Submitted via online portal

April 30, 2022

The Honorable Micky Tripathi, PhD MPP
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C Street SW, 7th Floor
Washington, DC 20201

Re: U.S. Core Data for Interoperability (USCDI) Draft Version 3

Dear National Coordinator Tripathi,

On behalf of OCHIN, I appreciate the opportunity to submit the following comments in response to the Draft U.S. Core Data for Interoperability (USCDI) Version 3. OCHIN is a national nonprofit health information technology (IT) innovation and research network with over two decades of experience transforming health care delivery, providing leading-edge technology, data analytics, research, and support services to more than 1,000 community health care sites and 21,000 providers, reaching more than 6 million patients in 47 states. OCHIN applauds the Office of the National Coordinator of Health Information Technology’s (ONC) efforts to drive widespread adoption of national digital data standards and interoperability.

Recommendations

The overarching goal of national digital data standardization via USCDI should be to promote nationwide interoperability that supports clinical care and public health while advancing equity and accounting for the end-user experience, particularly among patients and providers in underserved communities. In the appendix, OCHIN provides detailed comments on the proposed USCDI version 3 categories and elements and immediately below we offer several global recommendations.

We urge ONC to:

1. Create a regulatory roadmap for adoption of each version of USCDI. Driving national adoption of the USCDI (and by extension improving national interoperability) requires that all stakeholders including developers, vendors, health systems, and providers are able plan, prepare, and provide feedback that reflects their capacity to implement needed changes. The ambiguity concerning adoption of version 2, 3 and future versions hinders appropriate planning and prioritization. At a minimum, we urge ONC to offer a session with stakeholders to elaborate on regulatory mechanisms or other policy levers that will drive uptake of each version of USCDI and the timing. We also request that ONC clarify the role of testing and/or certification in the success of the Trusted Exchange Framework and Common Agreement (TEFCA) and in the establishment and development of the USCDI. ONC has previously noted that once the final TEFCA is published, Qualified Health Information Networks (HINs) and their participants will be required to update their technology to support all the data classes included in USCDI in accordance with the requirements in the final TEFCA. Finally, OCHIN supports the coordination of the annual review process for the USCDI with the Interoperability Standards Advisory Board (ISAB).
(ISA) annual review process and urges ONC to explain the relationship between the USCDI and ISA before finalizing.

2. **Continue to prioritize the data categories and elements related to equity and public health.** The process continues to skew towards the needs of patients who face the least structural inequality and well-resourced organizations that are able to dedicate staff, financial resources, and time to provide crucial input into the prioritization, design, development, and validation of standards considered for inclusion in USCDI. As a result, the categories and elements (along with the associated standards and technical guides) can often be “good enough for now” while leaving some of the most underserved patients and communities – the remaining 20% — without data and corresponding standards that meet their needs. The clearest example of this problem concerns patient identification. Current options do not adequately uniquely identify patients who are housing insecure, face barriers to accessing the internet or emails and smart phones or face other forms of persistent structural inequality. The proposed data standards would continue to exacerbate structural inequality and place such patients at heightened risk for potential harm. We urge ONC to elevate this issue within the U.S. Department of Health & Human Services (HHS) and the Administration to ensure there are resources to systematically address this type of inequity in data collection and standards testing and evaluation.

3. **Partner with other federal agencies with discretionary funding to work with community health partners to accelerate standards development and technical testing for categories and elements (such as additional SDOH domains and elements) needed to drive equity in federal programs such as the Centers for Medicare and Medicaid Services (CMS), the Centers for Disease and Control and Prevention (CDC), Indian Health Services (IHS), and Health Resources and Services Administration (HRSA) programs.** There is an immediate need to rapidly complete the development and testing of these standards for public health readiness and mitigation as well as health care practice transformations that can improve care while bending the cost curve. Ultimately, federal programs and agencies will benefit from accelerating the development, testing, and adoption of such standards. The Administration cannot wait for the least resourced stakeholders in healthcare to accelerate the development and testing of these needed data and elements. HHS should allocate sufficient financial resources and technical support for these foundational infrastructure investments needed to promote equity in federal programs and policies.

4. **Partner with other federal agencies such as HHS’ Office of Minority Health to fund user-centered designed testing for each USCDI version in community clinics and local public health settings to promote equity and overcome structural inequality while identifying a sustainable process for introducing regulatory changes.** Despite the many advantages of technology, one commonly reported barrier compounding clinician burnout is the ever-changing landscape of health IT itself. Even routine software upgrades can slightly alter the look and feel of health IT systems in a way that has the potential to impact end-user workflows – workflows that impact direct patient care. To mitigate this challenge for our members, OCHIN has streamlined its software release schedule with the aim of minimizing unnecessary changes, while continuing to meet the core operational needs of the network. In addition, OCHIN is also working with our end-users to better connect tools and technology to workflows that are seamless and adaptable to various clinical settings. OCHIN has engaged our network’s Clinical Operations Review Committee (CORC) to review priority categories for USCDI. The CORC is open to all OCHIN network health clinic staff who have an expressed interest in participating in the development, review, and testing of clinical tools and workflows. This CORC is composed of clinical, billing, operations, administrative, and Practice Improvement/Quality
Improvement staff. The data classes and categories they have indicated are a priority include those related to SDOH, care plans/chronic Dx management, and clinical laboratory orders and results.

5. **Engage with state health and Medicaid agencies developing health information exchange policies to ensure they are involved in the process to prevent fragmented and disparate digital data policies.** States around the nation continue to adopt digital data standards that conflict with USCDI or, at the very least, create duplicative standards that lead to confusion and increased cost. This disproportionately adversely impacts underserved communities and their providers that do not have the extra funding to easily reconcile and identify solutions for these differences. For example, a number of states are working on sexual orientation and gender identity digital data standards and are not aware consideration is being given to modify what is contained in USCDI version 2.

**Conclusion**

Additional funding and resources are needed to accelerate existing efforts that lead to the adoption of national digital data standards aimed at advancing equity and strengthening public health. While we urgently need USCDI data classes and elements supporting public health and equity, poorly developed, tested, timed, and implemented technology and standards result in the largest missed opportunities for underserved communities. These communities have faced historic underinvestment and currently their providers are experiencing high rates of clinician burn-out. According to monthly OCHIN satisfaction surveys, the percentage of OCHIN network clinicians reporting burnout increased from roughly 24% pre-pandemic to a peak of 47% in September 2021, with an overall rating of 35% across the network.\(^1\)

Commonly cited challenges—ranging from dwindling staff and financial resources to pandemic fatigue and the everchanging landscape of compliance and billing requirements —echo across the health care industry at large. In the OCHIN network, standard patient encounters are growing at a rate faster than the growth of our network’s workforce.\(^2\) COVID encounters continue to create a challenge for the workforce in OCHIN member clinics. OCHIN network members face not only clinician shortages, but shortages of equally essential staff trained to bring the benefits of 21st century health information technology and data to patients in underserved communities across the nation.

As a learning collaborative and research network, OCHIN knows first-hand that data has a direct impact on the quality and accessibility of care, particularly for people of color and other underserved or marginalized communities. Ensuring all providers and patients benefit and participate in a national data standardization effort is essential for success. Thank you for the opportunity to comment. Please contact me at stollj@ochin.org should you have any questions.

Sincerely,

Jennifer Stoll
Executive Vice President
External Affairs

\(^1\) "Addressing Clinician Burnout: Using Data to Support Care Team and Patient Well-being" OCHIN Blog (December 6, 2021)

\(^2\) Source: Epic User Reports and Patient Encounter Reports retrieved 1/27/22, excludes members who onboarded or terminated during the reporting period.
APPENDIX

Social Determinants of Health
OCHIN urges ONC to coordinate with other federal agencies to fund the acceleration of development and technical testing of the additional identified Gravity Project SDOH domains and categories for inclusion, at a minimum, in version 3 of USCDI.

Data Class: Assessment and Plan of Treatment
OCHIN supports the inclusion of SDOH Assessment in the Assessment and Plan of Treatment Data Class in USCDI V3 and recommends that the Applicable Vocabulary Standard(s) category be expanded to include ICD-10-CM Z codes recently developed for Social Determinants of Health.

Level 2 Data Element: Outcomes
OCHIN recommends the proposed Level 2 data element Outcomes for USCDI V3. ONC is strongly urged to allocate resources to further accelerate the development of vocabulary standards along with published technical specification.

Patient Demographics

Level 2: Tribal Affiliation
OCHIN strongly supports the addition of Tribal Affiliation. OCHIN urges ONC to consider several value sets including utilizing the IHS’ Standard Code Book (SCB) Tribe Data Table with the appropriate codes for each Tribe. Alternatively, the US Core detailed race extension (extension: detailed) uses a CDC Race and ethnicity value set that includes all US Native American Tribes. Additionally, ONC should, in its USCDI Version 3 Implementation Guides, provide guidance on how best to capture an individual that may align to more than one Tribe. Finally, OCHIN recommends that ONC directly consult Tribal community stakeholders.

USCDI version 2: Sexual Orientation and Gender Identity
OCHIN supports modification of USCDI version 2 data elements for Sexual Orientation/Gender Identity/Sex (Assigned at Birth). OCHIN recommends that ONC include the following data elements:

- Gender Identity
- Sex for Clinical Use
- Recorded Sex or Gender
- Name to Use
- Pronouns

In addition to the foregoing, OCHIN recommends the following value set which combines values from both Gender Harmony and USCDI version 2:

- Female
• Male
• Nonbinary
• Unknown
• Additional gender category or other, please specify
• Choose not to disclose

This selection offers patients the ability to select whatever gender identity they feel most comfortable with while also ensuring providers are able to gather as much pertinent information from each patient as possible. Expanding this selection is crucial to inclusive language and options that build trust between clinicians and patients.

The following elaborates on the above summary recommendations. Gender Harmony proposes three fields: Gender Identity, Sex for Clinical Use, and Recorded Sex or Gender, which is close to OCHIN’s Sex at Birth (Sex for Clinical Use) and Legal Sex (Recorded Sex or Gender). Because the concept of “Sex for Clinical Use” can be problematic (as it can differ depending on the specific clinical use), OCHIN has been moving to more organ-specific logic to drive screenings and reminders. OCHIN recommends that following:

• Changing label and definition of Sex Assigned at Birth to become one part of Recorded Sex or Gender, i.e., recorded at birth.
• Gender Identity remain in the Patient Demographics data class, and that Name to Use and Pronouns be included in that class as well.
• Gender Identity, Name to Use, and Pronouns should be specified as typically, being self-reported by the individual.
• Recorded Sex or Gender may be clinical values derived through clinical assessment or legal documentary sources.
• Sex for Clinical Use should be specified as context dependent and should not be interpreted as a singular assessment.
• For some patient populations, Sex for Clinical Use may be different at the same point in time for different assessments or procedures (e.g., imaging studies vs laboratory assessments).
• Include associated metadata identifying the source (e.g., individual self-report, clinical observation) and method of collecting values for each data element.

Health Status

Level 2 Pregnancy Information
OCHIN strongly supports including Pregnancy Status in the Health Status Category. Enhancing equity in maternal health is crucial as rates of maternal morbidity continue to climb in the U.S., particularly among minority communities, with rates 63% higher in Black communities and 32% higher in Hispanic communities when compared to White communities. Including these data elements in USCDI version 3 will help ensure information essential for a successful pregnancy is conveyed to every member of a mother’s care team.

However, maternal health care requires the use of additional data elements that are unique to prenatal care. Prenatal care is a collaborative practice that requires several transitions of care in the ambulatory and acute environments, necessitating a standard and universal data entry and
retention system. These data elements inform all clinicians caring for actively pregnant patients and are conveyed in nearly every transition of care. Ensuring that these elements are required for maternal health in any national data standard is essential. The following are data elements that should be the focus of HHS (and by extension ONC) efforts to address maternal health equity:

- **Estimated Due Date** – This element is critical for clinicians when patients present in labor.
- **Cervical exam** – This element details observations such as dilation, effacement, and station.
- **Fetal heart tones** – Establishes fetal viability.
- **Fundal height** – Indicates fetal growth.
- **Fetal number**
- **Gestational age**
- **Fetal presentation** – This element is key for preparation of delivery.
- **Intent to become pregnant (Y/N)** – Establishes intent and capacity for childcare.

**Unique Patient Identifier**

**OCHIN urges ONC to work towards methods to uniquely identify patients who are underserved and face increased safety risks because there is not a method that uniquely identifies them.** In the OCHIN network, mismatching and duplication disproportionately affect communities of color, thus undermining health equity and contributing to structural inequality. This inequality is unique to the United States, as we are one of the only developed nations that does not use or allow a UPI. According to the U.S. Census Bureau, the average American will move **11.7 times** in their lives. Each time a person moves and changes providers they risk losing part of or all of their medical history, history that is particularly essential if they have any chronic conditions. Adopting a UPI will ensure that patient data is never lost or misattributed, saving time, money, and most importantly, patient’s lives.

The current methods for identifying patients through phone number, address, social security number, or legal name work well for the majority of patients but is inadequate for a growing population of people who do not have a permanent address or phone number, or who may not have a legal name that is unique to them in combination with the other identifying information.

Last year, during the state’s legislative session period, a state legislature considered mandating a state-specific “solution” to uniquely identify patients. While the principle and thought behind the measure is sound, implementation and use of such a state specific identifier is fraught with problems. Multiple “unique” identifiers for patients who move among states, providers, health plans, and public health jurisdictions would undermine efforts to improve not only interoperability but also privacy, security, patient safety, and equity.

**Laboratory**

Data Element: Tests
Data Element: Values/Results
Level 2 Data Element: Specimen type
The fragmentation and layering of requirements by state and local public health departments and the lack of national normalization of reporting processes and systems is driving up costs for providers (via add-on work from vendors), expending valuable staff resources and impacting the quality and timeliness of data transfer. Rules and requirements are applied disparately across the health care sector with different standards for different providers. For example, ambulatory providers are not always required to report results, while emergency departments and urgent care providers have more uniform reporting requirements.

Streamlining requirements for sending electronic results across provider types, whether they are received through a lab or independently, is necessary for a more robust and equitable public health system built on timely, complete, high-quality data. National clearing houses are needed to normalize reporting processes so data flows seamlessly through one mechanism to multiple jurisdictions instead of through multiple, unique reports to multiple jurisdictions. Provider burden in the lab reporting process as it exists today is significant.

As a result, there is a need to limit local and state add-on reporting requirements for providers as any change, even marginal, drives up costs which create inequities for small clinics. To ease the burden on providers, lessen complexities and confusion, and to bridge the gap between the majority and the underserved, a national standard set of laboratory reporting fields should be included in USCDI. Further, providers should not be required to report results beyond the scope of those fields.

In addition, to simplify and unify reporting requirements, OCHIN urges ONC to adopt certain data elements in USCDI version 3 that provide greater detail into laboratory results, origination, and identification. It is important to note that these elements are only needed when the information is present to the reporting provider. The data elements OCHIN recommends for inclusion are:

- Unit of Measure
- Results Status with date and time stamps
- Laboratory Test Performed Date
- Specimen Source Site
- Test Kit Unique Identifier

These are already included in CLIA and mapped to existing certification requirements for FHIR, C-CDA and ELR specifications. It should be specified that the inclusion of these data elements in USCDI does not imply a requirement of collection.