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To whom it may concern,

As a leading global medical technology and digital solutions innovator, GE Healthcare, believes in the importance of promoting health IT in the areas of a data-driven ecosystem, security, and interoperability. With over 100 years of healthcare industry experience and around 50,000 employees globally, we share the commitment of the goals of Office of the National Coordinator (ONC) to improve Health IT. We submit these comments in support of that shared goal.

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

- **ONC Prioritization criteria for Level 2 data elements:** Significant gaps in USCDI v1 concepts
- Supported by existing ONC Certification
- Modest technical standards development
- Modest aggregate lift for vendor development and implementation, especially during pandemic

Diagnostic Imaging

- Diagnostic Imaging Order

  We strongly support the proposed addition of this new data element for the USCDI v2 and, other than what is indicated below, the rationale in the "Additional Information" table. We believe that this data element is consistent with the ONC prioritization criteria for moving Level 2 data elements to the USCDI v2.

  We propose the following additions/revisions to the "Additional Information" table regarding the Diagnostic Imaging Order data element:

  - **Use Case Description**: 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, assignment of device acquisition protocols, 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.

- o **Applicable standard(s)** should also include
    - ▪ HL7 v2.5.1: ADT, OMG, OMI, ORM
    - ▪ DICOM 3.0
    - ▪ FHIR R4 ImagingStudy resource https://www.hl7.org/fhir/imagingstudy.html
- o **Estimated number of stakeholders capturing, accessing using or exchanging:** 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 ask the ONC to consider promoting the current Level 2 data element "Types of orders for medical care/services" for inclusion in USCDI v2. Orders and order notifications contain information useful for laboratory, procedures, medications, and imaging, alike. The submission from CMS to support "Types of orders for medical care/services" meets ONC Level 2 criteria; it addresses a gap, is widely used, and poses minimal burden to intra-organizational API workflow.

- • Diagnostic Imaging Report

We strongly support the proposed addition of this new data element for the USCDI v2 and, other than what is indicated below, the rationale in the "Additional Information" table. We believe that this data element is consistent with the ONC prioritization criteria for moving Level 2 data elements to the USCDI v2.

We propose the following additions/revisions to the "Additional Information" table regarding the Diagnostic Imaging Order data element:

- o **Use Case Description**: 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.
- o **Applicable standard(s)** should also include
    - ▪ DICOM 3.0 PS 18: DICOMweb (retrieve and search), Key Objects (KOS), Radiation Dose Summary (RDSR), DICOM controlled terminology, Structured Reports (SR)
    - ▪ 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
    - ▪ SNOMED International, Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) U.S. Edition, September 2020 Release
    - ▪ FHIR R4 ImagingStudy resource https://www.hl7.org/fhir/imagingstudy.html
- o **Estimated number of stakeholders capturing, accessing using or exchanging:** 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".

We note that the "Diagnostic Imaging Narrative" USCDI v1 element is typically structured <u>within</u> a Diagnostic Imaging Report. ONC should consider removing " Diagnostic Imaging Narrative," or include a clarification of this real-world relationship; that the "Diagnostic Imaging Report" is likely to contain a "Diagnostic Imaging Narrative".

Encounter Information

We strongly support the proposed addition of these new data elements for the USCDI v2 and, other than what is indicated below, the rationale in the "Additional Information" table. We believe that these data elements are consistent with the ONC prioritization criteria for moving Level 2 data elements to 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, as this data element facilitates care-coordination inter and intra enterprise . We note that the FHIR R4 Encounter resource https://www.hl7.org/fhir/encounter.html includes these Level 1 and Level 2 Elements, imposing minimal new development burden.

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

We comment that patient administration data elements consisting of orders, admissions, bed requests, discharge and transfers are necessary to establish a comprehensive API-based workflow when using apps that connect multiple health IT applications used by a healthcare organization. Administrative notifications are relied upon as triggers to prompt other elements of clinical workflow, and/or queries of patient clinical data.

ONC should also 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. In either case, we believe that these data elements should also be included in the USCDI v2.

Patient administration data elements trigger notification that enable care coordination to payors, providers, and ancillary systems. We believe with increased focus on APIs in inter and intra organizational workflow, there is added value to include these universally implemented, well defined elements in USCDI v2. For completeness, these have been submitted through the USCDI ONC New Data Element and Class (ONDEC) website: https://www.healthit.gov/isa/node/5931/submission-view , https://www.healthit.gov/isa/node/5936/submission-view, https://www.healthit.gov/isa/node/5941/submission-view and https://www.healthit.gov/isa/node/5946/submission-view.

ONC should also consider promoting the current Level 2 data element "Types of orders for medical care/services" for inclusion in USCDI v2. Orders and order notifications contain information useful for laboratory, procedures, medications, and imaging, alike. The submission from CMS to support "Types of orders for medical care/services" meets ONC Level 2 criteria; it addresses a gap, is widely used, and poses minimal burden to intra-organizational API workflow.

Care Team Member(s)

We strongly support the proposed addition of these new data elements for the USCDI v2 and, other than what is indicated below, the rationale in the "Additional Information" table. We believe that these data elements are consistent with the ONC prioritization criteria for moving Level 2 data elements to the USCDI v2.

- Provider Identifier
- Provider Name

    We note that the NPI (National Provider Identifier) is referenced as the applicable standard. While the NPI is adequate for covered health care providers, in our experience, we have found that many allied health practitioners, such as respiratory therapists, radiologic technologists, case managers, physical therapists and nurses do not have an NPI, and as a result, it is not used as an identifying key in healthcare IT systems. We suggest that the ONC include a note in this data element that where the NPI is available, it should be used, otherwise use of a local identifier is acceptable.

Problems

- Date of Diagnosis
- Date of Resolution

    We note that "Other Implementation Challenges" for "Date of Resolution" in the "Additional Information" table should address handling of chronic problems that may not be expected to have a resolution.

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

Patient Identifiers

Patient identifiers, even if not nationally standardized, are very important for a variety of intra and inter enterprise use cases, including patient matching and API workflows.

To that end, we suggest:

- 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

- We also believe that the current Level 1 data element in the Patient Demographics Data Class, "Medical Record Number" (MRN) | Interoperability Standards Advisory (ISA) (healthit.gov) should be promoted from Level 1 to Level 2 and included in the USCDI v2. This data element meets the criteria for Level 2, in our view, and is very important for certain types of app integration via APIs, 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

Observations are very important to communicate specific information such as actionable finding (critical results) in a well-specified and coded manner in scheduled and encounter-based imaging.

To that end, we suggest:

- Including the current Level 2 Observations data class in USCDI v2.
  We believe that such an addition is consistent with ONC's stated criteria for inclusion of Level 2 Data Classes and Data Elements in USDCDI v2.
- For the elements within Observations, include HL7 v2.5.1 ORU within Applicable standard(s)

We believe that this data element is consistent with the ONC prioritization criteria for moving Level 2 data elements to the USCDI v2. The use of Observations is universal, we note that the FHIR R4 Observation resource https://www.hl7.org/fhir/observation.html and HL7 v2.5.1 ORU includes proposed Level 2 Elements, imposing minimal new development burden.

We commend the ONC for its hard work and transparency in the development of the USCDI. If you have any further questions, please do not hesitate to contact Steve Nichols, Director of Interoperability, at steven.nichols@ge.com or (262) 352-9867.

Sincerely,

Steven J Nichols