The Joint Commission

June 20, 2023

Micky Tripathi, Ph.D., M.P.P.
National Coordinator for Health Information Technology
Department of Health and Human Services
Mary E. Switzer Federal Office Building
330 C St. SW
Washington, D.C. 20201

[RIN: 0955-AA03. Submitted electronically via https://regulations.gov]

Dear Coordinator Tripathi:

The Joint Commission appreciates the opportunity to comment on the Office of the National Coordinator for Health Information Technology (ONC) proposed rule, *Health Data, Technology, and Interoperability: Certification program Updates, Algorithm Transparency, and Information Sharing.*

Founded in 1951, The Joint Commission seeks to continuously improve health care for the public in collaboration with other stakeholders, by evaluating health care organizations (HCOs) and inspiring them to excel in providing safe and effective care of the highest quality and value. An independent, not-for-profit organization with a global presence, The Joint Commission has programs that accredit or certify more than 22,000 HCOs and programs in the United States. The Joint Commission evaluates across the continuum of care, including most of the nation's hospitals. Although accreditation is voluntary, a variety of federal and state government regulatory bodies, including CMS, recognize The Joint Commission's decisions and findings for Medicare or licensure purposes.

The Joint Commission provides the following comments regarding several sections of the proposed rule:

III. ONC Health IT Certification Program Updates
C. New and Revised Standards and Certification Criteria
1. The United States Core Data for Interoperability Standard (USCDI) v3
i. Social Determinants of Health (SDOH)
xi. Patient Demographics/ Information
ONC proposes to adopt United States Core Data for Interoperability (USCDI) v3 as the new data set baseline across applicable certification criteria. In addition, ONC proposes to add data classes or data elements in the USCDI standard and to be incorporated as part of ONC's proposal to adopt USCDI v3. Certified health IT with Health IT Modules certified to criteria would be required to be capable of representing Sexual Orientation and Gender Identity in SNOMED CT® as well as the development of a new data element Sex for Clinical Use.

The Joint Commission
Washington, DC Office
701 Pennsylvania Ave. NW, Suite 700
Washington, D.C. 20004
202 783 6655

The Joint Commission's Comments:

The Joint Commission supports adopting USCDI v3 because it includes the addition of important classes of information to support person-centered care, including health insurance information, sexual orientation, gender identity, and health-related social needs (HRSNs). We also support the proposal to adopt final versions of HL7 Clinical Document architecture (CDA) and Fast Health Interoperability Resources (FHIR) US Core, which provide base technical requirements for interoperability of data represented in the USCDI v3 data classes.

In addition, The Joint Commission recommends that other existing and commonly used data elements proposed for USCDI+ be added to USCDI. Elements such as care experience preference, advanced directives, and newborn delivery information are key data to communicate patient preferences and patient outcomes. For example, newborn delivery information is currently used to measure *Unintended Complications in Term Newborns*, a nationally implemented electronic clinical quality measure (eCQM) developed by The Joint Commission.

The Joint Commission supports capturing Sexual Orientation and Gender Identity (SOGI) in SNOMED CT® to standardize and facilitate common coding and terminology. Standardizing collection of SOGI data elements can facilitate identifying disparities and improving outcomes for the LGBTQ+ population. Capturing Social Determinants of Health (SDOH) and SOGI data elements will also assist HCOs and other stakeholders to stratify data and enable them to identify and address disparities experienced by specific populations (based on SDOH data elements/characteristics).

The Joint Commission supports capturing "*specific codes for representing Sex… 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"* because this would enable FHIR data standardization and sharing. This approach is consistent with other FHIR Implementation Guides. The use of NullFlavor supports the ability to capture specific codes representing Sex. ONC should consider applying this approach for race/ethnicity value sets as well.

Regarding Sex for Clinical Use, The Joint Commission perceives that there can be benefit in knowing a patient's clinical anatomy and physiology (i.e., applicable cancer screenings, or hormone levels) and support this proposed data element. To facilitate implementation, The Joint Commission suggests ONC work with agency partners within HHS, implementers, and other stakeholders to identify and disseminate best practices in data collection, use, and exchange. Education resources on these topics should also promote efforts to collect this and other sensitive data in a culturally appropriate manner. Such resources will be helpful for administrative and clinical staff to ensure they are collecting sex and gender data in a way that is respectful and builds trust in the meaningful use of the data.

III. ONC Health IT Certification Program Updates
C. New and Revised Standards and Certification Criteria
3. "Minimum Standards" Code Sets Updates
ONC proposes to add § 170.207(f)(3) to reference Centers for Disease Control and Prevention (CDC) Race and Ethnicity Code Set Version 1.2 (July 2021) and incorporate it by reference in § 170.299. …ONC proposes to revise §170.207(n)(2), which is currently reserved, to reference the version of SNOMED CT® codes specified. ONC proposes to add the version of LOINC® codes specified.

ONC proposes to change the heading from "sexual orientation and gender identity" to "sexual orientation and gender information". Additionally, as described in this proposed rule in sections III.C.1 and III.C.8, ONC proposes to reference the version of SNOMED CT® codes and to reference the version of LOINC® codes for Pronouns.

The Joint Commission's Comments:
The Joint Commission supports efforts to standardize the collection and use of race and ethnicity data. At The Joint Commission, we are also taking significant steps to make this a priority for our accredited HCOs. For example, starting in July 2023, The Joint Commission will require hospitals and health systems to comply with a National Patient Safety Goal (NPSG.16.01.01): *Improving health care equity for the organization's patients is a quality and safety priority*.[1] Within this NPSG, we identify the importance of the collection and use of data such as race, ethnicity, and health related social needs because they are key to understanding and addressing health disparities and achieving health equity. Requiring a specific code set would help organizations to consistently collect, report, and use race and ethnicity data to improve patient care.

The Joint Commission does have concerns about the completeness of the CDC Race and Ethnicity Code Set. The CDC Race and Ethnicity Code Set Version 1.2 is missing an option for race unknown, unreported, or patient opted not to respond. We recommend CDC and ONC consider adding codes for those options, which provide facilities with more detailed information to help determine additional steps to improve data collection efforts. Further, we recommend ONC consider providing additional guidance outside of the USCDI classes to support implementation. The guidance should include standard approaches for collecting data regarding individuals identifying as multiple races and ethnicities and methods for aggregating hierarchical race information. The aggregation methodology should be clear as to how multiple responses should be aggregated and permit reporting on all races/ethnicities selected, not just one. Guidance is a critical part of establishing and communicating standards or requirements for how disaggregated data are then aggregated in a consistent manner to the minimum categories to permit exchange and comparisons at a national level.

[1] The Joint Commission's National Patient Safety Goals were established to help accredited organizations address specific, high priority areas of concern in regard to patient safety.
See: National Patient Safety Goal to Improve Health Care Equity https://www.jointcommission.org/-/media/tjc/documents/standards/r3-reports/r3_npsg-16.pdf

The Joint Commission recently provided support for the Office of Management and Budget's (OMB) proposal to adopt additional categories to capture race and ethnicity as part of its Statistical Policy Directive No 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity. Collecting data using a greater number of fully enumerated, representative, and standardized values would improve the quality and usability of the data. We recommend that ONC advance adoption of the final OMB Standard through USCDI and the standards advancement process.

Also, The Joint Commission cautions against changing the heading from "sexual orientation and gender identity" to "sexual orientation and gender information." This change may cause confusion within the greater health care environment as the SOGI acronym is already commonly used to indicate "gender identity" and not "gender information."

III. ONC Health IT Certification Program Updates
C. New and Revised Standards and Certification Criteria
5. Decision Support Interventions and Predictive Models
c. Proposed Requirements for Decision Support Interventions (DSI) Certification Criterion
ONC proposes that Health IT Modules that enable or interface with predictive DSIs enable a user to review predictive DSI "source attribute" information through the Health IT Module. ONC also proposes that developers of certified health IT with Health IT Modules that enable or interface with predictive DSIs employ or engage in "intervention risk management" practices. ONC also proposes that summary information regarding these intervention risk management practices be made available via a publicly accessible hyperlink.

The Joint Commission's Comments:
The Joint Commission supports efforts to bolster transparency in the development and use of algorithm-enabled software. As artificial intelligence and machine learning (AI/ML) capabilities improve, HCOs will see an increase in the deployment of these tools across the health care environment, including DSI-enabled EHRs. These decision support tools have the potential to be valuable tools for clinicians. However, care and consideration must be taken when developing these tools. Improperly trained or deployed AI-enabled software could produce biased outcomes, as many reports have already documented.[2] ONC's proposal to require developers utilizing DSI tools to employ or engage in intervention risk management practices and provide the public with information about those practices is a foundational step in building transparency into the design of these next-generation clinical tools.

III. ONC Health IT Certification Program Updates
C. New and Revised Standards and Certification Criteria
6. Synchronized Clocks Standard
ONC proposes to remove the current named specification for clock synchronization, which is Network Time Protocol (NTP v4 of RFC 5905). However, ONC proposes to amend certification so that Health IT Modules certified to applicable certification criteria continue to utilize any

[2] Z. Obermeyer, et al., *Dissecting Racial Bias in an Algorithm Used to Manage the Health of Populations,* 366 SCIENCE 447 25 OCT 2019.

network time protocol (NTP) standard that can ensure a system clock has been synchronized and meets time accuracy requirements.

The Joint Commission's Comments:
The Joint Commission does not oppose removing the Network Time Protocol and permitting organizations to use any network time protocol standard. However, consistency across organizational networks and systems remains important. Certified health IT developers and HCOs using their products should ensure that they are still using the same, consistent network time protocol across all servers and platforms.

III. ONC Health IT Certification Program Updates
C. New and Revised Standards and Certification Criteria
7. Standardized API for Patient and Population Services
b. FHIR United States Core Implementation Guide (IG) Version 5.0.1
In the ONC Cures Act Final Rule, ONC adopted the FHIR US Core Implementation Guide (IG) STU3 version 3.1.0 implementation specification in § 170.215(a)(2). Since the publication of the ONC Cures Act Final Rule, the US Core IG has evolved. Yearly US Core IG updates reflect changes to USCDI versions and requests from the HL7 US Realm FHIR community. The US Core IG v6.0.0 is anticipated to include support for the data elements and classes added to USCDI v3. 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, ONC believes US Core IG v6.0.0 will be published before ONC issues a final rule. Therefore, it is 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 ONC proposes to adopt USCDI v3 in this rule

The Joint Commission's Comments:
The Joint Commission strongly supports the adoption of FHIR US Core as a base interoperability standard and commends ONC for anticipating and adopting US Core IG v6.0.0. US Core IG v6.0.0, published in early May, reflects additions to align with the data classes finalized in USCDI v3. Specifically, the US Core Observation Screening Assessment and Questionnaire Response profiles finalized with the publication of US Core, enables exchange of findings on standardized HRSN screening instruments, consistent with the USCDI v3 added data classes. US Core v6.0.0 also provides guidance on Screening and Assessments and defines a US Core Simple Observation Profile to communicate clinician-interpreted findings in the absence of patient-reported data. The additions to US Core IG v6.0.0 have benefited from testing and guidance by implementers in the Argonaut Project Team and collaboration projects such as Sync for Social Needs, which is dedicated to establishing consensus on exchange standards for SDOH data.

As a founding member of Sync for Social Needs, The Joint Commission has engaged in discussions with standards developers, patients, clinicians, HCOs, and technology providers to confirm that US Core 6.0.0 supports HRSN collection, use, and exchange. The balance between flexibility and specificity defined in the US Core Observation Screening Assessment and the Questionnaire Response profiles supports multiple methods of data exchange and enables meaningful collaboration among organizations supporting persons with unique social needs.

These US Core Profiles enable data to be shared consistently, efficiently, and reliably with clinicians and other entities.

III. ONC Health IT Certification Program Updates
C. New and Revised Standards and Certification Criteria
8. Patient Demographics and Observations Certification Criterion
ONC proposes to add the data elements "Sex for Clinical Use" in § 170.315(a)(5)(i)(F), "Name to Use" in § 170.315(a)(5)(i)(G), and "Pronouns" in § 170.315(a)(5)(i)(H) to the "Patient Demographics and Observations" certification criterion (§ 170.315(a)(5)). This addition reflects concepts developed by the HL7 Gender Harmony Project and help promote inclusivity in care delivery. ONC proposes that health IT be capable of recording Pronouns using the LOINC® terminology code set standard specified.

ONC requests comments 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 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.

The Joint Commission's Comments:
The Joint Commission supports adding data elements "Sex for Clinical Use," "Name to Use," and "Pronouns" to the "Patient Demographics and Observations" certification criterion because these additions align with the HL7 Gender Harmony Project. Having the ability to consistently capture these SOGI demographic data elements will provide a more inclusive care experience for patients. Capturing and assessing these SOGI elements within the EHR can assist clinicians and patients in developing individualized care plans and improve trust and respect between LGBTQIA+ patients and facility staff.

Considering the options for recording Sex, The Joint Commission supports Option 2: Replace Sex with "Recorded Sex or Gender" because it is consistent with, and recommended by, the HL7 Gender Harmony Project. This option allows the data elements "Sex for Clinical Use" *and* "Recorded Sex or Gender," which provides more options for patients to share as much as they feel comfortable, or they can refuse to answer.

III. ONC Health IT Certification Program Updates
C. New and Revised Standards and Certification Criteria
10. Patient Requested Restrictions Certification Criterion
ONC proposes to add the following in § 170.315(d)(14) for this new criterion "patient requested restrictions":
- *For any data expressed in the standards in § 170.213, enable a user to flag whether such data needs to be restricted from being subsequently used or disclosed; as set forth in 45 CFR § 164.522; and*
- *prevent any data flagged pursuant to paragraph (d)(14)(i) of this section from being included in a subsequent use or disclosure for the restricted purpose.*

ONC proposes that the developer of a certified Health IT Module, under this standards-agnostic approach, would have the flexibility to implement the restriction on the inclusion in a subsequent use or disclosure via a wide range of potential means dependent on their specific development and implementation constraints (e.g., flagged data would not be included as part of a summary care record, not be displayed in a patient portal, or not be shared via an API).

In addition, ONC seeks comment on any unintended consequences that the new criterion in § 170.315(d)(14) or the addition to the Privacy and Security Framework in § 170.550(h) might place on patients, clinicians, or other covered entities using certified health IT.

The Joint Commission's Comments:

As the U.S. health care industry moves towards more automated sharing of electronic health information, the ability for covered entities to denote within their EHR systems the reasons for why restricted "sensitive" information may be released becomes imperative.

The Joint Commission recommends that the proposed new certification criterion § 170.315(d)(14) include the requirement that the covered entity is able to denote global reason(s) why they would allow restricted data to be automatically shared via an application programming interface (API) request or other electronic means without having to wait for an individual at the covered entity to approve the release.

For example, the entity may agree to not provide specific "sensitive" drug information via an API; however, the entity may receive a request denoted as a 'data request for emergency treatment.' The software responding to the API request should be able to query a global repository of reasons why specific data can be automatically released. The Joint Commission additionally recommends multistakeholder collaboration to define a common set of global reasons that can be implemented consistently across platforms.

Further exploration will be required to understand how patient flagging of data impacts utility of data for secondary use for applications including but not limited to care coordination, clinical trials, and quality measurement. Additionally, missing data could impact clinical decision support (CDS) or DSI and could impact the quality and safety of care provided to the patient, particularly when data are shared with third-party DSI presented within the clinical workflow via API. Within the context of quality measurement, missing patient data may impact accuracy and usability of performance measures. Exclusions based on patient election not to share pieces of data would need to be considered. Further collaboration with CMS and other stakeholders is needed to evaluate the potential impact regarding missing (declined to share) data and its impact on measure performance results.

III. ONC Health IT Certification Program Updates
C. New and Revised Standards and Certification Criteria
11. Requirement for Health IT Developers to Update their Previously Certified Health IT
As ONC moves away from the use of editions to define timeframes for updating to new and revised certification criteria, ONC believes it is important to continue to provide clarity

regarding the obligations of developers who are seeking to certify health IT and maintain a Health IT Module's certification, including, as applicable, certification to revised certification criteria and the timely provision of such technology to their customers. ONC proposes to make explicit in the introductory text in § 170.315 that health IT developers voluntarily participating in the Program must update their certified Health IT Modules—including when new standards and functionality are adopted—and provide that updated certified health IT to customers in accordance with the timelines defined for a specific criterion or standard where included, such as via cross-reference, in § 170.315. ONC proposes that health IT developers with health IT certified to any of the certification criteria in § 170.315 would need to update their previously certified Health IT Modules to be compliant with any revised certification criterion adopted in § 170.315, including any certification criteria to which their Health IT Modules are certified that reference new standards adopted in 45 CFR part 170 subpart B, and capabilities included in the revised certification criterion. Health IT developers would also need to provide the updated heath IT to customers of the previously certified health IT according to the timelines established for that criterion and any applicable standards.

The Joint Commission's Comments:
The Joint Commission supports ONC's proposal to phase out year-based "editions" of the ONC Certification Criteria for Health IT in favor of a single set of incrementally updated criteria. "Editions" become stagnant the longer time passes between updates. The Joint Commission also supports updating the criteria in real time and implementing new criteria annually to be more responsive to constantly evolving standards.

III. ONC Health IT Certification Program Updates
F. Insights Condition and Maintenance of Certification
2. Insights Condition – Proposed Measures
The Cures Act specifies that a health IT developer be required, as a Condition and Maintenance of Certification requirement under the Program, to submit responses to reporting criteria in accordance with the "Electronic Health Record Reporting Program" established under section 3009A of the PHSA, as added by the Cures Act, with respect to all certified technology offered by such developer. ONC proposes to implement the Cures Act "Electronic Health Reporting Program" Condition and Maintenance of Certification requirements as the "Insights Condition and Maintenance of Certification" (Insights Condition) requirements in § 170.407. As a Condition of Certification, ONC proposes that health IT developers of certified health IT would submit responses to comply with the Insights Condition's requirements, described in this section of the preamble in relation to the Insights Condition's measures and associated certification criteria. The intent of the Insights Condition is to address information gaps in the health IT marketplace, as well as provide insights on how certified health IT is being used, consistent with Program certification criteria and associated conformance to identified technical standards.

The Joint Commission's Comments:
As ONC implements the Insights Condition and associated measures, we recommend ONC explore opportunities to harmonize data element definitions within the narrative measure specifications with existing computable data element definitions within electronic clinical quality measures. For example, denominator statements for several included measures are

"encounter-based" (e.g., measures pertaining to a count of encounters, interventions within specific encounters). The eCQM developer community, including the Joint Commission, has collaborated with CMS, EHR vendors, and other stakeholders to develop harmonized, computable definitions for different encounter types expressed in standardized terminology (SNOMED CT), a standard data model (FHIR, Quality Data Model), and expression language (CQL). We believe this work has utility for standardizing encounter definition in ONC Insight measures as well. For measures where patient encounters are relevant, The Joint Commission recommends that the definition of an encounter should be based on the National Committee for Quality Assurance (NCQA) outpatient value set and SNOMED CT inpatient encounter codes. For outpatient codes, eCQM developers use NCQA's Outpatient Value Set. For inpatient codes, developers use SNOMED CT codes 4525004, 183452005, 32485007, 8715000, and 448951000124107.

Similarly, to support clarity in definition, we recommend ONC expand on the specificity of the current narrative definitions where practical, providing guidance on value sets and codes appropriate to represent the indented concept. For example, within the "Immunization Administration Electronically Submitted to IIS" measure, ONC could consider adopting standardized methods for calculating age from date of birth, routinely captured in LOINC as "Birth date" (21112-8) and defined in the CQL operator "AgeInYears."

F. Insights Condition and Maintenance of Certification
3. Insights Condition and Maintenance of Certification Requirements
ONC proposes to implement the Insights Condition requirements in a way that does not unduly disadvantage small and startup health IT developers. The minimum reporting qualifications include whether a health IT developer has any applicable Health IT Modules certified to criteria associated with the measure, and whether the developer has at least 50 hospital users or 500 clinician users across its certified health IT products, which serves as a proxy for its size or maturation status (e.g., whether it is a startup). If a developer of certified health IT does not meet these minimum reporting qualifications, it would be required to submit a response that it does not meet the minimum reporting qualifications on specific measures for a given Health IT Module(s) subject to the Insights Condition requirements. In addition, if a health IT developer does not have at least one product that meets the applicable certification criteria specified in the measure requirements, or a developer of certified health IT that is certified to the criterion or criteria specified in the applicable measure during the reporting period but does not have any users using the functionality, the developer would still be required to submit a response that it does not meet the applicable certification criteria or the number of users required to report on the measure.

The Joint Commission's Comments:
Under the current proposal, Certified Health IT Developers would be permitted to aggregate reported performance across different versions of their product. The Joint Commission believes that aggregating data across versions would result in an "averaging" of performance across multiple versions with potentially significant differences in features and capability. As a result, it would limit the utility of the reported data for the purpose of evaluating a specific product

version, while potentially obscuring limitations in earlier versions that have since been addressed.

As an alternative, The Joint Commission recommends establishing a reporting threshold. A threshold of 50 hospital users or 500 clinician users is likely sufficient because most measures evaluate encounter-level activities. However, we would encourage ONC and the developer to evaluate measure reliability and validity using reported data before publicly reporting performance.

For the "Use of FHIR in Apps Supported by Certified API Technology" measure, we suggest that reporting both the FHIR version and the US Core IG version are necessary. As "base FHIR" matures, we anticipate fewer releases of FHIR versions. Concurrently, as adoption of FHIR increases, we anticipate continued updating of the U.S. Core Implementation Guide to reflect real world experience and emerging use cases. For this reason, we anticipate that FHIR and US Core IG will not be synonymous in describing the capabilities of a technology, and that capabilities may vary based on US Core version.

IV. Information Blocking Enhancements
A. Defined Terms
B. Exceptions
ONC notes the definition it proposes generally includes providing, supplying, or otherwise making available certified health IT under any arrangement or terms. ONC further proposes potential exclusions ONC is considering that would provide that an individual or entity is not considered to be offering health IT under the proposed definition while furnishing certain legal, health IT expert consulting, or management consulting services to health care providers or others who obtain and use health IT.

The Joint Commission's Comments:
The Joint Commission continues to support the aim of ONC's efforts to prevent information blocking. Free and unencumbered exchange of data is important for care coordination, population and public health, and ultimately patient safety. As such, limiting the reasons and exclusions for why a developer of health IT can refuse to share data is important.

In order to promote clarity, we acknowledge the need to strengthen term definitions including what it means to "offer health IT" and under which legal and consulting circumstances that definition does not apply; which stakeholders fall within the definition of "developer of certified health IT" and thus are subject to the certification requirements; and to clarify and extend the definition of Information Blocking outside of USCDI and remove the restrictive timeframe.

The Joint Commission agrees that efforts should be made to develop and adopt standard methods of exchange and the manner exception exhausted proposal seems to potentially reduce undue burden of trying to comply with every manner and mechanism of exchange requested while still preserving the importance of trying to offer alternates. The three factors proposed clarify when an actor would be considered "unable" to fulfill a request for access, exchange, or use of

electronic health information in a way that ensures fairness and reciprocity across requestors but also permits flexibility to try to provide/exchange the data using alternative modes or methods.

The Joint Commission is pleased to answer any questions you may have regarding our comments. If you have any questions, please do not hesitate to contact me or Patrick Ross, Associate Director, Federal Relations, at (202) 783-6655 or pross@jointcommission.org.

Sincerely,

Kathryn E. Spates, JD
Executive Director, Federal Relations