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Micky Tripathi, PhD, MPP
National Coordinator
Office of the National Coordinator for Health Information Technology (ONC)
Department of Health and Human Services
Hubert Humphrey Building, Suite 729
200 Independence Avenue SW
Washington, DC 20201

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

Re: ONC's Draft United States Core Data for Interoperability (USCDI) Version 4

Dear Dr. Tripathi:

We appreciate the opportunity to submit comments on the Goals data class and the Treatment Intervention Preference and Care Experience Preference data elements proposed for USCDI v4. ADVault **strongly recommends** the inclusion of both data elements in USCDI v4.

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 suffer a medical emergency and cannot communicate with those providing care and treatment. ADVault provides digital solutions that facilitate advance care planning (ACP) such as MyDirectives®, our free consumer-facing ACP platform, and our ACP solutions for healthcare providers which enable them to manage their ACP process and the resultant documents. 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 the ACP and portable medical order documents 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, 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 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, however, we and other HL7 standards development participants conducted exhaustive environmental scans to ensure we included as many versions of these forms as possible to inform our standards creation work and have further been guided by large 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. We are often relied upon to advise the industry and associations on interoperability of ACP documents as experts in this space, and we evangelize the work frequently in speaking engagements and educational sessions across the country. These projects often bring the opportunity to engage with, and educate, stakeholders at CMS, the ONC, and representatives of DHS as part of the work required to actively lead the nation's efforts to ensure these important documents can be accessed in an interoperable and standardized manner to inform care and treatment whenever, and wherever, they are needed. Based on all of these interactions and the work we have witnessed, we can tell you these standards are ready, they are mature, and their inclusion in USCDI v4 is necessary to drive change and improve care.

In addition, the inclusion of the Treatment Intervention Preference and Care Experience Preference data elements in USCDI v4 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 EMR can help decrease this distrust of the healthcare system, especially if healthcare providers are enabled to easily retrieve digitized ACP documents. Ample published research also exists showing that ACP document completion rates for historically marginalized populations are about half of those populations that are not. Even when such documents exist, under the current paradigm, patients can't find them in siloed EHRs – they have no idea how to look for them. And EHRs don't have to surface those documents as long as they can continue to argue "there are no required standards" around ACP information. Including the Treatment Intervention Preference and Care Experience Preference data elements in USCDI 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 and inform the care they receive, due to the existence of advance healthcare decision document data classes and data elements during data exchange by the nation's EMR and EHR systems 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 recommends** the inclusion of both of these data elements in USCDI v4. Thank you for your consideration.

Respectfully submitted,

L. Scott Brown
President and CEO

Maria D. Moen
SVP Innovation & External Affairs

Advance Directives as a Data Class

Over the last few years, the Post-Acute Care Interoperability (PACIO) project has been developing FHIR IGs to support advance directive document interoperability. By way of background, the PACIO Project, established February 2019, is a collaborative effort between industry, government, and other stakeholders, with the goal of establishing a framework for the development of FHIR implementation guides to facilitate health information exchange. The PACIO ADI w/FHIR Project Scope Statement was approved by HL7 in December of 2020. Under this charter, PACIO has been actively engaging both the provider and data standards communities in weekly meetings and enabling participation in testing events (HL7 & CMS Connectathons) to validate consensus guidance for representing advance directive information using FHIR. The first FHIR IG resulting from this work, which guides person-authored ACP document exchange, was balloted in January of 2022 and is in the final stages of ballot reconciliation prior to being published as a Standard for Trial Use (STU)1 in 2023. An important aspect of the work undertaken was the thoughtful alignment of the previously established HL7® PACP CDA and C-CDA Advance Directive Template IG's with the FHIR IGs currently in development, as part of ensuring that a key outcome of the work enabled forward and backward compatibility within the implementer community between these data exchange mechanisms.

Testing activities and experience has validated the use of our IGs and increased, along with community involvement that has expanded understanding of the advance directive data class. This maturation process also has advanced the clarity and specificity of the terms used to describe the data elements associated with this important class of data.

One of the most important aspects to appreciate about advance directives is the complexity of the information due to authorship by different stakeholders. Data provenance is critical for advance directive information, which includes such person-authored documents as state advance directives and personal advance care plans.

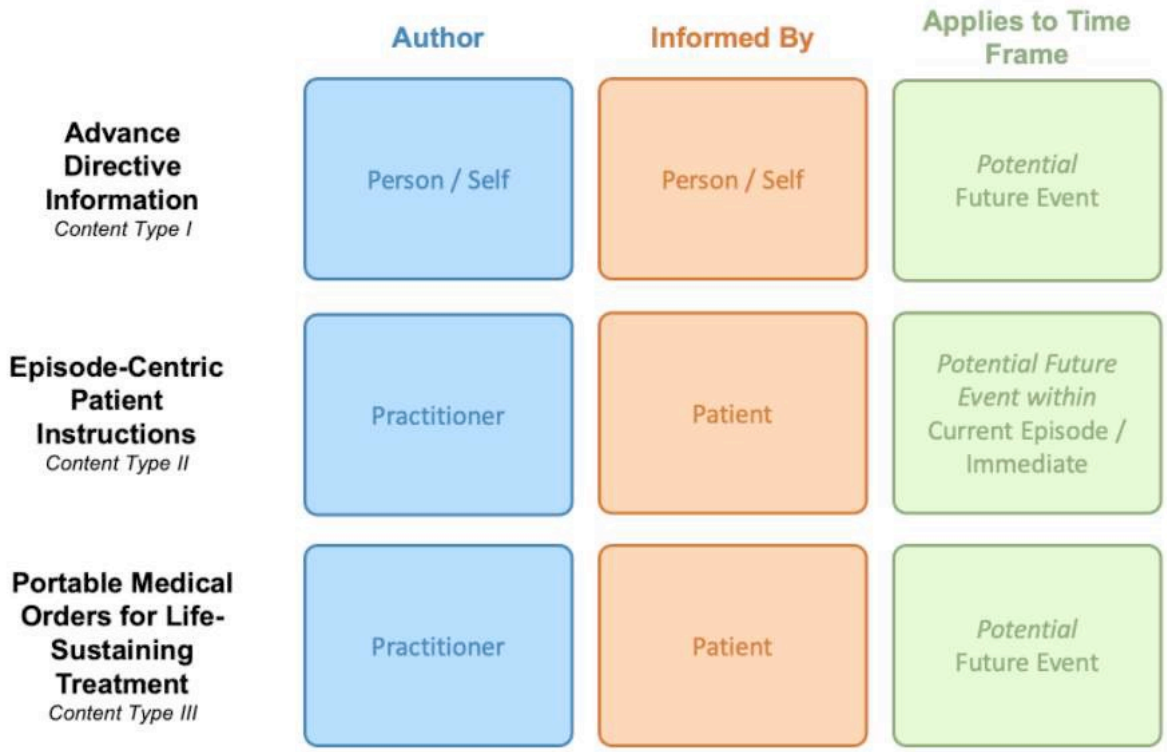
To address this complexity, the community has defined three categories of advance directive information.

- One of the categories describes information about a person's goals, preferences, and priorities for treatment interventions information authored by the individual themselves, which is the target of the ADI w/FHIR STU1 IG.

- For the other two categories that were defined, both of which represent practitioner-authored information which is based on the person's expressed treatment intervention preferences, one category treatment interventions related to the current episode of care, such as an In-Hospital DNR or DNAR order.

- The other category addresses practitioner orders for life-sustaining treatments should a future medical event require those decisions need to be made. There are multiple forms that are in use across the U.S. to represent this type of content such as POLST, MOLST, POST, MOST, and the like.

Below is an image of the three categories of advance directive information needed for interoperable data exchange, and the comparison of each to the total scope of ADI w/FHIR information that facilitates person-centered care planning and delivery:



Type I: Patient-Authored Advance Directive Information

- Person-authored information
- Used as a tool for sharing a person's goals, preferences and priorities (GPPs) for future care and treatment which can be grouped into four main areas:
    - Healthcare agent designation
    - Quality of life priorities
    - Care experience preferences
    - Treatment intervention preferences
- Provides guidance that a patient would want known as part of ensuring their care or treatment plan is informed by these documented GPPs during a potential future medical emergency, where the person is unable to communicate for himself or herself

Type II: Practitioner-Authored Encounter-Centric Advance Directive Information

- Practitioner-authored
- Physician documentation in the form of an order or chart note, created directly from the person's expressed GPPs as an Obligation or Prohibition for services
- Instructions are relevant to the current episode of care
- The person, or their healthcare agent, has provided direct input that practitioners take into consideration when creating instructions about treatments that shall or shall not be utilized during a medical emergency occurring within the current episode of care.

Type III: Portable Medical Orders for Life-Sustaining Treatments

- Practitioner-authored
- A set of medical orders intended to be portable or travel with a person and be actionable across the continuum of care

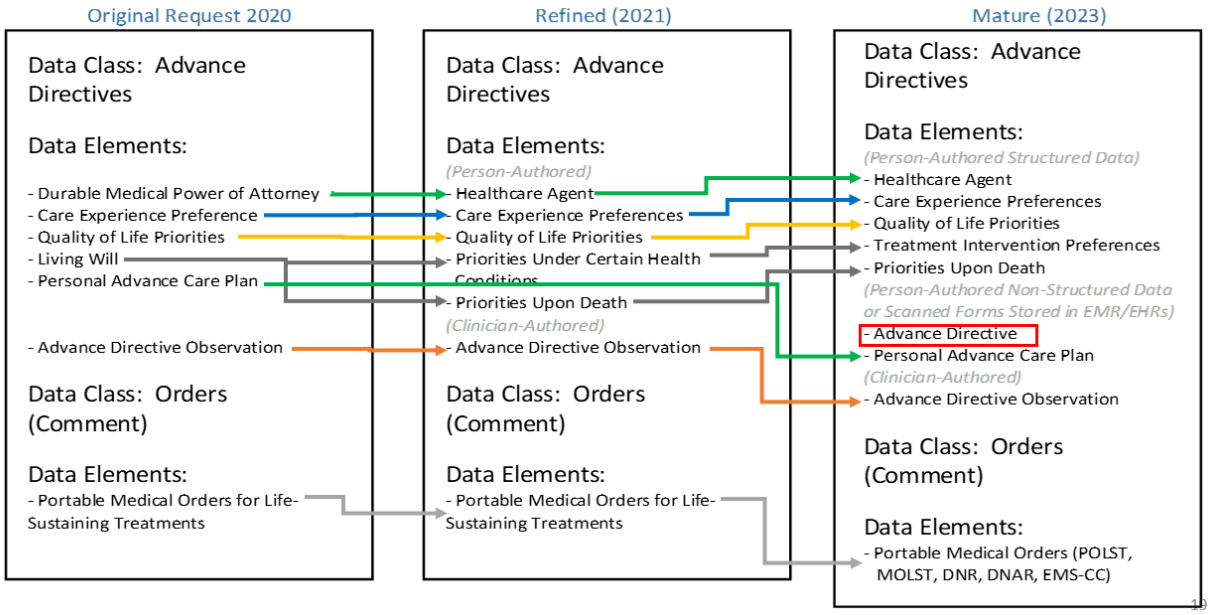
- The person, or their healthcare agent, provides direct input in the creation of the orders.
- These orders document a provider's directions regarding life-sustaining treatment interventions that shall or shall not be performed during a future medical emergency. The orders are based on a person's expressed preferences for or against the treatments under specific circumstances.

Over the past 2 ½ years, the work and testing within HL7 and the PACIO Community has brought about greater community consensus, drawn more implementers of the FHIR standard, and provided increased learning and experience around data exchange of standards-based advance directive information. Combined with our extensive updates to the Personal Advance Care Plan CDA IG to achieve greater alignment to the ADI w/FHIR IG, we have expanded our learnings to include both of the dominant mechanisms for data exchange of advance directive information.

These learnings have enabled greater clarity about the Advance Directive Data Class and Data Elements previously proposed for USCDI in 2020, including how the previously proposed Advance Directive Data Elements included concepts represented at different levels of organization. While some were specific data elements, others were collections that represented a bundle of data elements rather than a single data element. The feedback provided below explains recommended updates based on the considerable implementation experience with standards-based advance directive interoperability gained during the time this project has been working on data exchange of these important documents.

Based on the ongoing maturation in this area, there are recommendations for updates to the previously proposed Data Elements in the Advance Directives and Orders Data Class. The community that has advised our work, combined with the hundreds of forms reviewed and analyzed, have provided clarification of needed data elements, and how bundling of data elements would reveal more meaningful use and accessibility of these important documents. This complete write-up is being submitted to provide an overview of the full set of recommendations for advancement of advance directive interoperability Data Classes and the included Data Elements.

Recommendations Based on Expanding Experience in Testing and Implementing Standards for Advance Directive Interoperability



Update "Advance Directive" Data Class to USCDI v4

The first FHIR IG resulting from the work previously described, which guides person-authored ACP document exchange, was balloted in January of 2022 and is in the final stages of ballot reconciliation prior to being published as a Standard for Trial Use (STU)1 during 2023. Since December 2020, considerable progress has been made through testing and with implementer consensus about how to represent and exchange advance directive information using FHIR.

Over the last few years multiple organizations have used both CDA and FHIR standards to share person-generated information. In addition, the CDA guidance has been balloted twice within HL7 and is ready for v3 publication while the FHIR IG is finalizing ballot reconciliation in preparation for publication in 2023. As mentioned, the PACP CDA IG was aligned with the FHIR IG to ease implementer CDA to FHIR migration friction. The CDA data exchange has a distinct maturity level as it has been in production use for 5-6 years, further solidifying the need for the Advance Directive data class as an aggregator of the data elements listed below.

We strongly recommend this data class be advanced to USCDI v4.

Update "Advance Directive Observation" Data Element to USCDI v4

The clinician-authored data element of "Advance Directive Observation" is a critical component of the clinical workflow that enables recording and sharing information about available GPPs that may be considered under certain circumstances. This data element is typically captured in the context of a Patient Summary or Encounter Summary authored by a clinician or assembled in the clinician's EMR system. This observation is recorded when a clinician reviews and verifies, from a paper document, verbal instruction, or from a document viewed in the electronic health record, the presence of a person's advance healthcare decisions. The review and verification process, recorded as an observation, begins the workflow process of reflecting what the person wants in their personalized plan of care or treatment plan. The clinician needs to "confirm" that the instructions to receive or not receive treatment interventions are current and are therefore eligible for activating the rest of the workflow that initiates the plan of care.

Without the observation component, the instructions reviewed and verified are not able to be acted upon, making the observation and confirmation step a gateway to honoring the person's wishes. It should be noted that even portable medical orders, intended to be actionable across care settings, may require a clinical observation in some health systems and jurisdictions to begin the process of an encounter-centric advance directive order or note (Content Type II in the previous overview of ADI). As with person-authored information, the observation of a valid portable medical order initiates the workflow to reflect the obligation or prohibition of treatments in the personalized care plan.

We strongly recommend this data element be advanced to USCDI v4.

Remove the "Living Will" Data Element, and Advance 4 Distinct Data Elements "Care Experience Preferences", "Quality of Life Priorities", "Treatment Intervention Preferences", and "Priorities Upon Death" to USCDI v4 within the "Advance Directives" Data Class

As the healthcare system moves to a true person-centered delivery system where goal-concordant care is an essential part of achieving optimal outcomes, the current data element of "Care Experience Preferences" provides details on a person's preferences for their care experience based on cultural, religious or spiritual,

and personal preferences. The preferences expressed for how the person wants to experience care delivery is important to understand, honor and reflect in their plan of care.

- There is a LOINC Code that represents this data element (81338-6 Patient Goals, preferences, and priorities for care experience) which is included in both CDA and FHIR IGs defining standardized exchange of advance directive information.

- There is a well-established value set for representing care experience preferences. (Care Experience Preferences at End of Life Grouping, urn:oid:2.16.840.1.113762.1.4.1115.11)

Most treatments and interventions have a risk/benefit aspect to them, and it is the role of practitioners and clinical teams to provide care that results in the person enjoying some level of quality of life. The Level 1 data element of "Quality of Life Priorities" provides details on what the person defines makes a good quality of life for them, informed their own cultural, spiritual, or personal values, and can guide the decisions that clinical teams will make regarding treatment interventions.

- There is a LOINC Code that represents this data element (81340-2 Goals And/Or preferences in order of priority [Reported]) and it is part of both CDA and FHIR IGs.

- There is a well-established value set for representing priorities. (Health Goals at End of Life Grouping, urn:oid:2.16.840.1.113762.1.4.1115.7)

Advance the "Treatment Intervention Preferences" data element so that the important details about those treatments the person does, or doesn't, want to receive as part of urgent or emergent treatment decisions that need to be made can be informed by the person's GPPs. These decisions may be culturally or spiritually motivated or exist as a result of personal values or experiences that have necessitated the documenting of those preferences in order to inform medical teams of those treatments that should and should not be considered as part of their emergency treatment plan.

- There is a LOINC Code that represents this data element (81336-9 Patient Goals, preferences and priorities under certain health conditions) and instructions for using the code are included in both the CDA and FHIR IGs.

- Value sets for common treatments a patient may prefer to receive or not receive are defined and available for use in the NLM VSAC. (Intervention Preferences at End of Life, urn:oid:2.16.840.1.113762.1.4.1115.9 and Health Goals at End of Life Grouping, urn:oid:2.16.840.1.113762.1.4.1115.7) and instructions for using the codes are included in both the CDA and FHIR IGs.)

The combination of the data elements for "Care Experience Preferences", "Qualify of Life Priorities", and "Treatment Intervention Preferences" included together provide the essential information providers and caregivers need to understand about the people they treat as part of delivering personalized care.

While these elements of person-centered care can be expressed outside of advance healthcare decision documents as part of the patient discovery process, we strongly recommend that they be placed within the "Advance Directives" data class to preserve the context within which the information was gathered. The

context within which the GPPs were expressed is important to understanding how to activate the information within the clinical process that drives the plan of care.

- If a person is able to communicate their preferences for how they experience care in their current setting, or what makes a good quality of life for them personally in that moment, or make decisions about the treatments they do or don't want to receive as part of their current treatment plan, the context of having made those decisions is very distinct and actionable by the clinical team at that setting.

- However, if the person has memorialized those GPPs in an advance directive or personal advance care plan, then they are based on a conditional future health condition or crisis and are activated only when the individual is unable to communicate with the care team personally.

- It is important that what a person has documented is activated in the clinical workflow in the proper manner. GPPs made available under the context of Advance Directives would be used to inform the plan of care when the person is unable to tell the clinical team themselves what they want and don't want to receive in terms of care and interventions. GPPs made available under through verbal or written instruction by a person with capacity would mean that there is no future condition or situation needed to activate the information in the clinical workflow as the care team can confirmed those decisions with the person, or their caregiver, directly.

The data element of "Priorities Upon Death" provides details about the person's organ donation decisions, religious or cultural observances and rituals that they wish honored, and burial or funereal preferences should they pass away. This is all critically important information for providers and care teams to document and honor should the person pass away while in their care so that those very personal GPPs can be prepared for and honored, including decisions about the disposition of the body.

There is a tremendous need for organ donors in the U.S. and efforts to identify those who wish to donate organs or tissues upon death for a variety of reasons such as research, education, or to preserve and prolong the life of another human being is a basic right that can be exercised. Ensuring those priorities are available to medical teams is important to the many individuals who are waiting for those organs and tissues to have a better quality of life and is important to making sure that the healthcare system respects and honors the different cultures and religions that look at death rituals in diverse and important ways.

We strongly recommend the "Care Experience Preferences" data element be advanced to USCDI v4.
We strongly recommend the "Quality of Life Priorities" data element be advanced from Level 1 to USCDI v4.
We strongly recommend the "Treatment Intervention Preferences" data element be advanced to USCDI v4.
We strongly recommend the "Priorities Upon Death" data element be advanced to USCDI v4.

Modify "Durable Medical Power of Attorney" to "Healthcare Agent" and Advance to USCDI v4

While the concept of "Durable Medical Power of Attorney" remains important to be included in the USCDI, further community discussion led to modifying the data element from "Durable Medical Power of Attorney" to "Healthcare Agent". The notion of "Healthcare agent" is better described as a collection of data elements which may establish one or more "Durable Medical Powers of Attorney" and may include additional details about the specific powers or limitations associated with that established role.

Further, a person may designate an individual, or individuals, to make treatment decisions for them if they are unable to do so themselves and in many jurisdictional forms that role is referred to as the "healthcare agent". That designation of a healthcare agent is valid and legally enforceable without the services of a law professional in almost every jurisdiction, which a Durable Medical Power of Attorney requires, simply by documenting the information for the person who is to make decisions and obtaining witness or notary signatures to authenticate the designation.

It is important to note that while estimates of 1/3 of the adult population has completed an advance directive or personal advance care plan, most of which were completed on paper and are not available during a health crisis or emergency, the designation of a healthcare agent is perceived as a much more palatable step to take and in many cases can be more effective in guiding treatment than documented GPPs can be. The complexity of the disease process combined with the variability of individual human factors can make adherence to documented GPPs difficult to accomplish without the guidance of a designated healthcare agent who can advise clinical teams when decisions need to be made that weren't well accommodated on advance directive or advance care plan documents.

- There are LOINC Codes that represents this data element and it is part of both CDA and FHIR IGs. (81335-2 Patient Healthcare agent)

- There is a well-established value set for representing a primary, secondary, or tertiary healthcare agent when multiple agents are established. (Healthcare Agent or Proxy Choices, urn:oid: 2.16.840.1.113762.1.4.1046.35)

We strongly recommend this data element be advanced to USCDI v4.

Advance the "Personal Advance Care Plan" data element from Level 1 to USCDI v4 and Advance the "Advance Directive" data element to USCDI v4.

The existence of CDA guidance and FHIR guidance related to advance directive information is gaining traction across the nation, especially in view of the COVID-19 pandemic that raised awareness of these critical documents' role in supporting person-centered care. However, the documents that make up these two primary sources of person-authored GPPs has been based on paper for decades and until systems are required to make them available to inform care, may continue to exist on paper as well as in systems. Electronic health record systems have been storing scanned images of these forms for some time, and those documents need data elements to be eligible for data exchange if we are to begin to see them move across the healthcare continuum.

The implementors of the CDA and FHIR IGs for advance directive information appreciated that our work has resulted in guidance of how to exchange meaningful information when the data is structured and can be parsed into data elements such as have been described in this document. However, their feedback from ballot was often to point out that currently they house thousands of scanned paper images and there needs to be a way to increase data exchange and accessibility of those documents when there are not structured and cannot fit into the data elements described previously in this letter.

We strongly recommend that these data elements be advanced to USCDI v4 to enable scanned, unstructured ADI to be exchanged and accessible by systems.

Advance "Orders" Data Class to USCDI v4, and Change the "Orders for End of Life Care" Data Element to "Portable Medical Orders" and Advance to USCDI v4

These orders, intended to inform urgent and emergent care decisions that may at some point need to be made for a person, are established by a practitioner regarding treatments that restore, sustain, or prolong a patient's life. These types of medical orders are intended to be consistent with the patient's instructions and wishes.

While the concept of this data element remains important to be included in the USCDI, further community discussion led to modifying the data element from "Portable Medical Orders for Life-Sustaining Treatments" to "Portable Medical Orders". There is strong consensus among the medical community who authors these orders, and National POLST, that much more than life-sustaining treatment information is found on these documents and that having the additional words is not only mis-leading but is inaccurate.

They recognize that the previous concept of "Portable Medical Orders for Life-Sustaining Treatments" was too narrowly focused and additional practitioner-authored orders should be included such as DNRs, DNARs, and EMS-Comfort Care orders are part of this set of documents and are part of the ADI w/FHIR IG.

In addition, the wording "End of Life" is not accurate as there are some jurisdictions, Maryland to name a specific one, that suggests MOLST forms be created for all medical or clinical encounters, not just those that are related to end-of-life care. The delivery of care for those with chronic illnesses or life-limiting diseases such as cancer can span months and even years in many cases. While the creation and periodic update of portable medical orders may be best practice for these individuals, the instructions found in these orders may be activated during a non-life-ending health crisis from which the person recovers and goes on to live a longer life. Calling this category of orders that can follow a person across care settings and even across geographical locations anything more than portable medical orders fosters and feeds the mistaken perception that only those that are within a year or less of life expectancy should create one of these documents with their practitioner and this is not the case.

We strongly recommend the Orders data class be advanced to USCDI v4 and that the Portable Medical Order data element be added within the Orders Data Class in USCDI v4.

Conclusion

The recommendations provided for consideration continue to mature through thoughtful discussion, ongoing testing of the FHIR IG and increased adoption of the CDA IG for advance directive information. The result of the proposed changes will incorporate the guidance and experience of the clinical, practitioner, legal, systems, and subject matter experts who have informed our work for roughly 2 ½ years through weekly calls and meetings.

We strongly encouraged the Health Information Technology Advisory Committee to move the data elements contained in this document as recommended. The data elements as proposed and listed below are on cycle to progress to USCDI V4 in 2032 upon the publishing of ADI w/FHIR IG later this year, issuance of the updated PACP CDA v3 IG later this year, and publication of an ePOLST CDA IG last fall 2022. The clinicians that are part of the ADI w/FHIR community have been especially insistent that we must liberate this personal information from the bonds of paper it has been chained to for decades and create the on-ramp for a person-centered healthcare system that is based on a person's GPPs for care and treatment. We support their request and feel that we learned from the recent pandemic our healthcare delivery system has to

change and be focused on the people it serves and what is important to them if it is to survive. We believe this document includes vital elements of moving that goal forward and enabling people to have a clear voice in their care.