



June 20, 2023

Micky Tripathi, PhD, MPP
National Coordinator
Office of the National Coordinator for Health Information Technology (ONC)
Department of Health and Human Services
Mary E. Switzer Building, Mailstop 7033A
330 C Independence Avenue SW
Washington, DC 20201

Submitted electronically to:
<https://www.regulations.gov>

Re: ONC's Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing Proposed Rule

Dear Dr. Tripathi:

Health Level Seven (HL7) International welcomes the opportunity to submit comments on ONC's *Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing* proposed rule (HTI-1).

HL7 recognizes and applauds ONC's effort to put innovative provisions forward in the proposed rule relating to issues such as:

- Further implementation of the *21st Century Cures Act*;
- Updating ONC's information blocking regulations;
- Data standards that help to ensure information can be understood when it enters and leaves a system;
- New and revised standards and certification criteria, including the United States Core Data for Interoperability Standard Version 3 (USCDI v3);
- Application programming interface provisions that further support the secure movement of information between health information technology (IT) systems;
- Electronic case reporting that supports public health and emergency response; and
- Evolving, cutting-edge health care data use such as in clinical decision support, health equity, Social Determinants of Health (SDOH), Sexual Orientation and Gender Identification (SOGI) and artificial intelligence (AI).

Our organization also appreciates the inclusion of HL7 standards and accompanying implementation guides (IGs) in the proposed HTI-1 framework. This proposed rule is a critical incremental step in our nation's interoperability journey. As HL7 is the global authority on health care interoperability and a linchpin and driver in the standards arena, we stand ready to aid ONC in finalizing policy and implementation efforts related to this rule.

HL7's feedback on the Proposed Rule is detailed below. In addition to our leadership and Policy Advisory Committee, HL7 Work Groups contributing to these comments include Clinical Decision Support, Clinical Quality Information, Devices, Gender Harmony Project, Orders and Observations and Patient Empowerment. The HL7 Gravity Accelerator also provided input.

Our comments are featured in this letter by major topic areas, with relevant proposed rule provisions noted. HL7 recommendations and key observations are in blue italics.

HL7 comment areas address:

- Overarching issues
- Clinical Decision Support, Clinical Quality Information, HL7 CDS Hooks and Decision Support Intervention
- Device issues
- Laboratory data interoperability
- Patient empowerment
- Recording sex, sexual orientation and gender identity
- Social Determinants of Health

Should you have any questions about our attached comments, please contact Charles Jaffe, MD, PhD, Chief Executive Officer of Health Level Seven International at cjaffe@HL7.org or 734-677-7777. We appreciate this on-going collaborative process.

Sincerely,



Charles Jaffe, MD, PhD
Chief Executive Officer
HL7 International



Andrew Truscott
Board of Directors, Chair
HL7 International

Health Level Seven International (HL7) Response and Input Comments on the HTI-1 Proposed Rule

Overarching Issues

Section III. ONC Certification Program Updates

HL7 FHIR United States Core Implementation Guide Version 5.0.1

Reference: <https://www.federalregister.gov/d/2023-07229/> (page 23813)

Proposed Rule Language for Reference: We propose to adopt the FHIR US Core IG v5.0.1 in §170.215(b)(1)(ii) and incorporate it by reference in §170.299. Additionally, because the FHIR US Core IG v3.1.1 is currently referenced (via cross-references to 170.215(a)(2)) in §170.315(g)(10)(i)(A) and (B), (ii)(A) and (iv)(A), we propose to revise each of those sections to instead cross-reference 170.215(b)(1). At the time of publication of this NPRM, the US Core IG v6.0.0 has not been finalized. Based on the annual US Core release cycle, we believe US Core IG v6.0.0 will be published before ONC issues a final rule. Therefore, it is our intent to consider adopting the updated US Core IG v6.0.0 that supports the data elements and data classes in USCDI v3 since we propose to adopt USCDI v3 in this rule.

Section III. ONC Certification Program Updates

C–CDA Companion Guide Updates

Reference: <https://www.federalregister.gov/d/2023-07229/> (page 23751)

Proposed Rule Language for Reference: In section III.C.2, we propose to adopt the HL7 CDA R2 Implementation Guide: C–CDA Templates for Clinical Notes STU Companion Guide, Release 3—US Realm (C–CDA Companion Guide R3) in § 170.205(a)(6). The C–CDA Companion Guide R3 provides supplemental guidance and additional technical clarification for specifying data in the C–CDA Release 2.1, including data specified in USCDI v2. However, it is our understanding that HL7 is working on updating the C–CDA Companion Guide for USCDI v3. If the updated C–CDA Companion Guide Release 4 (R4) is published before the date of publication of the final rule, it is our intention to consider adopting the updated Companion Guide that provides guidance and clarifications for specifying data in USCDI v3.

HL7 Comments: *First, HL7 strongly supports adopting the most recent version of the FHIR US Core and related IGs for purposes of this final rule, which is FHIR US Core IG v6.0.0. Appropriate cross-references should also be made. We note that FHIR US Core v6.1.0 is also now in the pipeline to be published. Secondly, HL7 also supports adoption of the HL7 CDA R2 Implementation Guide: C–CDA Templates for Clinical Notes STU Companion Guide, Release 3—US Realm (C–CDA Companion Guide R3) in § 170.205(a)(6) or the C–CDA Companion Guide Release 4 (R4) if it is published before the date of publication of the final rule.* Document driven exchange is happening across the health care ecosystem today and we are still striving towards robust, ubiquitous FHIR-based exchange so both ecosystems should be supported. Meeting end-users where they are is vital. While looking forward in our national policy we need to accommodate discrete data API capabilities, as well as the well established document exchanges. HL7 stands ready to support ONC in these continued endeavors.

Clinical Decision Support (CDS), Clinical Quality Information (CQI), HL7 CDS Hooks and Decision Support Intervention Issues

Section III. ONC Health IT Certification Program Updates

Request for Information (RFI): FHIR Standard, Clinical Decision Support Hooks Request for Information

Reference: <https://www.federalregister.gov/d/2023-07229/> (page 23855)

Proposed Rule Language for Reference: Given the growing use of CDS and potential for CDS to improve clinical decision-making, we request comment on the scope and maturity of the FHIR CDS Hooks specification v1.0, which we are considering for future inclusion as part of the Program. Recognizing that CDS Hooks does not prescribe a default or required set of hooks for implementers, we further request comment on specific hooks that we might include in future certification criteria (the CDS Hooks specification, for example, defines a small set of hooks), as well as input on use of CDS Hooks for supporting workflow improvement and reducing health care provider burden. To the extent commenters have specific CDS Hook use cases for supporting the latter, we welcome input on this including comment on the readiness and feasibility of such use cases including, as an example, for the screening and assessing of social risk and health related social needs or history.

HL7 Comments: With regard to the CDS Hooks RFI, the CDS Hooks STU2 specification is published and is the most relevant version (<https://cds-hooks.hl7.org/2.0/>). *HL7 recommends that, until a more recent normative specification is published, this be the version that is referenced in guidance. As newer versions become available, HL7 recommends that the ONC consider updating the version of the specification to reference.* HL7 and its Clinical Decision Support Work Group would be happy to provide feedback on what version of the specification may be most appropriate to reference at any given point in time.

A fully normative specification for CDS Hooks is currently planned for ballot in the next 6 months to a year, including a normative specification for CDS Hooks. When these fully normative specifications become available, HL7 recommends these versions be referenced in guidance.

We do note that for purposes of certification, the HL7 CDS Hooks specification is not fully describing the specific data requirements and use in context of particular workflows, e.g., Appropriate Use Criteria or Prior Authorization. Therefore, where ONC is considering referencing HL7 CDS Hooks as part of certification criteria --which aim to drive wide adoption of consistent interoperability capabilities using standards such as HL7 CDS Hooks -- ONC should focus on the specific implementation guides for the workflows of interest which include use of HL7 CDS Hooks and also fully describe how to use HL7 CDS Hooks in that context. This will further advance consistent use of HL7 CDS Hooks for use cases that are deemed critical enough to advance through certification.

There are a number of implementations and successful projects using CDS Hooks. Electronic health record (EHR) vendors that support the standard currently include, to our knowledge, Epic, Allscripts, and CorroHealth System. There are also additional EHR vendors actively working on supporting the standard, including Oracle, Cerner, NextGen, and eClinicalWorks. In addition, there are also a number of CDS vendors supporting this standard, as well as planned key functionality such as electronic prior authorization using this standard. We believe these uses all indicate sufficient maturity of the standard to be included in guidance.

Section III. ONC Health IT Certification Program Updates

New and Revised Standards and Certification Criteria: Decision Support Interventions and Predictive Models

Reference: <https://www.federalregister.gov/d/2023-07229/> (page 23774)

Proposed Rule Language for Reference: We believe that the continued evolution of decision support software, especially as it relates to AI- and ML-driven predictive DSIs, necessitates new requirements for the Program's CDS criterion. These include proposed requirements for new sets of information that are necessary to guide decision-making based on recommendations (outputs) from predictive DSIs, such as an expanded set of "source attributes" and information related to how intervention risk is managed by developers of certified HIT with HIT Modules that enable or interface with predictive DSIs.

HL7 Comments: *With regard to the proposed guidance to include various detailed metadata on predictive and evidence-based decision support interventions (DSIs), HL7 applauds ONC for prioritizing equity in health care, including through encouraging transparency on how DSIs could inadvertently exacerbate health and societal disparities. However, as proposed, these regulations create significant implementation burden with unclear benefits.* These regulations may also paradoxically increase disparities by reducing innovation and the implementation of DSIs due to increased regulatory burden.

HL7 therefore recommends the following:

Prior to mandating a national regulation in this area, HHS/ONC should fund and conduct rigorous studies to evaluate the impact of the proposed regulations when implemented, as well as the implementation burden imposed on stakeholders including HIT vendors and clinical practices. To our knowledge, there have been no rigorous studies evaluating whether the proposed approach leads to any actual improvement in care. Even just for providing a simple literature reference for a DSI, the only directly relevant randomized controlled trial we are aware of is the study conducted by Dr. Clem McDonald over 40 years ago (McDonald CJ et al. Physician Response to Computer Reminders. JAMA. 1980;244(14):1579-1581. doi:10.1001/jama.1980.03310140037026). This study directly evaluated the impact of computer-generated DSI reminders with and without the provision of bibliographic citations and did not find a statistically significant difference in clinician response to the reminders.

In order to reduce implementation burden, and to avoid a potentially massive duplication of effort across HIT vendors and clinical providers, HL7 recommends that the ONC or other suitable federal agency maintain the recommended metadata on behalf of the US public for any DSIs whose underlying information/knowledge are available in the public domain (e.g., the ASCVD predictive DSIs cited in the proposed regulations). For example, the ONC could maintain a website for DSI meta-data that HIT systems and implementers from health systems could easily link to, which are updated once on behalf of the entire community. This would also allow patients and clinical users who are not using EHR systems (e.g., Web-based calculators) to easily find relevant information about these DSIs. *If ONC or the federal government does not want to endorse particular DSIs, HL7 recommends that HHS/ONC fund a non-governmental organization to maintain this information. To avoid ambiguity on what is required and what is not, HL7 recommends that ONC begin by requiring linkage to this information only for those DSIs centrally supported by a government-sponsored resource or when using DSIs that have been classified and regulated as a medical device by the U.S. Food and Drug Administration (FDA).*

The proposed regulations would allow compliance by noting not the specified metadata, but that the metadata are not available. We believe this addition could cause unintended harm. Some providers have alert fatigue, and adding yet more irrelevant information (e.g., alerts that more often than not have links to

information that, when clicked, simply notes that ONC-required metadata are not available) is likely to contribute to further provider burnout, dissatisfaction, and alert fatigue. It is even possible, and potentially probable, that such an approach would lead to patient harm by increasing the likelihood that providers ignore relevant alerts, including alerts critical for ensuring patient safety, due to an increase in alert fatigue. *HL7 therefore recommends that, if the information is not available, that the proposed regulations allow providing no information or additional links, rather than a link noting that information is not available.*

Device Issues

Section III. ONC Health IT Certification Program Updates

USCDI and Electronic Case Reporting

Reference: <https://www.federalregister.gov/d/2023-07229/> (page 23769)

Proposed Rule Language for Reference: We propose to update the USCDI standard in § 170.213 by adding the newly released USCDI v3 and by establishing a January 1, 2025, expiration date for USCDI v1 (July 2020 Errata) for purposes of the Program. We propose to add USCDI v3 in § 170.213(b) and incorporate it by reference in § 170.299. Specifically, USCDI v3 in this proposed rule refers to the USCDI v3 (October 2022 Errata). We propose to codify the existing reference to USCDI v1 (July 2020 Errata) in § 170.213(a). We propose that as of January 1, 2025, any HIT Modules seeking certification for criteria referencing § 170.213 would need to be capable of exchanging the data classes and data elements that comprise USCDI v3.

HL7 Comments: *The scope of the proposed rule is unclear as it applies to ‘devices’ such as imaging devices and patient connected monitoring or therapeutic devices. The NPRM does refer to software as a medical device (SaMD), and it is clear that ‘devices’ do and will contain Decision Support Interventions (DSI). These devices typically use specialized standards for nomenclature such as Digital Imaging and Communication in Medicine (DICOM) and the International Organization for Standardization/Institute for Electrical and Electronic Engineers (ISO/IEEE) 11073 series, which are not incorporated in the USCDI. We are concerned that this NPRM can be interpreted as extending to these classes of devices creating an expectation that the USCDI -- especially Logical Observation Identifiers Names and Codes (LOINC) and the Systemized Nomenclature of Medicine (SNOMED) applies directly to them, when it is quite inadequate to capture the extensive vocabulary needed to capture measurements and controls for these devices. For example, the ISO/IEEE 11073-10101 nomenclature standard has over 50,000 terms. The vast majority have no equivalent in LOINC or SNOMED. Some 11073 terms have been mapped into LOINC but this required considerable effort. We recommend that HIT systems, via the USCDI, support the native nomenclature of medical devices rather than translating them to LOINC and/or SNOMED in order to avoid potential safety related issues.*

Section III. ONC Certification Program Updates

HL7 FHIR United States Core Implementation Guide Version 5.0.1

Reference: <https://www.federalregister.gov/d/2023-07229/> (page 23813)

Proposed Rule Language for Reference: We propose to adopt the FHIR US Core IG v5.0.1 in §170.215(b)(1)(ii) and incorporate it by reference in § 170.299. Additionally, because the FHIR US Core IG v3.1.1 is currently referenced (via cross-references to § 170.215(a)(2)) in §170.315(g)(10)(i)(A) and (B), (ii)(A) and (iv)(A), we propose to revise each of those sections to instead cross-reference § 170.215(b)(1). At the time of publication of this NPRM, the US Core IG v6.0.0 has not been finalized. Based on the annual US Core release cycle, we believe US Core IG v6.0.0 will be published before ONC issues a final rule.

Therefore, it is our intent to consider adopting the updated US Core IG v6.0.0 that supports the data elements and data classes in USCDI v3 since we propose to adopt USCDI v3 in this rule.

HL7 Comments: HL7 supports *ONC's intent to consider adopting the updated US Core IG v6.0.0 that supports the data elements and data classes in USCDI v3 since we propose to adopt USCDI v3 in this rule. HL7 observes that the scope of the proposed rule is unclear as it applies to 'devices' such as imaging devices and patient connected monitoring or therapeutic devices. The proposed rule does refer to SaMD and it is clear that 'devices' do and will contain DSI.* These devices typically use Integrating the Healthcare Enterprise (IHE) profiles based on HL7 gateways designed to bridge the 'device world' and the 'HIT world'. There are also HL7 FHIR based Implementation Guides (IGs) under development in HL7 for gateways communicating between devices systems and HIT systems. *HL7 observes however, that HL7 FHIR is not an appropriate solution for device communications in high acuity use cases, which require millisecond latencies and management of life-supporting medical devices. Similarly, devices that need to operate at extremely low power also require specialized standards to support their communication requirements for which HL7 FHIR is not well suited. The ISO/IEEE 11073 series of standards has been designed to meet these requirements. HL7 recommends that these standards should be mentioned in the final rule, in accordance with the intended scope and that any related USCDI updates be made. If this is out of scope for the content of the final rule, HL7 recommends that this should be specifically mentioned.*

Laboratory Data Interoperability Issues

Section III. ONC Health IT Certification Program Updates

Request for Information (RFI): Laboratory Data Interoperability

Reference: <https://www.federalregister.gov/d/2023-07229/> (page 23847-23848)

Proposed Rule Language for Reference: We seek public feedback that may be used to inform a study and report required by Division FF, Title II, Subtitle B, Ch. 2, Section 2213(b) of the Consolidated Appropriations Act, 2023 (Pub. L. 117–328, Dec. 29, 2022), or future rulemaking regarding the adoption of standards and certification criteria to advance laboratory data interoperability and exchange. ONC specifically seeks comments from the public on the following:

1. Which implementation guides or other standards should ONC adopt in certification criteria for HIT supporting transmittal and receipt of laboratory orders, laboratory results and directory of services?
2. The utility and maturity of existing HL7 v2 and Consolidated Clinical Document Architecture (C-CDA) standards supporting laboratory interoperability and the impact of moving to FHIR-based laboratory data exchange.
3. What barriers would additional HIT certification criteria for laboratory interoperability create for developers and other interested parties, and how might this affect adoption and use of such technology?
4. Would developers of laboratory information systems or in vitro diagnostics systems that have not traditionally submitted products for certification under the Program seek out and benefit from certification to criteria relevant to such developers' products?
5. Are there any other steps that ONC and HHS should consider taking to advance laboratory interoperability?

Question #1: Which implementation guides or other standards should ONC adopt in certification criteria for HIT supporting transmittal and receipt of laboratory orders, laboratory results and directory of services?

HL7 Comments: When considering implementation guides for certification it is not only a matter of maturity, but also adoption, effort, and incentives. We note that the ONC Certification Program, while positioned as a HIT certification program, is primarily focused and used by EHRs. HIT developers and providers using them are incented to adopt certain implementation guides. Eligible Providers and Eligible Hospitals were incented to adopt certified HIT. Consequently, HIT developers, most EHR developers and various laboratory (LIS) developers supporting Eligible Hospitals reporting to public health were incented to participate in ONC's certification program to adopt certain implementation guides. However, clinical, commercial, and public health laboratories were not similarly incented to adopt those same implementation guides. Note though that some do support LRI and Electronic Lab Reporting (ELR) guides. *As a result, there is clear adoption of the HL7 Clinical Document Architecture (CDA) C-CDA and Companion Guides for document based laboratory results sharing. In contrast, in play is the HL7 FHIR US Core based RESTful API access to laboratory results and HL7 v2 (Version 2) ELR for electronic laboratory reporting to public health agencies. However, adoption of the HL7 v2 LRI guide for electronic laboratory results reporting supporting formal results reporting under CLIA, has been limited.* The cost of adopting certified LRI capabilities by providers was not offset by the cost, even as capabilities were available, as the incremental benefits were minimum.

Reporting electronic laboratory results supporting CLIA requirements has been based on multiple versions of HL7 v2 messages well before ONC started its certification program. Some of these versions do not support complete specimen information needed by public health, cancer registries, and genomics. Without additional resources, most laboratories have been unable to voluntarily adopt additional IGs or standards. *HL7 importantly observes that other than for new interfaces, including the HL7 v2 Laboratory Orders Interface (LOI) and Laboratory Results Interface (LRI) (including the latest guidance for ELR reporting to Public Health) in ONC's Certification would not yield the advancements expected. The benefits of replacing existing interfaces in full do not outweigh the cost of such an upgrade, even though the guides provide a fully aligned set of implementation guides addressing CLIA requirements and establish consistent use of HL7 v2 for various complex interoperability use cases. For existing interfaces, HL7 recommends a more targeted approach, which the guides also support, introducing individual profiles that can be used with any existing HL7 v2 laboratory order or result message can advance data quality and consistency at a lower cost by focusing on use of the aligned value sets. Also, focusing on more consistent adoption of standard vocabularies (in particular LOINC, SNOMED and Unified Codes for Units of Measure) would likely have more benefit than promoting the adoption of up to date LOI/LRI versions when other HL7 v2 interfaces have been widely adopted.*

Question #2: The utility and maturity of existing HL7 v2 and C-CDA standards supporting laboratory interoperability and the impact of moving to HL7 FHIR-based laboratory data exchange.

Background explanation:

HL7 v2, CDA, and HL7 FHIR all support laboratory test ordering, resulting, and sharing to a greater or lesser extent with varying areas of focus and levels of maturity adoption. The following provides a brief overview of the current state of these standards in this context.

HL7 v2 continues to be the primary vehicle to support laboratory testing workflows using various versions and implementation guides. HL7 v2.3.1 through v2.5.1 are the predominant standards version used, while

more current versions are mostly used as a source to pre-adopt specific capabilities otherwise not available. This typically has occurred through the LOI and LRI guides that not only cover the full ordering and results workflow, but also specific profiles within them enabling inclusion of those profiles in any existing HL7 v2 standard use of order or result workflow, whether highly localized/customized or not. These standards versions are primarily used, while adoption of the full LOI and LRI implementation guides are limited. Various health information technologies (HIT) have adopted the LRI guide associated with ONC's 2014 Certification Edition with EHRs being certified by ONC to a particular version referenced in ONC 2014 Certification Program and some laboratories' LIS having validated its ability to support *Clinical Laboratory Improvement Amendments* (CLIA) requirements. HL7 v2 also includes a EHR functional specification that further defines the ordering provider's HIT responsibilities when receiving the official results report in response to their order, recognizing that others copied or forwarded on that report may not have the same requirements (i.e. secondary data reporting).

With the pandemic, guidance was expanded to not only cover general ordering and results reporting plus specific guidance for Ask at Order Entry questions (AOEs), Newborn Dried Blood Spot testing (NDBS), and genomic data, but also additional AOEs to pass critical demographics and Social Determinants of Health (SDOH) data through the laboratory, and include test device data (supporting both test kit/reagents and instrument and model information leading to multiple UDIs often being messaged). While the implementation guides support these data, actual adoption has been more challenging due to availability of the data and/or sufficient drivers to adopt.

HL7 v2 also includes an ELR implementation guide that is currently used for certification for reporting to Public Health. Its most current version is now expressed as a profile within the LRI implementation guide and is suitable for use. In fact, COVID related additional data requirements are currently fully incorporated in both LRI and its ELR profile within, as well as LOI. HL7 v2 includes a directory of service (eDOS) where a laboratory can share available tests for ordering with a provider. Some organizations support an earlier version, but widespread adoption, including using the latest version has not occurred at any scale. HL7 CDA, through the C-CDA Implementation Guide and Companion Guide permits sharing of laboratory order and result information, along with other health data, as part of the information in the document types currently required under ONC's Certification Program. However, implementation of CDA is mainly downstream from the origination of laboratory data in the LIS, occurring in the EHR, health information exchange (HIE) or other downstream or modules. CDA is utilized for document exchange but is not intended to manage workflow or other individual discrete data exchanges. There are no plans to expand the use of HL7 v3, CDA, and C-CDA in particular for additional laboratory messaging needs, especially given CDA, and C-CDA are not designed to support laboratory ordering processes.

HL7 FHIR is emerging as the new, broad based data sharing and exchange standard. Certified EHRs support HL7 FHIR based query access to some laboratory data, exposing a subset of the lab order and result data, particularly data required by USCDI. However, currently many LISs do not have such HL7 FHIR functionality. FHIR equivalent IGs are lacking for LRI and LOI to support the laboratory order and results reporting workflow between a provider and laboratory in a CLIA compliant manner. Additionally, efforts are in progress to publish an HL7 FHIR based directory of service, as well as an HL7 FHIR based Laboratory IVD Test code mapping (LIVD) IG where manufacturers of laboratory tests can provide guidance on the most suitable mapping of IVD test codes (organized by instrument and model) to LOINC codes for results. The guide is also being expanded to cover IVD test result values mapped to SNOMED

and or LOINC answer codes. We note that while catalog and mapping information needs to be available to all participants in the workflow, this does not mean that all EHRs and LISs need to ingest such data, thus having to support these use cases in full. The advancement of on-line directories, through web sites or Apps that can be accessed in context, can provide alternate means of enabling those configuring their systems to have the necessary guidance available at their fingertips. Lastly, there are HL7 FHIR based IGs for clinical genomics (recently developed) and electronic pathology and cancer reporting (under development) for results reporting, usability of data within genomics, anatomic pathology and related laboratory areas that historically used non discrete text blob-based reports such as pdf documents. Therefore, most uses of HL7 FHIR involving laboratory data involve exposing a subset of the lab order and result data, at least data required by USCDI although could be more depending on the system, that is made available through FHIR based APIs for query in some implementations. Other implementations may "transform" HL7 v2 laboratory message data into FHIR in a downstream system.

HL7 Comments: *In summary HL7 observes and recommends:*

- *HL7 v2 LOI and LRI are sufficiently mature to support the respective workflows and CLIA compliant implementations for order and result sharing.*
- *While HL7 v2 eDOS is available and provides guidance on AOE's and information on laboratory ordering, it is not widely implemented.*
- *HL7 CDA, C-CDA, and Companion Guide are sufficiently mature to support sharing information about orders and results without workflow management; and*
- *Although HL7 FHIR profiles are available for basic display and sharing of laboratory data, these profiles and implementation guides are generally insufficient for laboratory orders and reporting in a clinical context. HL7 FHIR elements, profiles, implementation guides, like US Core, and others needs further development and testing in order to be sufficiently mature.*

HL7 recommends as a general note, that as data requirements for Social Determinants of Health (SDOH) and Sexual Orientation and Gender Identification (SOGI) change -- SDOH data for public health reporting in particular and some SOGI data as well -- should be an increased area of focus for case reporting, thus reducing the load on the laboratory workflow having to share data not relevant to the performance of the laboratory. HL7 also importantly observes that:

- *All the above noted guides are subject to enhancements, which are currently in flight for SOGI data in particular.*
- *Regarding most reportable laboratory tests, a case report would be required as well thus aligning case reporting is reasonable.*
- *Some laboratory tests have no corresponding case report requirement, so a better understanding is required regarding how data flows can be made less cumbersome.*

Question #3: What barriers would additional HIT certification criteria for laboratory interoperability create for developers and other interested parties, and how might this affect adoption and use of such technology?

HL7 Comments: *As indicated in the prior question, HL7 emphasizes that key barriers include having aligned incentives for all stakeholders (in particular EHR developers, LIS developers, providers, laboratories, and public health) to adopt the same versions of the standards and implementation guides. Having the EHR developers and providers aligned on*

HL7 CDA C-CDA plus Companion Guide and HL7 FHIR US Core is sufficient for other HIT to consistently be able to receive and share general laboratory results data. HL7 recommends that:

- *Regarding workflow management focused the same incentive program, alignment should occur; while the respective HIT vendors should focus on adoption of key profiles in LOI and LRI to begin alignment.*
- *ONC's Certification Program should align with CLIA and laboratory regulatory requirements to minimize overhead to all stakeholders and enable adoption of those IGs and profiles for laboratory data. HL7 notes that LISs have long lifecycles during which interfaces rarely change as a whole.*
- *ONC should explore opportunities for new interfaces and providing laboratories funding to implement with a spotlight on adopting the newest versions, but ONC must recognize that this is a longer term challenge to balancing cost and benefit.*

HL7 emphasizes that the more critical barrier to focus upon is the accurate adoption and consistent use of appropriate vocabulary standards, particularly LOINC, Unified Codes for Units of Measure (UCUM), and SNOMED. HL7 recommends that fidelity of these mappings should be preserved in downstream systems when orders and results are shared to prevent loss of test meaning and computerizability. Having improved services directories with the correct encoding, HL7 recommends encouraging the use of IVD LIVED coding maps, as well as encoding the results correctly as close to the source is essential. Additionally, where relevant, HL7 recommends adding device/instrument data, and aligning public health laboratory reporting with case reporting as it may further optimize and increase data quality. For example, the more laboratories adopt LOINC encoding for their test orders and results (where available), the more these "trigger codes" are available downstream to help meet electronic case reporting (eCR) reporting requirements.

Question #4: Would developers of laboratory information systems or in vitro diagnostics systems that have not traditionally submitted products for certification under the Program seek out and benefit from certification to criteria relevant to such developers' products?

HL7 Comments: LIS developers have not been subject to ONC Certification Program style certification, while laboratories using their systems have been subject to CLIA requirements such as the laboratory obtaining a CLIA certificate. The CLIA program primarily focuses on laboratory quality requirements such as data content (presence of critical data in the report), but not how these are met. CLIA originally involved paper based processes, which some laboratories still utilize for their ordering and reporting. *HL7 observes however, as HIT was implemented, the requirements still must be met, but now IGs, profiles and other standards utilized in meeting them, must permit users to implement HIT in a CLIA compliant manner, no matter the version of HL7 (v2, FHIR, etc.) including IGs, profiles, etc. utilized. HL7 emphasizes from an interoperability perspective, alignment on a common version of a standard, including a specific implementation guide version, including use of common vocabularies and value sets, reduces friction when implementing those interoperability capabilities.*

Unlike the rollout of HL7 C-CDA and FHIR US Core where certification drove adoption, HL7 v2 messages have been in wide and varied use well before ONC started its certification program. Upgrading laboratories and their LISs, all EHR vendors, public health LIMS and information systems all at once will be a significant and challenging lift with incremental benefit. *Consequently, while there are clear benefits to having both EHRs and LIS certified to the same standards and implementation guide versions, HL7 emphasizes that without the necessary incentives for providers and laboratories to implement the upgrades, and considering the cost of adopting the latest standards and*

implementation guide versions, not many LIS developers seek out certification or laboratories voluntarily adopting these latest standard versions as seen during the Meaningful Use era.

HL7 recommends addressing the alignment of incentives and creating a progression of steps towards adoption of a common standard and implementation guide, focusing on key profiles defined in the LOI and LRI guides that can be pre-adopted into existing interfaces. This can substantially address these challenges and ease the adoption challenges of the most desired capabilities to foster interoperability. For LIS developers and laboratories as well as for EHR developers and providers, HL7 recommends a critically important focus on the accurate and consistent use of vocabulary and value sets, considering LOINC, UCUM and SNOMED in particular. HL7 also recommends attention be given to introducing new data requirements consistently across the board, e.g., Newborn Dried Blood Spot (NDBS), pandemic data, device information, and genomics data as it would yield substantial benefits at a more affordable cost.

As ONC's Certification Program is voluntary, adoption is primarily driven by other programs, such as the Center for Medicare and Medicaid Services' (CMS) payment programs. Currently, legislation such as the *Protecting Access to Medicare Act (PAMA)*, with its reduced reimbursement and cuts to laboratories, has negatively impacted funds available to laboratories, including for adoption and upgrades to HIT and standards. *To reverse these impacts, which have been on hold during the pandemic, HL7 recommends adding additional funding for laboratories.* This could incent laboratories to adopt most current HL7 v2 standards and implementation guides and incentives to additional laboratory data stakeholders to help spur HL7 FHIR US Core based application programming interfaces (APIs) for laboratory data access. *HL7 emphasizes that appropriate incentives must be in place for both providers and laboratories to subsequently drive demand for use of EHR and laboratory information system (LIS) certified products and to incent developers to participate in the relevant certification programs, without increasing vendor related costs to laboratories and providers.*

HL7 FHIR elements, profiles, implementation guides, like US Core, and others need further development and testing in order to be sufficiently mature. However, the US and global FHIR community is working in several projects towards refinement and adoption of FHIR for the exchange of laboratory orders and results. We encourage participation from the providers, vendors and government agencies in order to make FHIR a significant tool in this domain. This will enable faster and more seamless communication between providers and enable modernization of public health reporting.

Question #5: Are there any other steps that ONC and HHS should consider taking to advance laboratory interoperability?

HL7 Comments: *HL7 recommends that ONC work closely with the FDA and its Standardization of Lab Data to Enhance Patient-Centered Outcomes Research and Value-Based Care (SHIELD) initiative to advance the adoption and consistent use of critical vocabulary and focus on adoption of key functionality to advance the consistent exchange of NDBS, device, pandemic, AOE's, and genomic data using HL7 v2 messages for systems needing to share that.*

HL7 also recommends that further alignment and optimization of electronic lab reporting (ELR) and electronic case reporting (eCR) data flows should be considered to reduce impact on ELR reporting, where data that is not necessary for the performance of the lab tests needs to be communicated by the ordering provider to the lab solely for inclusion in the ELR transaction to public health.

HL7 recommends that ONC encourage participation from providers, vendors and government agencies in projects to advance the use of FHIR for laboratory orders and results. Lessons and benefits from these projects could help spur modernization more broadly across the health ecosystem.

To advance laboratory interoperability especially with public health reporting (e.g., ELR and cancer), HL7 recommends laboratory order messages contain adequate discretely encoded specimen information (e.g. ,collection procedure, specimen type, specimen source) at a minimum as needed for these laboratory and public health reporting needs. HL7 also recommends ONC find ways to ensure providers are using the existing capability in EHRs to record those elements.

Lastly, HL7 recommends ONC direct attention to more consistent adoption of standard vocabularies, better defining the use of SNOMED for specimen attributes as an additional profile in V2, CDA and FHIR IGs as that would greatly improve quality of this vital clinical context to the lab result.

Patient Empowerment Issues

Section III. ONC Health IT Certification Program Updates

Patient Request Restrictions Certification Criterion

Reference: <https://www.federalregister.gov/d/2023-07229/> (page 23819-23822)

Proposed Rule Language for Reference: Through our efforts to advance interoperability across a nationwide HIT infrastructure, ONC has specifically focused on how HIT can support efforts to reduce health care disparities and provide both insights and tools for the purposes of measuring and advancing health equity. This includes specific steps to expand the capabilities of HIT to capture and exchange data that is essential to supporting patient-centered clinical care that is targeted to supporting a patient’s unique needs. We propose to adopt a new certification criterion specifically in support of the HIPAA Privacy Rule’s “right to request a restriction” on certain uses and disclosures (See also 45 CFR 164.522(a)). We propose to add the new certification criterion “patient requested restrictions” in 170.315(d)(14) to enable a user to implement a process to restrict uses or disclosures of data in response to a patient request when such restriction is agreed to by the covered entity. We propose that a HIT Module certified to the criterion in 170.315(e)(1) must also enable an internet-based approach for patients to request a restriction of use or disclosure of their EHI for any data expressed in the USCDI standards in 170.213. Specifically, we propose to modify 170.315(e)(1) to add a paragraph (iii) stating patients (and their authorized representatives) must be able to use an internet-based method to request a restriction to be applied for any data expressed in the standards in 170.213. Such methods would be accessed via an API, patient portal, or other internet-based means. We believe a similar approach is appropriate for the additional functionality supporting a patient request.

HL7 Comments: *HL7 applauds the addition of new fields now required as part of certification with USCDI V3. We also want to encourage "control" or "consent" as an over-arching principal that is timed along with USCDI's expansion to more person-centered information and concepts. HL7 emphasizes the critical importance of ensuring that not only should the data be made available through APIs, but that data should also be made available when contributed by patients. Related to this, HL7 is concerned that the current provenance type in USCDI V3 is insufficient for representing a patient or a caregiver as author. We submitted comments relating to these issues during the USCDI V4 comment period and advocate for inclusion in USCDI V4 and beyond. On a related note, HL7 is committed to taking the internal actions to make the case for inclusion of the provision outlined above in the next version of HL7 FHIR US Core.*

To successfully support patient and caregiver provenance in future, HL7 recommends the following additional fields for future editions of USCDI, which the HL7 FHIR standard supports:

- *Author Role: to clarify the type of actor, such as patient, especially where information is contributed by individuals. Author should also accommodate device-generated data such as wearables.*
- *Updates: to understand whether data has changed either from the point of creation or in exchange.*

HL7 is concerned that USCDI V3 contains numerous sensitive health topics such as pregnancy status, sexual orientation, gender identity, disability, and mental function as well as others. HL7 observes that the inclusion of these fields is a fundamental step forward, but this action also highlights the technical need for formal consent to a relatively granular level. HL7 observes and cautions that some of the sensitive data discussed above are obvious (pregnancy flag) and others such as indications of pregnancy are found in less obvious data elements such as a Lab Test that also could reveal that someone is pregnant. Although “Clinical” data is highlighted here, it also has a direct impact on billing and claims creation. Information for adolescents is also a particularly sensitive area that involves both the patient and their guardian. HL7 recommends these issues be considered for relevant future versions of USCDI and that information from the following document be considered:

HL7 Patient Contributed Health Data White Paper offers information regarding information contributed by patients.
http://www.hl7.org/documentcenter/public/ballots/2022SEP/downloads/HL7_PCD_R1_I1_2022SEP.pdf

HL7 is concerned that Certified HIT would need to be updated to USCDI v3 by the end of 2024 using the US Core IG and C-CDA Companion Guide but that a patient’s ability to request privacy restrictions to that data won’t be required until 2026. HL7 recommends that these two requirements be aligned and harmonized such that the privacy controls are available at the same time or before the USCDI V3 changes, so as to provide the best outcomes from the intent of this rule.

HL7 observes that it is unclear if privacy restrictions on use and disclosure supports restrictions would be able to support information requested on patients (in cases where patients do not feel their portal is safe to show specific fields), proxies (which patients may want to restrict some access to), or others (providers, etc.) distinctly. All are valid. The privacy restrictions requirement discusses an Authorized User but does not define authorized user. HL7 recommends clarification for this term.

HL7 observes it is not clear if the ability for patients to request privacy restrictions using Internet-based method includes using a standards based approach – and in particular, HL7 FHIR. Having a standard FHIR-based method to specify restrictions would allow patients and caregivers using personal health records (PHRs) to request these restrictions. Numerous patient advocates have highlighted a “too many portals” challenge. HL7 recommends requiring an HL7 FHIR-based method. This would support patients using PHRs to manage their health care data received from multiple sources and all appropriate data flows.

HL7 applauds the code set updates advancing interoperability. The API Revisions and Related API Conditions Updates include the ability for a patient authorization revocation to occur within 1 hour of a request. HL7 believes this is a notable improvement to provide patient’s more control of the access, exchange, and use of their data. HL7 inquires if there will there be a way for patients to check regarding electronic case reports sent about them to a public health authority, for example via an HL7 FHIR API call or notification?

Notable health care services are delivered in the long-term and post-acute care (LTPAC) setting. HL7 observes that because there is no CEHRT requirement for LTPAC, interoperability with LTPAC and other providers and with patients is significantly lacking. A famous patient advocate, Casey Quinlan, at the end of her life in 2023, was transferred to LTPAC

and did not receive necessary pain medication due to missing information on medications. If standards-based interoperability existed between hospitals and LTPAC, this might not have happened.

Recording Sex, Sexual Orientation and Gender Identity Issues

Section III. ONC Health IT Certification Program Updates

Patient Demographics and Observations Certification Criterion in § 170.315(a)(5)

Reference: <https://www.federalregister.gov/d/2023-07229/> (page 23819)

Proposed Rule Language for Reference (Overarching): In the 2015 Edition Final Rule (80 FR 62601), ONC required the recording, capture, and access to a patient’s sex, sexual orientation, and gender identity for HIT Modules certified to the “Demographics” certification criterion (§ 170.315(a)(5)) (80 FR 62747). This rule also defined a required set of standardized terminology to represent each of these data elements (80 FR 62618–62620). Since then, ONC has received recommendations through the Health Information Technology Advisory Committee (HITAC) and public feedback that the current terms and terminologies used to represent sex, gender identity, and sexual orientation are limited and need to be updated.

Meanwhile, the health care industry had similarly taken note of the need for precision for ideas encompassed in terms such as “sex” and “gender” and launched the Gender Harmony Project to capture these concepts consistently within health care. The Gender Harmony Project introduced for the HIT context the concepts “Sex for Clinical Use” (SFCU), “Recorded Sex or Gender,” (RSG), “Name to Use,” and “Pronouns.” The Gender Harmony Project defines Sex for Clinical Use as a category that is based on clinical observations typically associated with the designation of male and female; Name to Use provides the name that should be used when addressing or referencing the patient; Recorded Sex or Gender is the documentation of a specific instance of sex and/or gender information; and Pronouns are determined by a patient and used when referring to the patient in speech, clinical notes and in written instructions to caregivers (*e.g.*, she/her/ hers or they/them.) Sex for Clinical Use, Name to Use, Recorded Sex or Gender, and Pronouns are new concepts currently not present in the certification criteria.

Vocabulary Standards

Reference: <https://www.federalregister.gov/d/2023-07229/> (page 23820)

Proposed Rule Language for Reference: We propose to revise the terminology standards specified for “Sex” in 170.315(a)(5)(i)(C). ONC has received significant feedback reflecting the need to be more inclusive in the terminology representing the data element. As such, ONC proposes to revise the fixed list of terms for “Sex” in § 170.315(a)(5)(i)(C), which are represented by HL7 Value Sets for AdministrativeGender and NullFlavor in § 170.207(n)(1). We propose to ultimately replace § 170.207(n)(1) with the SNOMED CT code set proposed in § 170.207(n)(2).

HL7 Comments: *HL7 supports ONC's intent to move value set definition out of regulatory text and instead delegate value set definition and maintenance to industry groups. We also support the "at a minimum" language, which makes it clear that values beyond those specified may be adopted by developers. However, HL7 observes that naming specific value sets indicates to developers the minimum expectations of what codes should be recorded and exchanged, while still allowing the adoption of codes beyond those included in the value sets. HL7 also importantly notes that changing the value set for Sex (birth sex) from AdministrativeGender and NullFlavor to SNOMED CT may introduce confusion, as changing the value set implicitly changes the meaning of Sex (birth sex) from administrative semantics (e.g., legal sex on birth certificate) to clinical finding semantics.*

Additionally, HL7 specifically recommends:

- ONC should reference the VSAC value set for **Sex** ([VSAC 2.16.840.1.113762.1.4.1099.53](https://vsac.nlm.nih.gov/sets/2.16.840.1.113762.1.4.1099.53)) rather than the unconstrained SNOMED CT code system.
- If ONC adopts the Sex for Clinical Use concept as proposed (see comments below), ONC should reference the HL7 value set for **Sex Parameters for Clinical Use** (<http://terminology.hl7.org/ValueSet/sex-parameter-for-clinical-use>) rather than the unconstrained LOINC code system.
- ONC should reference the US Core value set for **Sexual Orientation** (<http://hl7.org/fhir/us/core/ValueSet/us-core-sexual-orientation>) rather than the unconstrained SNOMED CT code system.
- ONC should reference the HL7 value set for **Gender Identity** (<http://terminology.hl7.org/ValueSet/gender-identity>) rather than the unconstrained SNOMED CT code system.
- ONC should reference the HL7 value set for **Pronouns** (<https://terminology.hl7.org/ValueSet/pronouns>) rather than the unconstrained LOINC code system.
- ONC should retain the proposed "at a minimum" language so that the industry can adopt codes beyond those specified in the named value sets.

Name to Use and Pronouns

Reference: <https://www.federalregister.gov/d/2023-07229/> (page 23820)

Proposed Rule Language for Reference: We propose to add new data elements Name to Use in § 170.315(a)(5)(i)(G) and Pronouns in § 170.315(a)(5)(i)(H), respectively, to advance the culturally competent care for lesbian, gay, bisexual, transgender, queer, intersex, asexual, and all sexual and gender minority (LGBTQIA+) people. Multiple values for a given patient may be valid over time. For the purposes of this proposal, we require at least one value for Pronouns and Name to Use be recorded. Additionally, in order to align with current industry practice and to provide flexibility to HIT developers, we propose that HIT be capable of recording Pronouns using the LOINC terminology code set standard specified in proposed § 170.207(o)(4).

HL7 Comments: *HL7 supports the inclusion of Name to Use and Pronouns in the patient demographic and observation criteria. HL7 recommends ONC adopt in Name to Use and Pronouns as proposed, the final rule.*

Sex for Clinical Use

Reference: <https://www.federalregister.gov/d/2023-07229/> (page 23820)

Proposed Rule Language for Reference: We also propose to add Sex for Clinical Use (SFCU) as a new data element in § 170.315(a)(5)(i)(F). SFCU is a category based upon clinical observations typically associated with the designation of male and female. It supports context specificity, is derived from observable information, and is preferably directly linked to the information this element summarizes.

HL7 Comments: The Gender Harmony Project (GHP) has renamed "Sex for Clinical Use" (SFCU) to "Sex Parameter for Clinical Use" (SPCU). The meaning, intent, and use of the data element are

unchanged. *In order to align with the Gender Harmony Project terms, HL7 recommends that ONC update all references to "Sex for Clinical Use" to be "Sex Parameter for Clinical Use".* The Gender Harmony Project has heard concerns within their community around the *end user entry* of a patient-level SFCU in the context of patient demographics. HL7 emphasizes that end-user entry of a patient-level SFCU is not the intention of the GHP project. Two approaches that GHP stakeholders do support are: 1) having systems *automatically* determine a patient-level SFCU by algorithmically reviewing clinical data such as organ inventory, obstetric and gynecology history, menarche status, etc. and 2) enabling end user capture of SFCU in a specific clinical contexts, such as ordering workflow.

Overall HL7 recommends:

- *ONC should NOT add SFCU (SPCU) as a patient-level demographic that individual users can capture, change and access.*
- *ONC should use the iterative USCDI update process to incorporate SFCU (SPCU) into the industry.*

If ONC does retain the SFCU (SPCU) concept, HL7 notes that the GHP's experience has been that SPCU is often misunderstood based on name of the concept alone, and including an in-line definition may mitigate initial confusion and misunderstanding of the concept. *HL7 offers this concise definition and recommends its inclusion in the final rule:*

A summary parameter that provides guidance on how a receiver should apply settings or reference ranges that are derived from observable information such as an organ inventory, recent hormone lab tests, genetic testing, menstrual status, obstetric history, etc.. The values of this parameter represent that available data indicates that diagnostics, analytics, and treatments should consider best practices associated with the respective reference populations.

Recorded Sex or Gender

Reference: <https://www.federalregister.gov/d/2023-07229/> (page 23820)

Proposed Rule Language for Reference: In addition to the other data elements proposed in this section, the HL7 GHP created an element named Recorded Sex or Gender (RSG). RSG documents a specific instance of sex and/or gender information. RSG is considered a complex data element that includes provision for a sex or gender value, as well as reference to the source document where the value was found, whereas Sex is a simple data element. RSG provides an opportunity for HIT developers to differentiate between sex or gender information that exists in a document or record, from Sex for Clinical Use (SFCU), which is designed to be used for clinical decision-making. Given the work undertaken by the Gender Harmony Project to develop an implementation guide that would work with all HL7 product families, we request comment on the following options we could pursue for a final rule.

Option 1 (proposed in regulation text): Require HIT developers to record Sex as proposed in 170.315(a)(5)(i)(C). This would enable Sex to be recorded in accordance with the SNOMED CT standard, specified in § 170.207(n)(2), as well as the standard specified in 170.207(n)(1) for the time period up to and including December 31, 2025. It would mean, however, that HIT developers would not be required to differentiate between sex and/or gender information when recording the information.

Option 2: Replace Sex with Recorded Sex or Gender in § 170.315(a)(5)(i)(C). Adopt the data element Recorded Sex or Gender as specified in the HL7 Gender Harmony Project. This would require HIT developers to capture the source documents while recording sex and/or gender information. Recorded Sex

or Gender would further provide an opportunity for health HIT developers to differentiate between sex or gender information that exists in a document or record, from Sex for Clinical Use (SFCU), which is designed to be used for clinical decision-making.

HL7 Comments: *HL7 recommends ONC should **refrain** from adopting any Recorded Sex or Gender data elements. Instead ONC should focus on adoption of Sex Parameter for Clinical Use (formerly "Sex for Clinical Use") via the iterative USCDI process, and social attributes (Name to Use, Pronouns, and Gender Identity) via this rule. HL7 emphasizes there does not yet appear to be a clear consensus around the Recorded Sex or Gender concept, even within the Gender Harmony Project group.* Additionally, significant changes are being made to the Recorded Sex and Gender concept as part of the ballot reconciliation process, and those changes have not yet been widely reviewed by the industry.

Social Determinants of Health (SDOH) Issues

Section III. ONC Health IT Certification Program Updates

USCDI Standard—Data Classes and Elements Added Since USCDI v1: Social Determinants of Health

Reference: <https://www.federalregister.gov/d/2023-07229/> (page 23764)

Proposed Rule Language for Reference: USCDI Standard—Data Classes and Elements Added Since USCDI v1 ONC proposes to update the USCDI standard in § 170.213 by proposing January 1, 2025 expiration date for USCDI v1 (July 2020 Errata) and by adding the newly released USCDI v3 (October 2022 Errata). ONC proposes to incorporate USCDI v3 by reference in § 170.299. USCDI v3 includes all data elements defined in USCDI v1 and USCDI v2, and includes additional data elements added in USCDI v3. Adopting USCDI v3 would provide more comprehensive health data for providers and patients accessing and exchanging electronic health information. USCDI v3 includes Sexual Orientation, Gender Identity, Functional Status, Disability Status, Mental/ Cognitive Status, and Social Determinants of Health data elements including: SDOH Assessment, SDOH Goals, SDOH Interventions, and SDOH Problems/Health Concerns. Access, exchange, and use of these data elements can support more informed care for patients.

HL7 Comments: *HL7 and the Gravity Project voices support for Section C.1.c.i, "USCDI Standard Data Classes and Elements Added since USCDI v1: Social Determinants of Health (SDOH)." As Gravity Project works to implement data standards to address the social determinants of health, we recognize the importance of USCDI as a regulatory driver to advance implementation toward the shared goal of health equity.*