April 13, 2023

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

Re: ACP Comments on Draft United States Core Data for Interoperability Version 4

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 4 (Draft USCDI v4). ACP thanks ONC for the opportunity to provide input on these 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 160,000 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 some of the proposed data elements in Draft USCDI v4 are worth including in USCDI but has reservations about or strongly opposes the addition of others. The following is an overview of the College's determinations:

ACP ***Supportive*** of or ***Not Opposed*** to Inclusion in USCDI v4	ACP ***Not Supportive*** of or ***Opposed*** to inclusion in USCDI v4
Encounter Information	**Allergies and Intolerances**
Encounter identifier	*Substance (non-medication)*
Facility information	**Goals**
Facility identifier	*Treatment intervention preference*
Facility type	*Care experience preference*
Facility name	**Medications**
Health Status Assessments	*Medication adherence*
Alcohol use	**Vital Signs**
Substance use	*Average blood pressure*
Physical activity	

Medications *Medication instructions* **Procedures** *Time of procedure*	

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 v4 (SB23-1). 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.

In general, the College does not support the addition of any new data elements to USCDI that would require additional work on behalf of the care team. If the necessary data for a proposed data element is already being captured elsewhere and could be applied or integrated within the electronic health record (EHR) or practice systems, the College would be willing to consider supporting the addition.

Before supporting any given data element, the College needs more detailed information about how the data is being captured. Expecting clinicians and health systems to collect unstructured data without an existing standard would not only be confusing, but it could also lead to more errors and patient safety risks. While standards exist for much of the data that is currently collected, the standards are not followed in a useful way. Many EHRs collect relevant data in an unstructured (textbox) form, making it much less likely—and in many cases impossible—for that data to be usefully synthesized and automatically deduplicated. Without proper standards and implementation guidance, data will likely show up in duplicate, disorganized, etc., which would be unimaginably burdensome for physicians. Therefore, the College hesitates to support the addition of any of these proposed data elements unless ONC can guarantee that the data would be integrated properly. Moreover, if the data for any proposed new data element would be collected in an unstructured way without standards in existence, our members would not want to capture unstructured data that can inadvertently lead to patient safety issues.

New Data Classes and Data Elements in Draft USCDI v4

Goals: *Treatment intervention preference, Care experience preference*
The College **strongly opposes** addition of the *Treatment intervention preference* and *Care experience preference* data elements to USCDI. While ACP believes this information is important and the proposed addition of these data elements are well-intentioned, such preferences are very difficult to capture in a structured way, and terminology differs from state to state, which makes it extremely challenging for technology to integrate and deduplicate data successfully. Not only is there too much nuance and variability in how this information can be collected and digitized, but patients' views and ideologies on treatment interventions and care experiences are dynamic and can change based on context and health status at the time the goals are discussed. Therefore, even if this information could be captured in a

structured and consistent manner, what is captured may not be current. While the College admits that certain contextual information (e.g., patient's beliefs, goals for care) can be helpful when a patient is being transferred from one facility to another, we question whether enough meaning will be transferred via structured data elements in such a way that the conversation about these preferences would not need to be repeated with the patient.

Furthermore, if added to USCDI, these elements are very likely to be particularly burdensome for primary care physicians because they tend to have longer, better-established relationships with their patients. Moreover, this burden will be exacerbated because, as noted, diagnoses are not static. Diagnoses (and therefore prognoses) can change, and what was true the day of a given patient visit is not necessarily still true two years—or even two months—later. Patients' goals of care and their preferences can even change from visit to visit or from inpatient to outpatient, and they often report different goals of care to different clinicians. Physicians cannot know, and data classes and elements cannot reflect, how a patient will feel once new medical situations arise.

Allergies and Intolerances: *Substance (non-medication)*
The College **opposes** addition of the *Substance (non-medication)* data element to USCDI. ACP cautions that the collection of this patient data can be very inconsistent and is not likely to provide any meaningful information for clinicians. Furthermore, the College views intolerances and allergies as distinct patient characteristics that, if collected, should be captured separately within the patient record.

Vital Signs: *Average blood pressure*
The College has reservations about adding the *Average blood pressure* data element to USCDI, and therefore **does not support** its inclusion. The contexts where this data element would not be useful far outweigh the situations where it potentially could be useful. The data element is too nuanced, has very little clinical value, and could even be misleading. For example, when a patient has multiple blood pressure readings in a single visit, it is usually because there were circumstances (e.g., climbing stairs to get to the physician's office) that elevated their initial blood pressure reading. If a practice then retakes a patient's blood pressure later in the visit to ensure an accurate reading, a physician would not want to average those two readings, as doing so would negate the reason the second reading had been done in the first place. Additionally, the College questions who would be responsible for calculating average blood pressure and what the parameters would be (e.g., whether two readings on the same day would both be considered when averaging).

Medications: *Medication instructions, Medication adherence*
The College **does not oppose** addition of the *Medication instructions* data element to USCDI, because it is information that is typically captured during a patient encounter anyway. However, the College has reservations about addition of the *Medication adherence* data element to USCDI, and therefore **does not support** its inclusion. While ACP believes medication reconciliation is an important aspect of patient care and understands that this is a well-meaning proposal, it is important to be cautious about what labels are used when collecting *Medication adherence* data because they can be unfairly stigmatizing, which can perpetuate false narratives and stereotypes about patients. Including this information in the patient record can create expectations and narratives in advance of meeting a patient. There are many reasons patients do or do not take medications, and the College is not confident that *Medication adherence* data exchange would be able to capture that nuance meaningfully or that the data would be useful without that nuance. Collection and inclusion of this data in the patient record could potentially even be harmful; if a physician is reviewing the record of a patient they have never met, any indication of lacking adherence could reinforce and perpetuate bias around "poor" medication adherence.

Furthermore, patient safety issues can arise if these categories of data are not clearly and appropriately defined and represented. The medications prescribed by a physician can be very different from the medications taken by the patient, but this is often not represented as it should be in the patient record; if a physician prescribes a medication and a patient never picks up the medication from the pharmacy, it still shows up on the patient's medication list.

The potential issues involved in collecting and accurately representing this data without furthering stigma raise serious questions about whether the tenuous value of this data would be worth the increased burden involved in collecting it.

Encounter Information: *Encounter identifier*
The College **does not oppose** addition of the *Encounter identifier* data element to USCDI, mainly because this information is typically captured anyway and thus would not add significant burden for clinicians and their staff.

Facility information: *Facility identifier, Facility type, Facility name*
The College **does not oppose** addition of the *Facility Information* data class and *Facility identifier*, *Facility type*, and *Facility name* data elements to USCDI. The collection of this information is not likely to be particularly burdensome to physicians, particularly those in larger health systems. However, the proposed new data class should define what specifically a facility was used for in each case. For instance, if a patient with lab data from Facility A and radiology data from Facility B is being seen at Facility C, this data class should be able to present or indicate to which facility each set of data should be attributed (i.e., provenance of the data points).

Health Status Assessments: *Alcohol use, Substance use, Physical activity*
The College **does not oppose** addition of *Alcohol use*, *Substance use*, and *Physical activity* data elements to USCDI. However, while ACP acknowledges that these data have clinical significance, we worry that the responsibility and burden of collecting this information will fall upon physicians – particularly primary care physicians. The College would consider supporting the collection of this information and the addition of these data elements to USCDI if collection was voluntary or if collection by non-physician members of the care team was mandated. ACP cautions, however, that there is significant variation among and within practices and health systems in terms of how this information is collected, making it difficult to collect via standardized data elements and inherently burdensome.

Procedures: *Time of procedure*
The College **does not oppose** addition of the *Time of procedure* data element to USCDI, as long as this information is captured in the patient record automatically and will not add data collection requirements for physicians.

Conclusion

The College greatly appreciates the opportunity to share our perspective and provide feedback on ONC's Draft USCDI v4. 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 Brian Outland, Director, Regulatory Affairs, at boutland@acponline.org or (202) 261-4544 with comments or questions about the content of this letter.

Sincerely,

Deepti Pandita

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