 2, or consider developing a Patient Administration Data Class to incorporate these elements for Level 2.

Patient administration data elements also trigger notifications that enable care coordination to payors, providers, and ancillary systems. We believe increased use of

APIs within inter- and intra-organizational workflows adds additional value to include these universally implemented, well-defined elements in USCDI v2.

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On Proposed New Level 1 or 2 Data Elements, Including Those Appropriate for USCDI v2

Provider Identifier, Name

MITA strongly supports the proposed addition of the following elements to USCDI v2:

- Provider Identifier
- Provider Name

In addition, we suggest ONC include a note in this data element that National Provider Identifier (NPI) be used when available, but that use of a local identifier is acceptable. While the NPI is adequate for covered health care providers, many allied health practitioners (such as respiratory therapists, radiologic technologists, case managers, physical therapists, and nurses) may not have an NPI. As a result, it is not used as an identifying key in healthcare IT systems.

Date of Diagnosis, Resolution

MITA strongly supports the proposed addition of the following elements to USCDI v2 and believe that they are consistent with the ONC prioritization criteria for moving Level 2 data elements to the USCDI v2: it addresses a gap, is widely used, and poses minimal burden to intra-organizational API workflow.

- Date of Diagnosis
- Date of Resolution

In addition, we suggest that "Other Implementation Challenges" for "Date of Resolution" in the "Additional Information" table be expanded to address handling of chronic problems that may not have resolution dates.

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On Current Level 1 or 2 Data Elements Not Proposed by ONC for USCDI v2

Patient Identifier Element

We strongly encourage ONC to adopt a Patient Identifier element. Even without a nationally standardized system for patient identification, ID elements are very important for a variety of intra- and inter-enterprise use cases, including patient matching and API workflows.

To establish this element, MITA proposes:

- Refining the current Level 2 Patient Demographics data element "Identifier" | Interoperability Standards Advisory (ISA) (healthit.gov) and including it in USCDI v2. The need for a patient identifier described in the Submission Form includes, but certainly extends beyond, the Electronic Case Reporting use case described in the submission.

- Promoting the current Level 1 data element in the Patient Demographics Data Class, "Medical Record Number" (MRN) | Interoperability Standards Advisory (ISA) (healthit.gov) Level 1 to Level 2 and included in the USCDI v2. This data element meets the criteria for Level 2 and supports certain application integration, such as those used for SMART on FHIR. The lack of a specific standard for MRN should not be a deterrent to its use.

Observations Element

We strongly encourage ONC to adopt Observations as an element. Observations are important to communicating specific information, such as actionable findings (critical results), in a well-specified and coded manner within encounter-based imaging workflows.

To establish this element, MITA proposes:

- Including the current Level 2 Observations data class in USCDI v2.
- For the elements within Observations, include HL7 v2.5.1 ORU within Applicable standard(s).

The use of Observations is universal. The FHIR R4 Observation resource and HL7 v2.5.1 ORU also include proposed Level 2 Elements, imposing minimal new development burden.

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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.