April 10, 2024

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

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 5 (Draft USCDI v5). ACP thanks ONC for the opportunity to provide input on the proposed 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, 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.

ACP has long supported ONC's goal of expanding interoperability in the healthcare system by establishing a standardized set of data that can be commonly exchanged across care settings for a wide range of uses. The College believes nearly all of the proposed data elements in Draft USCDI v5 are worth including in USCDI but has reservations about or does not support the addition of at least one of the data elements as proposed. The following is an overview of the College's determinations:

Support **or** ***Do Not Oppose*** **inclusion in USCDI v5**	***Oppose*** **or** ***Do Not Support*** **inclusion in USCDI v5**
Clinical Notes *Emergency department note* *Operative note* **Immunizations** *Lot number* **Laboratory** *Test kit unique device identifier*	**Observations** *Sex parameter for clinical use (generic; under Observations data class)*

Medications *Route* **Observations** *Advance directive observation* **Orders** *Orders* **Patient Demographics/Information** *Interpreter needed* *Pronoun(s)* *Name to use* **Provenance** *Author* *Author role*	

While the following context-specific *Sex parameter for clinical use* (SPCU) data elements have not been proposed for addition to Draft USCDI v5, we tentatively support addition to their respective data classes (in place of a generic SPCU data element under the Observations data class) with some caveats as discussed further below:

Clinical Tests

Clinical test(s) SPCU

Diagnostic Imaging

Diagnostic imaging SPCU

Laboratory

Laboratory SPCU

Procedures

Procedure(s) SPCU

ACP's reasoning behind these determinations is provided below. Our comments primarily respond to the proposed new data classes and elements and the questions posed throughout the ONC Standards Bulletin regarding Draft USCDI v5 (SB24-1). The College's principal consideration when thinking about the inclusion of each new data element was its burden-to-benefit ratio for physicians. The main questions ACP considered for each proposed new data element, and urges ONC to also consider, 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 healthcare 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.

New Data Classes and Data Elements in Draft USCDI v5

Clinical Notes: *Emergency department note*, *Operative note*

The College **supports** the addition of the *Emergency department note* and *Operative note* data elements to USCDI. We believe doing so would drastically improve the lack of standardization in how these notes are currently stored and conveyed and could potentially reduce overall burden. However, we seek clarity on whether such notes would be labeled granularly versus being bundled into these two overarching categories. For instance, within operative notes there may be "bedside procedure notes" or "surgicenter notes," or within emergency department notes, they can be "pediatric emergency room notes" or "general emergency room with OB triage notes." The College would support more granularity in the labeling of this data. Overall, while we support the addition of these data elements and believe having this information exchanged in a standardized manner would be very helpful, we caution that their addition should not add to the burden of physicians.

Immunizations: *Lot number*

The College **supports** the addition of the *Lot number* data element to USCDI. We welcome the standardization of this data, which we believe is currently exchanged by most organizations. We also believe the addition of this data element has the potential to reduce errors. Furthermore, we have minimal concerns about burden related to this data element because the handling of this information is typically the responsibility of non-physician care team members.

Laboratory: *Test kit unique device identifier*

The College **supports** the addition of the *Test kit unique device identifier* data element to USCDI. Like the proposed *Lot number* data element, we believe the standardization of this data is important and have minimal concerns about burden related to this data element because the handling of this data is typically the responsibility of non-physicians. As long as non-physician entry remains the expectation and routine, we support this addition.

Medications: *Route*

The College **supports** the addition of the *Route* data element to USCDI. The current lack of standardization in medication route data often results in limited interoperability and thus re-entry of this data (e.g., when a patient switches clinics and a refill is requested) adding to physician burden. We believe having medication route data available in a standardized format would be very valuable in terms of patient safety and will likely reduce physician burden.

Observations: *Advance directive observation*, *Sex parameter for clinical use*

The College **supports** the addition of the *Advance directive observation* data element to USCDI. The ability to record and know whether an advance directive exists and is on file for a patient, as well as the type of document and whether it has been verified, is very important from a clinical care perspective.

The College **does not support** the addition of a generic *Sex parameter for clinical use* (SPCU) data element to USCDI; however, the College **tentatively supports** addition of context specific SPCU data elements within each applicable data class (e.g., Clinical Test(s) SPCU, Diagnostic Imaging SPCU, Laboratory SPCU, Procedure(s) SPCU, etc.), with some caveats and reservations. We seek clarity regarding where this information would come from, whether it would be determined by someone other than the patient (i.e., assigned), and if so, how it would be assigned. We believe this is an important clarification because there is potential for assumptions to be made about a patient's sex that might not be accurate. Furthermore, to ensure appropriate, consistent usage and patient safety, we emphasize that the latest guidance from the HL7 Gender Harmony Project should be strictly adhered to in the collection and exchange of this data.

Orders: *Orders*
The College **supports** the addition of the *Orders* data element to USCDI, with some caveats. While we recognize that there are some advantages in having this information collected and exchanged (e.g., from a liability standpoint), we believe the addition of this data element is likely to contribute to burden. We anticipate that a wide array of "orders" could fall under this broad category and that exchange of this data element would still involve physicians sifting through large amounts of data within the *Orders* category to determine whether appropriate orders were placed as well as the appropriate care to provide. Therefore, we have reservations about the addition of this data element without the ability to present *Orders* data broken down by order type or subcategory.

Patient Demographics/Information: *Interpreter needed*, *Pronoun*, *Name to use*
The College **supports** the addition of the *Interpreter needed* data element to USCDI, with some caveats. While we believe the *Interpreter needed* data element is important and can be very helpful, we worry about the burden that is likely to be involved in the increased exchange of this information and whether it will fall on physicians. However, we believe that on balance it would be helpful and could promote efficiency to have this information as early as possible in a standardized way for the purposes of planning and operations, so that the interpretative needs of a patient can be anticipated and addressed in advance.

The College **strongly supports** the addition of the *Pronoun* and *Name to use* data elements to USCDI, also with some caveats. The College believes that it is very important for physicians and other members of the clinical care team to have access to and use a patient's preferred pronoun(s) and name to use when speaking to or about a patient and applaud ONC for proposing the addition of these important data elements. Furthermore, we are extremely supportive of the usage note clarifying that information for both data elements should be provided by the patient.

We appreciate that the description of the "Pronoun" data element reflects that a patient may have more than one preferred pronoun ("word or words"). To reflect this reality, we strongly encourage ONC to consider renaming the *Pronoun* data element to the potential plural form (e.g., "Pronoun(s)"). Furthermore, we emphasize that the solicitation of pronoun information

should involve the following response options (at a minimum), with the ability to select multiple options:

- He/him
- She/her
- They/them
- Any/all
- None (i.e., use name only)
- Other (free response)

Provenance: *Author*, *Author role*
The College **strongly supports** the addition of the *Author* and *Author role* data elements to USCDI. The ability to track and know the source of information in the EHR, particularly by whom any information was entered, is essential, and we therefore welcome this enhancement. However, we emphasize that the tracking of this provenance information should be entirely automated by EHR vendors and should not involve any added burden for the physicians or clinical care team members (e.g., manual tagging of information in the EHR).

Conclusion
The College greatly appreciates the opportunity to share our perspective and provide feedback on ONC's Draft USCDI v5. While we acknowledge the sincerely good intent behind these proposed new data elements, ACP believes the burden of collecting data must not outweigh the clinical benefit of the data for successful implementation and use of proposed data elements. The College looks forward to continuing to work with ONC to implement policies that support and improve the practice of internal medicine. Please contact Nadia Daneshvar, Health IT Policy Associate, Regulatory Affairs, at ndaneshvar@acponline.org or (202) 261-4586 with comments or questions about the content of this letter.

Sincerely,

Deepti Pandita

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Chair, Medical Informatics Committee