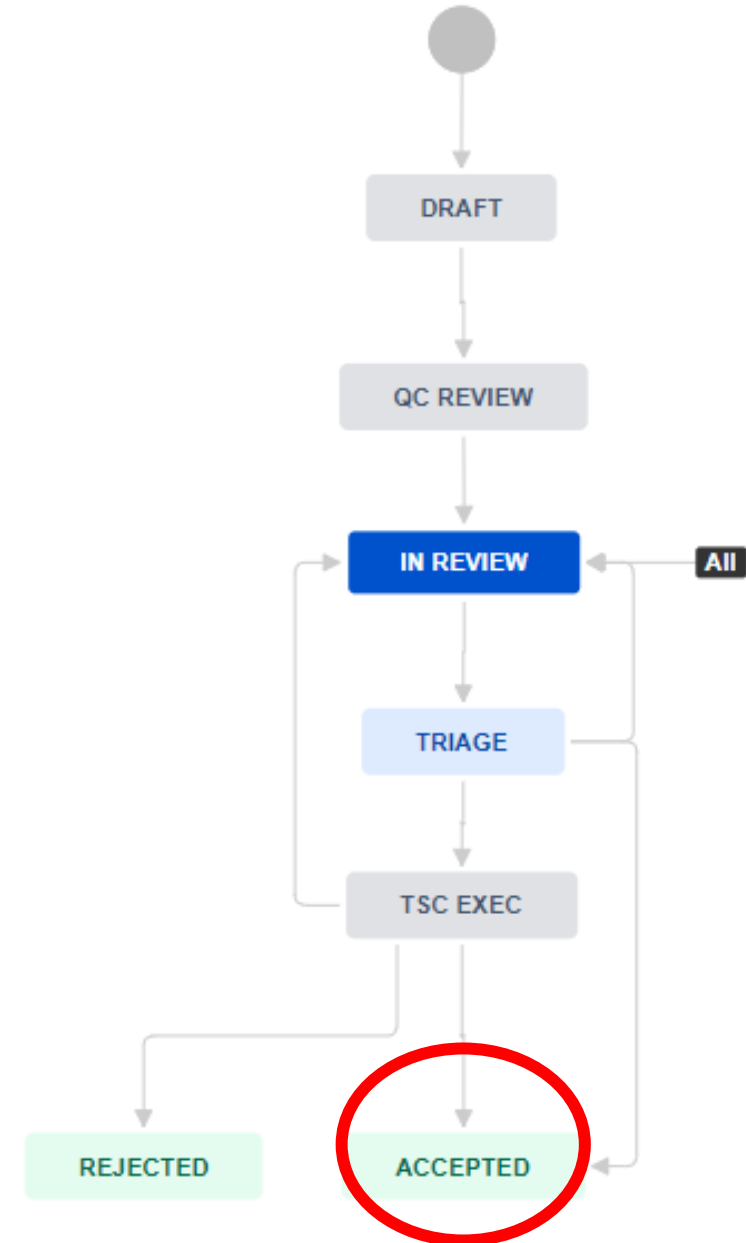# Advance Directives Interoperability (in FHIR)

Solicit WG Comments on Project Proposal

(FHIR IG May 2021 Ballot)

Project Proposal: PSS-1664

- Project Proposal
  - Accepted on October 8th

https://jira.hl7.org/browse/PSS-1664

Project Scope Statement

- Project Sponsor: Accepted
  - Patient Empowerment (10/1)
- Project Co Sponsors:
  - Community-Based Care and Privacy: (10/6) - monthly updates **(1/27/21 Q2 Time Block)**
  - Patient Care (10/7) – Updates at the Care Plan WG meetings and upon request **(1/27/21 Q2 Time Block)**
  - Orders and Observations (10/8) - Updates based on progress and focus and particularly during design and as part of O&O calls **(1/27/21 Q2 Time Block)**
- PMO – Received October 9, 2020
- US Realm (10/27) and FHIR Management Group (10/28) voted to approve the PSS
  - US Realm would like the ADI FHIR IG to work with Structured Doc to ensure that the previous work related to CCDA is incorporated into the FHIR IG work.
- Administrative Steering Division Approval (12/15)
- TSC e-vote and approval 12/21
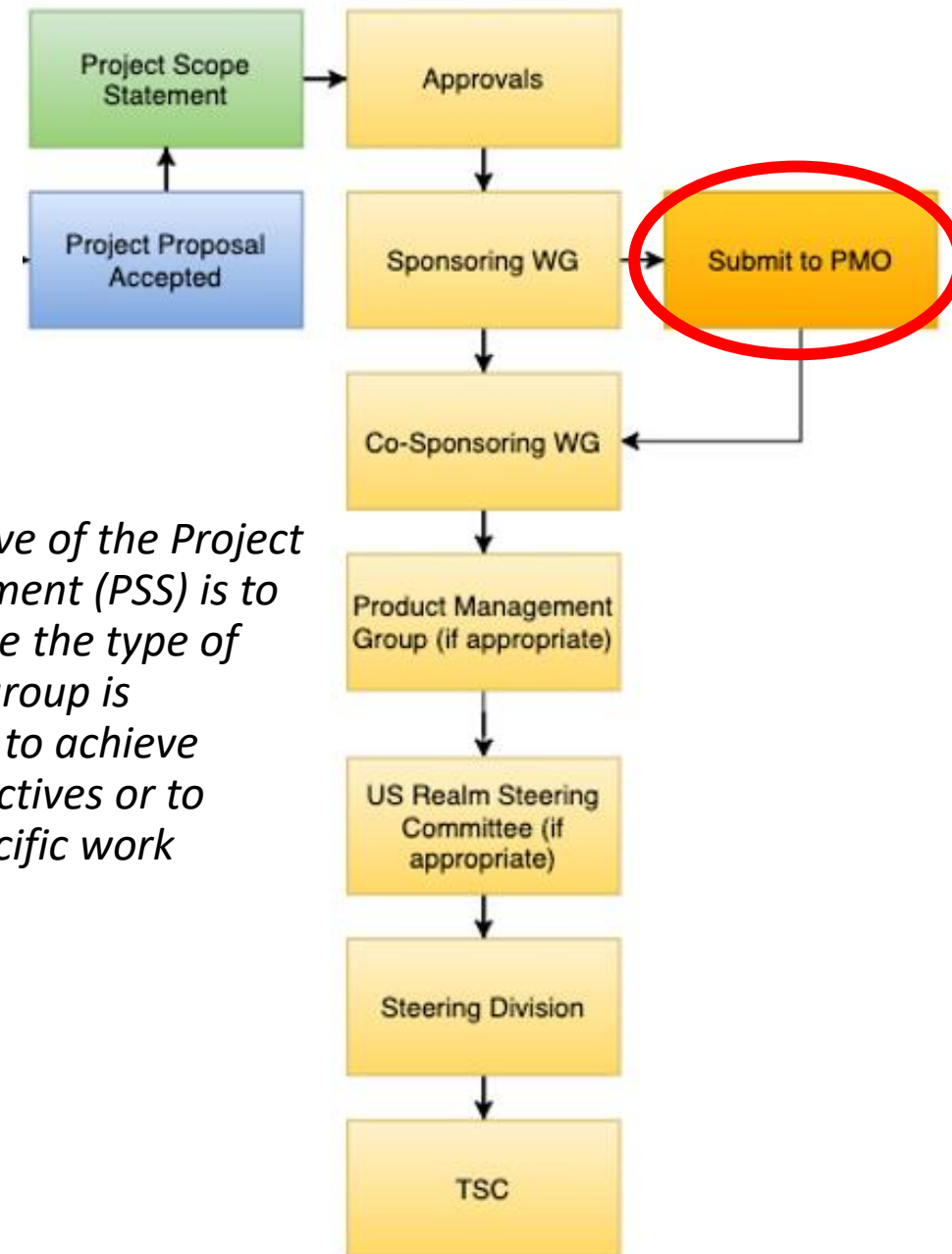
"The objective of the Project Scope Statement (PSS) is to communicate the type of activities a group is undertaking to achieve specific objectives or to produce specific work products."

https://confluence.hl7.org/display/PE/PACIO+Project%3A+PSS+for+Advance+Directives

3

Milestones for Advance Directives FHIR IG

- *FHIR IG Proposal – November 2020*
- Connectathon 1 – January 2021
- Connectathon 2 – March 2021
- Ballot an STU 1 IG – May 2021
- Connectathon 3- June 2021
- Connectathon 4 – September 2021
- Publish FHIR IG STU1 V1.0.0 – September 2021

Project Proposal and Project Scope Statement

- Project Proposal:

https://jira.hl7.org/browse/PSS-1664

- Project Scope Statement:

https://confluence.hl7.org/display/PE/PACIO+Project%3A+PSS+for+Advance+Directives

Patient Empowerment as a Sponsoring WG

Patient Empowerment Mission:

The Patient Empowerment Work Group promotes and amplifies the viewpoint of patients and their caregivers in HL7's standards work, in support of the HL7 mission.

Patient Empowerment Vision:

In the past decade, the culture of medicine has begun to recognize that healthcare value is measured by the person getting care: the consumer, the patient, and the family. The recipients of care inevitably have a different perspective than those creating and working in the healthcare system, and that perspective needs to be included by direct participation of patients and caregivers in the standards process.

Post Acute Care Interoperability (PACIO) Community

The Post Acute Care Interoperability (PACIO) Project is a collaborative effort between industry, government and other stakeholders, with the goal of establishing a framework for the development of a Fast Healthcare Interoperability Resource (FHIR) technical implementation guide(s) and Reference Implementations to facilitate health information exchange.

PACIO Use Cases

- Use Cases

- PACIO Leadership
  - **CMS:** Lorraine Wickiser
  - **ONC:** Elizabeth (Liz) Palena-Hall
  - **MITRE:** Dave Hill, Siama Rizvi, Sean Mahoney
- More details at https://confluence.hl7.org/display/PC/PACIO+Project+Use+Cases

PACIO Community

- Broad community outreach (Clinical, Industry, Technical)
- Deep FHIR Development capabilities
- FHIR Connectathon testing commitments
- Ballot Reconciliation commitments
- Ongoing terminology maintenance commitments
- Drive community adoption

How to Join the PACIO Community

Membership in the project is open to any participant willing to commit to the roles and responsibilities identified by the working group to support the overall success of the initiative. Contributions may include, but are not limited to:

- Knowledge of the subject matter
- Scalability of implementing the eventual solution
- Willingness to assist in the delivery of key outputs and working group artifacts
- Developing a testing framework for reference implementations
- Testing

Join the PACIO Project by reaching out to info@PACIOproject.org

Advance Directive Interoperability (ADI) Project Need

Systems used to create and update patient-generated advance care plans through a patient-directed process need a way for individuals to communicate information about their advance medical care goals, preferences, and priorities.

Individuals need a way to generate and update information related to their advance directives so that their current wishes can inform provider-generated care plans.

Interoperable exchange of the advance directive information supports more effective sharing of advance directive information across transitions in care and enables practitioners to create person-centered care plans that align with a patient's values, goals of care, treatment preferences, and quality of life priorities when a patient cannot communicate for themselves.

ADI External Drivers

The aging population receiving healthcare in skilled nursing facilities and assisted living communities have been under forced isolation to reduce the risk of contracting COVID-19. During COVID as well, those requiring medical care have found themselves during a transition of care without anyone to accompany them to influence medical care or be at their side. The impact is a sense of disempowerment, isolation, and a disconnection with the world they can no longer safely interact freely with.

Never before has the availability of verifiable digital advance directive information been so essential to delivering care.

The role of technology and expanded adoption by the aging population, providers, and care teams has brought to the forefront the expectation of seamless accessibility of advance directive information. An additional factor is an increased understanding that a person's goals, preferences, and priorities for care are a critical element in a person-centered healthcare system.

ADI Project Scope

This project will create FHIR implementation guidance for Advance Directives Interoperability (ADI).

It is a complex area that involves many stakeholders. The Post-Acute Care Interoperability (PACIO) Community has a strong interest in the topic of advance directives and will support the community engagement and technical FHIR IG development needed for Advance Directives Interoperability. PACIO is supported by MITRE, CMS, ONC and many other stakeholders (both clinical and technical).

FHIR profiles will be developed for several existing FHIR resources to represent advance directive content such as: living will, durable medical power of attorney, personal health goals at end of life, care experience preferences, patient instructions (obligation, prohibitions, and consent), and portable medical orders for life-sustaining treatments.

The FHIR IG will cover the use of RESTful API interactions for query, retrieve and verification of advance directive information between systems.

The guidance will be consistent with FHIR US Core IG and will build upon existing standards such as: HL7 CDA® R2 Implementation Guide: Personal Advance Care Plan (PACP) Document, Release 1 - US Realm STU Release 2 August 2020 and HL7 CDA® R2 Implementation Guide: C-CDA R2.1: Advance Directives Templates, Release 1 - US Realm

Volunteer Request Sent Out Dec. 11, 2020

- AAEM American Academy of Emergency Medicine
- AAHPM American Academy of Hospice and Palliative Care
- ACEP American College of Emergency Physicians
- AHA American Hospital Association
- AHCA American Health Care Association
- AHIMA Long-Term Care Practice Panel
- Altarum Institute
- AMA American Medical Association
- AMDA The Society for Post-Acute and Long-Term Care Medicine
- Apple Health
- ASLME American Society of Law, Medicine, and Ethics
- CAPC Center to Advance Palliative Care
- Carin Alliance
- Carequality
- CommonWell
- CPB Center for Practical Bioethics

- DaVinci Project
- Direct Trust
- eHealth Exchange
- EMS Leadership Academy
- FEHRM Defense Health Agency Federal Electronic Health Record Modernization
- Google Health
- HIMSS LTPAC Committee
- Leading Age
- Mayo Clinic
- MIDEO Institute on Healthcare Directives
- NASL National Association for the Support of Long-Term Care
- National POLST
- NHPCO National Hospice and Palliative Care Organization
- NPCRC National Palliative Care Research Center
- NHDD National Health Decisions Day
- NQF National Quality Forum

- SHIEC Strategic Health Information Exchange Collaborative
- VA Connected Care

Advance Directive Interoperability (ADI) FHIR IG Use Case Overview

Use Cases

Use Case 1: Create and Share/Make Available [Content]

Use Case 2: Update and Share/Make Available [Content]

Use Case 3: Request and Access [Content]

Use Case 4: Verify Current Version of [Content]

Content

Advance Directive Information
(person-authored information)

Episodic Patient Instruction
(person-authored information)

Portable Medical Order for Life-Sustaining Treatments
(practitioner-authored information)

Advance Directive Interoperability FHIR IG
Use Case Overview Continued

Use Case 1: Create and Share/Make Available [Content]

Use Case 1a: Create and Share/Make Available Advance Directive Information

Use Case 1b: Create and Share/Make Available Episodic Patient Instruction

Use Case 1c: Create and Share/Make Available Advance Portable Medical Order for Life-Sustaining Treatments

Use Case 2: Update and Share/Make Available [Content]

Use Case 2a: Update and Share/Make Available Advance Directive Information

Use Case 2b: Update and Share/Make Available Episodic Patient Instruction

Use Case 2c: Update and Share/Make Available Advance Portable Medical Order for Life-Sustaining Treatments

Use Case 3: Request and Access [Content]

Use Case 3a: Request and Access Advance Directive Information

Use Case 3b: Request and Access Episodic Patient Instruction

Use Case 3c: Request and Access Advance Portable Medical Order for Life-Sustaining Treatments

Use Case 4: Verify Current Version of [Content]

Use Case 4a: Verify Current Version of Advance Directive Information

Use Case 4b: Verify Current Version of Episodic Patient Instruction

Use Case 4c: Verify Current Version of Advance Portable Medical Order for Life-Sustaining Treatments

Break the Glass (Emergency)

Create and Share/Make Available (rev 1)

1a: Create and Share/Make Available Advance Directive Information

Angie has Sickle Cell Disease
She worries that if she contracts COVID-19 and becomes unable to communicate with medical personnel, they won't be familiar with her history and specific treatment needs.

Reluctance to allow paper advance directive documents due to infection risk – ineligible as a source of information

Restrictions on Non-Patient Visitors Prohibits Healthcare Agent Presence to Communicate on Her Behalf

Create

She uses a consumer-facing tool to create a digital advance directive or upload a scanned copy of her paper advance directive document

Her interoperable digital advance directive information is stored in a registry/repository/HIE/QHIN/EHR
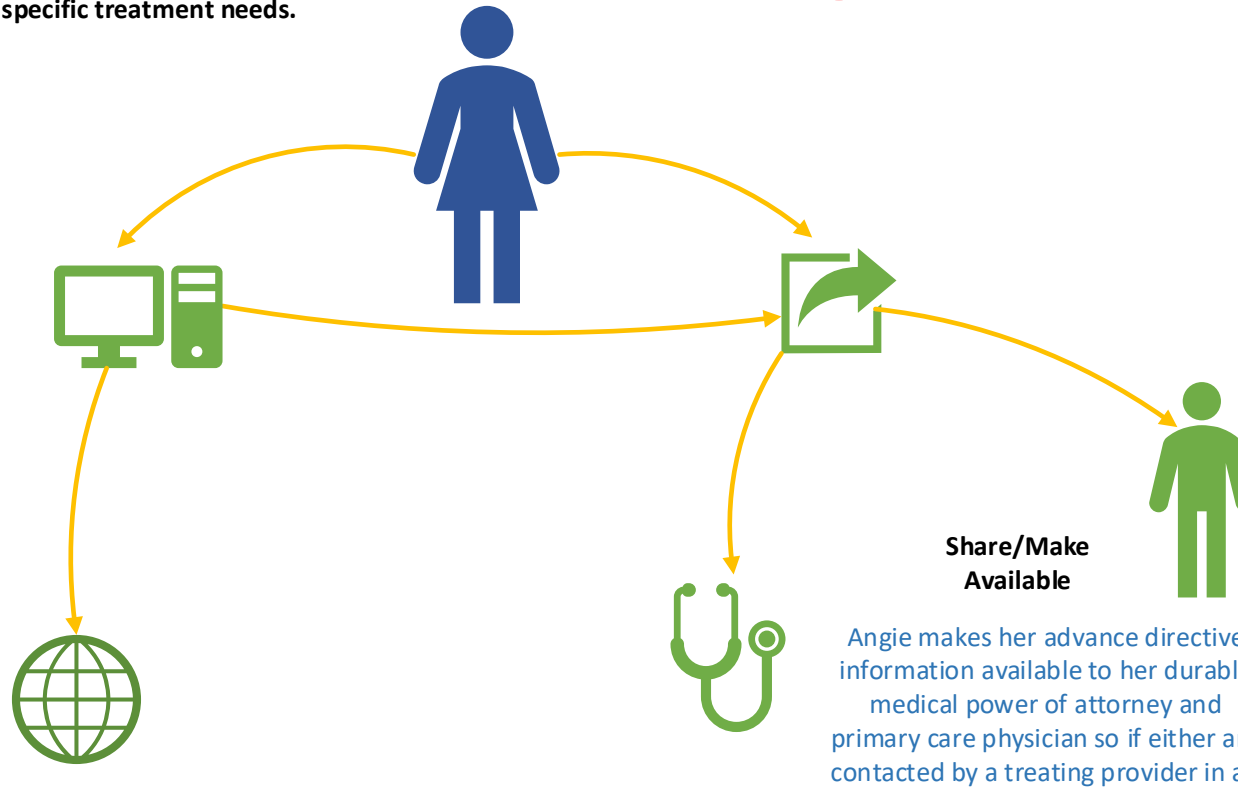
Share/Make Available

Angie makes her advance directive information available to her durable medical power of attorney and primary care physician so if either are contacted by a treating provider in an emergency they can make her ACI available, to inform treatment

Advance Directive Information Parking Lot

- We need to account for cognitive status of the person to change during the episode of care
- Is the End Date on an Adv Dir blank until replaced/altered?
  - Should we enforce an End Date or at least enforce review of existing ADI to allow for mis-matches to occur?
- We also need to ensure that delete/inactivate is accommodated when updates are made
  - Hence the idea of a document id that allows the "current" document to be retrieved if more than one of that type exists for a single individual
- Jube said there are standards in existence from a legal stance so we should piggy-back on them instead of building a new set of rules
  - The gap in the current state is that even with legal designations for how to prioritize the documents, the legal prioritization of existing ADI documents isn't communicated to the providers that render the care, so our job is to create a framework that is accessible to all who work with the patient
  - Legal and clinical jurisdictions don't see the problem the same way, which is part of what we need to work through
- What exists from beginning to end might be in the world of blockchain, which we can model

Create and Share/Make Available (rev 1)

1b: Create and Share/Make Available Episodic Patient Instructions

Steven is a 34 year old man who has had Cystic Fibrosis all his life. He created his advance directive a few years ago when his condition sharply worsened. He is eligible for a lung transplant due to his age and disease state.

His episodic patient instructions and associated order is made available to other care settings (outside the clinical record) by being stored in a registry/repository/HIE/QHIN/EHR as a result of integration that exists

His advance directive states that he wants no life-sustaining treatment if he has a health crisis that warrants those measures, and is unable to communicate for himself.
Steven doesn't want to be resuscitated only to wait for a lung transplant that may never happen.

Steven's episodic patient instructions are recorded in the clinical record along with an order/clinical note to enable the entire medical team to have visibility to his instructions during his surgical procedure.

Steven gets the call one night that he has been matched to a donor and goes immediately to the hospital for his lung transplant.

The surgeon meets with Steven prior to the procedure and asks him if he has any specific instructions related to the transplant, should a situation arise during surgery that requires life-sustaining treatment decisions be made.

Steven creates an episodic patient instruction that states he wants to receive life-sustaining treatment during the current episode of care.
He feels he has a chance at a longer life with a new lung that he hasn't been able to consider until now.
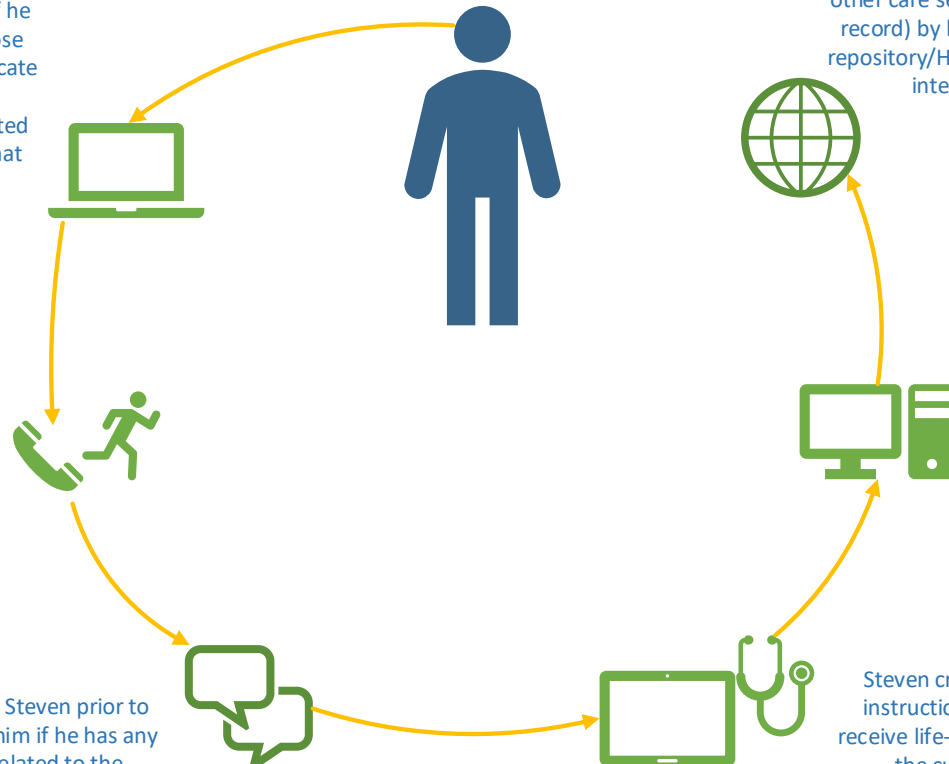
Episodic Patient Instruction (EPI) Parking Lot

- Should the EPI be time-boxed?
  - Logically the patient instruction related to an episode of care would have a start/end date.
  - Requiring an End Date isn't always possible, you don't know when the current episode will end, so how can we require it?
  - Does the end of the Episode = the End Date of the EPI?
- What happens when it conflicts with a previously issued advance directive?
- EPI creation is just intended to just cover a surgery or episode of care
  - What about the impact on that existing Adv Dir, should we enforce a requirement that existing ADI is reviewed when an EPI is issued?
  - Would it potentially replace the Adv Dir, and what does that chain of events in that enforcement look like?
  - The patient may not understand the relationship between an EPI and ADI, so how can we ensure we provide for consistency across forms/documents?
  - If we don't require some level of consistency between forms in use, we'll end up with conflicting ADI and confusion about what to do OR care setting standards that favor 1 form over another

Create and Share/Make Available (rev 1)

1c: Create and Share/Make Available
Portable Medical Order for Life-Sustaining Treatment

Frank is a 78 year old man who has end stage kidney disease and receives dialysis 3x per week. He receives long-term supportive services in his home. Frank is cognitively intact.

One evening Frank sustains a significant change in condition that renders him unconscious. The SNF care team reviews his portable medical order for life-sustaining treatment document to find he doesn't want to receive life-sustaining treatment. They call 911 in accordance with facility policy. Emergency access to Frank's ADI is granted, and the EMS personnel render comfort measures in concordance with his wishes.

Frank suffers from a chronic health condition that has resulted in a limited life-expectancy of 6-12 months. He creates an advance directive with his caregiver. Frank does not want to have life-sustaining treatment rendered if his condition warrants those measures, if he is unable to communicate for himself.

The facility's medical record is integrated to the broader healthcare eco-system which accessed Frank's advance directive, and now enables his portable medical order for life-sustaining treatment document to be available in a registry/repository/HIE/QHIN so as to inform treatment during a transition of care.

Frank's condition worsens sharply one day and he is taken by ambulance to the nearest hospital for treatment. Frank tells the ER physician about his advance directive and the physician writes a DNR order, valid for that hospitalization only, to Frank's medical record.

The practitioner ensures the portable medical order for life-sustaining treatment document is added to Frank's SNF medical record so it is accessible by facility staff in case of emergency. Frank also receives a copy of this new document, which he places in his bedside table.

Frank is transferred to a skilled nursing facility for post-acute care. The practitioner overseeing his care in the SNF meets with Frank to discuss his goals of care, his hospital DNR, and review his advance directive with him. He recommends creation of a portable medical order for life-sustaining treatment to align with Frank's desire to prevent an unwanted hospital transfer.

Portable Medical Order for Life-Sustaining Treatment Parking Lot

- Portable today = paper

- In a hospital setting, the P-MOLST might be done by the neurologist or ICU Attending (in our story)
  - A DNR is customary, with variations such as DNR Full, DNR Partial, No DNR
  - It is typically valid for that stay ONLY

- SNF physician discussion:
  - SNFs require an on-staff practitioner care for their residents
  - SNFs will sometimes allow an outside MD (PCP) in to care for their patient, but only as a courtesy
  - A POLST for a resident while in a SNF must be signed by an on-staff practitioner
  - There was an expression of liability concerns that drives this arrangement

- We should look to standardize how the order is shared <u>OUTSIDE the EMR</u>, not how it is stored/shared <u>INSIDE the EMR</u>
  - There are also legality and accessibility barriers
  - Care setting preferences as to form can impact which form is completed and informs care

- POLST documents vary by state in some places
  - We should use the proposed National form to identify the core data elements and then add the state-specific ones as variations to the data set.

- Some states, California, request renewal and confirmation of the POLST every 90 days
  - The Council for Compassionate Care in CA has had POLST in the law since 2009
  - How would this play out in a home setting?

CDA Basics

CDA – Clinical Document Architecture is an HL7 v3 document standard. This standard specifies the structure and semantics of "clinical documents" for the purpose of exchange with other providers. One of the documents within this architecture is the CCD.

```
<component>
    <section>
        <code code='10157-6' codeSystem='2.16.840.1.113883.6.1'/>
            <!-- This code references « history of family member
            diseases » -->
        <title>Family History</title>
        <text>
            <table border='1'>
                <thead>
                    <tr>
                        <th>Family Member</th>
                        <th>Problem</th>
                        <th>Cause of Death?</th>
                    </tr>
                </thead>
                <tbody>
                    <tr>
                        <td>Father</td>
                        <td>Myocardial Infarction</td>
                        <td>Yes</td>
                    </tr>
                </tbody>
            </table>
        </text>
    </section>
</component>
```

CDA Basics Continued

CCD – Continuity of Care Documents and Continuity of Care Records (CCR) are standard formats for exchanging key clinical information.

A CCD was NOT intended to be a complete medical history or chart for a given patient/resident. It is a snapshot of information that is broken across 17 sections intended to ONLY be the information critical to effectively continue care in the current setting or during transitions of care, specifically in the context of a patient being transferred from one care setting to another.

CDA Templates as Building Blocks of Data

The consolidated library of reusable Clinical Document Architecture (CDA) templates and common document types for C-CDA R1.0/R1.1 include:

Consultation Note
Continuity of Care Document (CCD)
Diagnostic Imaging Report
Discharge Summary
History and Physical
Operative Note
Procedure Note
Progress Note
Unstructured Document

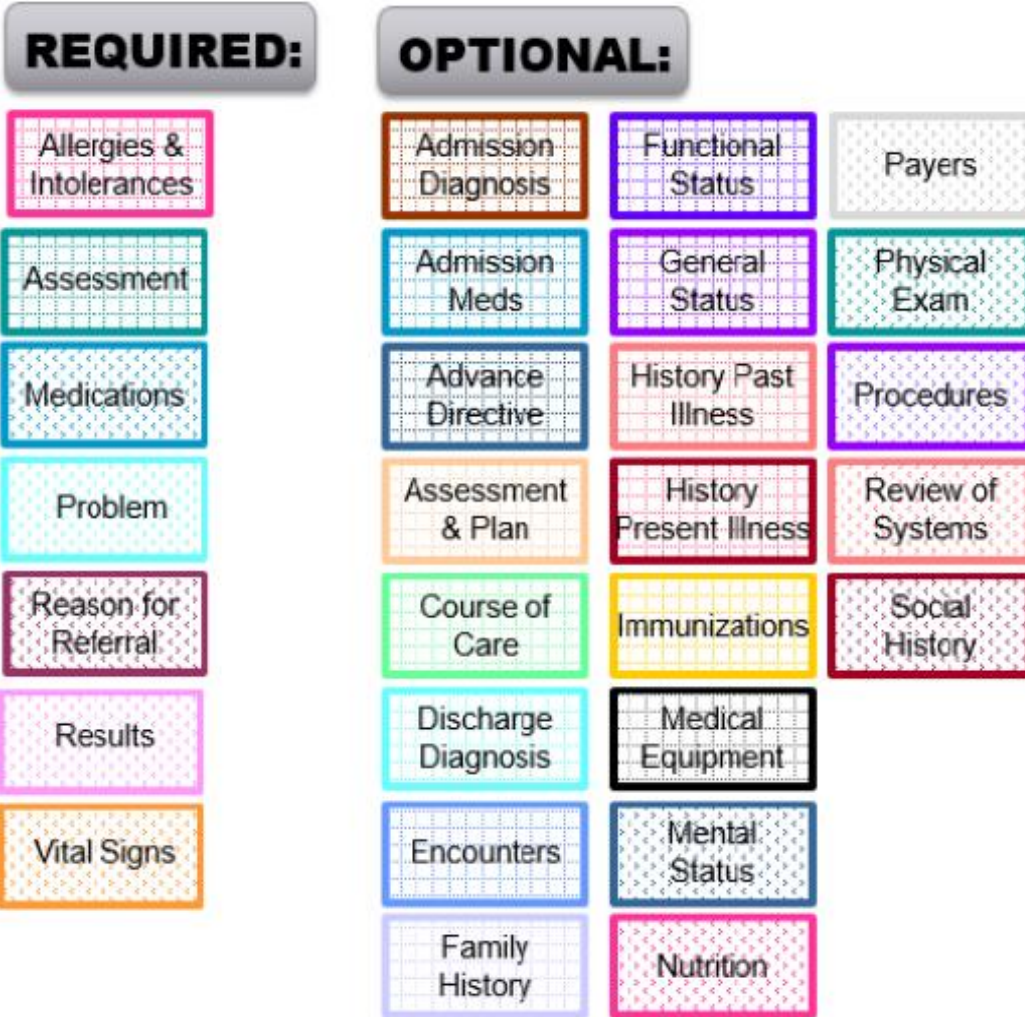New as of C-CDA R2.0/R2.1:
Care Plan
Referral Note
Transfer Summary

These same building blocks can then be reused in other CDA document types, **facilitating interoperability across a wide range of clinical uses and settings**.
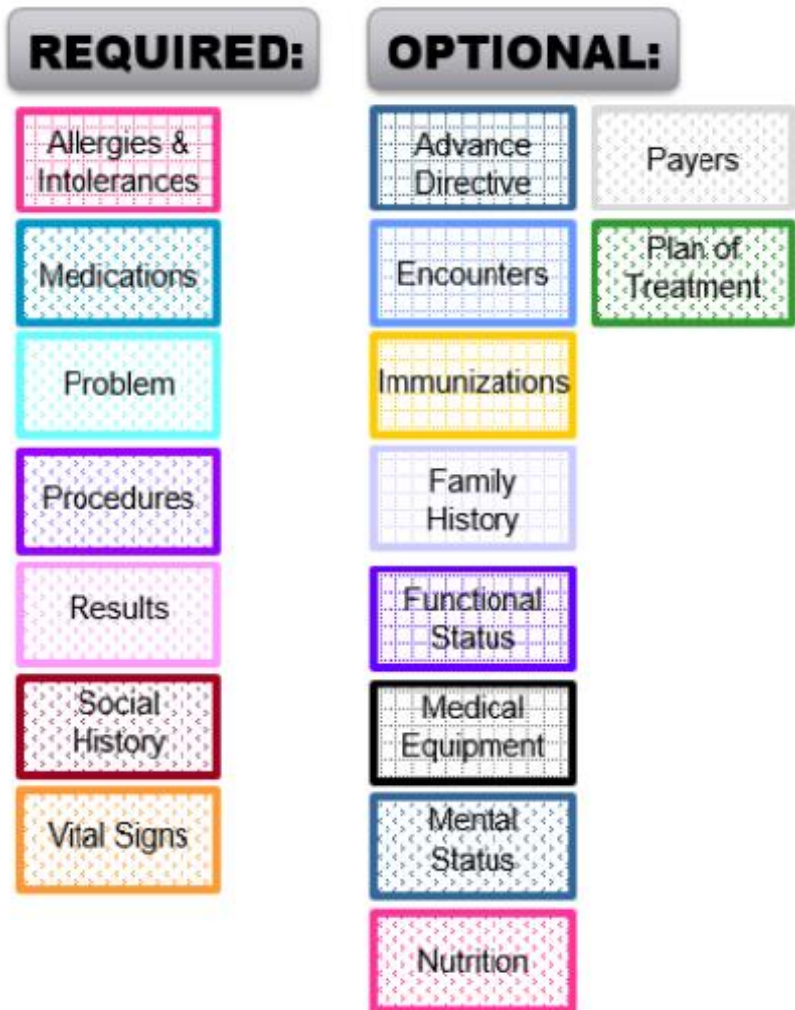
The 70 Document Sections in C-CDA R2.1

Admission Diagnosis	Admission Meds	Advance Directive	Allergies & Intolerances	Anesthesia	Assessment & Plan	
Assessment	Chief Complaint Reason for Visit	Chief Complaint	Complications	Course of Care	DICOM Object Catolog	Discharge Diagnosis	Discharge Diet
Discharge Medications	Encounters	Family History	Fetus Subject Context	Findings	Functional Status	General Status	Goals
Health Concerns	Health Status Eval/Outcomes	History Past Illness	History Present Illness	Hospital Consultations	Hospital Course	Hosp. Disch. Instructions	Hosp. Disch. Physical
Hosp. Disch. Studies Sum.	Immunizations	Implants	Instructions	Interventions	Medical (Gen) History	Medical Equipment	Medications Administered
Medications	Mental Status	Nutrition	Objective	Observer Context	Operative Note Fluids	Op Note Surgical Proc.	Payers
Physical Exam	Plan of Treatment	Planned Procedure	Postoperative Diagnosis	Postprocedure Diagnosis	Preoperative Diagnosis	Problem	Procedure Description
Procedure Disposition	Procedure Est. Blood Loss	Procedure Findings	Procedure Implants	Procedure Indications	Procedure Specimens	Procedures	Reason for Referral
Reason for Visit	Results	Review of Systems	Social History	Subjective	Surgery Description	Surgical Drains	Vital Signs

Example Templates

Transfer Summary

REQUIRED:
- Allergies & Intolerances
- Assessment
- Medications
- Problem
- Reason for Referral
- Results
- Vital Signs

OPTIONAL:
- Admission Diagnosis
- Admission Meds
- Advance Directive
- Assessment & Plan
- Course of Care
- Discharge Diagnosis
- Encounters
- Family History
- Functional Status
- General Status
- History Past Illness
- History Present Illness
- Immunizations
- Medical Equipment
- Mental Status
- Nutrition
- Payers
- Physical Exam
- Procedures
- Review of Systems
- Social History

CCD

REQUIRED:
- Allergies & Intolerances
- Medications
- Problem
- Procedures
- Results
- Social History
- Vital Signs

OPTIONAL:
- Advance Directive
- Encounters
- Immunizations
- Family History
- Functional Status
- Medical Equipment
- Mental Status
- Nutrition
- Payers
- Plan of Treatment

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CDA and Data Exchange

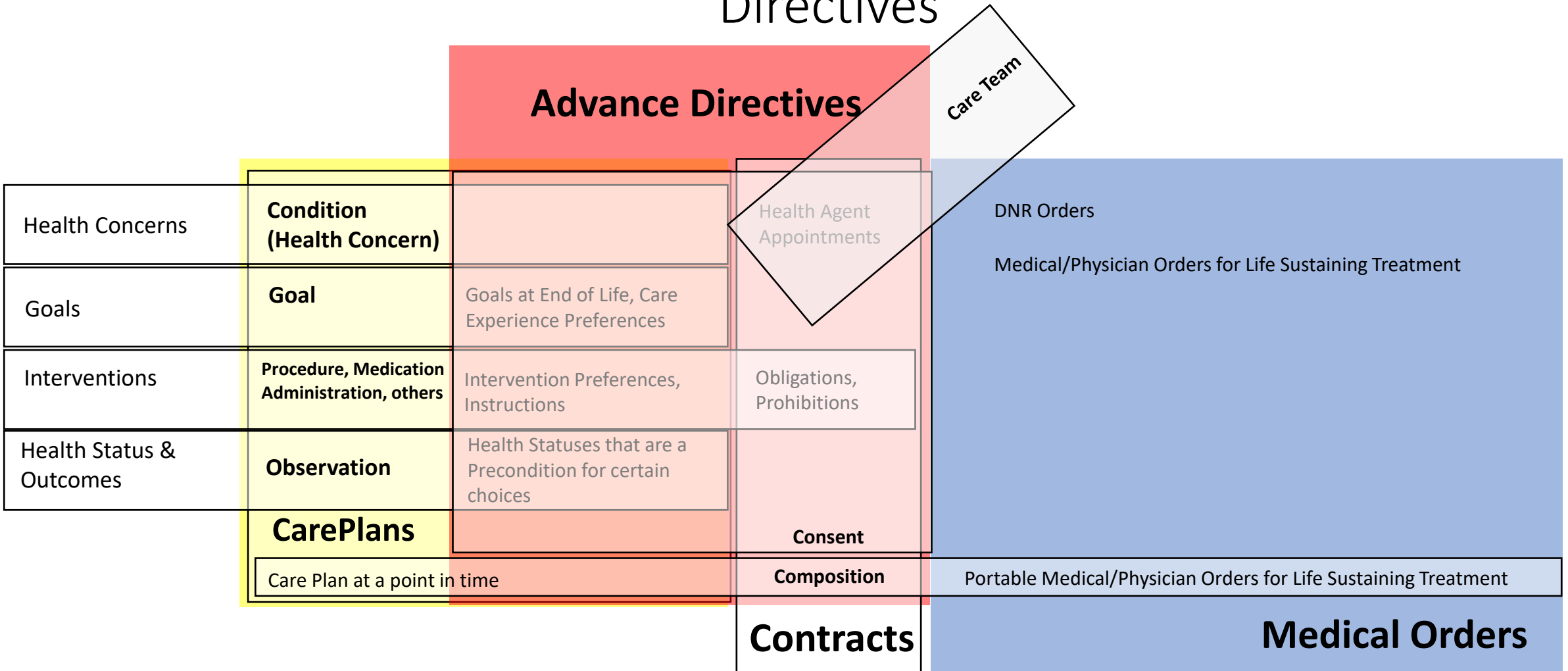C-CDA Provides Semantic Building Blocks!

CDA and FHIR – They Can Be Used Together

- CDA is limited to "clinical" use cases and documents that deal with patients.

- Template IDs are required to support interoperability and are required to understand the meaning of instances.

- Requires coded data for Problems, Results, Medications, etc.

- Traditionally a read-only medium.

- Can be challenging to implement.

- FHIR documents have no limitation on their content and can have subjects other than patients.

- FHIR content references existing resources.

- FHIR represents common structures only one way, allowing for less deviation.

- Uses a "required if known" approach, so work-arounds for null are not needed.

- Allows developers to interact with the resources by creating, reading, updating, and deleting them.

- Fast and easy to implement.

FHIR Resources Anticipated for Use to Represent Advance Directives

		Advance Directives	Care Team	
Health Concerns	**Condition (Health Concern)**		Health Agent Appointments	DNR Orders
Goals	**Goal**	Goals at End of Life, Care Experience Preferences		Medical/Physician Orders for Life Sustaining Treatment
Interventions	**Procedure, Medication Administration, others**	Intervention Preferences, Instructions	Obligations, Prohibitions	
Health Status & Outcomes	**Observation**	Health Statuses that are a Precondition for certain choices		

CarePlans

| Care Plan at a point in time | **Consent** | | |
| | **Composition** | | Portable Medical/Physician Orders for Life Sustaining Treatment |

Contracts

Medical Orders

**No New FHIR Resources are needed

30