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HL7 CDA® R2 Implementation Guide: Personal Advance Care Plan (PACP) Document Edition 1 STU3 – US Realm

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HL7 STU

Sponsored by:
Structured Documents Work Group
Patient Care Work Group

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Structure of This Guide

Two volumes comprise this *HL7 IG for CDA® Release 2: Personal Advance Care Plan.* Volume 1 provides narrative introductory and background material pertinent to this IG, including information on how to understand and use the templates documented in Volume 2. Volume 2 contains the normative Clinical Document Architecture (CDA) templates for this guide along with lists of all templates, code systems, value sets, and changes from the previous version.

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Primary Editor/Co-Editor		
Lisa Nelson, MS, MBA	Maria D. Moen	Matt Elrod, PT, DPT, MEd
Natasha Kreisle		
Structured Documents Work Group Leadership		
Russell Ott	Gay Dolin MSN RN	Benjamin Flessner
Austin Kreisler	Sean McIlvenna	Andrew Statler
Matt Szczepankiewicz		
Patient Care Work Group Leadership		
Stephen Chu	Laura Heermann RN, PhD	Jay Lyle
Michelle Miler	Michael Padula MD, MBI	Emma Jones
Michael Tan		
PACP Content Contributors and Reviewers		
M'Lynda Owens, PhD, RN-BC, CHDA	David Tao, D.Sc.	Brian Scheller, MBA
Terrence A. O'Malley, MD	Judith R. Peres, LCSW-C	John F. Derr, RPh
L. Scott Brown	Ferdinand L. Mirarchi, D.O., FAAEM, FACEP	Rob Hausam
Joseph Schneider, MD	Rodolfo Alvarez del Castillo, MD	Michael Wasserman
Dan Morhaim	Remington Johnson	Dan Hanfling

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Evelyn Gallego	Swapna Bhatia	Douglas Renfield-Miller
Liz Palena Hall	Zabrina Gonzaga	

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1 INTRODUCTION

1.1 Purpose

This two-volume implementation guide (IG) defines the CDA R2 based templates for representing Personal Advance Care Plan (PACP) documents and advance directive documents which are both person-authored. It describes the document design and its envisioned use in information exchange (Volume 1). It contains a library of CDA templates applicable to the US Realm which can be applied to the HL7 CDA R2 standard to facilitate creation, validation, and consumption of information in the PACP format (Volume 2).

The terms in the name have been selected to communicate five key characteristics about this type of information exchange artifact:

1. Personal – While most other information in a care plan may be prepared by clinicians, this information is authored by the individual, possibly with the assistance of family, caregivers, or healthcare agents. This information expresses the individual's advance personal goals, preferences and priorities for medical treatments in advance of when the information may be needed because the individual is unable to communicate for his or herself.
2. Advance – The information is prospective. It is generated in advance of when it may be needed under certain emergency or critical care situations, or in circumstances associated with severely debilitating illness.This information expresses the individual's advance personal goals, preferences and priorities for medical treatments in advance of when the information may be needed because the individual is unable to communicate for his or herself.
3. Care – The information expresses the individual's preferences for his or her care experience and medical interventions.
4. Plan – The information describes a plan in that it proposes a course of action to be carried out or goals to be accomplished in the future.
5. Document – The information follows the document metaphor and document principles established by the HL7 Clinical Document Architecture standard.

The term "advance directive" in this IG does not refer to a specific form, document, or method of memorializing advance care planning, but is instead an overarching term used to describe all types of advance directive information. Advance directive information can be organized into three distinct categories. The HL7 FHIR PACIO Advance Directive Interoperability Implementation Guide defines these three categories as:

Content Type 1: Person-Authored Advance Directive, and Advance Care Plan Information,

Content Type 2: Encounter-Centric Documentation of existing Patient Care Goals and Treatment preferences and Current Instructions (obligations and prohibitions) and

Content Type 3: Portable Medical Orders for Life-Sustaining Treatment.

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This IG focuses on defining a standard representation for the above-described Type 1 Content.

This version of the IG does not define any additional templates. Modifications have been made to align this work with additional advance directive data exchange standardization taking place in the HL7 FHIR PACIO Advance Directive Interoperability Implementation Guide. and HL7 CDA R2 Implementation Guide: ePOLST: Portable Medical Orders About Resuscitation and Initial Treatment and clarify how this guidance fits in with the entire body of advance directive data exchange guidance being developed within HL7.

1.2 Prerequisite Information

Readers of this implementation guide should first read the HL7 FHIR PACIO Advance Directive Interoperability Implementation Guide.

For guidance on the use of CDA to exchange, share and retrieve the information previously described as Type 2 Content, reference HL7 CDA® R2 Implementation Guide: C-CDA R2.1 Supplemental Templates for Advance Directives, Release 1, STU2 - US Realm to facilitate exchange, sharing, and retrieval of Encounter-Centric Documentation of existing Patient Care Goals and Treatment preferences and Current Instructions.

For guidance on using CDA to exchange, share and retrieve practitioner-authored medical order information for the National POLST form, readers should consult the current version of the HL7 CDA R2 Implementation Guide: ePOLST: Portable Medical Orders About Resuscitation and Initial Treatment.

1.3 Audience

The audience for this IG includes implementers creating personal advance care plans and patient-authored advance directive information. The IG also is relevant to system architects and developers of healthcare information technology (HIT) systems in the US Realm that exchange clinical and non-clinical data. Business analysts and policy managers also benefit from gaining a basic understanding of the advance directive information use cases addressed by this IG. Finally, Quality Reporting Agencies, Standards Development Organizations (SDOs), Payors, Providers and Patients will benefit from this IG as it explains information representation details that are valuable when designing quality measures and expanding coded vocabularies.

1.4 Approach

Implementation Guidance for creation of a PACP document has been developed to align and be consistent with guidance and CDA templates established within the HL7 Consolidated CDA Release 2.1 IG.

Some of the content in this IG is similar to information in C-CDA, but has been further constrained. Other information has been created specifically for this IG.

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1.5 Organization of the Guide

This IG is organized into two volumes. Volume 1 contains material describing the context for creation and use of a PACP document. Volume 2 contains CDA template definitions.

1.5.1 Volume 1 Introductory Material

Volume 1 provides overview and background information that forms a context for understanding the purpose of a PACP document.

- **Chapter 1**—Introduction.
- **Chapter 2**—Background. This chapter contains background information about the information exchange needs and requirements addressed by the PACP document.
- **Chapter 3**—Design Considerations. This chapter includes design considerations that are addressed by the PACP document templates. It includes additional information and narrative guidance about how to use the templates defined in Volume 2 of this IG.
- **Chapter 4**—Using This IG. This chapter describes the rules and formalisms used to constrain the CDA R2 standard. It describes the formal representation of CDA templates, the mechanism by which templates are bound to vocabulary, and additional information necessary to understand and correctly implement the normative content found in Volume 2 of this IG.
- **Appendices**. The Appendices include a summary of format codes, a summary of extensions to CDA R2, and a crosswalk between the coding specified for content in the PACP document and the coding defined in C-CDA R2.1 for summarizing different types of advance directive and advance care plan information that a person may have documented.

1.5.2 Volume 2 CDA Templates and Supporting Material

Volume 2 includes CDA templates and prescribes their use for a set of specific document types. The main chapters are as follows:

- **Chapter 1**—Document-Level Templates. This chapter defines the US Realm Document and Header templates for the PACP and advance directive documents.
- **Chapter 2**—Section-Level Templates. This chapter defines the section templates referenced within the document template. A section template may contain other templated patterns within its design. Section templates can be reused by future specifications.
- **Chapter 3**—Entry-Level Templates. This chapter defines entry-level templates referenced within the section templates of this document. Entry-level templates are called clinical statements. They are used to encode information from a section of the document as machine processable data. Entry-level templates are always contained in section-level templates, and section-level templates are always contained in a document. Entry-level templates establish an allowable

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clinical statement pattern. An entry-level template may contain other templated patterns within its design. They can be reused by future specifications.

- **Chapter 4**—Template Ids in this IG**.**
- **Chapter 5**—Value Sets in this IG**.**
- **Chapter 6**—Code Systems in this IG.
- **Chapter 7**—Changes from previous versions.

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2 BACKGROUND

At some point in their lives, usually because of illness, a health crisis, or an emergency, many people will lose the ability to make medical decisions or communicate what they want from their health care. The documents that allow you to spell out your healthcare preferences ahead of time - so you continue to get the care you want and avoid treatments you do not want - are advance care plans which are one form of advance directives. These documents help patients and their families. It has been found that advance care planning helps people to have improved satisfaction with their quality of care, receive less intensive treatments at the end of life, receive care and even pass away in their preferred place, and reduce unwanted hospitalizations. Advance care planning also results in lower stress, depression and anxiety in the relatives of those who survive the person who has passed away.

Research from the Kaiser Family Foundation indicates that 92% of people say that talking to their loved ones about end-of-life care is important to them, but only 32% have actually done it. Similarly, 82% of people believe that it's important to put their values, preferences and priorities in writing, but only 23% of them have done it.[1]

In considering treatment decisions, your personal values are key. Is your main desire to have the most days of life? Or, would your focus be quality of life, as you personally define it? What makes life meaningful to you? If your heart stops or you have trouble breathing, would you want to receive life-sustaining treatment if it meant that, in the future, you could be well enough to spend time with family or doing the things you love the most to do? Would you be happy with your quality of life if an emergency leaves you simply able to spend your days reading or watching TV or gazing out the window at your favorite view? These are just a few of the scenarios to consider. Advance care plans are excellent tools for enabling a person's very unique, values-based thoughts to be memorialized beyond what statutory advance directives typically enable. An advance care plan or advance directive allows you to provide instructions for these types of situations and then to change the instructions as you get older or as your viewpoint changes. Advance directive information is critical to providing patients the care they both want and need. They effectively spell out the person's individual thoughts and expectations on balancing survival against quality of life - an important distinction in an age of ever-advancing technology and ability to prolong life artificially. They protect both patient interests and providers, yet another contentious issue in a litigation-prone era. Advance directive information belongs at the center of electronic health record systems and the pursuit of seamless interoperability - not as an afterthought. The effective, streamlined integration of advance directive information into digital records should be the benchmark for evaluating electronic health record and personal health record technologies, both in terms of their function and connectivity.[2]

If you are awake, alert, and competent, you have the power to make your own medical decisions about the care you want and don't want. But what happens when you can't speak for yourself due to an emergency or health crisis? Who speaks for you? That's when an advance directive or an advance care plan comes into play. In that document,

[1] https://www.washingtonpost.com/outlook/2020/03/23/end-life-coronavirus/
[2] https://www.healthitanswers.net/advanced-directives-and-interoperability-2/

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you can select others who would make those decisions for you, and you can specify the level and kind of care you want.

Advance directives typically consist of two main elements – a "living will," and a "medical power of attorney." A living will usually covers only specific life-sustaining treatments such as CPR (cardiopulmonary resuscitation), artificial nutrition (tube feeding) or artificial hydration (intravenous fluids), dialysis or the use of a ventilator to help with breathing in the event that you suffer a medical emergency and are unable to communicate with the medical team. You might also want to prepare documents that memorialize your values about a single medical issue or something not already covered in an advance directive, which is when a personal advance care plan can be an important complement to your advance directive. A medical power of attorney is used to designate one or more people to serve as advocates or "healthcare agents" empowered to make medical treatment decisions on your behalf if you are incapacitated and cannot communicate with medical providers.

Advance directives and advance care plans, whether written or recorded through electronic means, advisory or in a formal statutory document, are tools that give patients of all ages and health status the opportunity to express their values, goals of care, and treatment preferences to guide future decisions about the health care they may receive.

Thought leaders and healthcare policymakers have taken note of the need to address these issues. In its September 2014 report, the IOM committee states, "Electronic storage of advance directives, statements of wishes, health care proxies, or other relevant materials – either in the person's electronic health record or an external database – holds promise for solving some current problems with these documents." In Objective 6 of its Meaningful Use Stage 3 final rule with comment period published in the Federal Register on October 16, 2015, HHS also called for improvements in care coordination through patient engagement, specifically calling out the incorporation of patient generated and/or non-clinical data such as the information included in advance directives as a means for providers to satisfy Measure 3 of that objective. Quality Assurance and Performance Improvement (QAPI) requires all Long Term Care facilities to develop, implement, and maintain an effective comprehensive, data-driven QAPI program that focuses on systems of care, outcomes of care and quality of life which is informed by advance care planning documents. Person-centered care planning that requires a baseline care plan for each resident, within 48 hours of admission, which includes the instructions needed to provide effective and person-centered care that meets professional standards of quality care.

Additionally, the IMPACT Act of 2014 requires, among other things, that certain providers including long term care facilities take into account informing and assisting with the discharge planning process that takes into account treatment preferences and goals of care of residents.

If your health care team is uncertain of your goals, preferences and priorities for medical interventions, due to the absence of advance directive information, they may insist on prolonging care or performing invasive treatments on your behalf. These interventions can have serious side effects and result in low quality of life. When you document treatment preferences early, you are able to ensure medical care received in the future matches what was wanted and avoids unwanted heroic measures that are not desired. It also may result in the avoidance of unnecessary suffering, and ease

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decision-making burdens for your family and friends during moments of crisis or grief. Health IT systems should enable individuals to communicate information about their advance goals, preferences, and priorities to inform provider-generated care and treatment plans so these benefits can be realized for all patients, regardless of socio-economic status, so that health equity can be realized for all who pass through the healthcare system.

2.1 What is the PACP document?

The PACP document is a CDA document template designed to share information created by an individual to express his or her care and medical treatment goals, preferences, and priorities for some future point in time, under certain circumstances when the individual cannot make medical treatment decisions or communicate his or her goals, preferences, and priorities with the care team.

Within the family of documents that have been defined under Consolidated CDA, the PACP document can be classified as a type of Patient Generated Document. The PACP document facilitates digital exchange of information previously and currently captured and shared using paper documents. It may include information relating to any or all of the following: the person authoring the advance care plan; designated healthcare agents and their powers and limitations; goals, preferences, and priorities for care (e.g., palliative and/or hospice care) and medical treatment at the end of life (e.g., attempts at resuscitation) or following death (e.g., organ donation and autopsy); other personal goals, preferences, and priorities relevant to care planning; and information about who has signed, witnessed, and notarized the information authored by the individual, if available and appropriate.

2.2 Why is digital exchange for advance care plan information needed?

Digital information exchange standards are needed to support within the emerging HIT ecosystem sharing of information generated by a patient or person involved in care activities directly or indirectly. Systems that create and manage patient-centered care plans need a standardized means for individuals to share information about their care and medical treatment goals, preferences, and priorities in order to support a patient-mediated process.

Individuals need a way to generate information about their health goals, treatment and care experience preferences and personal priorities so that their wishes will be considered when providers create and update their care plan.

Enabling interoperable exchange of this information makes it more possible (and likely) that a person's care plan will be centered on the person's goals, preferences and priorities.

2.3 Risk mitigation for common digital exchange issues?

When locating and retrieving digital documentation, there are challenges that must be addressed. These challenges exist for digital exchange of all types of documents and thus are relevant and need to be considered when exchanging PACP documents.

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1. Patient matching challenges. When a unique identifier is not available to reliably match patients across disparate systems, consideration must be given to metadata fields that will be used to support reliable patient matching. Systems such as Master Patient Index solutions can be used to minimize risks associated with identifying patients accurately.

2. Authorization to access the needed information. Business and technical processes are needed to determine and support information access that is appropriate and allowed given the considerations governing access to the information. These processes must address authorization from the declarant seeking to access the information and internal processes that control allowable authorization from inside an information source organization.

3. Authentication. Business and technical mechanisms are also needed to mitigate risks associated with establishing and confirming the identity associated with a person/system seeking to access patient information. All systems need policies and procedures to address this issue. Adherence to High Trust Information Security standards is a common level of adherence to best practices.

4. Accurate semantic meaning of digitized information. There also are risks associated with automated processing of coded data that may or may not fully capture the semantics of the associated information. Links between the narrative and coded clinical data are not sufficient to overcome this risk. This IG employs an approach to data representation that only codes questions used to determine a patient's care preferences under certain potential future situations. The answers to those questions are never coded. This ensures human intervention to understand and apply the information as input to care planning. This approach reduces the potential risk of machine processing of discretely coded data.

2.4 What are the envisioned Use Cases?

The purpose for exchange of PACP documents is to support person-centered emergency, critical and advance care planning. A system supporting the person who is authoring his or her advance care plan information would be acting as the Content Creator to create or update the PACP document. A system supporting a clinician or care team member who is authorized to review the advance care plan information would be acting as the Content Consumer to view, import, and/or consume content represented in the PACP document. The Content Creator and Content Consumer roles are technical roles that could be played by a PHR, an EHR, or any other system that fulfills the functional capabilities of creating or consuming the PACP document.

For use cases describing the exchange of patient authored advance directive information (Advance Directives Content Type 1) refer to the HL7 FHIR PACIO Advance Directive Interoperability Implementation Guide.

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3 DESIGN CONSIDERATIONS

This chapter describes the overall design for the PACP document. The design considerations are organized to do the following:

1. Describe the functional requirements to be addressed by information shared in the defined document.
2. Explain how the document template design supports multiple levels of machine readability for information exchanged and why all levels of exchange are valuable when sharing PACP documents.
3. Explain why the PACP document establishes tighter conformance requirements between a section's human readable text and the associated machine-readable entries.
4. Show how the design of the PACP document relates to the design of other C-CDA document types.
5. Explain why the entry-level templates used in a PACP document utilize standardized questions where possible and do not constrain the associated answers.
6. Clarify the sections of information when a structured body is used.
7. Describe standard information about roles and events populated in a CDA document header as they pertain to the PACP document.
8. Explain why assertion of template conformance in a document instance enables validation and improves interoperability.

3.1 Functional and content requirements for PACP documents

A PACP document needs to address, at a minimum, the following functional purposes:

Functional Requirements

1	Communicate the designated health care agent(s) that will represent the author's instructions related to treatment goals, preferences and priorities for care if there is a time the author is unable to do so due to incapacity of some kind.
2	Communicate instructions and choices to guide the designated healthcare agent(s) including potential limitations on "standard" powers granted to healthcare agents in a given jurisdiction or organization.
3	Communicate goals, preferences and priorities for medical treatments and interventions that may be made in an emergency or during a health crisis, to include palliative and hospice care, such as are typically found in living wills or other similar jurisdictional documents.
4	Communicate goals, preferences, and priorities following death, such as organ donation, autopsy, burial or funeral plans, etc.
5	Communicate other aspects of advance care planning content such as preferences for their care experience, priorities for what they define as a

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	good quality of life and goals of care (e.g., attend daughter's wedding, pass away at home, or avoid long-term dependence on machines), which are consistent with the author's personal, cultural, religious, or spiritual values.
6	Communicate whether the individual reserves or waives the right to change all of his/her goals, preferences, and priorities, even if he/she is later determined to be legally incompetent (because some jurisdictions allow for this).
7	Enable individuals to create and share advance care planning information with others in an interoperable, standards-based manner.
8	Update and share newer versions of personal advance care plan information with others.
9	Request and access the current version of a person's PACP document in a healthcare emergency or a critical care situation if the person cannot make medical treatment decisions or communicate with the care team.
10	Request and access the current version of a person's PACP document in a situation that is not a healthcare emergency or a critical care situation, and where the person is able to make medical treatment decisions and communicate with the care team.
11	Request and access previous versions of a person's PACP document.

A PACP document needs to specify how implementers can express the following types of content.

Content Requirements

1	Information used to identify and contact healthcare agent(s), as well as choices and instructions relevant to the healthcare agent's powers and limitations.
2	Personal health goals, treatment and care experience preferences, and priorities relevant for emergency, critical and end-of-life care and medical treatment decisions (including palliative care and/or hospice care).
3	Personal goals, preferences, and priorities pertinent following death, such as organ donation, autopsy, burial or funeral plans, etc.
4	Personal care planning goals, treatment and care experience preferences, and priorities which may be relevant for care and treatment decisions but not specific to emergency, critical or end-of-life care (e.g. attend daughter's wedding, die at home, messages for caregivers, likes and dislikes).
5	Indication of whether the individual reserves or waives the right to change all of his/her goals, preferences, and priorities, even if he/she is later determined to be legally incompetent (because some jurisdictions allow for this).

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6	Information to identify the entity responsible for maintaining original personal advance care plan information and digital instances of that information created for sharing with others.
7	Information needed to identify versions of personal advance care plan information as it existed and was saved or shared over time.

3.2 Support for multiple levels of machine readability

The design of the PACP document supports three different levels of machine readability. It allows for the exchange of an unstructured document, a Level Two CDA document, or a Level Three CDA document. As health information exchange of patient-generated information transitions from paper-based to digital sharing mechanisms, a gradual transition will need to be supported.

The PACP document standard supports multiple levels of machine readability so that implementers can gradually and incrementally improve the level of machine readability supported in data sharing documents as consensus around the representation of patient-generated data grows. The costs and challenges of encoding information for higher levels of machine readability also need to be weighed against the benefits. Further, findings from a study of the quality and variability of C-CDA documents produced by Meaningful Use Stage 2 Certified EHRs published in the Journal of American Medical Informatics Association in 2014 suggest that many EHR systems are not yet able to produce CDA documents of the quality required to support semantically interoperable data exchange.[3] As of 2022 there is little evidence that EHR systems' ability to process and exchange structured data has significantly improved.
While exchange of fully machine readable CDAs may be a future aim, exchange of human readable information in CDA documents is attainable today. The PACP document is specified to support multiple levels of machine readability so as to meet the needs of an evolutionary approach to adoption.

As background, implementers need to understand there are four kinds of HL7 CDA templates: (1) those that constrain the header and body of the document (document-level templates); (2) those that constrain the sections used to make up the body of a document (section-level templates); (3) those that constrain the entries that are used within sections (entry-level templates); and (4) those that constrain participations or act relationships used within other templates, not on their own. Templates are used to tailor the use of the HL7 CDA standard for exchange of particular types of information. A variety of terms are used to characterize the level of machine readability supported by a CDA document.

Different levels of granularity can be used to characterize the machine readability of the contents of a CDA document. The definitions below are established in the CDA R2 standard:

[3] D'Amore JD, et al. J Am Med Inform Assoc 2014;21:1060-1068. doi:10.1136/amiajnl-2014-002883. https://academic.oup.com/jamia/article/21/6/1060/2909300

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Table 1: Definition of CDA Levels from the HL7 CDA R2 standard.

Level	Definition in CDA R2
CDA Level One	The unconstrained CDA specification.
CDA Level Two	The CDA specification with section-level templates applied.
CDA Level Three	The CDA specification with entry-level (and optionally section-level) templates applied.

An unstructured CDA document may or may not assert conformance to a document-level template for the header content, but it has a non-xml body. The non-xml body is sometimes called an "unstructured" body, hence the term "unstructured document."

When a CDA document includes constraints at the section-level of the document, a machine readable section code is used to represent the type of information in the section.

When a CDA document includes constraints at the entry-level of the document, coded machine readable data is included to aid computer processing of the information contained in a document's sections.

3.2.1 Benefits of PACP unstructured CDA document exchange

Exchanging a PACP document as an unstructured document actually includes a great deal of structured information in the document's header, because it conforms to a specified PACP document header template.

Use of an unstructured PACP document offers a more attainable first step when taking a phased approach to adoption even though there is not structured information in the body. The rich range of structured data available in the header makes it possible to associate the PACP document with the correct person. The header information also can be indexed for efficient searching and retrieval. The structured data in the header also can be re-used by document consuming applications to support other data processing functions.

Figure 1: Unstructured PACP – Embedded

```
<ClinicalDocument xmlns="urn:hl7-org:v3"
                  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
                  xmlns:cda="urn:hl7-org:v3" xmlns:sdtc="urn:hl7-org:sdtc">

  <realmCode code="US"/>
    <typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040"/>
    <!-- PACP Header -->
    <templateId root="2.16.840.1.113883.4.823.1.2.1" extension="2022-03-25"/>
```


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```
    <!-- PACP Document -->
    <templateId root="2.16.840.1.113883.4.823.1.1.1" extension="2022-03-25"/>

. . .

    <code  code="81334-5" displayName="Personal advance care plan"
                codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
    <title>Personal Advance Care Document</title>


  ...

    <!-- CDA nonXML Body -->
    <component>
        <nonXMLBody>
            <text mediaType="application/pdf" representation="B64">
JVBERi0xLjQNJeLjz9MNCjI2IDAgb2JqDTw8L0xpbmVhcml6ZWQgMS9MIDE0MzcxMC9P

…

ZWFtDWVuZG9iag1zdGFydHhyZWYNMTE2DSUlRU9GDQ==
            </text>
            </nonXMLBody>
    </component>
</ClinicalDocument>
```

Figure 2: Unstructured PACP – Referenced

```
<ClinicalDocument xmlns="urn:hl7-org:v3"
                  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
                  xmlns:cda="urn:hl7-org:v3" xmlns:sdtc="urn:hl7-org:sdtc">

  <realmCode code="US"/>
    <typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040"/>
    <!-- PACP Header -->
    <templateId root="2.16.840.1.113883.4.823.1.2.1" extension="2022-03-25"/>
    <!-- PACP Document -->
    <templateId root="2.16.840.1.113883.4.823.1.1.1" extension="2022-03-25"/>
. . .

    <code  code="81334-5" displayName="Personal advance care plan"
                codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
    <title>Personal Advance Care Plan Document</title>

  ...
   <!-- CDA Body -->
     <!--Example of referenced document-->
   <component>
      <nonXMLBody>
         <text>
             <!-- This example assumes the pdf is in the same directory as the
CDA document. -->
             <!-- Assumptions about file location need to be addressed by
implementation. -->
            <reference value="Roger_McBee_2014-08-20.pdf"/>
         </text>
      </nonXMLBody>
   </component>
</ClinicalDocument>
```

3.2.2 Benefits of PACP Level Two CDA document exchange

Due to the nature of the content expressed in a PACP document, machine processing of individual clinical statements may be less needed for effective sharing of this type of

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content. PACP documents primarily are intended to be read and understood by humans involved in the care planning process. The documents permit information to be shared that expresses the wide variety of personal thoughts and considerations that individuals may wish to share regarding the care experience in emergency, critical, and end-of-life medical situations when they can't speak for themselves.

While encoded header information will improve access and offer many helpful machine processable data elements, coded section content makes content in the documents more accessible and more understandable.

A Level Two CDA PACP document includes structured content within the body of the document. A framework of section-level coding creates a context that gives machine processable meaning to the various human readable component sections of the document. The machine readable section-level information indicates the type of information in each section, the author of the section, the subject, and other participant information that tells a computer about the information in each section. In essence, the body of a Level Two CDA document is communicated in meaningful, machine processable parts. The sections of the document are coded in ways that allow a computer to discern one part from another and the type of content contained in each part is standardized.

Exchanging a Level Two CDA PACP document offers all the same benefits associated with sharing a CDA unstructured document because it conforms to the same PACP document header template. Additionally, using the section code information, a machine can find the individual sections of a PACP document. A Level Two CDA PACP document can be parsed by a computer to quickly identify the section of the document that includes information about the person's healthcare agent assignments or the section that includes his or her preferences upon death. Specific sections of the document can be rendered by the receiving application without requiring the human reader to scan through the whole document to find the needed information.

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Figure 3*: *Level Two CDA PACP Document

```
<?xml version="1.0" encoding="utf-8"?>
<?xml-stylesheet type="text/css" href="Sample_CDA_Style_Sheet-4.0.2-beta-
11/CDA.xsl"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xsi:schemaLocation="urn:hl7-org:v3
20201029_SDTC/infrastructure/cda/CDA_SDTC.xsd"
 xmlns="urn:hl7-org:v3" xmlns:sdtc="urn:hl7-org:sdtc">
  <realmCode code="US" />
  <typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040" />
  <templateId root="2.16.840.1.113883.10.20.29.1" extension="2015-08-01" /> <!-
- C-CDA Patient Generated Document Header -->
  <templateId root="2.16.840.1.113883.4.823.1.2.1" extension="2022-03-25" />
<!-- PACP Document Header -->
  <templateId root="2.16.840.1.113883.4.823.1.1.1" extension="2022-03-25" />
<!-- PACP Document -->
  <id root="2.16.840.1.113883.3.3208.101.4.27.1" extension="20130607100315-
CCDA-CCD-2701" />
  <code code="81334-5" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Personal advance care plan" />
  <title mediaType="text/plain" representation="TXT">Betsy's Personal Advance
Care Plan Document (Version
    1)</title>
 ....
   <component>
    <structuredBody>


      <component>
        <section>
          <templateId root="2.16.840.1.113883.4.823.1.3.7" extension="2022-03-
25" />
          <code code="81381-6" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Administrative information associated with
this personal advance care plan" />
          <title mediaType="text/plain" representation="TXT" language="en-
US">Administrative Information</title>
          <text>
            <paragraph ID = "AI_1">
            <content ID = "AI_1_1">
              <content styleCode="Bold">It is very important for you to discuss
your
              medical treatment goals and wishes with your healthcare agent,
your family, and your
              medical care providers.</content>
              Keep in mind that advance medical directives are
            simply expressions of your medical treatment goals and preferences.
There is no
            guarantee that your medical care providers will follow all of your
wishes, but one
            thing is certain:
              <content styleCode="Bold">If your advance medical directives
cannot
              be quickly located and retrieved in a time of need, then medical
care providers,
              your family and friends will not be able to take your wishes into
consideration when
              they make critical decisions regarding your treatment.</content>
            </content>
            </paragraph>

            <paragraph ID = "AI_2">I am emotionally and mentally competent to
make this uADD. I understand the
                purpose and effect of this uADD, I agree with everything that
is written in this uADD,
```


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```
                and I have made this uADD knowingly, willingly and after
careful
                deliberation.</paragraph>


            <paragraph>
              <content ID="HCA_3" styleCode="Answer">
                <content ID="HCA_3_C"> If at some point in the future I am
declared incompetent, </content>
                <content ID="HCA_3_PL"> I DO NOT want to be allowed to override
these preferences.
                      I want my doctors to follow the preferences I express in
this document.
                    </content>
              </content>
            </paragraph>
          </text>
          </section>
      </component>
....

      <component>
        <section>
          <templateId root="2.16.840.1.113883.4.823.1.3.5" extension="2022-03-
25" />
          <code code="81337-8" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Patient Goals, preferences, and priorities
upon death" />
          <title mediaType="text/plain" representation="TXT" language="en-
US">Preferences Upon Death</title>
          <text>
            <content ID="GPP_ud_1">
              <content ID="GPP_ud_1_Q" styleCode="Bold">Organ
Donation:</content>
              <br />
              <content ID="GPP_ud_1_A" styleCode="Answer"> I would like to
donate all organs and
                    tissues that would be useful for someone else.</content>
            </content>
            <br />
            <br />
            <content ID="GPP_ud_3">
              <content ID="GPP_ud_3_Q" styleCode="Bold">Autopsy:</content>
              <br />
              <content ID="GPP_ud_3_I" styleCode="Answer">I want an
autopsy</content>
              <content ID="GPP_ud_3_C_1" styleCode="Answer">only if there are
questions about my
                    death or</content>
              <content ID="GPP_ud_3_C_2" styleCode="Answer">a law enforcement
official requests it.</content>
            </content>
            <br />
            <br />
            <content ID="GPP_ud_5">
              <content ID="GPP_ud_5_Q" styleCode="Bold">Death
arrangements:</content>
              <br />
              <content ID="GPP_ud_5_A" styleCode="Answer">
                Please call Jim Houston, my lawyer, for arrangements I have
already made. I have purchased a funeral plat at
                    Graceful Acres in Belmont NC and have life insurance
policies filed with my
                    lawyer that you should access if anything happens to me.
                </content>
            </content>
            <br />
```


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```
            <br />
          </text>
          </section>
      </component>

....
    </structuredBody>
  </component>
</ClinicalDocument>
```

3.2.3 Benefits of PACP Level Three CDA document exchange.

A Level Three CDA PACP document includes a structured header just as described for the unstructured and Level Two CDA PACP document. It includes structured sections within the body of the document, just as described for a Level Two CDA PACP document. Additionally, a Level Three CDA PACP document includes machine readable entries which encode some or all of the human readable information recorded in the document's sections.

Exchanging a Level Three CDA PACP document offers all the same benefits associated with sharing a CDA unstructured or Level Two CDA PACP. It conforms to the same PACP header template and uses the same section-level coding. Additionally, entry-level information (discrete data elements, not just high-level sections) of a Level Three CDA PACP document can be parsed by a computer. The human readable information in a section also is included as machine readable structured data. Inclusion of additional machine coded entries may offer less utility, at least initially, compared to the benefits of exchanging unstructured or Level Two CDA PACP documents. For more information on the benefits of exchanging unstructured CDA and Level Two CDA PACP documents. See section 3.2.1 and section 3.2.2, respectively for more information about the benefits of unstructured CDA and Level Two CDA PACP documents.

When exchanging a Level Three CDA PACP, not only can each section of the PACP be found and displayed rapidly, but in addition, information like the healthcare agent name and contact information or organ donation preference information could be processed by the application as machine readable data. This capability is not feasible when the PACP is a Level Two CDA and the information in the document is only available as human readable text.

It is important to note there are risks associated with automated processing of coded data. These risks exist for processing all types of coded data, but should be highlighted for the PACP use case due to the nature of the content. Coded data may not accurately include nuances present in the narrative text. A PACP document contains content expressing a patient's preferences for care, especially in critical care decision-making situations. For this reason, this IG takes the approach of coding the questions and not the answers. The questions are coded as discrete data to support faster retrieval of needed patient input. Answers however remain a narrative component of the digitally shared information. Care providers must read and interpret the patient preferences, priorities and goals. This avoids inherent risks that could be introduced by automated processing. Human interpretation is not removed from the automated processes made possible by sharing PACP documents.

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Figure 4: Level Three CDA PACP Document

```
<ClinicalDocument xmlns="urn:hl7-org:v3"
                  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
                  xmlns:cda="urn:hl7-org:v3" xmlns:sdtc="urn:hl7-org:sdtc">

  <realmCode code="US"/>
<typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040" />
  <templateId root="2.16.840.1.113883.10.20.29.1" extension="2015-08-01" /> <!-
- C-CDA Patient Generated Document Header -->
  <templateId root="2.16.840.1.113883.4.823.1.2.1" extension="2022-03-25" />
<!-- PACP Document Header -->
  <templateId root="2.16.840.1.113883.4.823.1.1.1" extension="2022-03-25" />
<!-- PACP Document -->
  <id root="2.16.840.1.113883.3.3208.101.4.27.1" extension="20130607100315-
CCDA-CCD-2701" />
  <code code="81334-5" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Personal advance care plan" />
  <title mediaType="text/plain" representation="TXT">Betsy's Personal Advance
Care Plan Document (Version
    1)</title>
  ....
      <component>
        <section>
          <templateId root="2.16.840.1.113883.4.823.1.3.7" extension="2022-03-
25" />
          <code code="81381-6" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Administrative information associated with
this personal advance care plan" />
          <title mediaType="text/plain" representation="TXT" language="en-
US">Administrative Information</title>
          <text>
            <paragraph ID = "AI_1">
            <content ID = "AI_1_1">
              <content styleCode="Bold">It is very important for you to discuss
your
              medical treatment goals and wishes with your healthcare agent,
your family, and your
              medical care providers.</content>
              Keep in mind that advance medical directives are
            simply expressions of your medical treatment goals and preferences.
There is no
            guarantee that your medical care providers will follow all of your
wishes, but one
            thing is certain:
              <content styleCode="Bold">If your advance medical directives
cannot
              be quickly located and retrieved in a time of need, then medical
care providers,
              your family and friends will not be able to take your wishes into
consideration when
              they make critical decisions regarding your treatment.</content>
            </content>
            </paragraph>

            <paragraph ID = "AI_2">I am emotionally and mentally competent to
make this uADD. I understand the
                purpose and effect of this uADD, I agree with everything that
is written in this uADD,
                and I have made this uADD knowingly, willingly and after
careful
                deliberation.</paragraph>


            <paragraph>
              <content ID="HCA_3" styleCode="Answer">
```


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```
                <content ID="HCA_3_C"> If at some point in the future I am
declared incompetent, </content>
                <content ID="HCA_3_PL"> I DO NOT want to be allowed to override
these preferences.
                     I want my doctors to follow the preferences I express in
this document.
                   </content>
              </content>
            </paragraph>
          </text>
          <entry>
            <observation classCode="OBS" moodCode="INT">
              <templateId root="2.16.840.1.113883.4.823.1.4.16"
extension="2022-03-25" />
              <id root="BU12AA2-6D83-5841-8C0C-695781NH36D" />
              <code code="81381-6" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Administrative information associated with
this personal advance care plan" />
              <text>
                <reference value="#AI_1" />
              </text>
              <statusCode code="completed" />
              <value xsi:type="ED">
                <reference value="#AI_1_1" />
              </value>
            </observation>
          </entry>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.4.823.1.4.19"
extension="2022-03-25" />
              <id root="C0E16C64-6D83-4611-8C0C-85472IJNH36D" />
              <code code="75774-0" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Allowance to change advance directive
preferences in the future regardless of mental state [Reported]" />
              <text>
                <reference value="#AI_2" />
              </text>
              <statusCode code="completed" />
              <effectiveTime value="202005011429-0500"/>
              <value xsi:type="BL" value="true"/>
            </observation>
          </entry>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.4.823.1.4.4" extension="2022-
03-25" />
              <id root="C0E16C64-6D83-4611-8C0C-19494F1CF36D" />
              <code code="75786-4" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Powers granted to healthcare agent
[Reported]" />
              <text>
                <reference value="#HCA_3" />
              </text>
              <statusCode code="completed" />
              <value xsi:type="ED">
                <reference value="#HCA_3_PL" />
              </value>
              <precondition>
                <criterion>
                  <value xsi:type="ED">
                    <reference value="#HCA_3_C" />
                  </value>
                </criterion>
              </precondition>
            </observation>
          </entry>
```


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```
        </section>
      </component>

  ....
      <component>
        <section>
          <templateId root="2.16.840.1.113883.4.823.1.3.5" extension="2022-03-
25" />
          <code code="81337-8" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Patient Goals, preferences, and priorities
upon death" />
          <title mediaType="text/plain" representation="TXT" language="en-
US">Preferences Upon Death</title>
          <text>
            <content ID="GPP_ud_1">
              <content ID="GPP_ud_1_Q" styleCode="Bold">Organ
Donation:</content>
              <br />
              <content ID="GPP_ud_1_A" styleCode="Answer"> I would like to
donate all organs and
                    tissues that would be useful for someone else.</content>
            </content>
            <br />
            <br />
            <content ID="GPP_ud_3">
              <content ID="GPP_ud_3_Q" styleCode="Bold">Autopsy:</content>
              <br />
              <content ID="GPP_ud_3_I" styleCode="Answer">I want an
autopsy</content>
              <content ID="GPP_ud_3_C_1" styleCode="Answer">only if there are
questions about my
                    death or</content>
              <content ID="GPP_ud_3_C_2" styleCode="Answer">a law enforcement
official requests it.</content>
            </content>
            <br />
            <br />
            <content ID="GPP_ud_5">
              <content ID="GPP_ud_5_Q" styleCode="Bold">Death
arrangements:</content>
              <br />
              <content ID="GPP_ud_5_A" styleCode="Answer">
                Please call Jim Houston, my lawyer, for arrangements I have
already made. I have purchased a funeral plat at
                    Graceful Acres in Belmont NC and have life insurance
policies filed with my
                    lawyer that you should access if anything happens to me.
              </content>
            </content>
            <br />
            <br />
          </text>
          <entry>
            <observation classCode="OBS" moodCode="INT">
              <templateId root="2.16.840.1.113883.4.823.1.4.12"
extension="2022-03-25" />
              <id root="E9C0C416-5B1A-4A09-A246-7108035D8BEE" />
              <code code="75781-5" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Thoughts on organ and tissue donations
[Reported]">
                <originalText>
                  <reference value="#GPP_ud_1_Q" />
                </originalText>
              </code>
              <text>
                <reference value="#GPP_ud_1" />
              </text>
```


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```
              <statusCode code="completed" />
              <value xsi:type="ED">
                <reference value="#GPP_ud_1_A" />
              </value>
            </observation>
          </entry>
          <entry>
            <observation classCode="OBS" moodCode="INT">
              <templateId root="2.16.840.1.113883.4.823.1.4.14"
extension="2022-03-25" />
              <id root="E6F6E2E3-EA61-4272-A042-A9EAACD45861" />
              <code code="75782-3" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Thoughts regarding autopsy [Reported]">
                <originalText>
                  <reference value="#GPP_ud_3_Q" />
                </originalText>
              </code>
              <text>
                <reference value="#GPP_ud_3" />
              </text>
              <statusCode code="completed" />
              <value xsi:type="ED">
                <reference value="#GPP_ud_3_I" />
              </value>
              <precondition>
                <criterion>
                  <value xsi:type="ED">
                    <reference value="#GPP_ud_3_C_1" />
                  </value>
                </criterion>
              </precondition>
              <precondition>
                <criterion>
                  <value xsi:type="ED">
                    <reference value="#GPP_ud_3_C_2" />
                  </value>
                </criterion>
              </precondition>
            </observation>
          </entry>
          <entry>
            <observation classCode="OBS" moodCode="INT">
              <templateId root="2.16.840.1.113883.4.823.1.4.17"
extension="2022-03-25" />
              <id root="22E8DC22-B0E5-4D73-8E19-8F0B2BF4C566" />
              <code code="81356-8" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Death arrangements [Reported]">
                <originalText>
                  <reference value="#GPP_ud_5_Q" />
                </originalText>
              </code>
              <text>
                <reference value="#GPP_ud_5" />
              </text>
              <statusCode code="completed" />
              <value xsi:type="ED">
                <reference value="#GPP_ud_5_A" />
              </value>
            </observation>
          </entry>
        </section>
      </component>

 ....

    </structuredBody>
  </component>
```


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```
</ClinicalDocument>
```

3.3 Required relationship between human readable information and machine-readable information

The C-CDA recommends that clinical statements include a link between the narrative (section.text) and coded clinical data (entry). The HL7 C-CDA R2.1 Companion Guide R3 includes additional guidance saying, "The narrative text linkages are the mechanism that associates human readable information in the narrative text of each section to the entries carrying that information for machine processing. Without proper narrative text linking, it is impossible to accurately validate if the machine-readable entries and the human-readable representation of that information accurately reflect the same semantic meaning."

The PACP IG raises the bar to enforce this best practice guidance as a requirement.

This is an additional requirement on PACP content creators which may carry additional development (hence cost) to ensure the linkages are included between the corresponding human readable and machine readable content.

As defined in the base HL7 CDA R2.0 standard, an XML tag used to markup the narrative text in a CDA document can be used to wrap a string of text so that it can be explicitly referenced, or so that it can suggest rendering characteristics. The XML markup elements can nest recursively, which enables wrapping a string of plain text down to as small a chunk as desired.

For example, the <content> element contains an optional identifier that can serve as the target of a reference. All values of attributes of type XML ID must be unique within the document (per the W3C XML specification). The text element of a CDA clinical statement entry and the text element of an originalText component of a RIM attribute present in any CDA entry can make explicit reference to the identifier associated with the corresponding human readable information. This linking mechanism permits the relationship between the human readable narrative text and its associated CDA entry or one of its coded attributes to be represented explicitly.

The CDA R2 standard does not require CDA entries to reference into the CDA Narrative Block. However, it states, "the referencing mechanism can be used where it is important to represent the original text component of a coded CDA entry."

To ensure the integrity of the information within a PACP document and as part of the approach taken in this IG to address the risks associated with processing discrete data (see section 3.2.3), the document includes valid text linking between all machine processable clinical statements and the associated human readable information intended to convey the same meaning. This constraint has been added to ensure that applications processing the machine-readable content of the document receive information with the same semantic meaning as its corresponding human readable representation. The constraint also ensures that all clinically relevant content in

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machine readable entries must also be represented in human readable form within the CDA narrative content. While this constraint does not eliminate the risk that the semantic meaning of coded data may not be identical to the meaning of the associated human readable information, it at least makes it possible to determine which human readable narrative is intended to hold the information that corresponds to the machine processable data.

Text linking for all machine-readable entries in a PACP document is required for several reasons:

- Text referencing is required to increase patient safety. Human verification of information that may be used in automated clinical decision support (CDS) applications is essential to prevent unintended data processing results. The "reference links" between human readable information and machine-readable information provide a mechanism that can be used to permit comparison to be made or facilitated as a human review to confirm if the narrative and machine encoded data provide information with the same semantic meaning.
- Text referencing provides a mechanism that can be used to permit comparison between the human readable information and the machine-readable information in a document. It can facilitate a human review to confirm that a CDA document does not include clinical content in machine readable form that is not also represented as human readable information. Performing comparison testing of this sort may require author participation or specialized clinical and/or technical knowledge. Text reference links also make it possible to confirm that an exchange document does not include additional machine encoded content that includes information other than what was consented to be shared.
- When the information being exchanged in a CDA document is highly sensitive to author attestation, such as attestation that the information in the document accurately reflects the author's personal goals, preferences and priorities for care and treatment, text referencing ensures high integrity for the data. It reduces the risk that machine readable information does not carry the same semantic meaning as its corresponding human readable information.
- Text referencing also ensures that a CDA document does not include any additional clinical content in machine readable form which is not also represented as human readable information that the author can verify with a simple, standard mechanism. This mechanism uses the text linking references in the entry.text and originalText attributes of the machine-readable entries to compare the structured data in the document with the corresponding human readable information in the section.text elements of the document.

3.4 Information relationships with other C-CDA information exchange artifacts

This section explains how patient generated information in a PACP document relates to and is compatible with physician generated information in the Advance directives section defined in Consolidated CDA which can be used in Clinical Summary and Care Plan documents.

Figure 5 establishes a wireframe illustration format that makes it easier to construct diagrams representing these information relationships. It shows how this wireframe

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format can be used to create a diagram of the information relationships within a Care Plan document that is equivalent to the Care Plan relationships diagram included in C-CDA. The left-hand side of the figure shows the illustration format used in C-CDA. The right-hand side shows the same set of relationships using the new wireframe format.

Figure 5: Translation of Prior Care Plan Diagram

Care Plan Relationship Diagram Expressed in Wireframe Format

C-CDA R2.0, R2.1

Figure 25: Care Plan Relationship Diagram

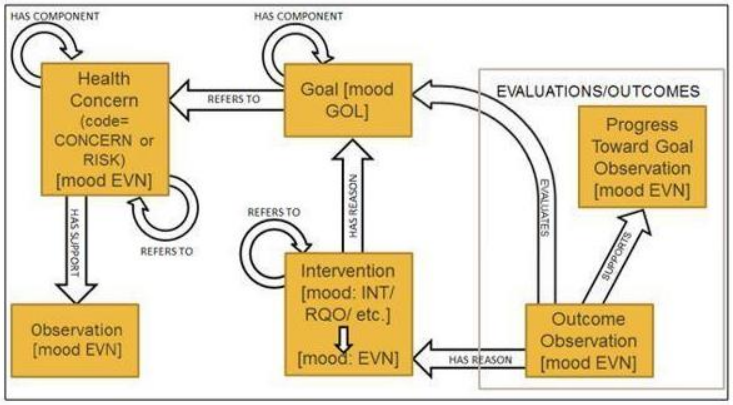

Table 10: actRelationship TypeCodes

Code	Display Name	Meaning
COMP	Has component	Shows that one component is part of another (overall goal has components consisting of one or more goals)
REFR	Refers to	Shows a general relationship between components (a goal refers to a health concern)
SPRT	Has support	Show that the one component is supporting evidence for another (Health Concern has support from a problem observation)
RSON	Has reason	Show the reason or rationale for a something (intervention has reason of achieving a goal)
GEVL	Evaluates goal	Used to link an observation (intent or actual) to a goal to indicate that the observation evaluates the goal

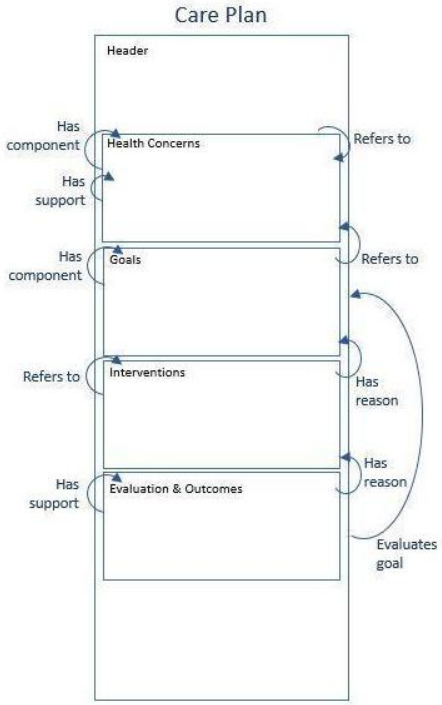

Figure 6 shows that information in the Advance directives section of a Clinical Summary can reference a PACP document as an external document (Arrow 1). Information in the Advance directives section can identify the person acting as the patient's healthcare agent. This information could come from the PACP document (Arrow 2). Information in the Advance directives section also can include observations made by the clinician about the type of advance care plan information that is available in the PACP document. The types of goals, preferences and priorities recorded in a PACP document could be determined based on the content in the PACP document (Arrow 3). (Note: the direction of the arrows shows newer information referencing previously created information. The Clinical Summary document contains information summarizing a care event that occurred after the PACP document information already existed. Thus, information in the Clinical Summary document references information in the PACP document.)

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Figure 6 also shows that information in the PACP document may provide the rationale for procedures and tests performed (or not performed) during the encounter or episode of care documented in the Clinical Summary (Arrows 4 & 5). Information in the PACP document also may provide the rationale for the recommended plan of treatment (Arrow 6).

Figure 6: Information Relationships: Clinical Summary to PACP document

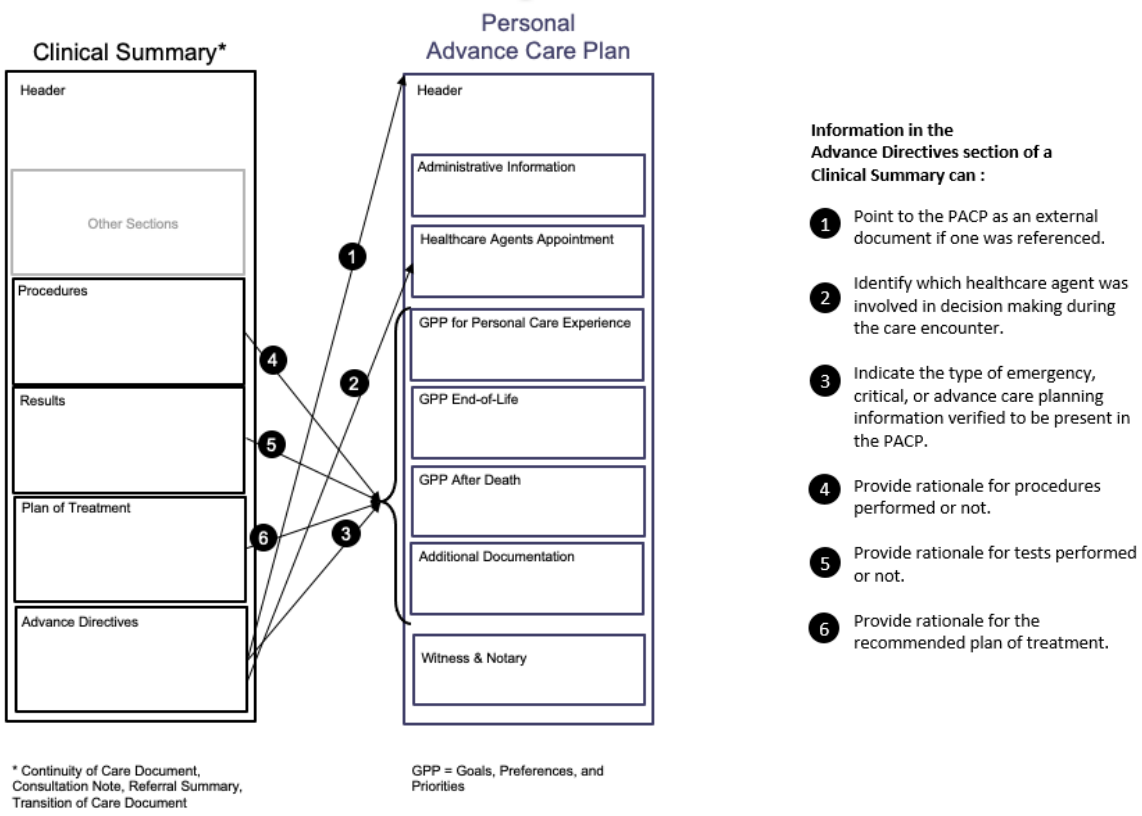

Figure 7 shows that a Care Plan document can include an Advance directives section because the template is an "open template" which permits additional sections of information to be included in the document (additional section shown in red). By including an Advance directives section, a Care Plan document can reference a PACP document as an external document (Arrow 7). Information in the Advance directives section can identify the person acting as the patient's healthcare agent. This information could come from the PACP document (Arrow 8). Information in the Advance directives section also can include observations made by the clinician creating the Care Plan about the type of advance care plan information available in the person's PACP document (Arrow 9).

Figure 7 also shows that information in the PACP document can inform the goals set by the clinician within the Care Plan (Arrow 10). Information in the PACP document also may provide the rationale for planned interventions (or interventions explicitly planned not to be performed) as part of the patient's Care Plan (Arrow 11). (Note: As in Figure 6,

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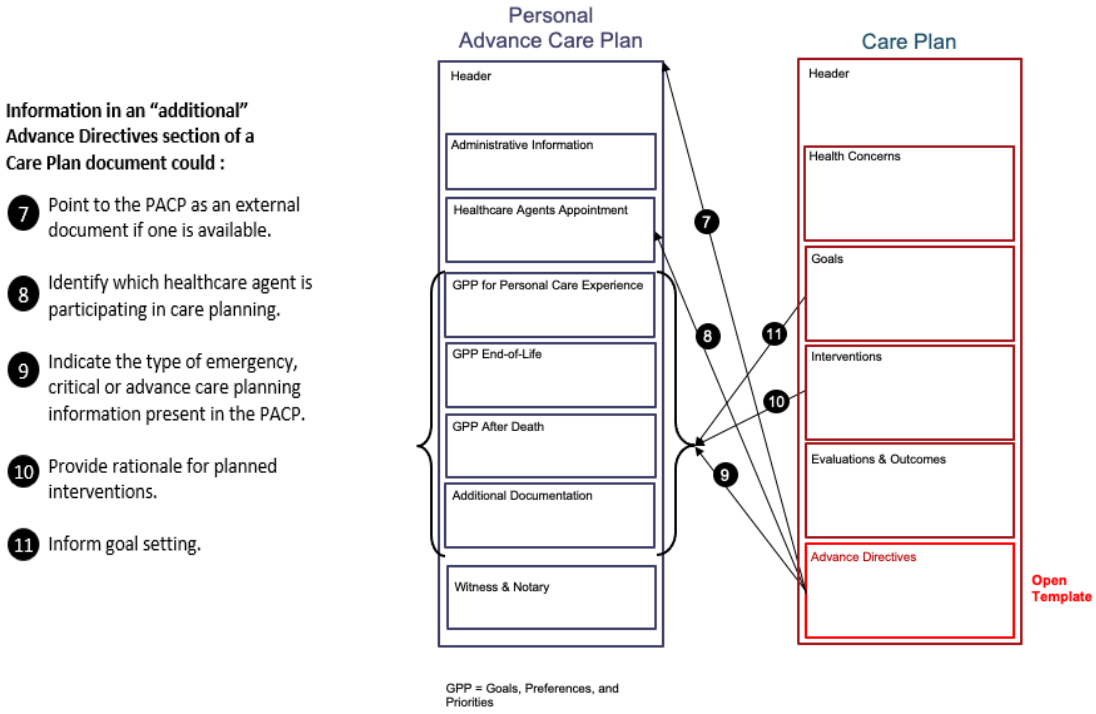
the direction of the arrows shows newer information referencing previously created information. The Care Plan document contains care planning information that was created after the PACP document information already existed. Thus, information authored by care providers in the Care Plan or in Clinical Summary documents references patient authored information in the PACP document.)

It is important to note that medical intervention decisions, when made, are documented as orders in a person's medical record. Decisions made take priority when it comes to delivering care. Advance directives are simply input provided for consideration when making medical intervention decisions. Information in advance directives is not legally enforceable. Advance directives provide a safe harbor when treatment decisions are made based on the advance directives provided. Medical orders (decisions made) do not need to be consistent with the input from the directives, though they certainly may be.

Figure 7: Information Relationship: Care Plan to PACP



The interoperability of the information shared in these CDA information exchange artifacts is possible due to the section-level and entry-level template designs developed in the PACP document specification. Careful consideration went into designing section-level and entry-level template patterns that align with the section-level and entry-level templates defined in C-CDA. The structure and vocabulary of the entry-level templates defined for the PACP document are intended to support this potential level of interoperability with Advance Directives Observation, Goal, Intervention, and other entry-level templates in Clinical Summary and Care Plan documents.

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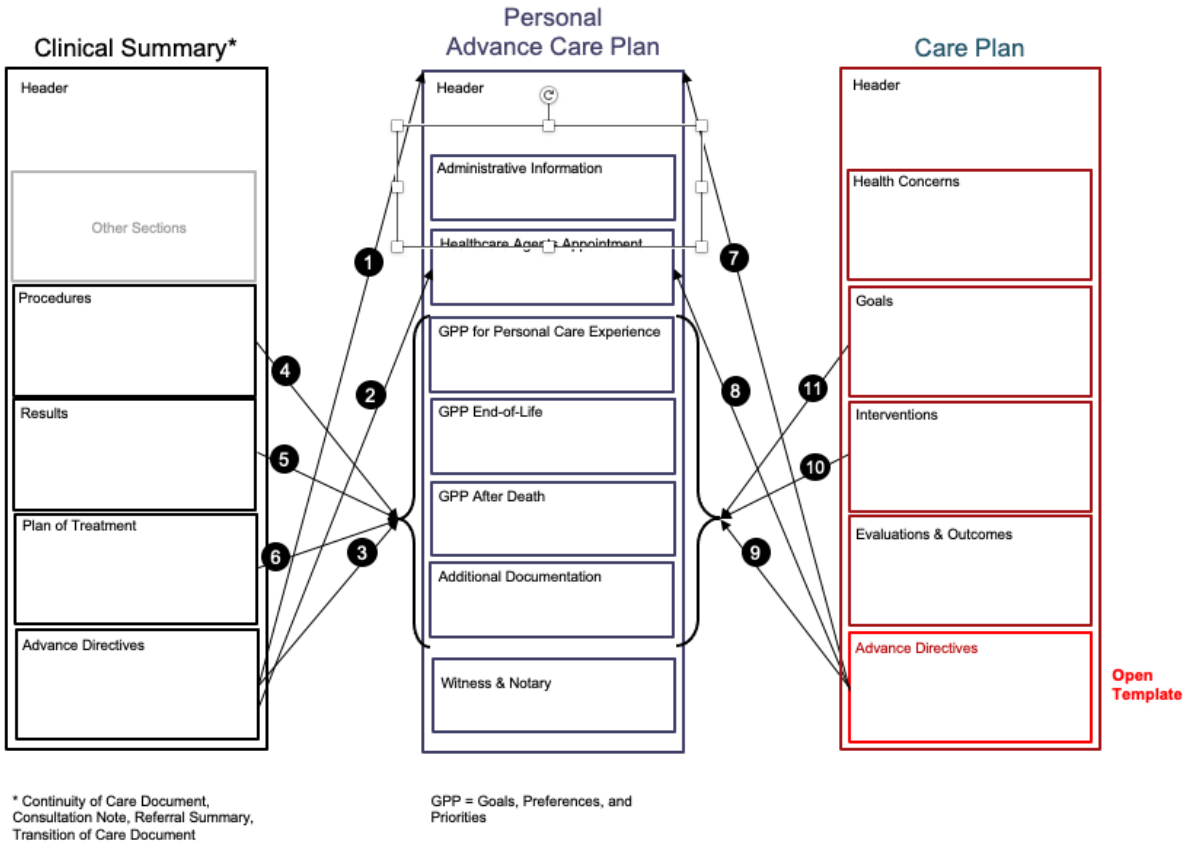
As advance care planning information becomes available digitally, additional consideration can be given to the processes used to verify the content expressed in standard PACP documents. Check-lists designed to guide clinicians in the review of patient-generated care planning information may reduce misunderstandings and minimize incorrect interpretation. Interactive forms used to record completion of verification steps could enhance patient safety and provide a record of the steps taken to review and incorporate patient goals, preferences, and priorities.

Figure 8 shows the combined view of the many relationships that can be established between patient-generated information in the PACP document and information recorded in EHRs by clinicians, then shared in Clinical Summary and Care Plan documents. It shows that information created by a person and shared in a standard digital CDA document can be re-used and referenced to make clinician documentation easier and more accurate. It can inform care delivery choices and care planning, making both more patient-centered, even when the patient's condition precludes participation in his or her care decisions.

Figure 8: Information Relationships: Combined View



3.4.1 Coded Content Crosswalk

Appendix C includes a content map which shows the crosswalk between: on one side the concepts used to encode personal goals, preferences, and priorities according to the PACP document standard, and on the other side coded concepts from the value set

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used within C-CDA R2.1 to summarize types of advance directives information recorded in a PACP document. The crosswalk enables a clinician to record what kind of advance care plan information is available in the person's referenced PACP document.

The crosswalk maps LOINC codes used in a PACP document to indicate the question a person is addressing in his or her advance care plan information to the corresponding SNOMED CT concepts used in an EHR to classify various types of advance directives content. For example, if a PACP document includes content encoded with the LOINC code 75787-2 (Thoughts on Intubation), then the clinician's system can use SNOMED CT code 52765003 (Intubation) to indicate that a person has documented intubation preferences.

Note that when an EHR records an Advance Directives Observation encoded with SNOMED CT code 52765003 (Intubation), the recorded observation does not indicate what the person's preferences were. It indicates the clinician observed that the person's advance care plan information includes preferences regarding intubation. In other words, the Advance Directives Observation in the Advance directives section of a Clinical Summary document summarizes the types of goals, preferences and priorities in the referenced PACP document. Also, when a clinician records an observation to indicate that a type of advance care plan information exists, it is not equivalent to recording an order to perform or an order not to perform a certain procedure. The recording of an Advance Directives Observation only classifies the types of information available in the referenced PACP document. Within an EHR, classification of the types of available personal advance care plan information can speed clinician access to person-centered information in time-sensitive decision-making situations such as organ donation, resuscitation, or initiation of emergency department services.

3.5 Use of coded questions in machine readable entries

One coding strategy used in the design of machine readable entry-level templates in the PACP document utilizes standardized coded concepts to encode the questions addressed within the information rather than the answers. This approach has been taken to maximize the ability for each person to personalize his or her answers, but at the same time improve the ease with which certain types of information can be identified within the document. The Personal Health Goal template [observation: identifier urn:hl7ii:2.16.840.1.113883.4.823.1.4.6:2022-03-25 (open)] and the Personal Intervention Preference template [observation: identifier urn:hl7ii:2.16.840.1.113883.4.823.1.4.5:2022-03-25 (open)] demonstrate this technique.

At this point in time, different advance directive formats ask the same type of question in different ways. When the question intends to solicit the same type of information, the machine readable entry will carry a code to indicate the standard question being addressed. The originalText of that code will reference the question as it was posed in the source material, if one is explicitly included. Otherwise, there will be no additional originalText reference for the coded question. The answer to the question will be encoded in the value element, and the originalText will reference the answer. See section 3.3 for guidance on the use of originalText with the code and value elements.

The nuance of classifying question content as the same or different is managed with the code system used to classify the types of questions. The LOINC ontology is designed

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around the "question and answer" paradigm and is well suited to support this approach.

In other cases, where content is specifically a goal statement or an explicit preference for a particular treatment (or not), clinical statement patterns established to represent goals and interventions in Consolidated CDA have been used.

Due to the nature of the content expressed in a PACP document, machine processing of individual clinical statements may be less needed for effective sharing of this type of content. PACP documents primarily are intended to be read and understood by humans involved in the care planning process. The documents permit information to be shared that expresses the wide variety of personal thoughts and considerations that individuals may wish to share regarding the care experience in emergency, critical, and end-of-life medical situations when they can't speak for themselves.

While encoded header information will improve access and offer many helpful machine processable data elements, and coded section content will make content in the documents more accessible and more understandable, inclusion of additional machine coded entries may offer less utility, at least initially. For more information on the benefits of exchanging unstructured CDA and Level Two CDA PACP documents, see section 3.2.1 and section 3.2.2, respectively.

Volume 2 includes several clinical statement patterns that can be used to encode specific types of information expressed as a goal or treatment (intervention) preference. A specific clinical statement pattern for encoding an ordered set of priorities has also been included. Other less specific types of clinical statement patterns have been defined to encode other types of directives and general statements that may be relevant to the care experience.

Implementers exchanging personal advance care planning information will need to determine the optimal type of clinical statement pattern to use when representing this information in a PACP document. The entry-level template choice will depend on the content being shared and the use case for the content.

As implementer experience with this specification increases, additional use cases may emerge that demonstrate a need for additional machine level encoding. The design strategy for this IG was to define a minimal set of clinical statement patterns with some more and some less specific meanings, then allow actual use of the standard to drive development of additional machine readable entry patterns.

3.6 Sections in a PACP document

The Personal Advance Care Plan Document encompasses the following sections of information:

Table 2: PACP Sections

Section Name	Description
Administrative Information	Information that is important to all readers and could be related to guidance for information users, or information to help readers interpret the content such as jurisdictional considerations, or best practice recommendations.

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Healthcare Agent Appointment	Information about and related to the appointment of a healthcare agent and up to two alternates.
GPP for Personal Care Experience	Information about other goals, preferences, or priorities relating to personal care experience.
GPP for Certain Conditions	Advance care planning information relating to end-of-life or severely debilitating conditions.
GPP upon Death	Advance care planning information for after death has occurred.
Additional Documentation	Information about additional advance directive documents for the subject, such as physician order for life sustaining treatment (MOLST or POLST) or Do Not Resuscitate Order (DNR) exist and a reference to the document.
Witness and Notary	Information about who has witnessed and notarized the advance care planning information, if available and appropriate.

When advance care plan information supplied by a person appears within the context of a larger clinician generated Care Plan, the section design remains identical to the structure used in the body of the PACP document. This design reduces complexity and makes data processing consistent regardless of where the PACP document information is represented.

3.7 Overview of header data elements in the context of a PACP document

The header of a CDA document is a tightly specified set of information at the top of every CDA document. Header information can be used to search for and find the document in a repository or used to index the document into a registry. While the body of each type of CDA document may be very different, the rules of CDA R2 require the header of all CDA documents to be very similar. In simplistic terms, the elements of the CDA document header summarize the “who, what, when, and where” context for the health story contained in the document.

Nine specific “participations'' and five “act relationships'' have been defined for the CDA document header. Three of the participations are required. Some of the header elements are repeatable. Each type of CDA document must define which of the other participations and act relationships to include (in addition to those that are required) and provide implementer guidance regarding what information to populate in the header elements.

In the context of a PACP document, the CDA header elements record the information described in the table below. (See Volume 2 for additional PACP header template constraints.) The table below summarizes the guidance specific to PACP document and which further constrains the C-CDA US Realm Header for Patient Generated Document Header, which in turn is a further constraint on the C-CDA US Realm Header.

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Table 3: PACP Header Element Constraints

Header Participations:	
recordTarget (the subject of the document)	The PACP document header SHALL include 1 recordTarget. The recordTarget SHALL record information about the person whose advance care plan information is recorded in the document. If the subject of the document has a legal guardian, the recordTarget/patientRole/patient/guardian SHALL record information about the guardian. Multiple guardians MAY be included to support situations when the subject of the document has more than one legal guardian.
author	The PACP document header SHALL include only 1 author person. The author SHALL be the same person as the recordTarget. Note: In the case where the recordTarget is not able to "write" the PACP contents due to literacy constraints or physical disability, e.g. hemiplegia, the recordTarget/subject is still considered author of the content, and a data enterer will fill the role of physically creating the document by entering the author's requested information into the system used to assemble the document.
custodian	The PACP document header SHALL include 1 custodian. The custodian SHALL record the organization which maintains the "original copy" of the document created to record the person's advance care plan information. If the custodian of the document is an individual, he or she SHALL be recorded as the custodian organization due to current limitations of CDA R2.
participant	The PACP document does not further constrain the cardinality or use of the participant participation. It can be used to document other individuals with a personal, legal, or care relationship to the patient. A participant with typeCode of "DEV" and a functionCode of "assembler" MAY be used to represent the organization responsible for assembling the information into the document. Currently CDA R2.0 does not provide a way to record the name of the system used to do the digital "assembling" process.
authenticator	The PACP document MAY include zero or more authenticators. Each authenticator SHALL represent someone who signs the information including the person authoring the document or any witness(es) who attest(s) to the identity of the author who created the document.
legalAuthenticator	The PACP document MAY include zero or one legalAuthenticator. The legalAuthenticator SHALL represent the person who notarized the information. This person is attesting to the identity of the author who created the document.

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informant	The informant participation SHALL NOT be included in a PACP document header because all goals, preferences, and priorities are intended to be the personal thoughts of the author.
Header Act Relationships:	
authorization/consent	No further constraints on CDA R2.
componentOf/encompassingEncounter	No further constraints on CDA R2.
documentationOf/serviceEvent	No further constraints on CDA R2.
infulfillmentOf/order	No further constraints on CDA R2.

The PACP header may include zero or one relatedDocument element. A relatedDocument element is only included in the PACP header when the PACP document is intended to replace a prior document. Otherwise this act relationship is not included. In the relatedDocument element, use the typeCode of RPLC. This indicates that the current document replaces the referenced parent document. Other typeCodes are not permitted. To avoid any confusion regarding appending or transforming a PACP doc, when dealing with advance directive documents we limited the relationship to replace for safety reasons. This avoids the possibility of appending material that contradicts statements in the earlier document

These established specifications are defined in greater detail within the PACP document header template in Volume 2.

3.8 Assertion of template conformance for instance validation and interoperability

Within the definition of a template, there are two ways to ensure interoperability.

One option is to design templates that include a “conforms to” relationship. An assertion that Template A conforms to Template B means that Template A adopts by reference all of the conformance statements contained in Template B. This design relationship asserts every conformance statement contained in Template B without having to reassert these conformances in the definition of Template A. Validators and other applications consuming information that conforms to Template A, also must validate an interoperate on the information according to the conformance requirements of Template B.

The other option is to assert conformance to another template directly in an instance of the template. One template can include an assertion of conformance to another template. Template A can require assertion of Template B. The design choice to assert Template B when asserting Template A directly signals validators and other applications consuming information conforming to Template A that the information also conforms to Template B. For example, using this type of explicit template conformance assertion tells an application that can process information conforming to the US Realm Header

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(V3) template that it can safely use the same processing capabilities on information conforming to the PACP document Header.

The PACP document is designed to be conformant with Consolidated CDA. The PACP header template conforms to the US Realm Header (V3) template used in C-CDA. That means the PACP header adopts all the conformance statements asserted by the US Realm Header (V3) template. When applicable, entry templates defined in PACP explicitly assert conformance with C-CDA entry templates. Thus ensuring the interoperability of PACP documents for all systems that support and process C-CDA documents.

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4 USING THIS IG

This chapter describes the rules and formalisms used to constrain the CDA R2 standard. It describes the formal representation of CDA versioned templates, the mechanism by which templates are bound to vocabulary, and additional information necessary to understand and correctly implement the content found in Volume 2 of this IG.

4.1 Conformance Conventions Used in This Guide

Conformance statements within this IG are presented as constraints from Trifolia Workbench, a template repository. Functionality within the Trifolia Workbench may influence the conventions used in this IG.

4.1.1 Templates and Conformance Statements

When defining CDA templates using Trifolia Workbench, an algorithm converts constraints recorded in Trifolia to a printable presentation. Each constraint is uniquely identified by an identifier at or near the end of the constraint (e.g., CONF:86-7345). The digits in the conformance number before the hyphen identify which IG the template belongs to and the number after the hyphen is unique to the owning IG. Together, these two numbers uniquely identify each constraint. These identifiers are persistent but not sequential. Conformance numbers in this guide associated with a conformance statement that is carried forward from a previous version of this guide will carry the same conformance number from the previous version. This is true even if the previous conformance statement has been edited. If a conformance statement is entirely new it will have a new conformance number.

Bracketed information following each template title indicates the template type (section, observation, act, procedure, etc.), currently a uniform resource name (URN) and previously an object identifier (OID), and whether the template is open or closed. As of May 2014, templates are identified by a URN that includes version information (e.g., urn:hl7ii). The URN identifier includes both the @root and @extension value for the templateId (for example, this uniform resource urn:hl7ii:2.16.840.1.113883.10.20.5.5.41:2014-06-09 has an @root of 2.16.840.1.113883.10.20.5.5.41 and an @extension of 2014-06-09). The @extension value is a date identifying the version of the template. Templates defined prior to May 2014 were not versioned and include only the @root value. These earlier templates are identified using an object identifier (OID) and include an @root value and no @extension value.

Each section and entry template in Volume 2 of this IG includes a context table. The "Contained By" column indicates which templates use the template being defined, and if the template is optional or required in the containing template. The "Contains" column indicates any templates that the template uses.

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Table 4: Contexts Table Example—Allergy Concern Act (V2)

Contained By:	Contains:
Allergies and Intolerances Section (entries optional) (V2) (optional) Allergies and Intolerances Section (entries required) (V2) (required)	Allergy - Intolerance Observation (V2) Author Participation

Each entry template also includes a constraints overview table to summarize the constraints in the template.

Table 5: Constraints Overview Example—Allergy Concern Act (V2)

XPath	Card.	Verb	Data Type	CONF#	Value
act (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.30:2014-06-09)					
@classCode	1..1	SHALL		1098-7469	2.16.840.1.113883.5.6 (HL7ActClass) = ACT
@moodCode	1..1	SHALL		1098-7470	2.16.840.1.113883.5.1001 (ActMood) = EVN
templateId	1..1	SHALL		1098-7471	
@root	1..1	SHALL		1098-10489	2.16.840.1.113883.10.20.22.4.30
@extension	1..1	SHALL		1098-32543	2014-06-09
...					

The expression “such that it” at the end of one conformance statement links that conformance statement to the following subordinate conformance statement to further constrain the first conformance statement. To understand the full effect of this conformance construct, the two conformances must be considered as a single compound requirement. The subordinate conformance statement functions as a subordinate clause (like a "where" clause), which is being applied on the first conformance statement.

The following example shows a compound conformance statement made up of two conformance statements joined by a "such that it" clause. The effect of this syntax can be interpreted as a "where" clause. Thus...

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:81-7899) such that it
    a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.31" (CONF:81-10487).

...is understood as:

> This template **SHALL** contain exactly one [1..1] **templateId** where it contains exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.31".

This means that you must have a template id with **@root**="2.16.840.1.113883.10.20.22.4.31", but you can also have other template ids with different valued attributes.

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The following figure shows a typical template's set of constraints presented in this guide. The following chapters describe specific aspects of conformance statements—open vs. closed templates, conformance verbs, cardinality, vocabulary conformance, containment relationships, and null flavors.

Figure 9: Constraint Conformance Including "such that it" Syntax Example

Age Observation

`[observation: identifier urn:oid:2.16.840.1.113883.10.20.22.4.31 (open)]`

SHALL contain exactly one [1..1] **`@classCode`**="`OBS`" Observation (CodeSystem: `HL7ActClass 2.16.840.1.113883.5.6` **STATIC**) (CONF:81-7613).

SHALL contain exactly one [1..1] **`@moodCode`**="`EVN`" Event (CodeSystem: `ActMood 2.16.840.1.113883.5.1001` **STATIC**) (CONF:81-7614).

SHALL contain exactly one [1..1] **`templateId`** (CONF:81-7899) such that it

> **SHALL** contain exactly one [1..1] **`@root`**="`2.16.840.1.113883.10.20.22.4.31`" (CONF:81-10487).

...

4.1.2 Template Versioning

A new version of an existing IG reuses templates from the previous version. During the ballot phase or update phase, templates carry the designation "Published" to indicate the template is unchanged from the previous version or "Draft" to indicate a new or revised template. Substantial revisions to previously published templates are indicated by the version number (V2, V3, etc.) in all phases: ballot, update, and published guides.

If there are no substantive changes to a template that has been successfully published, the template will carry the same `templateId/@root` (`identifier oid`) and `templateId/@extension` as in the previous IG. (In the case of older templates, the `@extension` attribute will not be present.) During a new ballot or update phase, "Published" is appended to the main heading for the template to indicate that the template cannot be commented on in the ballot or update. The "Published" designation is removed in the final publication versions.

A revised version of a previously published template keeps the same `templateId/@root` as the previous version but is assigned a new `templateId/@extension`. The notation "(Vn)" (V2, V3, etc.) is also added to the template name. Versions are not necessarily forward or backward compatible. A versioning may be due to substantive changes in the template or because a contained template has changed. The "(Vn)" designation is persistent; it appears with that template when it is used in subsequent guides. During a new ballot or update phase, "Draft" is appended to the main heading for the template to indicate that it may be voted on in the ballot or commented on in the update; the "Draft" designation is removed in the final publication versions.

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A new version of a template is explicitly linked to the prior version, enabling the automatic generation of the detailed change log found in Volume 2, Chapter 9 “Changes From Previous Version”.

As an example, the change log for a versioned template is shown in the following figure. In this example, Medication Activity (2.16.840.1.113883.10.20.22.4.16) has versioned to Medication Activity (V2) (2.16.840.1.113883.10.20.22.4.16:2014-06-09).

Table 6: Change Log for Versioned Templates

Change	**Old**	**New**
Name	Medication Activity	Medication Activity (V2)
OID	urn:oid:2.16.840.1.113883.10.20.22.4.16	urn:hl7ii:2.16.840.1.113883.10.20.22.4.16:2014-06-09
Description	A medication activity describes ...	A medication activity describes ...
CONF #: 1098-30822 Added		SHALL contain exactly one [1..1] Drug Monitoring Act (NEW) (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.123) (CONF:1098-30822).
...		
CONF #: 81-7511 Removed	SHALL contain exactly one [1..1] low (CONF:81-7511).	
...		
CONF #: 1098-7516 Modified	SHOULD contain zero or one [0..1] doseQuantity	SHALL contain exactly one [1..1] doseQuantity
...		

Structured Documents Work Group (SDWG) collaborated with Templates Work Group to establish template versioning recommendations, published in the following specification: HL7 Templates Standard: Specification and Use of Reusable Information Constraint Templates, Release 1. SDWG leverages that specification to create guidance for template IDs and template versioning.

4.1.3 Open and Closed Templates

In open templates, all of the features of the CDA R2 base specification are allowed except as constrained by the templates. By contrast, a closed template specifies everything that is allowed, and nothing further may be included.

Estimated Date of Delivery (`templateId 2.16.840.1.113883.10.20.15.3.1`) is an example of a closed template in this Implementation Guide.

Open templates allow HL7 implementers to develop additional structured content not constrained within this Implementation Guide. HL7 encourages implementers to bring their use cases forward as candidate requirements to be formalized in a subsequent version of the standard to maximize the use of shared semantics.

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4.1.4 Conformance Verbs (Keywords)

The keywords **SHALL, SHOULD, MAY, NEED NOT, SHOULD NOT**, and **SHALL NOT** in this document are to be interpreted as described in the HL7 Version 3 Publishing Facilitator's Guide.[4]

- **SHALL:** an absolute requirement.
- **SHALL NOT:** an absolute prohibition against inclusion (Note: SHALL NOT on an element prohibits the inclusion of that element, which means including the null flavor attribute on the element would not be possible. Thus, MSK would not be allowed.)
- **SHOULD/SHOULD NOT:** best practice or recommendation. There may be valid reasons to ignore an item, but the full implications must be understood and carefully weighed before choosing a different course.
- **MAY/NEED NOT:** truly optional; can be included or omitted as the author decides with no implications.

The keyword "**SHALL**" allows the use of `nullFlavor` unless the requirement is on an attribute or the use of `nullFlavor` is explicitly precluded.

When conformance statements are nested (or have subordinate clauses) the conformance statements are to be read and interpreted in hierarchical order. These hierarchical clauses can be interpreted as "if then, else" clauses. Thus...

a. This structuredBody **SHOULD** contain zero or one [0..1] **component** (CONF:1098-29066) such that it
   i. **SHALL** contain exactly one [1..1] **Plan of Treatment Section (V2)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.2.10:2014-06-09) (CONF:1098-29067).

...is understood as:

a. It is recommended (**SHOULD**) that the structureBody contains a component.
   i. **If** the component exists, **then** it must contain a Plan of Treatment Section (V2),
   ii. **else** the component does not exist, and the conformance statement about the Plan of Treatment Section (V2) should be skipped.

In the case where the higher level conformance statement is a **SHALL,** there is no conditional clause. Thus...

b. This structuredBody **SHALL** contain exactly one [1..1] **component** (CONF:1098-29086) such that it
   i. **SHALL** contain exactly one [1..1] **Problem Section (entries required) (V2)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.2.5.1:2014-06-09) (CONF:1098-29087).

...means that the structuredBody is always required to have a component.

[4] HL7, *Version 3 Publishing Facilitator's Guide.* http://www.hl7.org/v3ballot/html/help/pfg/pfg.htm

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4.1.5 Cardinality

The cardinality indicator (0..1, 1..1, 1..*, etc.) specifies the allowable occurrences within a document instance. The cardinality indicators are interpreted with the following format “m…n” where m represents the least and n the most:

- 0..1 zero or one
- 1..1 exactly one
- 1..* at least one
- 0..* zero or more
- 1..n at least one and not more than n
- 0..0 no occurrences are permitted

When a constraint has subordinate clauses, the scope of the cardinality of the parent constraint must be clear. In the next figure, the constraint says exactly one participant is to be present. The subordinate constraint specifies some additional characteristics of that participant.

Figure 10: Constraints Format – only one allowed

1. **SHALL** contain exactly one [1..1] **participant** (CONF:2777).
   a. This participant **SHALL** contain exactly one [1..1] **@typeCode**="LOC" (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType) (CONF:2230).

In the next figure, the constraint says only one participant “like this” is to be present. Other participant elements are not precluded by this constraint.

Figure 11: Constraints Format – only one like this allowed

1. **SHALL** contain exactly one [1..1] **participant** (CONF:2777) such that it
   a. **SHALL** contain exactly one [1..1] **@typeCode**="LOC" (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType) (CONF:2230).

In the next figure, the constraint prohibits an assignedAuthor element from being included. The phase “shall not contain” implies a cardinality of [0..0] for the element.

Figure 12: Constraints Format – none like this allowed

ii. This assignedAuthor **SHALL NOT** contain [0..0] **assignedAuthoringDevice** (CONF:2211-33108).

4.1.6 Optional and Required with Cardinality

The terms *optional* and *required* describe the *lower* bound of cardinality as follows:

Optional means that the number of allowable occurrences of an element may be 0; the cardinality will be expressed as [0..1] or [0..*] or similar. In these cases, the element may not be present in the instance. Conformances formulated with **MAY** or **SHOULD** are both considered "optional" conformances.

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Required means that the number of allowable occurrences of an element must be at least 1; the cardinality will be expressed as [m..n], where m >=1 and n >=1 (for example, [1..1] or [1..*]). In these cases, the element must be present in the instance. Conformance statements formulated with **SHALL** are required conformances. If an element is required but it is not known, the @nullFlavor attribute must be used.

4.1.7 Containment Relationships

Containment constraints between a section and its entries allow indirect containment in this guide. This means that where a section asserts containment of an entry, that entry either can be a direct child or a further descendent of that section.

For example, in the following constraint:

1. **SHALL** contain at least one [1..*] **entry** (CONF:8647) such that it
    a. **SHALL** contain exactly one [1..1] **Advance Directive Observation** (templateId:2.16.840.1.113883.10.20.22.4.48) (CONF:8801).

The Advance Directive Observation can be a direct child of the section (i.e., `section/entry/AdvanceDirectiveObservation`) or a further descendent of that section (i.e., `section/entry/…/AdvanceDirectiveObservation`). Either of these are conformant.

All other constraints are direct and do not allow an indirect containment relationship, for example:

1. **SHALL** contain exactly one [1..1] `templateId/@root="2.16.840.1.113883.10.20.22.2.21"` (CONF:7928).

The `templateId` must be a direct child of the section (*i.e.,* section/templateId).

4.1.8 Vocabulary Conformance

The templates in this document use terms from several code systems. These vocabularies are defined in various supporting specifications and may be maintained by other bodies, as is the case for the LOINC® and SNOMED CT® vocabularies.

Note that value set identifiers (*e.g.,* ValueSet `2.16.840.1.113883.1.11.78 Observation Interpretation (HL7)` **DYNAMIC**) used in the binding definitions of template conformance statements do not appear in the XML instance of a CDA document. The definition of the template must be referenced to determine or validate the vocabulary conformance requirements of the template.

Value set bindings adhere to HL7 Vocabulary Working Group best practices and include both an indication of stability and of coding strength for the binding. Value set bindings can be **STATIC**, meaning that they bind to a specified version of a value set, or **DYNAMIC**, meaning that they bind to the most current version of the value set. If a **STATIC** binding is specified, a date **SHALL** be included to indicate the value set version. If a **DYNAMIC** binding is specified, the value set authority and link to the base definition of the value set **SHALL** be included, if available, so implementers can access the current version of the value set. When a vocabulary binding binds to a single code, the stability of the binding is implicitly **STATIC**.

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Figure 13: Binding to a Single Code

2. **SHALL** contain exactly one [1..1] **code** (CONF:15403).
   a) This code **SHALL** contain exactly one [1..1] **@code**="11450-4" Problem List (CONF:15408).
   b) This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.6.1" (CodeSystem: LOINC 2.16.840.1.113883.6.1 **STATIC**) (CONF: 31141).

The notation conveys the actual code (`11450-4`), the code's `displayName` (Problem List), the OID of the `codeSystem` from which the code is drawn (2.16.840.1.113883.6.1), and the `codeSystemName` (LOINC).

HL7 Data Types Release 1 requires the `codeSystem` attribute unless the underlying data type is "Coded Simple" or "CS," in which case it is prohibited. The `displayName` and the `codeSystemName` are optional, but recommended, in all cases.

The above example would be properly expressed as follows.

Figure 14: XML Expression of a Single-Code Binding

```
<code code="11450-4" codeSystem="2.16.840.1.113883.6.1"/>

<!-- or -->

<code code="11450-4" codeSystem="2.16.840.1.113883.6.1"
      displayName="Problem List"
      codeSystemName="LOINC"/>
```

A full discussion of the representation of vocabulary is outside the scope of this implementation guide. For more information, see the *HL7 V3 Normative Edition 2010*[5] sections on Abstract Data Types and XML Data Types R1.

There is a discrepancy between the HL7 R1 Data Types and this Implementation Guide in the use of translation code versus the original code. The R1 data type requires the original code in the root. The convention agreed upon for this IG specifies that a code from the required value set be used in the element, and other codes not included in the value set are to be represented in a translation for the element. This discrepancy is resolved in HL7 Data Types R2.

In the next example, the conformant code is SNOMED CT code 206525008.

Figure 15: Translation Code Example

```
<code code='206525008'
      displayName='neonatal necrotizing enterocolitis'
      codeSystem='2.16.840.1.113883.6.96'
      codeSystemName='SNOMED CT'>
   <translation code='NEC-1'
      displayName='necrotizing enterocolitis'
      codeSystem='2.16.840.1.113883.19'/>
</code>
```

Value set tables are present below a template, or are referenced if they occur elsewhere in the specification, when there are value set bindings in the template. The value set table provides the value set identifier, a description, and a link to the source of the

[5] *HL7 Version 3 Interoperability Standards,* http://www.hl7.org/memonly/downloads/v3edition.cfm - V32010

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value set when possible. Ellipses in the last row indicate the value set members shown are examples and the true source must be accessed to see all members.

If a value set binding has a **DYNAMIC** stability, implementers creating a CDA document must go to the location in the URL to check for the most current version of the value set expansion.

Table 7: Example Value Set Table (Advance Directives Categories)

Value Set: Advance Directives Categories urn:oid:2.16.840.1.113883.11.20.9.69.4
(Clinical Focus: Categories of Advance Directives.),(Data Element Scope: Concepts represent different categories of Advance Directive statements.),(Inclusion Criteria: Includes concepts from LOINC that indicate a category (or kind) of advance directive that may be specified in a standard advance directive document.),(Exclusion Criteria:)

This value set was imported on 10/17/2022 with a version of Latest.
Value Set Source:
https://vsac.nlm.nih.gov/valueset/2.16.840.1.113883.11.20.9.69.4/expansion

Code	Code System	Code System OID	Print Name
42348-3	LOINC	urn:oid:2.16.840.1.113883.6.1	Advance directives
64298-3	LOINC	urn:oid:2.16.840.1.113883.6.1	Power of attorney
81334-5	LOINC	urn:oid:2.16.840.1.113883.6.1	Patient Personal advance care plan
86533-7	LOINC	urn:oid:2.16.840.1.113883.6.1	Patient Living will
92664-2	LOINC	urn:oid:2.16.840.1.113883.6.1	Power of attorney and Living will

4.1.9 Data Types

All data types used in a CDA document are described in the CDA R2 normative edition.[6] All attributes of a data type are allowed unless explicitly prohibited by this specification.

4.1.10 Document-Level Templates "Properties" Heading

In Volume 2 of this IG, each document-level template has a "Properties" heading for ease of navigation. The Properties heading is an organizational construct, underneath which relevant CDA act-relationships and roles are called out as headings in the document.

4.2 XML Conventions Used in This Guide

4.2.1 XPath Notation

Instead of the traditional dotted notation used by HL7 to represent RIM classes, this document uses XML Path Language (XPath) notation[7] in conformance statements and

[6] *HL7 CDA Release 2.* http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7
[7] W3C, XML Path Language. http://www.w3.org/TR/xpath/

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elsewhere to identify the XML elements and attributes within the CDA document instance to which various constraints are applied. The implicit context of these expressions is the root of the document. This notation provides a mechanism that will be familiar to developers for identifying parts of an XML document.

XPath statements appear in this document in a `monospace font`.

XPath syntax selects nodes from an XML document using a path containing the context of the node(s). The path is constructed from node names and attribute names (prefixed by a '@') and catenated with a '/' symbol.

Figure 16: XML Document Example

```
<author>
  <assignedAuthor>
  ...
    <code codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'
          code='17561000' displayName='Cardiologist' />
  ...
  </assignedAuthor>
</author>
```

In the above example, the `code` attribute of the code could be selected with the XPath expression in the next figure.

Figure 17: XPath Expression Example

```
author/assignedAuthor/code/@code
```

4.2.2 XML Examples and Sample Documents

Extensible Mark-up Language (XML) examples appear in figures in this document in this `monospace font`. XML elements (`code, assignedAuthor`, etc.) and attribute names (`SNOMED CT, 17561000`, etc.) also appear in this `monospace font`. Portions of the XML content may be omitted from the content for brevity, marked by an ellipsis (...) as shown in the example below.

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Appendix A: Format Codes

The PACP IG declares the following format codes to be used in the metadata to indicate the technical format for the document. HL7 has defined a pattern for establishing format codes for documents that meet a published technical specification. Thus, the IG should explicitly make this information available for implementers. The format codes for PACP documents which are conformant to this version of the PACP IG are:

urn:hl7-org:sdwg:pacp-structuredBody:1.3 For documents following PACP 1.3 constraints using a structured body.

urn:hl7-org:sdwg:pacp-nonXMLBody:1.3 For documents following PACP 1.3 constraints using an unstructured body.

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The format codes for PACP documents which are conformant to earlier versions of the PACP IG are:

urn:hl7-org:sdwg:pacp-structuredBody:1.2 For documents following PACP 1.2 constraints using a structured body.

urn:hl7-org:sdwg:pacp-nonXMLBody:1.2 For documents following PACP 1.2 constraints using an unstructured body.

urn:hl7-org:sdwg:pacp-structuredBody:1.1 For documents following PACP 1.1 constraints using a structured body.

urn:hl7-org:sdwg:pacp-nonXMLBody:1.1 For documents following PACP 1.1 constraints using an unstructured body.

Appendix B: Extensions to CDA R2

Where there is a need to communicate information for which there is no suitable representation in CDA R2, extensions to CDA R2 have been developed. This appendix serves to summarize extensions that potentially are relevant to the PACP document. Additional implementation guidance is available on the Structured Documents Confluence page https://confluence.hl7.org/display/SD/CDA+Extensions

Extensions are also described in the context of the templates where they are used in Volume 2.

Extensions potentially relevant to this IG include:

- `sdtc:raceCode` - The `raceCode` extension allows for multiple races to be reported for a patient.
- sdtc:ethnicGroupCode – The ethnicGroupCode extension allows for multiple ethnicities to be reported for a patient.
- `sdtc:id` - The id extension on the related subject allows for unique identification of the subject.
- `sdtc:deceasedInd` - The `deceasedInd extension` (true or false) for the patient or related subject is used to indicate if the subject is deceased.
- `sdtc:deceasedTime` - The `deceasedTime` extension for the patient or related subject is used to indicate when the subject has died.
- `sdtc:birthTime` - The `sdtc:birthTime` element allows for the birth date of any person to be recorded. The purpose of this extension is to allow the recording of the subscriber or member of a health plan in cases where the health plan eligibility system has different information on file than the provider does for the patient.
- `sdtc:signatureText – The sdtc:signatureText` element provides a location in CDA for a textual or multimedia depiction of the signature by which the participant endorses and accepts responsibility for his or her participation in the Act as specified in the Participation.typeCode. Details of what goes in the field are described in the HL7 IG for CDA® Release 2: Digital Signatures and Delegation of Rights, Release 1.

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- `sdtc:priorityNumber` – The `sdtc:priorityNumber` element provides an integer priority number within the set of components in an organizer.

Implementers of this implementation guide follow guidance on creating and managing CDA extensions established by HL7 SDWG.

Appendix C: Coded Content Crosswalk

This appendix includes a content map which shows the crosswalk between: on one side the concepts used to encode personal goals, preferences, and priorities according to the PACP document standard and on the other side coded concepts from the value set used within C-CDA R2.1 to summarize types of advance directives information recorded in a PACP document. The crosswalk enables a clinician to record what kind of advance care plan information is available in the person's referenced PACP document.

The crosswalk maps LOINC codes used in a PACP document to indicate the question a person is addressing in his or her advance care plan information to the corresponding SNOMED CT concepts used in an EHR to classify various types of advance directives content. For example, if a PACP document includes content encoded with the LOINC code 75787-2 (Thoughts on Intubation), then the clinician's system can use SNOMED CT code 52765003 (Intubation) to indicate that a person has documented intubation preferences.

Note that when an EHR records an Advance Directives Observation encoded with SNOMED CT code 52765003 (Intubation), the recorded observation does not indicate what the person's preferences were. It indicates the clinician observed that the person's advance care plan information includes preferences regarding intubation. In other words, the Advance Directives Observation in the Advance directives section of a Clinical Summary document summarizes the types of goals, preferences and priorities in the referenced PACP document. Also, when a clinician records an observation to indicate that a type of advance care plan information exists, it is not equivalent to recording an order to perform or an order *not to perform* a certain procedure. The recording of an Advance Directives Observation only classifies the types of information available in the referenced PACP document. Within an EHR, classification of the types of available personal advance care plan information can speed clinician access to person-centered information in time-sensitive decision-making situations such as organ donation, resuscitation, or initiation of emergency department services.

Table 8: Crosswalk between PACP Entry Types and Advance Directive Observation Types

Code System Name	Code System OID	Version
SNOMED-CT	2.16.840.1.113883.6.96	2022-03
LOINC	2.16.840.1.113883.6.1	2.72

Personal Advance Care Plan Document Entry Type	Code System Name	Advance Directives Observation content type (2.16.840.1.113883.10.20.22.4.48 :2022-02-14)	Code System Name

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entry/../code		observation/../code (see Note 1)	
75787-2 (AD-13) Thoughts on Intubation	LOINC	52765003 Intubation (procedure)	SNOMED CT
75788-0 (AD-14) Thoughts on Tube Feeding	LOINC	61420007 Tube feeding of patient (regime/therapy)	SNOMED CT
75789-8 (AD-15) Thoughts on Life Support	LOINC	78823007 Life support procedure (procedure)	SNOMED CT
75779-9 (AD-7) Thoughts on CPR	LOINC	89666000 Cardiopulmonary resuscitation (procedure)	SNOMED CT
75790-6 (AD-16) Thoughts on IV Fluid and Support	LOINC	14152002 Intravenous infusion (procedure)	SNOMED CT
75791-4 (AD-17) Thoughts on Antibiotics	LOINC	281789004 Antibiotics	SNOMED CT
75792-2 (AD-18) Thoughts on Resuscitation	LOINC	304251008 Resuscitation	SNOMED CT
75793-0 (AD-19) Other Directive	LOINC	71388002 Other Directive	SNOMED CT

Note 1: As of June, 2019, the C-CDA Advance Directive Observation template (urn:hl7ii:2.16.840.1.113883.10.20.22.4.48:2022-02-14) has been updated to include the following conformance statement with a vocabulary binding strength that is dynamic.

1. **SHALL** contain exactly one [1..1] **code**, which **SHOULD** be selected from ValueSet **Advance Directive Type Code** `urn:oid:2.16.840.1.113883.1.11.20.2` **DYNAMIC** (CONF:1198-8651).
   a. This code **SHALL** contain exactly one [1..1] **translation** (CONF:1198-32842) such that it
      i. **SHALL** contain exactly one [1..1] **@code**="75320-2" Advance directive (CONF:1198-32843).
      ii. **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.6.1" (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:1198-32844).

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