These comments are submitted by Quest Diagnostics, Inc.

We support the comments submitted by the American Clinical Laboratory Association (ACLA) but have additional comments in response to the questions in the Standards Bulletin 2022-1.
In future, we suggest any request for additional feedback, especially re: data classes or data elements, be included more prominently in the draft USCDI version .pdf file, in addition to the Standards Bulletin, for better visibility of the request.

Public Feedback Process (From draft USCDI V3, page 3)
3. Are there significant barriers to development, implementation or use for any of these data elements that warrant removing them from Draft USCDI V3?

QD Comment:
We suggest that any proposed additions, in particular Sex for Clinical Use, Personal Pronouns, and modifications to Sexual Orientation and Gender Identity should be subject to another interim comment period (30 days?) vs. adding them to the USCDI V3. Some of these data elements must be further specified in the context of use, especially Sex for Clinical Use which could be highly impactful to the laboratory industry and the precision of patients' results, but must be exchanged in a specified context, e.g., related to a specific laboratory test, procedure, etc.

ONC REQUESTS ADDITIONAL FEEDBACK ON THE FOLLOWING DATA ELEMENTS (from the Standards Bulleting 2022-1 pdf

Sex (Assigned at Birth)

The Certification Program has long required certified health IT to be able to capture Sex Assigned at Birth (2015 Edition certification criteria that reference USCDI v1 (formerly CCDS) and the 2015 Edition Demographics certification criterion (45 CFR 170.315(a)(5))) using a defined set of standardized terminology. However, in participating in and monitoring industry activities, we have observed that changes to the concept may be in order. The Health Level 7® (HL7®) Gender Harmony project (Gender Harmony) has been working to clarify the purpose and use of Sex Assigned at Birth, including distinguishing it from other sex and gender related concepts, such as "gender identity" and "sex for clinical use." Gender Harmony developed the new term "Recorded Sex or Gender" to represent any recording of "sex or gender" in health records or other documents. They recognized that "Sex assigned at birth" is one example of a "Recorded Sex or Gender," and that it preserves the historic value of sex assigned at birth as recorded in health records. ONC recently highlighted this issue on the Health IT Buzz Blog. During this public feedback period, ONC seeks input on the USCDI concept of Sex Assigned at Birth, its associated vocabulary standards (value set), and specifically whether the term itself and its value set should align with Gender Harmony's definition for Recorded Sex or Gender.

QD Comment:
Under ONC's original 2015 Certification for Common Clinical Data Set (CCDS), the data element was titled 'Sex' and the associated standard was for "Birth Sex".

In ONC's Interoperability Standards Advisory (ISA) the data element is "Patient Sex (At Birth) associated with LOINC® code: 76689-9 Sex assigned at birth, defined as "The sex that was assigned and recorded on the birth certificate at the time of an individual's birth."

Laboratories need the genetic gender for the patient since some laboratory test results differ based on the patient's genetic gender. Since patients can modify the gender marker on their birth certificate, and implementers may not realize the subtleties of the LOINC code definition, this data element is suspect for patient matching, clinical processes, etc. We suggest it should be phased out or become another type of "Recorded Sex or Gender", proposed by the Gender Harmony Project, since "Recorded Sex or Gender" provides the necessary contextual information.

Gender Identity

Gender Identity and Sexual Orientation have been a required part of the Demographics certification criterion (45 CFR 170.315(a)(5)) since its adoption in 2015, but are not currently required to be exchanged via HL7® FHIR® or C-CDA as part of certification criteria that reference USCDI v1. While Gender Identity and Sexual Orientation data elements were included in USCDI

v2, USCDI v2 is not yet an option for meeting Certification Program requirements under SVAP. The SVAP comment period has been extended until May 2, 2022. If USCDI v2 is included in SVAP for certification in 2022, certified health IT would be able to voluntarily update to USCDI v2 and be capable of making Gender Identity and Sexual Orientation data elements available for access and exchange consistent with established value sets.
Gender Harmony proposed a value set to represent Gender Identity that differs from the value set adopted by ONC for the Demographics certification criterion and USCDI v2. For example, Gender Harmony does not include terms for transgender male and transgender female. ONC requests feedback on the most appropriate value set to represent Gender Identity for USCDI v3.

QD Comment:
We recommend that ONC retain the original terminology defined for the 2015 Edition Certification which EHR systems (and others) have already adopted. This terminology matches ONC's Interoperability Standards Advisory (ISA) and the USCDI V2 as mentioned above. According to the Gender Harmony Project, value sets can be extended for local jurisdiction; this was affirmed in the January 2022 FHIR US Core ballot which aligned to the USCDI V2: [FHIR-35677] Gender Identity Value set - Jira (hl7.org)

From a clinical perspective, reference ranges may be different for MTF vs. FTM. If there is only a "transgender" designation (e.g., 'M', 'F') it would be very difficult to do any reference range studies. This is tempered by the fact that even if a lab does receive the FTM or MTF designation, reference range studies will be difficult without knowing the hormone regimen of the patient.

Although you don't mention HL7 Version 2 (V2), for your awareness, several state public health agencies (PHA) are already requiring laboratories to report Gender Identity, even though SOGI data doesn't directly impact the patient's laboratory results. The HL7® Version 2.5.1: Implementation Guide: Electronic Laboratory Reporting to Public Health (US Realm), Release 1, required under Meaning Use Stage 1 is used for this reporting, in conjunction with guidance from HL7's Orders & Observations (OO) and V2 Management Group. The HL7 Lab Work Group, with input from the national PHAs, has recently agreed to use USCDI V2 as the standard terminology for reporting GI, so disrupting this terminology during deployment is clearly not conducive to interoperability.

For background see:

- 2022-04-08 LAB - Orders & Observations - Confluence (hl7.org)
- https://confluence.hl7.org/display/V2MG/V2+Management+Group+Proposal+for+a+Short-Term+Solution+for+Sharing+SOGI+Data?focusedCommentId=94654919&refresh=1649354866612#comment-94654919
- HL7 V2 Management group voted to point to USCDI for vocabulary 2022-04-08 v2MG call

Patient Address (data element in Patient Demographics)
Throughout 2021, ONC worked with a broad community to improve the quality and standardization of patient address. One output of this collaborative work was the publication of the new Unified Specification for Address in Health Care (Project US@). Now that this first version has been released, ONC believes this specification can serve as the standard for patient address in health care settings. ONC seeks feedback on whether this specification should be the required standard for Current and Previous Address in USCDI v3 or a future USCDI version.

QD Comment:
The team reconciling comments on the Project@US ballot rejected a number of Quest Diagnostics' comments as "out of scope" stating that "No ONC certification or other regulatory requirement exists at this time.". However, if ONC declares the Project@US standard applicable to the Patient Address USCDI data element, ONC effectively declares a new regulatory, and perhaps certification, requirement. Therefore, the rejected comments need to be considered and are summarized below with a recommendation.

Additionally, a 65 page technical specification and 112 page companion guide seems excessive for a single data element. We suggest that ONC declare the companion guide as "informative best practice" so developers can focus initially on the technical specification. Additionally, it helps if data is not duplicated in both documents. Perhaps the companion guide could reference the "source of truth" text in the technical specification?

Comment #55 - STANDARDIZED PATIENT ADDRESSES
You are proposing solutions that may not be needed in all systems. Some systems already have patient matching software and/or interface processes that minimize patient match issues and have field tested between established trading partners. There must be a process for established organizations/systems to request exemption from adhering to the proposed patient matching rules if there are limited patient matching issues.

Disposition: Reject

Out of scope. No ONC certification or other regulatory requirement exists at this time.

Recommendation:
We suggest that ONC "grandfather" or exempt existing patient matching protocols already implemented between established trading partners. It would be a huge burden to "rip and replace" existing interoperable systems.

Comment #56 - STANDARDIZED PATIENT ADDRESSES
Applying the proposed matching rules with existing patient records will not work effectively unless the existing patient records have the same rules applied. However, the receiving system cannot surreptitiously alter the patient address data for historical/audit (and maybe CLIA) purposes. Many fields recommended may not be supported by sending or receiving system therefore the anticipated matching likely will not be successful.

Disposition: Reject
Out of scope. Project US@ does not prescribe how data should be stored and used or obligate systems to change any existing data.

Recommendation:
We suggest that ONC indicate historical address data is not subject to the new ProjectUS@ address standard.

Comment #58 –Content and Exchange
If an order for lab test is received inbound to the lab from an EHR vendor which does not meet this patient address standard, the lab cannot alter the data in the result outbound to the provider. This also calls into question who is the owner/source of truth for the data and who will govern compliance. It is not the lab's responsibility to correct erroneous data received from the provider.

Disposition: Reject
Out of scope.

Recommendation:
We suggest that ONC indicate receivers are not expected to alter non-conformant address data.

Comment #60 Content and Exchange
Laboratories are already regulated by the Clinical Laboratory Improvements Amendments of 1988 (CLIA) [https://ecfr.federalregister.gov/current/title-42/chapter-IV/subchapter-G/part-493/subpart-K/subject-group-ECFR9482366886d579f/section-493.1291]. CLIA regulation (c)(1) requires laboratories to use patient name and/or patient identification for identification, therefore laboratories should not be required to alter their well-established CLIA conformance processes. (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. Additionally, CLIA regulates test request (orders) requirements for patients. § 493.1241 Standard: Test request. [https://ecfr.federalregister.gov/current/title-42/chapter-IV/subchapter-G/part-493/subpart-K/subject-group-ECFR5f8f0b6639946fd/section-493.1241]. CLIA does not require the ordering provider to include patient address in the test request.

Disposition: Reject
Out of scope. No ONC certification or other regulatory requirement exists at this time.

Recommendation:
We suggest that ONC exempt laboratories which are already regulated by CLIA and must adhere to CLIA requirements.

Comment #62 Content and Exchange; #72 PATIENT ADDRESS METADATA SCHEMA; and #75 APPENDIX B. STREET SUFFIX ABBREVIATIONS
Please add text clarifying that any federally required standard/specification format requirements supersede this suggestion.
For example the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) [http://www.hl7.org/implement/standards/product_brief.cfm?product_id=98] is federally required. [https://www.federalregister.gov/documents/2015/10/16/2015-25597/2015-edition-health-information-technology-health-it-certification-criteria-2015-edition-base]
Requiring systems that have expended tremendous effort and funds to implement federally required interfaces to now rip and replace with new process that will require additional development, testing and roll out is not fiscally responsible and/or feasible. Laboratories typically do not see the patient, only the specimen and therefore are dependent on the data provided by the provider requesting the test.

Disposition: Reject
Out of scope. No ONC certification or other regulatory requirement exists at this time.

Recommendation:

Please add text clarifying that any federally required standard/specification format requirements supersede USCDI address requirements.

Comment #65 – All Sections

Please add text clarifying that any federally required specification format supersedes this suggestion, such as the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm), February 2010 (Meaningful Use Stage 1) and HL7 VERSION 2.5.1 IMPLEMENTATION GUIDE: S&I FRAMEWORK LAB RESULTS INTERFACE, RELEASE 1 – US REALM, DSTU, July 2012 (Meaningful Use Stage 2)

For example the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) [http://www.hl7.org/implement/standards/product_brief.cfm?product_id=98] is federally required. [https://www.federalregister.gov/documents/2015/10/16/2015-25597/2015-edition-health-information-technology-health-it-certification-criteria-2015-edition-base]

Requiring systems that have expended tremendous effort and funds to implement federally required interfaces to now rip and replace with new process that will require additional development, testing and roll out is not fiscally responsible and/or feasible. Laboratories typically do not see the patient, only the specimen and therefore are dependent on the data provided by the provider requesting the test.

Disposition: Reject

Out of scope. No ONC certification or other regulatory requirement exists at this time.

Recommendation:

Please add text clarifying that any existing federally required standard/specification format requirements supersede USCDI address requirements.

Comment #68 STANDARDIZED PATIENT BUSINESS ADDRESSES

The patient's business address is typically not received by the laboratory with a "patient record" and therefore can't be used to match patients. Please clarify, this entire section is optional.

Disposition: Reject

Some patients use business addresses for one or more of their addresses for a number of reasons. For example, patients may be housed in a homeless shelter or domestic violence shelter, they may reside in a correctional facility, dormitory, long term care facility, or work camp, or they may live in a remote area where it is common practice to receive mail at a nearby business. Regardless of the reason, our goal is to standardize all patient addresses as much as possible and whenever feasible.

Recommendation:

Please clarify that those receivers are not expected to standardize data they do not receive, and that Business Address is optional. In our experience, most patient's do not want their health information sent to their place of employment.

Comment #70 Remove Certain Words

The context of usage of these words must be considered, e.g., some addresses contain the words you are suggesting to remove. Please change SHOULD to MAY as this should be negotiated with trading partners. As example: ATTENTION HOMES, Pine Street, Boulder, CO

Disposition: Reject

No disposition Comments provided

Recommendation:

Since a valid address could be altered by removing "certain words" as shown in the example above where "Attention" is a component of a valid address, we suggest you change this to an optional requirement (change "should" to "may").

Comment #93 APPENDIX D. TWO–LETTER STATE AND POSSESSION ABBREVIATIONS

Please revise this statement to: Trading partners SHOULD use the abbreviations below when capturing or transforming patient address.

> **Current wording:** Use the abbreviations below when capturing or transforming patient addresses.
> **Proposed wording:** Trading partners SHOULD use the abbreviations below when capturing or transforming patient address.

Disposition: Reject

MUST stated earlier in Technical Specification.

Recommendation:
We suggest you add text clarifying that any federally required standard/specification format requirements supersede this requirement. For example the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm), February 2010 (Meaningful Use Stage 1) and HL7 VERSION 2.5.1 IMPLEMENTATION GUIDE: S&I FRAMEWORK LAB RESULTS INTERFACE, RELEASE 1 – US REALM, DSTU, July 2012 (Meaningful Use Stage 2) 'coincidentally' use USPS Alpha State Codes, but the address field component for State is a ST (string) data type, not a coded element.