June 20, 2023

Micky Tripathi, Ph.D., M.P.P., National Coordinator for Health IT
Steven Posnack, M.S., M.H.S., Deputy National Coordinator for Health IT
Office of the National Coordinator for Health Information Technology
Office of the Secretary, United States Department of Health and Human Services

Re: RIN: 0955-AA03, Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing

Submitted electronically to:
https://www.federalregister.gov/documents/2023/04/18/2023-07229/health-data-technology-and-interoperability-certification-program-updates-algorithm-transparency-and#open-comment

Dear Dr. Tripathi and Mr. Posnack,

The Fenway Institute at Fenway Health, the Whitman Walker Institute, and a coalition of 19 partner organizations working in health care, LGBTQIA+ equality, sexual and gender minority (SGM) health, and HIV prevention and care submit the following comment regarding ONC's proposed rule posted April 18, 2023, RIN: 0955-AA03, Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing. This proposed rule would update the Electronic Health Record Reporting Program provision of the 21st Century Cures Act by establishing new requirements for the ONC Health IT Certification Program, and establish a new baseline for the US Core Data for Interoperability (USCDI).

The Fenway Institute is the research, education and training, and policy arm of Fenway Health, a federally qualified health center and Ryan White Part C HIV clinic in Boston, Massachusetts. We provide care to about 35,000 patients every year. Half of our patients are LGBTQIA+, and about 5400 are transgender and nonbinary. About 2,300 of our patients are people living with HIV. Whitman-Walker Institute is the research, policy, and education arm of Whitman-Walker, a community health system in Washington, DC. The Institute is affiliated with Whitman-Walker Health, a Federally Qualified Health Center with more than 50 years of service to diverse communities across the DC area, particularly people

living with HIV and LGBTQ+ people, including approximately 3000 transgender patients.

In our comment we present content from the proposed rule in italics, and then provide comment on that section of the proposed rule:

I. *We propose to adopt USCDI v3. If finalized, the adoption of USCDI v3 would update the USCDI standard to include data elements such as sexual orientation and social determinants of health.*

We support adopting USCDI v3 as the new baseline for certification. We agree that this change will support the concept of "health equity by design" and help capture more accurate and complete patient characteristics that are reflective of patient diversity and could potentially help data users address disparities in health outcomes for all patients, including those who may be marginalized and underrepresented.

II. *We also propose to change the heading of § 170.207(o) from "sexual orientation and gender identity" to "sexual orientation and gender information" to acknowledge that § 170.207(o) may include standard code sets to support other gender related data items.*

We understand the rationale for this change. Given the unprecedented legislative and cultural attacks on transgender and gender diverse people occurring across the country at the moment, it is important that ONC reiterates the importance of collecting and using gender identity information, as well as Name to Use and Pronouns, to improve quality of patient care. We appreciate that ONC does this elsewhere in this comment and in other documents.

III. *We propose to replace the specific codes sets referenced in § 170.315(a)(5)(i)(D) and (E), Sexual Orientation and Gender Identity, respectively, with the Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT ®) code set, as referenced in the standard proposed in § 170.207(o)(3).*

Some of the existing SNOMED CT codes for SOGI are out of date and clinical. They are not affirming of gay and lesbian people, of transgender people, or of intersex people. Many transgender people consider several terms in SNOMED to be offensive.[1] There is a risk that a clinical staff person will use these terms with a patient. We agree with the proposal to remove the explicit codification of the existing SNOMED CT codes in the rule and to refer instead generically to the most recent version of SNOMED CT. In the interim as the SNOMED CT codes continue to evolve, we recommend that ONC create guidance for vendors and healthcare organizations to encourage them to not use or display terms such as "homosexual," "transsexual," or "hermaphrodite"[2] but instead to display them as "gay or lesbian," "transgender," or "intersex." We also urge ONC to leverage its power as the Health IT agency of the U.S. government and work with SNOMED to modernize its language regarding LGBTQIA+ patients expeditiously. The Fenway Institute and Whitman Walker Institute are also available to be a resource in the process of developing modernized next-generation SOGI standards with SNOMED, ONC, and other standards-setting bodies.

(1) Standard. Birth sex must be coded in accordance with HL7 Version 3 Standard, Value Sets for AdministrativeGender and NullFlavor (incorporated by reference, see § 170.299), up until the adoption of this standard expires January 1, 2026, attributed as follows:
(i) Male. M; (ii) Female. F; (iii) Unknown. nullFlavor UNK.

(2) Standard. Sex must be coded in accordance with, at a minimum, the version of SNOMED CT ® codes specified in § 170.207(a)(1).

(3) Standard. Sex for Clinical Use must be coded in accordance with, at a minimum, the version of LOINC ® codes specified in § 170.207(c)(1).

(o) Sexual orientation and gender information--(1) Standard. Sexual orientation must be coded in accordance with, at a minimum, the version of SNOMED CT® codes specified in paragraph (a)(4) of this section for paragraphs (o)(1)(i) through (iii) of this section and HL7 Version 3 Standard, Value Sets for AdministrativeGender and NullFlavor (incorporated by reference, see § 170.299),

[1] Ram A, Kronk CA, Eleazer JR, Goulet JL, Brandt CA, Wang KH. Transphobia, encoded: an examination of trans-specific terminology in SNOMED CT and ICD-10-CM. *J Am Med Inform Assoc*. 2022 Jan 12;29(2):404-410. doi: 10.1093/jamia/ocab200. PMID: 34569604; PMCID: PMC8757305.
[2] https://bioportal.bioontology.org/ontologies/SNOMEDCT?p=classes&conceptid=18978002

up until the adoption of this standard expires on January 1, 2026, for paragraphs (o)(1)(iv) through (vi) of this section, attributed as follows:

(i) Lesbian, gay or homosexual. 38628009
(ii) Straight or heterosexual. 20430005
(iii) Bisexual. 42035005
(iv) Something else, please describe. nullFlavor OTH
(v) Don't know. nullFlavor UNK
(vi) Choose not to disclose. nullFlavor ASKU

(2) Standard. Gender identity must be coded in accordance with, at a minimum, the version of SNOMED CT® codes specified in paragraph (a)(4) of this section for paragraphs (o)(2)(i) through (v) of this section and HL7 Version 3 Standard, Value Sets for AdministrativeGender and NullFlavor (incorporated by reference in § 170.299), up until the adoption of this standard expires January 1, 2026, for paragraphs (o)(2)(vi) and (vii) of this section, attributed as follows:

(i) Male. 446151000124109
(ii) Female. 446141000124107
(iii) Female-to-Male (FTM)/Transgender Male/Trans Man. 407377005
(iv) Male-to-Female (MTF)/Transgender Female/Trans Woman. 407376001
(v) Genderqueer, neither exclusively male nor female. 446131000124102
(vi) Additional gender category or other, please specify. nullFlavor OTH
(vii) Choose not to disclose. nullFlavor ASKU
(3) Standard. Sexual Orientation and Gender Identity must be coded in accordance with, at a minimum, the version of SNOMED CT® codes specified in § 170.207(a)(1).
(4) Standard. Pronouns must be coded in accordance with, at a minimum, the version of LOINC codes specified in 170.207(c)(1).

We recommend against displaying the terms "Female-to-Male (FTM)" and "Male-to-Female (MTF)." Fenway Health stopped displaying these options in our EHR's gender identity response options, and we encourage other organizations to do the same in our training and technical assistance on how to collect and use SOGI data. The percentage of transgender people using these identities appears to have declined, although some transgender patients still identify as FTM or MTF. These terms suggest a directionality instead of acknowledging the individual's gender.

We think that the optimal approach is to display the terms “transgender man” and “transgender woman.”

ONC should encourage health care organizations to offer the term “nonbinary” as a gender identity field, before or after “genderqueer.” At Fenway Health and with the 1400 FQHCs that we train to collect SOGI data through our National LGBTQIA+ Health Education Center, we encourage health centers to include this response option to the current gender identity question:

- Nonbinary, genderqueer, or not exclusively female or male

The “nonbinary” field could reference SNOMED CT code 772004004, “Non-binary gender” finding.[3] Apparently SNOMED recognizes “non-binary” with a hyphen, but not “nonbinary” without a hyphen.[4] The former is more common in the UK, while the latter is more common in the US. SNOMED should recognize nonbinary without a hyphen.

Of Fenway Health’s roughly 5400 transgender and gender diverse patients, about 1800—or one-third—identify as nonbinary. Many thousands of patients in FQHCs across the U.S. also identify as nonbinary. In the 2015 US Transgender Survey, 31% of the 27,715 transgender and gender diverse people surveyed said that they identified as nonbinary.[5] “Nonbinary” is a very common identity among gender diverse people in the U.S.

We encourage ONC to make clear that health care providers serving Indigenous patients, whether in urban areas or near American Indian/Alaska Native reservations, should consider making Two-Spirit a response option for Indigenous patients in response to both sexual orientation and gender identity questions, as per the recommendation in the recent National Academy of Sciences, Medicine and Engineering (NASEM) report.[6] For the sexual orientation question this Two-Spirit response option could correspond to SNOMED CT code nullFlavor OTH. For gender identity it could correspond to code nullFlavor OTH. It would be even better if SNOMED were to add Two-Spirit as response options for SOGI questions for individuals who identify as Native American or Alaska Native.

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[3] https://browser.ihtsdotools.org/?perspective=full&conceptId1=772004004&edition=MAIN/SNOMEDCT-US/2023-03-01&release=&languages=en

[4] Ram et al., 2021.

[5] James, S. E., Herman, J. L., Rankin, S., Keisling, M., Mottet, L., & Anafi, M. (2016). *The Report of the 2015 U.S. Transgender Survey*. Washington, DC: National Center for Transgender Equality. Page 44.

[6] National Academies of Sciences, Engineering, and Medicine. 2022. *Measuring Sex, Gender Identity, and Sexual Orientation*. Washington, DC: The National Academies Press. https://doi.org/10.17226/26424.

ONC should uses its leverage as the Health IT agency of the U.S. government to encourage SNOMED to make these suggested changes.

IV. *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 health IT developers, we propose that health IT be capable of recording Pronouns using the LOINC® terminology code set standard specified in proposed § 170.207(o)(4).*

We support the addition of these new data elements, and agree that collecting and using Name to Use and Pronouns is essential to providing affirming care to transgender and nonbinary patients, as well as other patients who may not use their legal or given name.

V. *[W]e have recharacterized the USCDI data element Sex (Assigned at Birth) to Sex. We note that this is presently a change in the name of the element and will have no immediate impact on health IT developers of certified health IT, which will continue to exchange the value of patient's sex they have been historically exchanging using USCDI. However, we anticipate this change to support future enhancements to improve precision in the meaning through work done by health IT developers of certified health IT.*

USCDI v3 does not require the use of certain specific codes for representing Sex. As discussed previously, we propose to remove the requirement in § 170.315(a)(5)(i)(C) and § 170.315(b)(1)(iii)(G)(3) to code Sex according to the adopted value sets of HL7 Version 3 Value Sets for AdministrativeGender and NullFlavor as referenced in the value sets in §

170.207(n)(1). We propose instead to permit coding according to either the adopted value sets of HL7 Version 3 Value Sets for AdministrativeGender and NullFlavor as referenced in the value sets in § 170.207(n)(1) until December 31, 2025, or in accordance with the standard in proposed § 170.207(n)(2).

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 health IT 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 health IT 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 health IT developers to capture the source documents while recording sex and/or gender information. Recorded Sex or Gender would further provide an opportunity for health IT 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.

In preparing comments, we encourage commenters to fully review our proposed certification criterion in § 170.315(a)(5) and USCDI v3. Notably, if we were to adopt RSoG in a final rule as an alternative to Sex for the proposed certification criterion in § 170.315(a)(5), then health IT developers would be required to ensure that they perform the necessary transformations to meet the requirements associated with USCDI v3 and associated certification criteria. We highly encourage commenters to express their perspectives and explicitly note their preferred option in comments.

We believe that assigned sex at birth is medically and clinically relevant data that should be collected and used in Electronic Health Records, along with SOGI data and anatomical inventory data, to inform clinical decision support, preventive screenings, and population health management. Both of the options described above (§ 170.207(n)(1) and § 170.207(n)(2)) allow for the collection and use of sex assigned at birth information. Option 2 would allow the use of sex on birth certificates as well as other identity documents. Of the two options proposed, we support Option 2. If ONC ends up choosing Option 1, we would prefer that you continued to call this Sex Assigned at Birth, and not just Sex. Sex Assigned at Birth has become a term widely used in the field.

VI. *Finally, we have taken note of the substantial effort in this area to develop a clinically meaningful way for identifying a patient's sex from observable information (e.g., Clinical Observation, Radiology report, Laboratory report, genetic testing data) that may be suitable for clinical care, including the development of a new data element Sex for Clinical Use, which we may consider including in future standards adoption. We welcome public comment on this concept and approach. In addition, as noted in our proposals to the Patient Demographics and Observations certification criterion in § 170.315(a)(5), we have proposed to adopt the same changes for relevant certification criteria that reference these standards (see sections III.C.8 and III.C.9).*

We approve of the NPRM's proposal and reasoning to develop a new data element Sex for Clinical Use. ONC should also consider adding a sex characteristics question to measure intersex status, or differences in sexual development. The Fenway Institute encourages ONC to work with LGBTQIA+ stakeholders, the intersex community and its leading organization interACT: Advocates for Intersex Youth, and health IT standards-setting entities such as SNOMED to develop interoperable health IT standards that reflect the categories used by intersex people to describe themselves. Researchers at the Fenway Institute are examining the best ways to ask patients about sex characteristics, working closely with intersex community leaders. We encourage ONC to connect with intersex leaders and researchers to help develop culturally competent health IT standards to better serve members of the intersex community.

VII. *We propose in § 170.315(b)(11)(vi)(A)(5) that the use of Patient Demographics and Observations data identified in proposed § 170.315(a)(5)(i) be included as a source attribute.*

We support the proposal because we agree these data can influence how effective the decision support intervention (DSI) is for a given patient population and use case.

As in previous comments to ONC, the Fenway Institute, Whitman Walker Institute, and our colleague organizations continue to support the inclusion of consent affordances for patients during instances of health information exchange and exchanges of patient data using interoperability standards, particularly during transfers of care. We believe that patients should be asked to *opt in* for data sharing of sensitive information, including sexual orientation, gender identity, and sex characteristics (SOGISC) data.

Thank you for the opportunity to comment on the proposed rule, RIN: 0955-AA03, Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing. We greatly value the relationship with ONC that we have developed over the past 11 years, and appreciate your support of SOGI data collection and use and use of Name in Use and Pronouns to improve quality of care and to enhance LGBTQIA+ health equity. Should you have any questions, please contact Sean Cahill, PhD, Director of Health Policy Research at the Fenway Institute, at scahill@fenwayhealth.org.

Sincerely,

The Fenway Institute
The Whitman Walker Institute
AIDS Foundation Chicago
The AIDS Institute
American Atheists
Apicha Community Health Center
Campaign for Tobacco-Free Kids
Cascade AIDS Project
CenterLink: The Community of LGBTQ Centers
Five Horizons Health Services
Human Rights Campaign

interACT: Advocates for Intersex Youth
International Association of Providers of AIDS Care
Lambda Legal
Latino Commission on AIDS
Minority Veterans of America
National Health Law Program
SIECUS: Sex Ed for Social Change
Transhealth
The Trevor Project
Trillium Health