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September 20, 2023

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Submitted electronically to: https://www.healthit.gov/isa/ONDEC

Re: ONC's Draft United States Core Data for Interoperability (USCDI) Version 5

Dear Dr. Tripathi:

We appreciate the opportunity to submit comments on the standardized health data classes and constituent data elements eligible for promotion to version 5 of the USCDI. We want to particularly **express our appreciation** for some specific improvements noted in version 4 of the USCDI such as **expanding the health data class "Goals" into "Goals and Preferences"** so that clear acknowledgement of the role of the person and what is important to them as they move through our healthcare system is expressly supported by the ONC. Further, we **applaud inclusion of the "Treatment Intervention Preferences"** and **"Care Experience Preferences"** data elements within the expanded Goals and Preferences health data class as it sends a clear message to all technical implementers of health technology that the ONC is leading the way to a person-centered healthcare system and intends to honor the voices of those receiving care.

As we look to version 5 of USCDI and those items that will enable individuals to express the things that will allow them to ensure systems make the information available across care settings that are most impactful to their healthcare experience, ADVault **strongly recommends** that the following health data classes and constituent data elements, including clarifications to their naming convention, be included.

Recommendations for USCDI v5:

Data Class	**Data Element**	**Recommendation**	**Reasoning for Recommendation**
Advance Directives	Advance Directives	Promote from Level 2 to USCDI v5	The organizing concept of an Advance Directive data class will enable other concepts to be associated such as Person-Authored Advance Directives, Consents, and Instructions supplied by patients to guide services provided during an encounter, and Portable Medical Orders, which are able to span multiple healthcare encounters and care settings. We recommend promoting the broad data class named Advance Directives, but then to distinguish the various forms of those documents as listed below. These changes are essential to fully accommodating and honoring the voice of the individual receiving care.
Advance Directives	Advance Directives	Promote from Level 2 to USCDI v5 and Modify Name of Data Element	Systems used across the U.S. have captured scanned images of these paper documents and stored them for many years. This data element enables those many existing scanned forms to be liberated for data exchange and accessibility. We further propose this data element be renamed **Person Authored Advance Directives** to ensure the context of those documents is maintained across care settings and systems. This data element will also accommodate statutory forms that contain both Healthcare Agent and Living Will preferences and goals, as those "combined" forms are in use in many jurisdictions that chose not to create two separate healthcare advance decision documents but instead chose to combine them into a single form.
Advance Directives	Personal Advance Care Plan	Promote from Level 1 to USCDI v5	Systems used across the U.S. have captured and stored personal advance care plan documents for many years, with the knowledge that the information found within them are from scanned paper forms. This data element enables those many existing scanned forms, which some individuals intend to take the place of jurisdictional advance directive documents or intend to further clarify the documented choices in those high-level advance directive documents for greater context as to their personal values and priorities, to be liberated for data exchange

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			and accessibility. Personal advance care plan documents, like advance directives, are intended to inform care when the individual receiving care is unable to communicate with the medical team due to health status.
Advance Directives	Durable Medical Power of Attorney	Promote from Level 1 to USCDI v5 and Modify Name of Data Element	Individuals are able to designate someone to speak for them if they are unable to express their goals, preferences, and priorities for healthcare themselves due to a health crisis or emergency. This is a critical step to enabling a person-centered healthcare system and is often the easiest and most frequently completed step in the advance care planning (ACP) process. These documents enable the voice of the individual receiving care to be honored through a trusted designee. The health condition of individuals can be highly complex and unique, making statutory documents difficult to honor in some cases, but the voice of the individual represented through a trusted designee can bring the person-centeredness of care back into focus. Further, the term “Durable Medical Power of Attorney” is only found on a subset of existing statutory documents, as it is a highly prescriptive term with a narrow legal definition. The term “**Healthcare Agent**” is a broader term that encompasses the content that can be identified and exchanged, of which the “Durable Medical Power of Attorney” is a subset. Concepts such as “Resident Representative,” “Healthcare Proxy,” and “Health Care Surrogate” from existing forms and documents would be reflected in the proposed Healthcare Agent data element, and those instruments do not use the “Durable Medical Power of Attorney” term. In many states, the valid expression of designating a person to speak on the individual’s behalf can be done via verbal, recorded, or hand-written means and retains a legal status that is able to be honored without the legal formality that a “Durable Medical Power of Attorney” requires. We recommend the more inclusive term of “Healthcare Agent” for this data element.

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Care Team Member(s)	Proxy Decision Maker	Remove from Level 0 and do not promote	The proposed data element's concepts are accommodated in the previously detailed "Healthcare Agent" data element making this data element redundant.
Goals and Preferences	Religious & Spiritual Preferences	Remove from Level 0 and do not promote	The proposed data element's concepts are accommodated in the existing value sets which will populate the content found in the new data elements "Treatment Intervention Preferences" and "Care Experience Preferences" and is therefore redundant. Further, it does not refer to the many different *cultural* or *values-based* goals, preferences, and priorities that an individual may want to express so as to guide their care or treatment, making it too narrow to achieve the intended purpose.
Orders	Orders	Promote from Level 2 to USCDI v5	The organizing concept of an Order data class will enable other concepts to be associated such as those listed below, all of which are essential to fully accommodating the voice of the individual receiving care.
Orders	Orders for End of Life Care	Promote from Level 2 to USCDI v5 and Modify Name of Data Element	Portable medical orders are a familiar concept to the majority of healthcare practitioners and emergency responders and include not only those state-specific instruments known as POLST or MOLST, but also include statutory instruments used predominantly by EMS responders such as Do Not Resuscitate (DNR), Do Not Attempt Resuscitation (DNAR), and Out of Hospital DNR (OOH-DNR) emergency orders. The term "Portable" indicates that these orders apply across care settings and follow the individual, rather than being applicable to only one encounter of care. In addition, these orders are not *SOLELY* related to end-of-life (EOL) care. For example, in Maryland, all adults over 18 years of age are encouraged to have current Maryland MOLST documents active as they move through the healthcare system which means they apply to the whole population of that state and are therefore not restricted to only those experiencing an EOL health condition. Hence, the name "**Portable Medical Order**" is more inclusive and representative of the vast array of documents that exist within this

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			category of practitioner-authored advance healthcare decision documents in use today.
Orders	Portable Medical Orders for Life-Sustaining Treatments	Remove from Level 0 and do not promote	The proposed data element's concepts are accommodated in the recommended data element "Portable Medical Orders" and is therefore redundant. Further, it has a narrow scope that in actuality is no longer used by most state organizations that guide the rules surrounding them, including National POLST, which refers to its recommended standardized model form without the words "for Life-Sustaining Treatments." This is an outdated and redundant term with our above recommendation to use "Portable Medical Order" for this data element.
Provenance	Author	Promote from Level 2 to USCDI v5	Technology has made it easier than ever for people to self-monitor their own health and participate in their own care using tools such as apps, devices, and sensors. This information can be used to understand progress, deterioration, or cyclical variations in health conditions. This information can further offer a depth of insight that has not been available in the past and can illuminate previously unappreciated patterns and trends relevant to the person's health or disease state. There is a legacy clinician bias or reluctance to accepting person-authored information of all kinds due to their concerns about being liable for any information that is not authored by, or validated by, a clinician. While there is the notion in clinical document architecture (CDA) of "Performer" of an observation, which is often considered the "Author" by systems and their users, there is an opportunity to clearly define through standards who is the "enterer" and who is the "doer" of the observation activity. A Preference is a "self-observation" and is an important aspect of data exchange, accessibility, and inclusion into electronic systems to ensure is accommodated. All that said, promoting this data element to USCDI v5 would enable systems to clearly delineate the information accessible to them based on the source of the information, potentially reflect it differently in the system than information

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			authored by clinicians or care teams, and would further enable recognition of the value of the patient and their information while also fostering compliance, buy in, and respect.

Since 2007, ADVault has focused solely on empowering individuals, including Medicare beneficiaries, to have a voice in their healthcare, especially during those times in their lives when they experience a medical emergency or health crisis and cannot communicate with those providing care and treatment. ADVault provides digital solutions that enable creation and update of structured, interoperable personal advance care plans and interoperable creation and storage of scanned paper advance care planning (ACP) documents. Our solutions facilitate ACP management for individuals, providers, and health systems such as MyDirectives®, our free consumer-facing ACP platform, and MyDirectives for Clinicians™, our provider-facing ACP solution which enables healthcare providers to manage their ACP process and the resultant documents, including creation of structured, interoperable POLST, MOLST, and other similar portable medical order forms. ADVault also works with some of the largest healthcare payers in the United States to support engagement of their members in the process of creating, storing, and sharing high-quality digital ACP documents and portable medical orders such as DNR and POLST forms. We provide those health plans with reports and analytics to help them comply with requirements established by the Centers for Medicare & Medicaid Services (CMS) for Value-Based Insurance Design (VBID) Model participation.

In addition to the products we have created, which tangibly demonstrate our company's commitment to supporting the evolution of the U.S. healthcare system to a truly person-centered care delivery model, we have devoted thousands of staff hours to the work HL7® undertakes as they create interoperable data standards to support the data exchange and accessibility of ACP documents and portable medical order forms across transitions of care within the unique care settings. Our leadership co-authored the development of the Personal Advance Care Plan (PACP) Clinical Document Architecture (CDA) Implementation Guide (IG) in 2015, the Consolidated CDA (C-CDA) Supplemental Templates for Advance Directives in 2018, both of which were recently updated in 2023, and most recently is leading the Advance Directive Interoperability (ADI) Fast Healthcare Interoperability Resources (FHIR) IG development that enables interoperable data exchange of jurisdictional advance directive, personal advance care plan, and portable medical order documents.

We are aware of the concerns expressed by other commentators that the inclusion of digital patient treatment and care preferences in the electronic medical record is "too difficult" or "too complicated" due to state variations of ACP documents and terminology used. As part of the standards creation projects we have been intimately involved in leading however, we worked with a wide variety of other HL7 standards development participants to conduct exhaustive environmental scans to ensure we included as many versions of these forms as possible to inform our standards creation work. We have further been guided by large, actively-contributing communities comprised of healthcare workers, medical professionals, ethicists, electronic medical record vendors, personal health record vendors, and various other thought leaders on this topic. Our leadership is often relied upon to advise the industry and associations on the importance of interoperable ACP documents as experts in this space, and we evangelize the work frequently through our speaking engagements, publications, and educational sessions across the country. These projects often bring the opportunity to engage with, and educate, not only stakeholders at CMS, the ONC, and representatives of DHS but also those executives or front-line workers within the healthcare system, as part of the culture change required to actively lead the nation's efforts to ensure these important documents can be accessed in a secure, interoperable, and standardized manner to inform care and treatment whenever, and wherever, they are needed. Based on the vast amount of these interactions and the work we have witnessed is currently live and in use in many care settings, we can tell you these standards are ready, they are mature, and their inclusion in USCDI v5 is necessary to continue to drive change and improve care.

In addition, the inclusion of the above detailed data classes and data elements in USCDI v5 will drive two much broader objectives of DHS, CMS/CMMI, and ONC – **health equity** and **patient access**. Racial minorities, ethnic minorities, and other historically marginalized populations such as LGBTQ2S+ individuals distrust the healthcare system. Ensuring their goals, preferences, and priorities for treatments and interventions are included in the systems used by healthcare teams can go a long way to decreasing this distrust of the healthcare system, especially if healthcare providers and their systems are able to easily retrieve digitized ACP documents to inform and shape personalized care and treatment. Ample published research also exists showing that ACP document completion rates for historically marginalized populations are about half of those populations that do not fall into this important category of individuals. Even when such documents exist, under the current paradigm, patients and their providers cannot find or access them in siloed EHRs – they have no idea how to look for them. As long as those systems are not required to surface those documents, if they indeed exist due to low confidence that they will be used to inform care, providers will continue to argue “there are no required standards” around ACP information as a basis for not providing personalized care during emergencies or health crises and will stick with their existing, one-size-fits-all “Standard of Care.” Including the above detailed data elements in USCDI v5 to remove that baseless argument is long overdue.

In short, we believe the ONC in concert with CMS and CMMI have made a great difference in both the healthcare provider space and the health plan payer industry with their recognition of the importance of ACP. However, we believe there are additional steps DHS, CMS/CMMI, and ONC can and should take to further enable people to be able to receive personalized, goal-concordant care which can reduce the cost of unwanted or low value care, or over-treatment, that costs the nation hundreds of millions of dollars each year. Increasing the confidence of the consumer that their ACP documents will be accessible to medical teams to inform the care they receive is based on what is important to them as individuals, due to the existence of advance healthcare decision document data classes and data elements that support data exchange by the nation’s electronic health information systems, and will go a long way to continuing the steady march of our healthcare system to being truly person-centered. Through USCDI we can move the technology companies that enable interoperable health information exchange to add the data classes and data elements to their systems that inform care and treatment plans based on the patient’s values, goals, and preferences for treatment interventions. For these reasons, ADVault **strongly promotes the recommendations we have provided for USCDI v5**. Thank you for your consideration.

Respectfully submitted,

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