Clarify Advance Directive Information in C-CDA R2.1

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# About the C-CDA Advance Directive Templates Update Project

As a result of discussions with SDWG, on 1/30/2017, consensus was reached that several improvements are needed to clarify the agreed functionality for the Advance Directives templates in C-CDA R2.1.

## Initial Objectives

STU Comments to Advance Directives:

1. Clarify the description (last paragraph on page 418)
2. Revise the Figure 124 example,
3. Recommend a tighter conformance statement <CONF:1198-30804> for the value attribute
4. Maintain backward compatibility

### Visual Overview

Figure : Overview of Advance Directive Template Revisions

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# New Version: Advance Directives Section (V4)

Name: Advance Directives Section (entries required) (V4) 2017-07-01

[note: there will be both an “entries optional” and an “entries required” flavor for this template design.]

This section contains information describing the patient’s advance directives. The description includes the kind of advance directive source documents and the type of advance directive content included in each kind of advance directive source document. The section includes information about who verified the content available in each advance directive source document, if applicable. It also includes information about who was the relevant healthcare agent or surrogate decision-maker, if available. It provides references to the supporting documentation, including all kinds of advance directive source documents.

This section differentiates between an "advance care plan document" and an “advance care plan order.” It also distinguishes an advance directive that is a consent. Information in this section shall only include information about the person’s current/relevant goals and preferences, advance directive orders, or advance directive consents.

The “entries required” version of this section template requires one or more entries and would permit the optional use of the Advance Directive Observation V3 (Deprecated), Advance Directive Organizer V2 (Deprecated); or Advance Directive Organizer (V3) 2017-07-01 template. The “entries optional” version does not require one or more entries, but includes the template purpose revisions to clarify the intention for the information to be included in the narrative text of the section.

# New Version: Advance Directives Organizer (V3)

Name:Advance Directive Organizer (V3) 2017-07-01

This clinical statement groups a set of advance directive observations documented by a particular author at a particular time and associated with a particular version of the referenced advance directives source information.

The organizer SHOULD include an author and a verifier participant and it SHOULD include at least one reference to an external document, which when present, prevents the need to repeat this information for each component Advance Directive Observation unless greater specificity at the component level is needed.

# New Version: Advance Directives Observation (V4) Template

Name: Advance Directive Observation (V4) 2017-07-01

**Background**

Advance directives are called “advance directives” because these documents are established “in advance” of the time when the information would be relevant to medical treatment decisions, care delivery, and care planning. The term “advance directive” is not restricted to include only the statutorily defined documents such as living wills and durable medical powers of attorney. An advance directive can be a personal expression of a health goal, treatment preference or personal priority that would contribute input for care planning when the patient cannot communicate or lacks decision-making capacity. An advance directive also can be a portable medical order such as a Medical Order for Life-Sustaining Treatment (MOLST) or a Physician Order for Life-Sustaining Treatment (POLST), or an Out-of-hospital Do Not Resuscitate (DNR) Order: These kinds of advance directives establish a standing medical order for future emergent medical care.

**Template Purpose**

The Advance Directive Observation template is used when creating an entry to record the type of advance directive content available in a kind of advance directive document, as determined by a person who verified that content.

An Advance Directive Observation records the kind of advance directive source document observed by the person verifying the information and the type of content that was determined to be present. It also records the person who created the documentation (author) as well as the person who did the verification of the advance directive information (verifier), when applicable. An Advance Directive Observation entry should record healthcare agents established by the advance directive. An Advance Directive Observation also may record the location of the source advance directive document containing the information that was reviewed.

The kinds of advance directives source documents could include, but are not limited to:

* Personal advance care plans
* MOLST/POLST orders
* Out-of-Hospital DNR orders

The types of advance directive content could include, but are not limited to:

* Healthcare agent consents
* Antibiotics administration preferences
* Artificial nutrition and hydration administration preferences
* Intubation and Ventilation procedure preferences
* Resuscitation procedure preferences
* Diagnostic Testing procedure preferences
* Preferences relating to palliative care
* Preferences relating to hospice care at the end of life
* Organ donation preferences
* Autopsy procedure preferences
* Burial preferences
* Transfer of Care preferences
* Information about where a person wants to die (e.g., home, hospital, nursing home)
* Information about a personal goal, such as seeing a grandchild born, attending at a child’s wedding, or finding care for a beloved pet.

**Examples**

A personal advance care plan may contain information about a person’s treatment preference regarding resuscitation. A personal advance care plan (PACP) document is a kind of advance directive. “Resuscitation” is a type of advance directive information that may be present in a PACP.

A person may consent to having a healthcare agent. The advance directive source may indicate that the person’s spouse has been established as the primary healthcare agent, and the person’s daughter as the first alternative healthcare agent. If the spouse was deceased, or was unavailable at the time, or unwilling to act as healthcare agent during the encounter being documented, then person’s daughter would be identified as the acting healthcare agent at that time.

A person could have a MOLST documenting that a physician has ordered the person’s resuscitation status to be “Full Code”. MOLST is the kind of advance directive, and “Resuscitation” is the type of advance directive content that is present.

The type of information included in an advance directive source document may be verified by the primary care physician and documented by the primary care physician, or it could be verified by the primary care physician and documented by an assistant. These are simply examples, and there are many more possibilities with respect to how the type of information included in an advance directive source document may be verified and recorded.

**Template Structure**

The Advance Directive Observation template constrains the Observation act. The moodCode is always constrained to indicate the documented observation has already occurred (EVN). The statusCode is always completed. A state model is not required for this type of observation.

The observation/code element indicates the kind of advance directive being observed but classifies all the different kinds together as advance directives.

The observation/effectiveTime represents the interval of time for which the advance directive applies. The effectiveTime/low element indicates when the advance directive was first established and the effectiveTime/high element indicates when the advance directive stops being effective. When an advance directive does not have an end time, the effectiveTime/high will be omitted (or included as an empty tag). However, if the advance directive has a bounded expiration date/time, then the effectiveTime/high would be populated with that information.

The observation/value element categorizes the type of advance directive content which may be described using coded or textual information. For example, a type of directive content might be “antibiotics”. The actual preference specified by the person in the advance care plan may describe the healthcare situations under which the person would prefer intravenous antibiotics or not. The person’s actual preference is not summarized, nor is it copied out of the source document. The type of information available is recorded and the advance directive source document is linked for reference.

The information recorded in an Advance Directive Observation does not constitute a legal document, not does it substitute for the advance directive source document.

**Value Sets and Value Set Bindings**

The observation/code element SHOULD be populated with a coded concept from the following value set.

Kinds of Advance Directives:

|  |  |  |  |
| --- | --- | --- | --- |
| Concept | Code System | Display Name | Status |
| 75773-2 | LOINC | Personal  Goals, preferences, and priorities for medical treatment | Active |
| 81352-7 | LOINC | MOLST/POLST | Active |
| 81351-9 | LOINC | DNR Order | Active |

The observation/code SHALL include a translation element which SHALL be populated with a coded concept from the following value set.

All kinds of advance directives SHALL be characterized as “Advance Directives” by translating them all to the single concept of :

|  |  |  |  |
| --- | --- | --- | --- |
| Concept | Code System | Display Name | Status |
| 75320-2 | LOINC | Advance Directive | Active |

The observation/value element, if populated with a coded concept, SHOULD use a code from the following value set.

Types of Advance Directive Content

|  |  |  |  |
| --- | --- | --- | --- |
| Concept |  | Display Name | Status |
| 52765003 | SNOMED CT | Intubation | Active |
| 61420007 | SNOMED CT | Tube Feedings | Active |
| 78823007 | SNOMED CT | Life Support | Active |
| 89666000 | SNOMED CT | CPR | Active |
| 225204009 | SNOMED CT | IV Fluid and Support | Active |
| 281789004 | SNOMED CT | Antibiotics | Active |
| 304251008 | SNOMED CT | Resuscitation | Active |
|  |  | Burial |  |
|  |  | Hospice |  |
|  |  | Palliative Care |  |
|  |  | Care Experience |  |
|  |  | Pain Medication |  |
|  |  | Organ Donation |  |
|  |  | Autopsy |  |
|  |  | Healthcare Agent |  |
|  |  | Goal |  |
| 71388002 | SNOMED CT | Other Directive | Active |

The participantRole/playingEntity/code element of the participant with a typeCode of CST should use the code 81335-2 Patient Healthcare Agent.

# New Template: Advance Directive Intervention (V1)

Name: Advance Directive Intervention (V1) 2017-07-01

**Background**

A planned intervention to review and verify a person’s advance directives will be recorded in an Advance Directive Intervention template. A planned intervention to review and verify a person’s advance directives with the person also will be recorded in an Advance Directive Intervention template.

After an Advance Directive Intervention has been completed, an Advance Directive Observation template would be used to record that the content in a person’s advance directives document had been verified.

The only time the identity of the healthcare agent is recorded in an Advance Directive Observation template (participation with @typeCode=”CST”) is when the person is ACTING as the healthcare agent at the time the clinical summary or care plan document is created.

A second type of planned intervention may be to educate or counsel a person about advance directives and how to create them. This intervention may or may not result in an advance directive document being created. If it does result in an advance directive document being created, and that information is shared and a care team member reviews and verifies it, then an Advance Directive Observation would be recorded.

If present in a document that includes an Advance Directives Section, completed Advance Directive Observations SHALL be included in the Advance Directives Section.

If present in a document that includes an Interventions section, Advance Directive Interventions SHALL be included in the Interventions section.

**Template Purpose**

The Advance Directive Intervention template is used to record a planned intervention that involves reviewing and verifying a person’s directives, or involves educating and supporting a person on establishing or modifying his or her advance directives.

This template differs from the Advance Directive Observation template which is used after completing a review and verification of a person’s directives. The Advance Directive Observation template records the type of information observed to be present in an existing advance directive source document.

**Template Structure**

The Advance Directive Intervention template SHALL constrain a CDA procedure act. The procedure/@moodCode SHALL be constrained to a value set consisting of the following concepts:

INT – when the intervention is planned, but not formally ordered.

RQO – when the intervention is formally ordered.

The procedure/code element SHALL be included. See value set information below.

The effectiveTime/low of the procedure/time element SHALL indicate the time the intervention was established/planned.

The procedure/author records the person documenting that this intervention needs to be performed, and the procedure/author/time records the time when the author recorded the planned intervention.

The procedure/performer (optional) documents the person assigned to perform the intervention.

statusCode – state model same as other procedure interventions: active, completed, aborted, etc.

When the statusCode is active, the effectiveTime/high SHALL indicate the time by which the planned intervention should be completed.

When the statusCode is aborted or cancelled, the effectiveTime/high SHALL indicate the time by which the planned intervention was aborted or cancelled.

When the procedure/statusCode is completed, the effectiveTime/high of the procedure/time element SHALL indicate the time when the intervention is scheduled to be completed.

An Advance Directive Intervention that results in an advance directive document being created shall have an entryRelationship that uses the Entry Reference template with typeCode = “ OUTC “ (has outcome) and points to the id of an Advance Directive Observation entry which records the information about the completed advance directive document.

When a document does not include an Advance Directives Section, an Advance Directive Observation may be included in the Intervention Section of a Care Plan document. It would be present to record the reason why an intervention was planned or not planned, or to record information about the advance directives document reviewed and verified as a result of completing an Advance Directive Intervention. When an Advance Directive Section exists in a document, the Advance Directive Observation entries SHALL exist in the Advance Directive Section.

**Example:**

Need a clinically relevant example showing an intervention to refer to hospice care which is planned to be performed with a reason that points to an Advance Directive Observation about a person’s preference regarding palliative care.

Need an example of a completed Advance Directive Intervention that includes an Entry Reference of typeCode OUTC and points to the id of an Advance Directive Observation. If the document contains an Advance Directives Section, the Advance Directive Observation should be recorded in the Advance Directives Section. If the document does not contain an Advance Directives Section, the Advance Directive Observation may be included in the Interventions Section.

**Value Sets and Value Set Bindings**

This template uses the same Value Sets and Value Set Bindings in corresponding structural locations to the Advance Directive Observation template.

The procedure/code element @code attribute SHOULD come from a value set consisting of the following two concepts. This will be a dynamic binding.

|  |  |  |
| --- | --- | --- |
| Code | CodeSystem | Display Name |
| ICD10 | 99497 |  |
| ICD10 | 99498 |  |

# Backward Compatibility Assessment

## Advance Directive Observation (V4) template

The Advance Directive Observation (V4) template does not cause backward compatibility problems.

The Advance Directive Observation (V3) template SHALL have a code element which SHOULD be selected from a specified value set. The V4 version of the template recommends that the code element SHOULD be populated with a concept from a different value set. This does not violate backward compatibility.

The Advance Directive Observation (V3) template SHALL have a code element with a translation @code attribute fixed to 75320-2. The V4 version includes this same requirement.

The Advance Directive Observation (V3) template SHALL have exactly one value such that if it is of type CD, the value SHALL be a SNOMED-CT concept. The V4 version of the template recommends that the value element SHOULD be of type CD and SHOULD be populated with a concept from a specified value set of SNOMED-CT concepts. This does not violate backward compatibility.

Participation comparisons are as follows:

|  |  |
| --- | --- |
| Advance Directive Observation (V3) | Advance Directive Observation (V4) |
| Author: | |
| **SHOULD** contain zero or more [0..\*] **Author Participation** | Same constraint for V4. |
| Verifier: | |
| **SHOULD** contain zero or more [0..\*] **participant** (CONF:1198-8662) such that it  **SHALL** contain exactly one [1..1] **@typeCode**="VRF" Verifier (CodeSystem: HL7ParticipationType urn:oid:2.16.840.1.113883.5.90 **STATIC**) (CONF:1198-8663). The participant "VRF" represents the clinician(s) who verified the patient advance directive observation.  **SHALL** contain exactly one [1..1] **participantRole** (CONF:1198-8825).  i. This participantRole **SHOULD** contain zero or one [0..1] **code**, which **SHOULD** be selected from ValueSet **Healthcare Provider Taxonomy (HIPAA)** urn:oid:2.16.840.1.114222.4.11.1066 **DYNAMIC** (CONF:1198-28446).  This participantRole **MAY** contain zero or one [0..1] **playingEntity** (CONF:1198-28428).  1. The playingEntity, if present, **SHOULD** contain zero or one [0..1] **code**, which **SHOULD** be selected from ValueSet **Healthcare Agent Qualifier** urn:oid:2.16.840.1.113883.11.20.9.51 **DYNAMIC** (CONF:1198-28429). | V4 is the same (after processing a technical errata for the value set bindings.)  This participant **SHOULD** contain zero or one [0..1] **functionCode**, which **SHOULD** be selected from ValueSet **Care Team Member Role**  The playingEntity, if present, **SHOULD** contain zero or one [0..1] **code**, which **SHOULD** be selected from ValueSet **Healthcare Provider Taxonomy (HIPAA)** urn:oid:2.16.840.1.114222.4.11.1066 **DYNAMIC** (CONF:1198-28446). |
| Healthcare Agent: | |
| 11. **SHOULD** contain zero or more [0..\*] **participant** (CONF:1198-8667) such that it  a. **SHALL** contain exactly one [1..1] **@typeCode**="CST" Custodian (CodeSystem: HL7ParticipationType urn:oid:2.16.840.1.113883.5.90 **STATIC**) (CONF:1198-8668).  b. **SHALL** contain exactly one [1..1] **participantRole** (CONF:1198-8669).  i. This participantRole **SHALL** contain exactly one [1..1] **@classCode**="AGNT" Agent (CodeSystem: RoleClass urn:oid:2.16.840.1.113883.5.110 **STATIC**) (CONF:1198-8670).  ii. This participantRole **SHOULD** contain zero or one [0..1] **code**, which **SHOULD** be selected from ValueSet **Healthcare Agent Qualifier** urn:oid:2.16.840.1.113883.11.20.12.1 **DYNAMIC** (CONF:1198-28440).  A participant identified with a @typeCode of “custodian” (CST) is a legal representative for the patient. Examples of such individuals are called healthcare agents, substitute decision makers and/or health care proxies. If there is more than one legal representative, a qualifier may be used to designate the legal representative as primary or secondary. | The V4 version of the template requires that the healthcare agent information SHOULD specify the participant/functionCode and it SHOULD be populated with a concept from  Value Set: Healthcare Agent or Proxy Choices urn:oid:2.16.840.1.113762.1.4.1046.35  V4 also allows multiple healthcare agents to be recorded, but the participant/time element (IVL) SHALL be included for each. |

## Advance Directive Intervention (V1) template

The Advance Directive Intervention (V1) template is a new template. It does not cause backward compatibility problems. It MAY be used in any open template that does not expressly prohibit its inclusion.

## Advance Directive Organizer (V3) template

The Advance Directives Organizer (V3) template does not cause backward compatibility problems.

The Advance Directive Organizer (V2) template SHOULD have at least one author and SHALL have 1 or more components that are conformant to the Advance Directive Observation (V3) template.

The Advance Directive Organizer (V3) template SHOULD have at least one author and SHALL have 1 or more components that are conformant to the Advance Directive Observation (V4) template which in turn complies with the Advance Directive Observation (V3) template.

## Advance Directives Section (V4) template

The Advance Directives Section (V4) template does not cause backward compatibility problems.

The Advance Directives Section (V3) template requires an entry. The template does not constrain the type of entry that SHALL be present. The template permits Advance Directive Observation (V3) templates and permits Advance Directive Organizer (V2) templates. Other types of templates are not prohibited.

The Advance Directives Section (V4) template requires an entry. The template does not constrain the type of entry that SHALL be present. The template permits Advance Directive Observation (V3) templates (but notes they are deprecated) and permits Advance Directive Organizer (V2) templates (but notes they are deprecated). It also permits Advance Directive Organizer (V3) templates.

The Advance Directives Section (V4) template is therefore compliant with the V3 version. It can be used in place of the V3 template where ever it is required, suggested or permitted.

In C-CDA R2.1 the following document templates suggest or expressly permit the use of the Advance Directives Section (entries optional) V3 template:

* Consultation Note (V3) - MAY
* Continuity of Care Document (CCD) (V3) - MAY
* Referral Note (V2) - MAY

In C-CDA R2.1 the following document templates suggests the use of the Advance Directives Section (entries required) V3 template:

Transfer Summary (V2) - SHOULD

All of the document templates in C-CDA are open templates. A C-CDA 2.1 document would be backward compatible even if it included an Advance Directives Section (V4) template.

Documents that include an Advance Directives Section (V4) template are backward compatible with C-CDA 2.1 document templates because the newly defined Advance Directives Section (V4) templates (entries required and entries optional) are backward compatible with the Advance Directives Section (V3) templates.

Furthermore, the Advance Directive Section (entries required) (V4) template can be used in place of the Advance Directive Section (entries optional) (V4) template because it conforms to the V4 entries optional template.