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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: AHIP Comments on the USCDI Version 4

Dear Dr. Tripathi:

AHIP[1] appreciates the Office of the National Coordinator for Health Information Technology's (ONC) ongoing work to advance the interoperability of health information through the United States Core Data for Interoperability (USCDI). We agree that a common set of data classes and elements is essential to achieving interoperability. Patients deserve high-quality, equitable, and affordable care delivered by doctors, hospitals, health insurance providers, and other stakeholders working together— that includes sharing the data patients and their doctors need to make informed health care decisions. Additional data elements and classes can allow for more effective communication of patient needs and preferences, but the purpose and use of the data plays a significant role in its value to the system and the appropriateness of transmission.

As ONC adds additional data elements to the USCDI, the risk to patient privacy and data security grows not only because of the magnitude of data shared but also because of its tie to other downstream policies. Through a combination of ONC and Centers for Medicare & Medicaid Services (CMS) requirements, both health care and health insurance providers must share USCDI data through application programing interfaces (APIs) with third-party applications (apps) on behalf of consumers. While we see the value in and support giving patients easy access to their health data to help them engage in their health and health care, the policies are structured in such a way that the data are no longer subject to the robust federal privacy and security framework governing healthcare data once transferred. Apps that are now common in the marketplace were not contemplated, let alone included, as covered entities within the traditional Health Insurance Portability and Accountability Act (HIPAA), Health Information Technology for Economic and Clinical Health (HITECH), and 42 CFR Part 2 rules. This gap in the federal privacy and security framework leaves consumers' healthcare data vulnerable.

Current information sharing and interoperability policies advance an all or nothing approach. Stakeholders are required to share all requested data elements in the currently required version of the USCDI. While this may be what is technologically feasible and expeditious, it does not promote a consumer-centric model of information sharing that puts patients in control of their health data. Until technology sufficiently matures to allow easy data segmentation and to support

[1] AHIP is the national association whose members provide health care coverage, services, and solutions to hundreds of millions of Americans every day. We are committed to market-based solutions and public-private partnerships that make health care better and coverage more affordable and accessible for everyone.

consumer choice in which data to share with which parties, ONC should be mindful and judicious of what data elements it adds to the USCDI and what policies are required under the relevant information sharing and interoperability regulations from both ONC and CMS. Achieving a truly consumer-centric model for information sharing will require careful consideration about how, when, and to who data flows. To support consumer-centric information sharing, we recommend ONC consider 1) whether there is a clear clinical purpose, 2) the potential harms or risks to patient privacy from each data element, 3) the potential benefits of each data element, and 4) the feasibility of each data element. Heretofore, there have been data elements added to the USCDI through the standards version advancement process that do not meet all of these criteria.

Clinical Purpose
Information in the USCDI should advance patient care and care coordination. Data elements in the USCDI should have a clear clinical value and purpose to ensure information is relevant and useful. Adding data elements without a clear clinical value risks increasing administrative burden to both capture data to send and to parse and understand information received. For example, as detailed below, the USCDI v3 Health Insurance Information data class contains a number of data elements that are not germane to the provision and coordination of patient care and could create conflicting or inaccurate records.

Potential Risks
AHIP continues to be very concerned about the potential consequences for patients and their families. The risk grows as additional data elements are required to be shared particularly when shared with third-party apps not governed by the health care privacy legal requirements. For example, sensitive patient data, at an individually identifiable level, shared with an app developer under the CMS interoperability policies can be freely sold or disclosed as long as it is noted in the consumer terms and agreement provided by the app (which can be changed at any time). In April 2019, a JAMA© report found that 36 of the leading depression and smoking cessation apps in the U.S. and Australia routinely share user data with third parties, but just 12 third-party app developers accurately disclosed the practice within the privacy policy.[2,3] In addition, research[4,5,6] shows that third-party apps pose an unprecedented risk to consumers' privacy given their ability to collect user data that is highly valuable to commercial interests as well as their ability to re-identify consumers in other de-identified datasets. Moreover, consumers are also often unaware

[2] https://www.consumerreports.org/health-privacy/mental-health-apps-and-user-privacy-a7415198244/, https://www.statnews.com/2022/12/13/telehealth-facebook-google-tracking-health-data/
[3] https://www.scmagazine.com/analysis/application-security/senators-target-security-privacy-risks-of-mental-healthapps-misuse-of-health-data
[4]https://subscriber.politicopro.com/article/2023/02/data-broker-marketplace-research-shows-loose-controls-on-sensitive-mental-health-info-00082407
[5] https://www.washingtonpost.com/business/2019/04/22/smoking-depression-apps-are-selling-your-data-google-facebook-study-finds/
[6]https://www.wsj.com/articles/popular-apps-cease-sharing-data-with-facebook-11551044791

that the more individually identifiable data released, the easier it becomes for de-identified data to be reidentified.[7] Thus, with each data element included in the USCDI that then must be sent out via the APIs, consumer's privacy is at greater risk

We are also concerned about the potential risks to health care affordability by the forced disclosure of certain information around pricing and coverage status. We continue to urge ONC not to force the disclosure of confidentially negotiated rates, as the inclusion of granular price information could have unintended and anti-competitive consequences. As noted by the Federal Trade Commission, the Department of Justice, and leading economists, requiring public disclosure of pricing data could hinder fair negotiations and drive-up consumer prices. Moreover, consumers already have access to the information they need via plan transparency tools and the Patient Access API, negating the need for this data element in the USCDI or for providers to share second-hand information through electronic health records which are not designed to accurately capture claims data. ONC should not include any claims-level data in the USCDI, particularly confidentially negotiated rates or any other information that could harm consumers by making public competitively sensitive information.

Potential Benefits
As noted above, expanding the USCDI to include additional data classes and elements can enhance communication between providers, payers, and patients. ONC should focus on adding data elements and classes the promote the sharing of information that is clinically relevant or identifies patient needs and preferences. ONC should carefully consider the purpose and use of potential data elements, its value to the system, and the appropriateness of transmission.

Feasibility
Data elements required in the USCDI must be feasible to share in an interoperable, understandable format. ONC should not add data elements that do not have associated standards that are sufficiently tested and mature. AHIP supports a deliberate yet incremental approach to the expansion of data classes and elements. A balance must be achieved between the addition of data fields, especially in areas that are not yet well defined through standardized terminology, and a recognition of the need to minimize burden on front line providers

Revisions to USCDI v3
With this framework in mind, we recommend ONC revise the health insurance information data class currently included in USCDI v3. While we agree certain information about a person's coverage status is important for care coordination, quality measurement, and assessing disparities, ONC should revise certain data elements to protect patient privacy, avoid the disclosure of confidential pricing information, and ensure feasibility. For example, while there may be value in capturing if a patient is uninsured or on Medicaid as a proxy for social needs, there is not a clinical need for detailed insurance information. In fact, it may be off putting to

[7] https://techpolicy.sanford.duke.edu/data-brokers-and-the-sale-of-americans-mental-health-data/

patients and raise concern if a clinician asks for such information during the course of care rather than by office staff at check in or check out.

First, ONC should remove data elements that provide personally identifying information that does not support the provision of patient care. For example, Relationship to the Subscriber" and Group Identifier data elements do not have unique value or clinical significance. Information about a person's social supports and employment would be better captured by the SDOH-related data elements. Including specific and unnecessary information about a person's familial relationships and employer could be used by third-parties to identify someone in a different data set or even re-identify a de-identified data set.

Next, ONC should restructure the Coverage Status data element for focus broadly on whether a person has health insurance of any kind, rather than if specific services are covered. We are concerned that as currently written, the Coverage Status data element requires sharing of claim-level payment information through the USCDI. We continue to urge ONC not to force the disclosure of confidentially negotiated rates, as the inclusion of granular price information could have unintended and anti-competitive consequences. As noted by the Federal Trade Commission, the Department of Justice, and leading economists, requiring public disclosure of pricing data could hinder fair negotiations and drive-up consumer prices. Moreover, consumers already have access to the information they need via plan transparency tools, negating the need for this data element in the USCDI or for providers to share second-hand information through electronic health records which are not designed to accurately capture claims data. ONC should not include any claims-level data in the USCDI, particularly confidentially negotiated rates or any other information that could harm consumers by making public competitively sensitive information. Plans also share claims and encounter information directly with consumers via the Patient Access API. This method ensures consumers get such data from the source (their payer). Moreover, it is unclear how the Coverage Status data element would be operationalized. Such data is not currently in the EHR and would need to come directly from the payer.

We also note that data elements such as Member Identifier, Payer Identifier, and Subscriber Identifier do not have universally accepted standards. Without associated standards, such as national payer identification numbers, these data elements will not generate useful and usable information.
ONC should revise the Health Insurance Information data class to focus on sharing information that can be feasibly collected based on national standards and can facilitate patient care, help consumers and health care providers assess quality and understand the impacts of social determinants of health. A more streamlined approach could protect patient privacy, prevent the sharing of inaccurate information, and avoid market disruption. We suggest the Health Insurance Information data class focus on data elements that allow understanding of whether a person has insurance coverage, the type of coverage, and what payer(s) are covering the person. These data elements would allow health care providers to understand if a person has insurance coverage and the potential implications for care and care transitions, support quality and equity efforts, and

help consumers and providers connect with health insurance provider tools for up-to-date information on the coverage of specific services. ONC should work with health insurance providers to educate consumers about the Patient Access API and other tools available to encourage data access. Leveraging these tools would ensure consumers have access to their data while protecting their identities and ensuring the information they receive is accurate and up to date.

Revisions to Proposed Elements in USCDI v4

We are also concerned that a number of proposed data elements in USCDI v4 do not meet the criteria of having a clear clinical purpose, avoiding harm, conveying benefit, and ensuring feasibility. As detailed below, we are concerned that patients may not want to share detailed information about their alcohol or substance use broadly or when it is not directly clinically relevant. Consumers may fear their clinicians are judging them or this data could have risks to their privacy if it is shared outside the structure of HIPAA and the 42 CFR Part 2 rules.

We are also concerned that a number of proposed data elements do not have associated standards, including Facility Identifier, Facility Type, Specimen Identifier, and Specimen Condition and Disposition. We recommend ONC name standards or not include these data elements as required in USCDI until the standards are established.

As noted above, the current limits to technology necessitate including the minimum number of data elements necessary in the USCDI when stakeholders are required to share data through all-or-nothing approaches. As ONC and CMS consider advancing the required version of the USCDI, we recommend that rather than adopting versions of the USCDI wholesale, CMS and ONC should consider the contribution of each data element and whether it is necessary to share through the Patient Access API and expose to the risk of passing to a third-party app that is not a covered entity subject to HIPAA. CMS and ONC should consider removing personally identifiable data elements that do not provide unique value to avoid re-identification and the potential exposure of a person's health information or alternatively, revise policies that require automatic inclusion of all data elements in the named version of the USCDI through the APIs required in CMS's interoperability regulations.

AHIP and its members look forward to working with ONC to continue to advance interoperability to empower patients and support patient care. If you have any questions, please contact me at (202) 778-3246 or at dlloyd@ahip.org.

Sincerely,

Danielle A. Lloyd

Danielle A. Lloyd, MPH
SVP, Private Market Innovations & Quality Initiatives

Attachment: AHIP Comments on Specific Elements Proposed in USCDI V4

Data Element	AHIP Comment
Alcohol use	While we appreciate the clinical value of this data element, disclosure of someone's history of alcohol use could have unintended consequences if shared outside of a person's health care team. Moreover, consumers may not want this data shared broadly, even with certain clinicians. For example, a consumer may agree to share this data with a primary care physician managing their overall health but may not want providers they see for unrelated issues having this data. We recommend ONC consider the potential impact on patient privacy as more data is added to the USCDI. Sharing this information with third-party apps that are not covered entities within HIPPA, HITECH, and 42 CFR Part 2 rules could expose sensitive patient data and allow it to be used or disclosed. This data element could be particularly challenging as it will be based on a patient self-reported data, rather than a formal diagnosis. Patients may not realize what responses mean, data could be recorded incorrectly, or patients may choose to provide information to a particular clinician that they do not want to share with others. As ONC and CMS consider advancing the required version of the USCDI, we recommend that rather than adopting versions of the USCDI wholesale, CMS and ONC should consider the contribution of each data element and whether it is necessary to share through the Patient Access API and expose to the risk of passing to a third-party app that is not covered by HIPAA. CMS and ONC should consider removing personally identifiable data elements that do not provide unique value to avoid re-identification and the distribution of information that could be damaging such as certain diagnoses or information on a person's alcohol or substance use history.
Substance use	While we appreciate the clinical value of this data element, disclosure of someone's history of substance use could have unintended consequences if shared outside of a person's health care team. Consumers may not want this data shared broadly, even with certain clinicians. For example, a consumer may agree to share this data with a primary care physician managing their overall health but may not want providers they see for unrelated issues having this data. We recommend ONC consider the potential impact on patient privacy as more data is added to the USCDI. Sharing this information with third-party apps that are not covered entities within HIPPA, HITECH, and 42 CFR Part 2 rules could expose sensitive patient data and allow it to be used or disclosed. This data element could be particularly challenging as it will be based on a patient self-reported data, rather than a formal diagnosis. Patients may not realize what responses mean, data could be recorded incorrectly, or patients may choose to provide information to a particular clinician that they do not want to share with others. As ONC and CMS consider advancing the required version of the USCDI, we recommend that rather than adopting versions of the USCDI wholesale,

	CMS and ONC should consider the contribution of each data element and whether it is necessary to share through the Patient Access API and expose to the risk of passing to a third-party app that is not covered by HIPAA. CMS and ONC should consider removing personally identifiable data elements that do not provide unique value to avoid re-identification and the distribution of information that could be damaging such as certain diagnoses or information on a person's alcohol or substance use history.
Physical activity	We support the addition of this data element to the USCDI. Providing standardized information on an individual's physical activity would support care planning and quality improvement.
Facility name	While we support the addition of this data element and agree it will provide useful information for care coordination, we note that this data element could be challenging to operationalize given the lack of associated standards. Moreover, as consolidations occur, facilities may change names and even type. We recommend ONC name standards or not include these data elements as required in USCDI until the standards are established.
Facility Identifier	While we support the addition of this data element and agree it will provide useful information for care coordination, we note that this data element could be challenging to operationalize given the lack of associated standards. We recommend ONC name standards or not include these data elements as required in USCDI until the standards are established.
Treatment Intervention Preference	We agree that this data element would provide valuable clinical information. However, ONC should revise the data element to include the actual signed advanced directive/POLST documents. These documents may be crucial for treating providers to act as directed in accordance with treatment preferences.
Specimen Identifier	While we support the addition of this data element and agree it will provide useful information, we note that this data element could be challenging to operationalize given the lack of associated standards. We recommend ONC name standards or not include these data elements as required in USCDI until the standards are established.
Specimen Condition and Disposition	While we support the addition of this data element and agree it will provide useful information, we note that this data element could be challenging to operationalize given the lack of associated standards. We recommend ONC name standards or not include these data elements as required in USCDI until the standards are established.