



April 27, 2022

Micky Tripathi, Ph.D.  
National Coordinator  
Office of the National Coordinator for Health Information Technology  
330 C Street SW  
Washington, DC 20201

Re: ACP Comments on Draft United States Core Data for Interoperability Version 3

Dear National Coordinator Tripathi:

On behalf of the American College of Physicians (ACP), I am pleased to share our comments on the latest draft of the Office of the National Coordinator for Health Information Technology's (ONC) United States Core Data for Interoperability (USCDI), Draft United States Core Data for Interoperability Version 3 (Draft USCDI v3). ACP thanks ONC for the opportunity to provide input on the changes to USCDI. The College is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 161,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

The College appreciates ONC's efforts to include social determinants of health (SDOH)-related data elements that focus on promoting equity, reducing disparities, and promoting public health data interoperability to improve care and address inequalities in health care. The College previously advocated for the inclusion of SDOH data within USCDI in [comments](#) on ONC's *21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program* Notice of Proposed Rulemaking and appreciates ONC's addition of these new SDOH-related data elements. ACP strongly believes that physicians' awareness of SDOH information improves whole person, patient-centric care and lowers long-term costs. Because an individual's health is impacted by the sum of various social needs, having the most complete, comprehensive information about an individual is critical to delivering the best care.

The College has long been a proponent of using health information technology (IT) and electronic health record (EHR) systems as tools for collecting SDOH data. As stated in a 2018 position paper, [Addressing Social Determinants to Improve Patient Care and Promote Health Equity](#), "The [ACP] recommends development of best practices for utilizing [EHR] systems as a tool to improve individual and population health without adding to the administrative burden on physicians," and "recommends increased screening and collection of [SDOH] data to aid in health impact assessments and support evidence-driven decision making." The College continued to advocate for the collection of SDOH data in a 2021 position paper, [Understanding and Addressing Disparities and Discrimination Affecting the Health and Health Care of Persons and Populations at Highest Risk](#), where it stated, "ACP believes that more research and data collection related to racial and ethnic health disparities are needed to empower policymakers and stakeholders to better understand and address the problem of disparities. Collected

data must be granular and inclusive of all personal identities to more accurately identify socioeconomic trends and patterns.” Hence, the College has acknowledged the usefulness of SDOH data for certain purposes and supports the inclusion of certain SDOH-related data elements in USCDI v3.

The following is an overview of the College’s determinations:

ACP <i>Supportive</i> of Inclusion in USCDI v3	ACP <i>Opposed</i> to inclusion in USCDI v3
<ul style="list-style-type: none"> <li>○ Pregnancy Status</li> <li>○ Sex (Assigned at Birth)</li> <li>○ Gender Identity</li> </ul>	<ul style="list-style-type: none"> <li>○ Functional Status</li> <li>○ Disability Status</li> <li>○ Mental Function</li> <li>○ Date of Death*</li> <li>○ Tribal Affiliation</li> <li>○ Related Person’s Name</li> <li>○ Related Person’s Relationship</li> <li>○ Occupation</li> <li>○ Occupation Industry</li> <li>○ Current Address</li> <li>○ Previous Address</li> <li>○ Reason for Referral</li> <li>○ Coverage Status</li> <li>○ Coverage Type</li> <li>○ Relationship to Subscriber</li> <li>○ Member Identifier</li> <li>○ Subscriber Identifier</li> <li>○ Group Number</li> <li>○ Payer Identifier</li> </ul>

\* ACP would support the inclusion of the Date of Death data element if the data were gathered from public records and would not require physicians or health care staff to collect the information.

ACP’s reasoning behind these determinations is provided below. Our comments primarily respond to the proposed new data elements and the questions posed throughout the ONC Standards Bulletin regarding Draft USCDI v3 (SB22-1). The College’s primary consideration when thinking about the inclusion of each new data element was its burden-to-benefit ratio for physicians. The main questions ACP considered, and urge ONC to consider, for each proposed new data element are whether there is clinical value to the data element (i.e., whether the data element has the potential to improve patient care and/or physician decision-making), and if so, whether the burden on primary care physicians of collecting that data element throughout the full spectrum of health entities—from large health care systems to solo practitioners—outweighs its clinical value. ACP strongly believes that the effort and burden required to collect data, especially if the data are low in clinical importance, can be a significant barrier to implementation and use of any given data element.

***Health Status — Functional Status, Disability Status, Mental Function, Pregnancy Status***

ACP believes a practice or health system should be able to determine what data collection is key for their purposes and patients and be able to collect the data in situation-specific ways. ACP questions whether the specific information captured by the Functional Status, Disability Status, and Mental Function elements would be utilized often enough by the average physician to justify requiring

collection of the information. These three data elements are important, but the utility of their data values is likely concentrated in a relatively small number of patients in certain specialties and practices. While the College appreciates the relevance and helpfulness of these data elements in certain care contexts (e.g., hospice, palliative care, disability assessments, rehabilitation clinics, etc.), ACP believes that their clinical utility is limited (particularly as compared to other proposed USCDI data elements) and mostly circumstantial, with their nuanced, complex nature making the data values inherently more burdensome to collect in a structured way. Additionally, the information the elements are intended to capture would be collected and addressed *as needed* in a standard visit, whereas requiring a physician to collect these data would be disruptive to the flow of patient visits. Considering that collecting these data is possible in other, less burdensome ways, ACP is largely opposed to these data elements becoming federally required. The College is very concerned about the burden of collecting these data and wishes to emphasize that federally required standards should be adopted sparingly and thoughtfully, because the specific data that must be collected to best serve patients can vary widely from practice to practice.

As for Pregnancy Status, the College believes this data element is clinically useful and not particularly burdensome, and therefore it is a welcome addition to USCDI. It is worth noting that many EHRs already collect these data, but the data can be misleading because it is not always updated to indicate that a patient is no longer pregnant. Therefore, if collecting this data element is going to be required, ACP recommends ONC acknowledge it will need to be checked regularly to maintain data accuracy.

***Patient Demographics — Date of Death, Tribal Affiliation, Related Person’s Name, Related Person’s Relationship, Occupation, Occupation Industry***

For many of the newly proposed elements in the Patient Demographics data class (e.g., Date of Death, Occupation, Occupation Industry), ACP urges ONC to consider the end goal and whether data captured by health care systems is different from data captured via other sources, such as the Department of Labor and vital records offices. For these proposed elements, the College asks why physicians should be burdened with collecting data that is available elsewhere and lacks meaningful clinical context.

The Date of Death data element has limited clinical relevance, and ACP questions the need for it to be a required data element. Physicians will not necessarily know when a patient has passed away, making questionable both the need for and the purpose of physicians and their staff having to collect information that is so readily available from multiple public sources, such as state and federal records. ACP believes it would be much more helpful if Date of Death data could be incorporated into EHRs from these external sources.

ACP similarly questions the clinical relevance of the Tribal Affiliation data element and worries about the potential negative impact on the physician-patient relationship if these data are not properly protected. As our members have learned from direct patient care experiences, many American Indian and Alaska Native individuals are hesitant or downright unwilling to share their tribal affiliation outside of the Indian Health Service (IHS) for a litany of cultural and historic reasons. The College is concerned that if a private health system got access to a patient’s tribal affiliation through IHS data-sharing—that the patient otherwise would not have shared outside of the IHS—it could complicate or negatively impact the physician-patient relationship, especially if that information was visible to the patient (for example, via a portal). If this data element is required, the College strongly believes it should remain optional and self-reported, and that any incorporation of data elements associated with tribal affiliation into the USCDI must be done in partnership and deep consultation with Native American communities.

ACP strongly questions the clinical relevance of the Related Person's Name and Related Person's Relationship data elements and does not believe these data elements should be required because the information is often collected elsewhere in a patient's record, making its required collection within the EHR unnecessary and overly burdensome.

While the Occupation and Occupation Industry data elements can potentially be clinically relevant, most primary care physicians are already getting this information from their patients, particularly if and when it is clinically relevant, making the inclusion of these data elements in USCDI unnecessary and overly burdensome.

***Sex (Assigned at Birth) & Gender Identity — 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. ONC [also] requests feedback on the most appropriate value set to represent Gender Identity for USCDI v3.***

ACP supports the Sex (Assigned at Birth) data element. Having these data be a part of a patient's fundamental medical record would be helpful for patient care because, in some cases, there is a clinical basis for treating patients based on their gender at birth because diseases present differently, and medications react differently, in males (genetically XY) and females (genetically XX), making this important information for physicians to have. The data are typically collected only once and transacted upon many times thereafter, involving little to no burden for solo and small practices. Furthermore, these data are already being collected by some physicians in health care systems that have chosen to adopt EHR systems that enable their collection. However, the College has concerns about the costs associated with the technology necessary to collect any newly required data elements.

As ONC notes in the Standards Bulletin, the HL7 Gender Harmony Project (GHP) developed the new term "Recorded Sex or Gender" to represent any recording of "sex or gender" in health records or other documents. Under the GHP's definitions, "Sex assigned at birth" is an example of a "Recorded Sex or Gender" that preserves the historic value of sex assigned at birth as recorded in health records.

While ACP supports the adoption of the Sex (Assigned at Birth) and Gender Identity data elements and considers them important in caring for patients of all identities, it is critical that data requirements do not become an additional source of burden for smaller practices. Individual health systems will have to pay for the technology required to collect these new data elements, and this technology will add to the financial strains of solo and small practices. This is just one example of how federal data requirements will create opportunities for EHR vendors to increase their fees.

ACP believes a slightly modified version of GHP's value set for Gender Identity would be the most appropriate value set to use for the Gender Identity data element. ACP supports removing the current "Female-to-Male (FTM)/Transgender Male/Trans Man" and "Male-to-Female (MTF)/Transgender Female/Trans Woman" options from the applicable vocabulary standards for Gender Identity in USCDI v2, making the value set more aligned with that proposed by GHP (i.e., one that does not include terms for transgender male and transgender female) and the latest [preferred terminology](#). The College also proposes removing the words "or other" from the "Additional gender category or other, please specify" option to avoid "othering" patients, thereby marginalizing their identity. Therefore, ACP proposes the following value set for the Gender Identity data element:

- Male
- Female
- Genderqueer, neither exclusively male nor female
- Additional gender category, please specify
- Choose not to disclose

***Patient Address — ONC seeks feedback on whether ONC’s Unified Specification for Address in Health Care (Project US@) should be the required standard for Current and Previous Address in USCDI v3 or a future USCDI version.***

The College believes the Patient Address data element has very limited clinical relevance and is concerned about the impact of this data element, if required, on inclusiveness of certain patient populations. ACP questions whether standardized patient address is mature enough and includes enough of the U.S. to be acceptable, in addition to having inclusivity concerns regarding this data element because it may exclude portions of the population, especially if required. The College urges ONC to ensure that care can be provided to all persons regardless of whether their address meets any requirements.

***Procedures — Reason for Referral***

ACP sees no clinical value in the Reason for Referral data element. Physicians already document this information when necessary; therefore, the College sees no need for its inclusion in USCDI v3. Furthermore, as currently written, a reason for referral would have to be included with every type of transition of care, which is inherently burdensome. For example, if a primary care physician had to fill out a reason for referral form every time a patient took an ambulance, that would be unnecessary, tedious, and deeply burdensome.

***Health Insurance Information — Coverage Status, Coverage Type, Relationship to Subscriber, Member Identifier, Subscriber Identifier, Group Number, Payer Identifier***

ACP sees no clinical value in any of the proposed data elements in the Health Insurance Information data class and does not support inclusion of these data elements in USCDI v3.

General Comments

The College wishes to emphasize its view that federal data requirements should not end up being opportunities for EHR vendors to increase subscription fees. Additional federal data requirements should be included in regular, scheduled system updates that are part of existing EHR contracts and should not be allowed to be used by vendors as a means of increasing profit.

As a general matter, ACP strongly believes that a practice or health system should be able to determine what data collection is necessary for their purposes and patients. Federally required standards should be adopted sparingly and thoughtfully, because the specific data that must be collected to best serve patients can vary widely from practice to practice.

Privacy and Security of SDOH Data

While ACP believes physicians’ access to SDOH-related information is a fundamental aspect of providing

high quality care, the College also believes the collection and use of this information should be held to the highest standard and appropriate oversight, and enforcement should restrict inappropriate use and access of this information. As the College stated in a 2020 position paper, [\*Envisioning a Better U.S. Health Care System for All: Reducing Barriers to Care and Addressing Social Determinants of Health\*](#), “The [ACP] believes that all persons, without regard to where they live or work; their race and ethnicity; their sex or sexual orientation; their gender or gender identity; their age; their religion, status, and language proficiency; their health literacy level and ability to access health information; their socioeconomic status; whether they are incarcerated; and whether they have intellectual or physical disability must have equitable access to high-quality health care and must not be discriminated against based on such characteristics.”

Additionally, while ACP supports ONC’s efforts to improve health care disparities by requiring collection of SDOH data through USCDI, it is important to remember that SDOH data include extremely sensitive and private patient information, and inclusion of SDOH data elements and the subsequent collection of these data alone are not sufficient for reducing disparities. The potential for the collection of SDOH data to help in reducing health care disparities lies in the appropriate use of the data (e.g., for research on the causes of health care disparities and on the health and health care of specific populations). Furthermore, if health care systems and EHR vendors do not design and implement appropriate data privacy tools and safeguards for USCDI data, the data can end up in the wrong hands and might be used for inappropriate purposes in discriminatory ways that can worsen health disparities. Therefore, if collected, SDOH-related data must be properly protected to ensure the privacy and security of patient information and must be used in appropriate ways for appropriate purposes.

The College advocated for these kinds of data protections in a 2021 position paper, [\*Health Information Privacy, Protection, and Use in the Expanding Digital Health Ecosystem\*](#), where it stated, “ACP believes that health IT and other digital technologies, including personalized digital health products, should incorporate privacy and security principles within their design as well as consistent data standards that support privacy and security policies and promote safety.” In accordance with this principle, the College recommended that “Health IT standards should be developed and consistently implemented to collect and exchange relevant consent information along with the personal health information to which they apply,” and that “The source of all information, as well as the date and time the information was created or modified, within a medical record should be clearly identified and maintained as the information moves from system to system because of the risk that such information could be altered and therefore not retain its accuracy or relevance for clinical care decisions.” The College additionally recommended that “Health IT and other digital technologies should incorporate audit trails to help detect inappropriate access to personal health information,” and “should facilitate the provision of useful and appropriate disclosure notifications to persons when personal health information is disclosed and for what purpose, with the ability to customize the types of disclosure notifications received.”

The College further stated that “ACP believes that protecting the privacy and security of personal health information collected both within and outside the health care system—while providing individual rights to that information—is essential for fostering trust in the evolving digital health care system, maintaining ethical standards and respect for persons, and promoting the safe delivery of health care.” In accordance with this principle, the College recommended that “Persons should be able to access their personal health information conveniently, reliably, and affordably and have complete flexibility in making disclosure choices about their personal health information that is stored in their personal devices or health records (for example, mHealth apps and wearable devices).”

The College also addressed information sharing and patient consent in this position paper, stating, “ACP supports increased transparency and public understanding and improved models of consent about the collection, exchange, and use of personal health information within existing HIPAA rules as well as for entities collecting, exchanging, and using personal health information outside the health care system,” and recommending that “All entities that collect or use personal health information should provide standard and easily understandable notices of privacy practices, end-user licensing agreements, or terms of service to persons that contain the type of information collected, all allowable uses of information, and consent requirements.”

In conformity with the various principles and recommendations the College set forth in this position paper, ACP strongly believes that if SDOH data collected through EHRs are intended to be used by any entity (i.e., ONC, payers, physicians, EHR vendors, etc.) for purposes other than care and treatment of the patient (e.g., for research), patients should be notified of and provide consent to these potential uses in advance of data collection.

Thank you for this opportunity to comment on ONC’s Draft USCDI v3. ACP acknowledges the significance of SDOH data for providing person-centered care and supports the collection of clinically relevant SDOH data elements but believes the burden of collecting data must not outweigh the clinical benefit of the data for successful implementation and use of the proposed new data elements. The College appreciates the opportunity to offer feedback and looks forward to continuing to work with ONC to implement policies that support and improve the practice of internal medicine. Please contact Brian Outland, Director, Regulatory Affairs for ACP, at [boutland@acponline.org](mailto:boutland@acponline.org) or (202) 261-4544 with comments or questions about the content of this letter.

Sincerely,



Zeshan A. Rajput, MD, MBA, MS  
Chair, Medical Informatics Committee  
American College of Physicians