|  |
| --- |
|  |
| Health eDecisions |
| CDS Artifact Sharing |
|  |
|  |
| **9/13/2012** |

Table of Contents

[1.0 Preface and Introduction 4](#_Toc335381858)

[2.0 Initiative Overview 4](#_Toc335381859)

[2.1 Initiative Challenge Statement 4](#_Toc335381860)

[3.0 Use Case Scope 5](#_Toc335381861)

[3.1 Initiative Background 5](#_Toc335381862)

[3.2 In Scope 6](#_Toc335381863)

[3.3 Out of Scope 6](#_Toc335381864)

[3.4 Communities of Interest 7](#_Toc335381865)

[4.0 Value Statement 9](#_Toc335381866)

[5.0 Use Case Assumptions 10](#_Toc335381867)

[6.0 Pre-Conditions 12](#_Toc335381868)

[7.0 Post Conditions 12](#_Toc335381869)

[8.0 Actors and Roles 12](#_Toc335381870)

[9.0 Use Case Diagram 13](#_Toc335381871)

[10.0 Scenario 14](#_Toc335381872)

[10.1 User Stories Scenario 1 14](#_Toc335381873)

[User Story 1A 14](#_Toc335381874)

[User Story 1B 15](#_Toc335381875)

[10.2 Activity Diagram 15](#_Toc335381876)

[10.2.1 Base Flow – User Story 1A & 1B 15](#_Toc335381877)

[10.3 Functional Requirements 16](#_Toc335381878)

[10.3.1 Information Interchange Requirements 16](#_Toc335381879)

[10.3.2 System Requirements 16](#_Toc335381880)

[10.4 Sequence Diagram 17](#_Toc335381881)

[11.0 Dataset Requirements 17](#_Toc335381882)

[11.1 Artifact Data Element Structure Overview 17](#_Toc335381883)

[11.2 Metadata 19](#_Toc335381884)

[11.3 Reusable Components 23](#_Toc335381885)

[11.3.1 Actions 23](#_Toc335381886)

[11.3.2 Supporting Evidence 25](#_Toc335381887)

[11.3.3 Supporting Reference 28](#_Toc335381888)

[11.3.4 Clinical Mapping Data 28](#_Toc335381889)

[11.3.5 Expression 48](#_Toc335381890)

[11.3.6 Attribute-Value List 54](#_Toc335381891)

[11.4 CDS Knowledge Artifact Types Data Elements 55](#_Toc335381892)

[11.4.1 Event Condition Action Rules Data Elements 55](#_Toc335381893)

[11.4.2 Order Sets Data Elements 59](#_Toc335381894)

[11.4.3 Documentation Templates Data Elements 64](#_Toc335381895)

[12.0 Risks, Issues and Obstacles 72](#_Toc335381896)

[Appendices 74](#_Toc335381897)

[Appendix A: Glossary of Terms 74](#_Toc335381898)

[Works Cited 76](#_Toc335381899)

**List of Figures:**

[Figure 1. CDS Environmental Assumptions 10](#_Toc335381921)

[Figure 2: Use Case Diagram 13](#_Toc335381922)

[Figure 3: Context Diagram 14](#_Toc335381923)

[Figure 4: Activity Diagram 15](#_Toc335381924)

[Figure 5. Sequence Diagram 17](#_Toc335381925)

[Figure 6. Artifact Data Element Structure 18](#_Toc335381926)

**List of Tables:**

[Table 1: Communities of Interest 9](#_Toc335381906)

[Table 2: Actors and Roles 13](#_Toc335381907)

[Table 3: Base Flow of Scenario 1 16](#_Toc335381908)

[Table 4: Information Interchange Requirements 16](#_Toc335381909)

[Table 5: System Requirements 16](#_Toc335381910)

[Table 6. Metadata 22](#_Toc335381911)

[Table 7. Reusable Components - Actions 25](#_Toc335381912)

[Table 8. Reusable Component - Supporting Evidence 27](#_Toc335381913)

[Table 9. Reusable Components - Supporting Reference 28](#_Toc335381914)

[Table 10. Reusable Component - Clinical Data Mapping 47](#_Toc335381915)

[Table 11. Reusable Components - Expression 54](#_Toc335381916)

[Table 12. Reusable Components - Attribute-Value Lists 55](#_Toc335381917)

[Table 13. Event Condition Action Rules Data Elements 59](#_Toc335381918)

[Table 14. Order Sets Data Elements 63](#_Toc335381919)

[Table 15. Documentation Templates Data Elements 71](#_Toc335381920)

# 1.0 Preface and Introduction

To fully realize the benefits of health IT, the Office of the National Coordinator for Health Information Technology (ONC), as part of the Standards and Interoperability (S&I) Framework is developing Use Cases that define the interoperability requirements for high priority health care data exchange; maximize efficiency, encourage rapid learning, and protect patients’ privacy in an interoperable environment. These Use Cases address the requirements of a broad range of Communities of Interests including; patients, their significant others and family members, providers, payers, vendors, standards organizations, public health organizations, and Federal agencies.

These Use Cases describe:

* The operational context for the data exchange
* The stakeholders with an interest in the Use Case
* The information flows that must be supported by the data exchange
* The types of data and their specifications required in the data exchange

The Use Case is the foundation for identifying and specifying the standards required to support the data exchange and developing reference implementations and tools to ensure consistent and reliable adoption of the data exchange standards.

# 2.0 Initiative Overview

The goal of the Health eDecisions (HeD) initiative is to identify, define and harmonize standards that facilitate the emergence of systems and services whereby shareable CDS interventions can be implemented via:

* Standards to structure medical knowledge in a shareable and executable format for use in CDS, and
* Standards that define how a system can interact with and utilize an electronic interface that provides helpful, actionable clinical guidance

In order to facilitate integration of a system with CDS interventions, the scope includes standards to refer to data in electronic health records and standards to map recommendations to locally implementable actions.

## 2.1 Initiative Challenge Statement

Clinical Decision Support (CDS) is the user facing representation of clinical guidance. Effective CDS interventions require availability of computable biomedical knowledge, person-specific data, and a reasoning or inference mechanism that combines these elements to generate and present helpful and actionable information to clinicians, individuals, or caregivers in the right way – at the right time. In order to optimize these benefits, CDS interventions must be made more easily shareable and implementable so that any organization can easily acquire and deploy CDS interventions. To this end, standards must be advanced to enable either the routine or regular consumption of CDS interventions through a Web service or the repeated import and update of CDS artifacts into CDS systems.

# 3.0 Use Case Scope

This Use Case defines the requirements to build a standard for the contents of CDS Knowledge artifacts.  The use case focuses on the following artifact types: Event Condition Action (ECA) Rules, Order Sets, and Documentation Templates. To support this purpose the Use Case has one scenario:  A CDS Knowledge Artifact Supplier makes computable CDS Knowledge Artifact available to CDS Artifact Integrator.

## 3.1 Initiative Background

At least two core pillars underlie the promised benefits of electronic health records: access to data through interoperable data exchange and intelligent management of data through clinical decision support (CDS). To realize these benefits, a clinician must have access to the necessary data to render care. In order to make these data accessible, the issues addressing what data to share, when to share data, with whom to share the data, and in what format to share data need to be resolved. Much of the early work supported by S&I initiatives has been to accelerate such data sharing activities.

However, realizing the full promise of electronic health records also requires that we utilize these data to improve patient care. This intelligent utilization of data is the domain of clinical decision support. That support may include facilitating efficiency of care delivery, providing timely access to relevant information, providing vigilance that the care delivered is compliant with intended best practice, and ultimately reducing the lag from the acquisition of new medical knowledge to its application at the bedside.

Similar to clinical data, if the tools of CDS are not available to the clinician, they cannot render their potential benefit. Accordingly, CDS has a need for interoperability just like clinical data. Currently there are only limited standards defining how CDS artifacts can be shared and how CDS consumers can access the resources of a CDS system.

This initiative is to establish a framework for the interoperability of CDS at the highest level. This initiative does not endeavor to establish which issues CDS should address (i.e., content) nor does it endeavor to establish all possible ways in which CDS could be exchanged. Instead, it focuses on a core set of exchange approaches that appear to offer the greatest impact in the present without constraining the future potential of CDS.

This initiative will support two general use cases consistent with the two models that arose from the ONC funded project “A Prototype Knowledge- Sharing Service for Clinical Decision Support Artifacts”. In the first use case, interoperability relates to the exchange of those artifacts (e.g., knowledge) that are required for a system to deliver clinical decision support. In our second use case, interoperability relates to the exchange of information that allows the delivery of the results derived from the execution of clinical decision support. That is, the first use case addresses how a clinical decision support system obtains the artifacts to enable the “decision making” process and the second use case addresses how a clinical decision support system receives data and returns its conclusions and recommendations in order to facilitate decision making.

The promise of clinical decision support can be summarized as a simple story. On Monday medical research provides a better way to deliver some aspect of care to some population. On Tuesday that new knowledge is incorporated into clinical decision artifacts. On Wednesday those artifacts are incorporated into a clinical decision support system. On Thursday a clinician is able to deliver better care to a patient because that care was informed by new medical knowledge. On Friday that patient’s care informs medical research to advance our medical knowledge. (Please note, with this example Monday and Tuesday could represent the first Use Case (CDS Artifact Sharing) while the Wednesday, Thursday and Friday examples could represent the second Use Case (CDS Guidance Services)). In the policy and regulatory realm, the legal issues related to the sharing of CDS artifacts and results remain undefined. The success of the proposed use cases in actual implementations assumes that the potential legal limitations related to CDS sharing will have been addressed and resolved.

Please note, only the first Use Case (CDS Artifact Sharing) will be defined within this document.

## 3.2 In Scope

* Standards to structure medical knowledge in a shareable and executable format for use in CDS
* In Scope Artifact Types (definitions for these artifact types can be found in Appendix A)
* Event Condition Action Rules
* Order Sets
* Documentation Templates

## 3.3 Out of Scope

* Tools:
  + Authoring tools, source “content” management.
  + Terminology server and mapping tools including management of concept coordination.
  + Semantic processing of text, including structured string processing and natural language processing.
* System Functions
  + Messaging Layer
  + Means of sharing
  + Security
* Authoring, creation and maintenance of clinical decision support knowledge
* Knowledge Repository Design
* Search and query mechanisms
* Implementation in systems
* User presentation, Transport layers
* Market factors: regulatory incentive/mandate, liability shield, IP shield (patent/licensing litigation), certification body, marketplace design, test procedures, FDA rules
* Clinical Decision Support Services (this will be covered in Use Case 2 CDS Guidance Services)
* CDS Content Development Activities, including the distribution and sharing of artifacts
* The following artifacts are out of scope:
  + Context-Aware information retrieval (HL7 Information Button) – This will be covered in UC 2 (CDS Guidance Service)

## 3.4 Communities of Interest

| **Member of Communities of Interests** | **Working Definition** |
| --- | --- |
| Healthcare Professionals | Healthcare providers with patient care responsibilities (including physicians, Advanced Practice Registered Nurses, Physician Assistants, nurses, pharmacists, emergency care providers and other patient care personnel) who may access CDS during the course of providing care. |
| Provider Organizations | 1) Providers/suppliers of healthcare services or products; 2) Healthcare Provider - Person or organization that submits claim for payment of healthcare services or products in the normal course of business. Includes, but is not limited to a healthcare system with multi-facility providers who need a way to create, authenticate, manage, standardize and localize CDS Artifacts for use in a set of facilities with typically disparate EMR-vendor systems and/or disparate terminologies for each facility.  Organizations that are engaged in or support the delivery of healthcare. These organizations include but are not limited to hospitals, ambulatory centers, provider practices, integrated delivery systems, preferred provider organizations, health maintenance organizations, accountable care organizations, academic health systems. |
| Patients | Persons who are the target of healthcare activity.  Persons who may access CDS to make personal healthcare and/or wellness decisions. |
| Health Professional Associations | An Organization or body of persons engaged in the healthcare profession or medical specialty, organized to establish profession standards of conduct, maintain those standards and oversee its membership, develop and published peer reviewed evidence based guidelines and “White Papers” directed at providing and improving quality of healthcare services delivered and represent the professional in discussions and recommendations with other bodies (e.g. AAFP, AMA, AOA, AADEP, ABQAURP, NMA). |
| Standards Organizations | Organizations whose purpose is to define, harmonize and integrate standards that will meet clinical and business needs for sharing information among organizations and for system interoperability. |
| Federal & State Agencies | Organizations within the federal and/or state governments that deliver regulate or provide funding for health, healthcare and clinical or biomedical research. This also includes organizations within the federal and/or state governments that disseminate clinical guidance. |
| Accreditation Organizations | Organizations that review and accredit healthcare professional organizations, provider practices, and suppliers against defined standards (which may include Medicare Conditions of Participation). Examples include but are not limited to the Joint Commission, The American Osteopathic Association, Accreditation Association for Ambulatory Health Care and Det Norske Veritas. |
| Healthcare Payer/Purchaser | A third-party entity that establishes indications and limitations of coverage for payments or underwrites coverage for healthcare expense. |
| EHR/EMR/PHR Vendors | 1) EHR: A longitudinal electronic record of patient health information produced by encounter in one or more care settings. 2) Vendor: A company/consortium that provides products and/or services.  These suppliers may include developers, resellers, integrators, operators and others who facilitate access to CDS artifact via their product. |
| CDS Vendor | An organization that produces Clinical Decision Support artifacts or Clinical Decision Support system |
| CDS Service Provider | An organization that provides Clinical Decision Support services to EHR, EMR or PHR Systems. These services could include the provision of terminology alignment services (localizing terms in a CDS artifact for use in an EHR/EMR/PHR), as well as management of the “standardized gold copies” of CDS Artifacts needed by multi-facility healthcare providers.  Please note: This implies that these CDS services are implemented separately from the EHR/EMR/PHR System; there may be CDS services built into the functionality of an EHR/EMR/PHR System, but such a system would not interact with a CDS Service Provider. |
| EHR/EMR/PHR Service Provider | An organization that operates an EHR, EMR or PHR System and manages its access to CDS artifacts and/or services. An EHR/EMR Service Provider might or might not be the Provider Organization in which the Healthcare Professional works. |
| CDS Healthcare Researchers | Individuals who use healthcare information to develop the rules that are used in CDS, as well as to investigate their usage by healthcare professionals, and their effectiveness in improving individual health. |
| CDS Health Informatics Researchers | Individuals who are interested in defining the representation of and studying implementations of CDS artifacts. |
| Healthcare Product & Service Companies | Organizations that develop products and provide services for healthcare. This includes but is not limited to, Pharmaceutical Companies, Medical Device Manufacturers, Ancillary Medical Service Providers. |

Table : Communities of Interest

# 4.0 Value Statement

Health information technologies designed to improve clinical decision making are particularly attractive for their ability to address the growing information overload clinicians face and to provide a platform for rapidly incorporating knowledge into care delivery.

Standardized expressions of Clinical Decision Support have a number of important benefits including:

* Increased quality of care and enhanced health outcomes for individuals and populations
* Improvement in workflow
* Avoidance of errors and adverse events
* Improved efficiency, cost benefit, and provider and patient satisfaction
* Reduced latency for incorporating new clinical knowledge and evidence-based guidelines into clinical practice

Focusing the S&I Framework community on Clinical Decision Support through the Health eDecisions Initiative will enable the translation of interventions into implementable components, increasing the speed and ease of adoption by the provider community.

Target outcomes of the HeD Initiative include:

Alignment with Meaningful Use

* The product of this initiative will help providers achieve meaningful use of HIT and their quality improvement goals through addressing a known barrier to CDS development, adoption, and implementation
* Repositories or catalogues emerge, supplied by a range of content creators such as societies or content vendors, whereby CDS artifacts can be selected and imported into HIT systems
* Each intervention will be represented by a standardized expression of a guideline that can be accessed by EHR system developers and users to simplify the process of incorporating guidelines into EHRs
* Clinical Decision Support Services can interact with EHRs and/or other Health Information Technology implementations
* Alignment with other S&I Initiatives, e.g., Query Health (HQMF)
* Close the gap between standard availability and widespread use/value
* Engagement of medical professional societies and guidance authors to promote their development of CDS interventions in addition to traditional guideline publications

# 5.0 Use Case Assumptions

***Contextual Assumptions (CDS Environmental Landscape)***

This diagram shows the major components of a CDS environment and included within this section to provide a pictorial representation of the necessary Use Case assumptions.

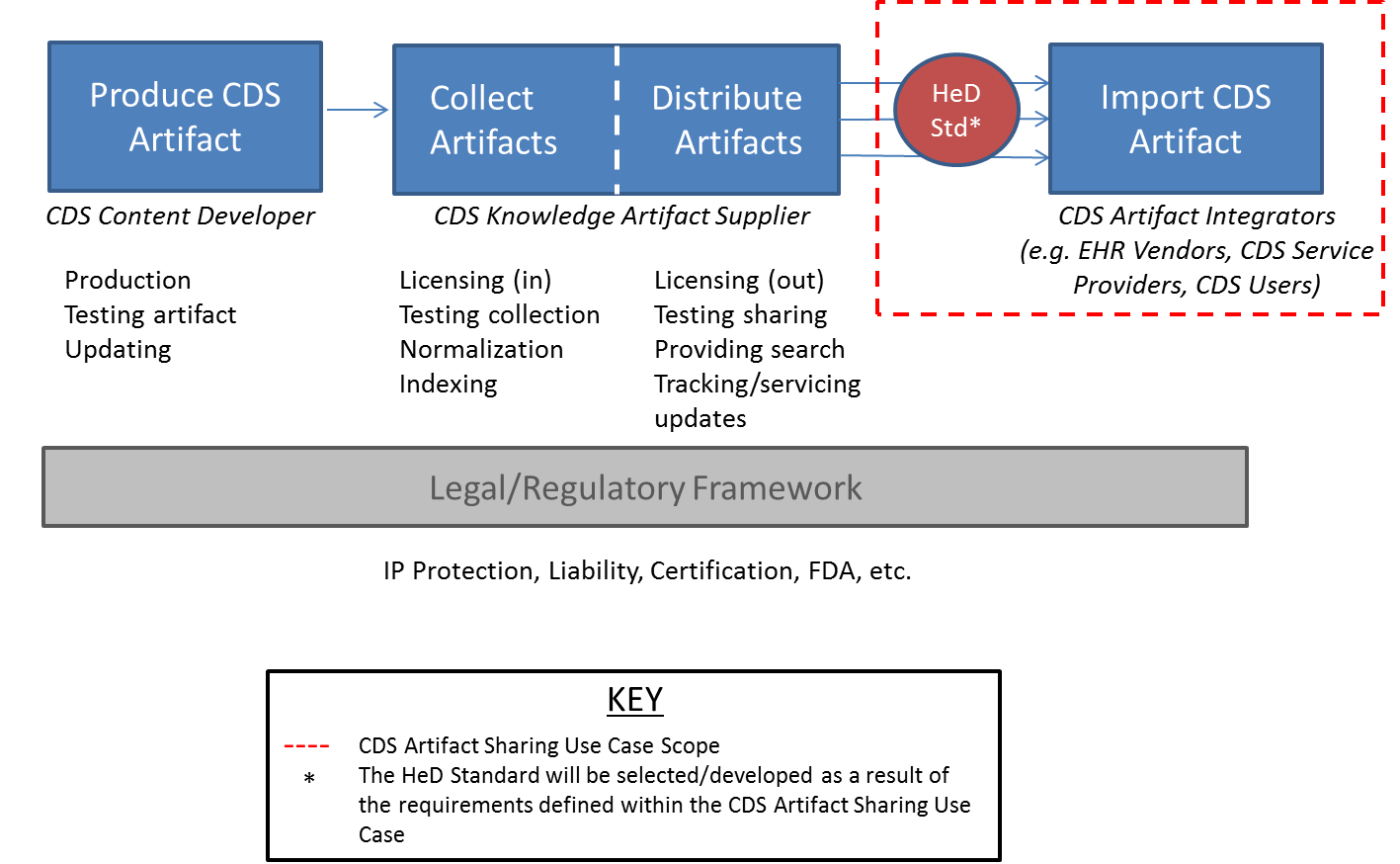


Figure . CDS Environmental Assumptions

***Producing CDS Artifacts (Actor: CDS Content Developer)***

* A methodology for testing the compliance and reliability of the CDS Knowledge Artifacts exists and is used to validate artifacts available within the CDS Knowledge Artifact Repository. This may include but is not limited to testing of the artifacts to ensure they perform as expected within a test environment.
* A process is in place to ensure that clinically important content updates are identified
* A governance structure is in place for oversight for the development and maintenance of the CDS Knowledge Artifacts

***Implementation/Integrating CDS Artifacts (Actor: CDS Artifact Integrator)***

* A governance structure and process is in place to determine which CDS Knowledge Artifacts will be implemented and in which context they will be applied in that organization (e.g., exclude patients in the oncology service from abnormal blood count alerts). In addition the governance structure provides guidelines on how artifacts and are revised, reviewed and approved for deployment.
* A User Adoption plan is developed to train and inform users of the purpose and use of the CDS Knowledge Artifacts.
* After obtaining a CDS Knowledge Artifact the CDS Integrator performs a series of integration steps which may involve structural transformation of the HeD artifact format into the format of the CDS system, importing the artifact into the CDS system, mapping triggers, data and actions within the artifact to triggers, data and actions in the CDS system, and adapting the knowledge for local use (e.g., restricting use to a specified clinical service or location).
* The requirements of the Use Case can be implemented in a variety of architectures.

***CDS Knowledge Artifact Repository: Collecting Artifacts from CDS Content Developers and Making these Artifacts available to CDS Artifact Integrators (Actor: CDS Knowledge Artifact Supplier & CDS Artifact Integrator).***

* CDS Knowledge Artifact repositories exist to store and distribute CDS artifacts Updates & maintenance of artifacts is supported.
* Mechanisms for licensing, distribution, integration into the end-user product exists.
* CDS Knowledge Artifact Supplier has a mechanism to track retrieval of CDS knowledge artifacts
* CDS Knowledge Integrator has a mechanism to track retrieval of CDS knowledge artifacts if needed.

***Legal/Regulatory Framework (Actors: ONC, regulatory and certification bodies)***

* Patent and intellectual property protection are addressed.
* A regulatory framework, exists, and will include appropriate classifications and reviews by FDA, CDC, CMS and other organizations.
* A liability framework exists to manage liability.
* A certification mechanism for compliance with the standard is in use.

# 6.0 Pre-Conditions

* CDS Artifact Supplier makes CDS artifacts available for search and consumption by CDS Artifact Integrators
* CDS Artifact integrator has the means to obtain the knowledge artifact from a CDS Repository (e.g. they have either browsed or queried the CDS Repository for available artifacts)
* CDS Artifact Integrator Selects Artifacts of Interest to Use in their CDS System

# 7.0 Post Conditions

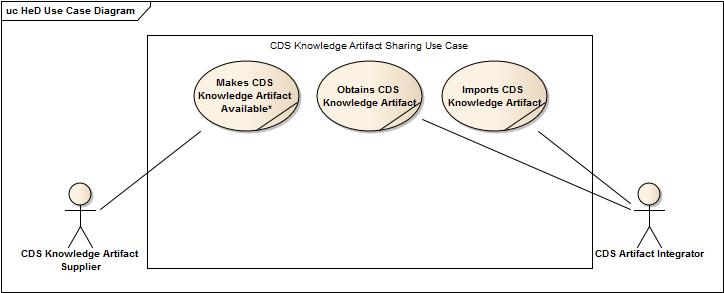
* The CDS Knowledge Artifact Supplier has sent the CDS Knowledge Artifact to the requesting CDS Artifact Integrator
* CDS Artifact has been received by CDS Integrator and is available for processing
* CDS Artifact is available for mapping, structural transformations and local adaptation

# 8.0 Actors and Roles

| **Role** | **Actor** | **System** | **Core Functions** |
| --- | --- | --- | --- |
| CDS Knowledge Artifact Supplier | CDS Vendor, Content Supplier | CDS Knowledge Artifact Repository | * Licensing (in/out) * Testing Collection/Sharing * Normalization * Providing Search Capabilities * Tracking/Servicing Updates * Facilitating Standardization and Localization * Value-added transformation of CDS artifacts from multiple sources for republication |
| CDS Artifact Integrator | EHR Vendor, Healthcare Delivery System | CDS System | * Adapting and mapping CDS artifacts to be embedded within a CDS system |

Table : Actors and Roles

# 9.0 Use Case Diagram



*\*Knowledge Artifacts in HeD Approved Format*

Figure 2: Use Case Diagram

Please Note: For the purposes of this Use Case obtain means to acquire a CDS Knowledge Artifact while import means to incorporate a CDS Knowledge Artifact into a CDS System.

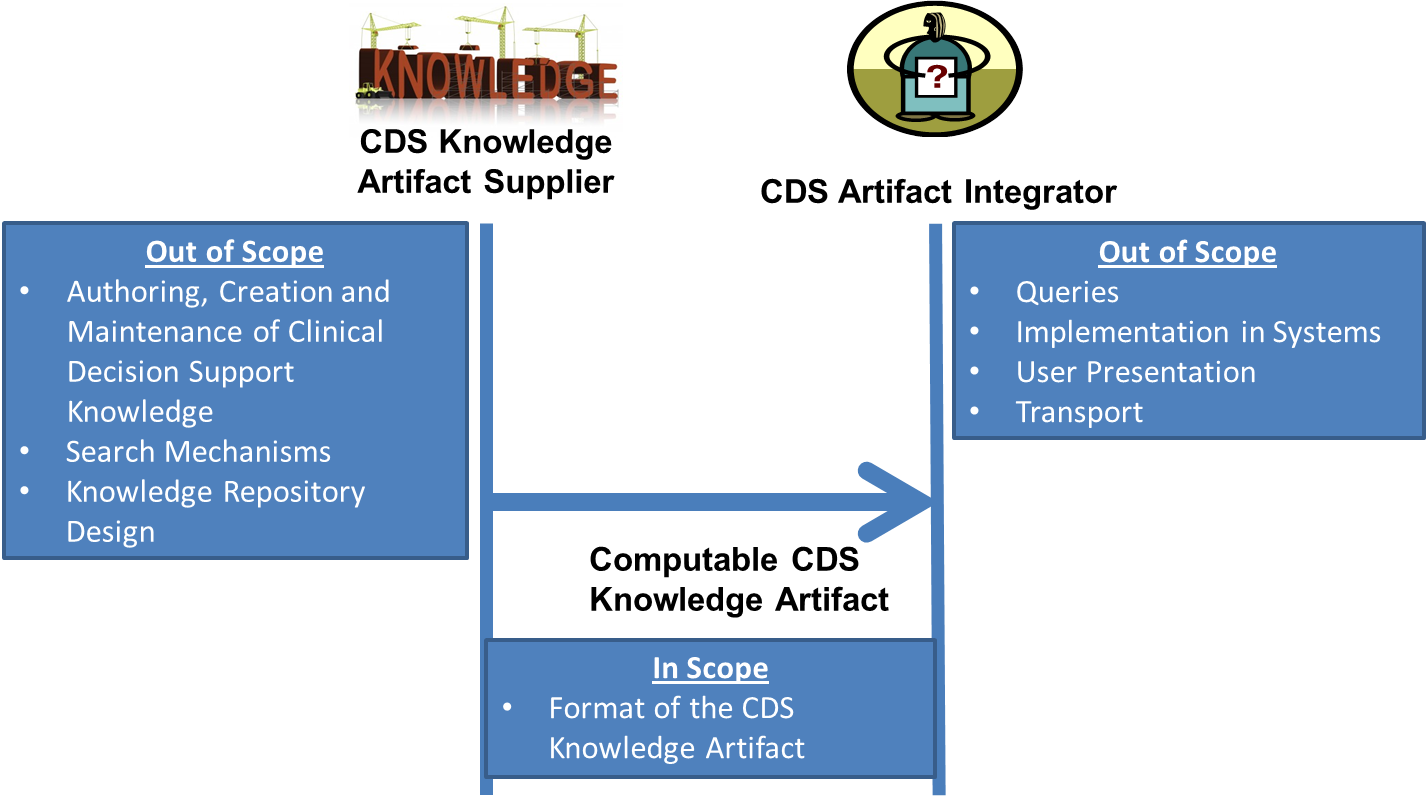


Figure 3: Context Diagram

# 10.0 Scenario

CDS Knowledge Artifact Supplier makes computable CDS Knowledge Artifact available to CDS Artifact Integrator.

## 10.1 User Stories Scenario 1

### User Story 1A

***Healthcare Delivery Organization would like to implement CDS aligned to MU***

A Healthcare Delivery System wants to have access to a catalog of CDS artifacts, aligned to Meaningful Use (MU), into its CDS or designated system. In order to have access and use this catalog, the Healthcare Delivery System, playing the role of a CDS Artifact Integrator, searches a CDS Knowledge Artifact Supplier’s repository or service for available artifacts in the Health eDecision approved format. After identifying the available artifacts that are of interest, the CDS Artifact Integrator imports or accesses the CDS artifacts, in the standardized structured format, from the supplier’s repository into the content management module of their CDS system. The CDS artifact(s) is structured in such a way as to facilitate structural transformation and mapping. Once imported, or accessed, the artifacts are configured and made computable within the CDS system or service; this configuration includes mappings, testing & verification. The CDS Artifact Integrator then releases the artifacts into their CDS system or service to make them available for the CDS users during care delivery.

### User Story 1B

***EHR vendor would like to provide its customers with CDS artifacts aligned to MU***

An EHR Vendor, playing the role of CDS Integrator, wants to embed a catalog of CDS artifacts, aligned to Meaningful Use (MU), into its EHR product, to enable the use of the artifacts by its customers, the Healthcare Delivery Organization. In order to build this catalog, the EHR vendor, playing the role of a CDS Artifact Integrator, searches a CDS Knowledge Artifact Supplier’s repository for available artifacts in the Health eDecision approved format. After identifying the available artifacts that are of interest, the CDS Artifact Integrator imports the CDS artifacts, in the standardized structured format, from the supplier’s repository into their release management system. The CDS artifact(s) is structured in such a way as to facilitate structural transformation and mapping. Once imported, the artifacts are configured and made computable within the vendor’s CDS system; this configuration includes transformations, mappings, testing & verification. The CDS Artifact Integrator then releases the configured, computable artifacts to their customers.

The customers, who are Healthcare Delivery Organizations, import the artifacts into the content management module of their CDS system, where they may further configure the artifacts before releasing them to their CDS system. The latter action makes the CDS usable during care delivery.

## 10.2 Activity Diagram

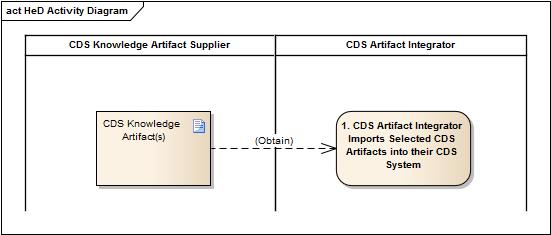
**

Figure 4: Activity Diagram

### 10.2.1 Base Flow – User Story 1A & 1B

| **Step #** | **Actor** | **Role** | **Event/Description** | **Inputs** | **Outputs** |
| --- | --- | --- | --- | --- | --- |
| 1 | Healthcare Delivery System | CDS Artifact Integrator | CDS Artifact Integrator Imports Selected CDS Artifacts into their CDS System | Selected CDS Artifacts of Interest | Imported CDS Artifacts |

Table : Base Flow of Scenario 1

## 10.3 Functional Requirements

### 10.3.1 Information Interchange Requirements

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Initiating System** | **(describes action)** | **Information Interchange Requirement Name** | **(describes action)** | **Ending System** |
| Artifact Repository | Makes Available | CDS Knowledge Artifact | Obtains | CDS System |

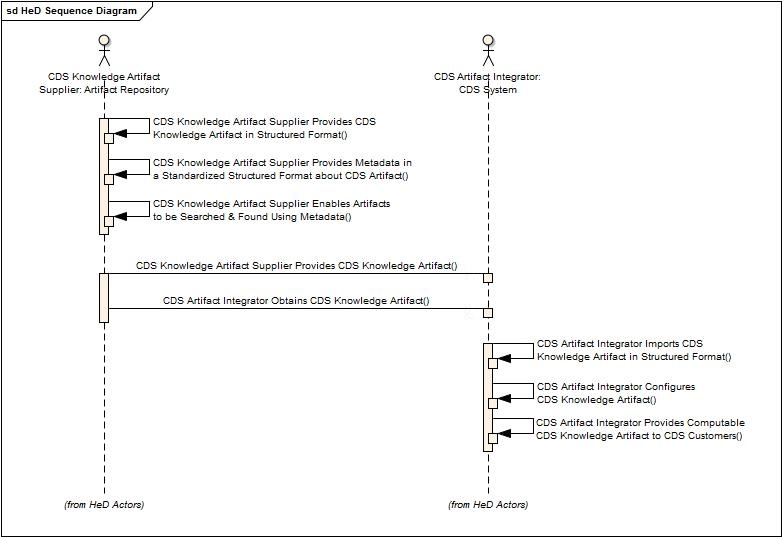
Table : Information Interchange Requirements

### 10.3.2 System Requirements

| **System** | **System Requirement** |
| --- | --- |
| Artifact Repository | * Provides CDS Knowledge Artifact in Structured Format * Provide metadata in a standardized structured format about CDS artifact * Enable ability to search metadata to find CDS Knowledge artifacts |
| CDS System | * Import & manipulate metadata as needed * Import CDS Knowledge Artifacts in Structured Format * Configure CDS Knowledge Artifact by providing mapping, structural transformation and local adaptation functions * Provide Computable CDS Knowledge Artifact to CDS Customers |

Table : System Requirements

## 10.4 Sequence Diagram

******

Please note, this Use Case does not specify the method of delivery or transport of the artifact.

Figure . Sequence Diagram

# 11.0 Dataset Requirements

## 11.1 Artifact Data Element Structure Overview

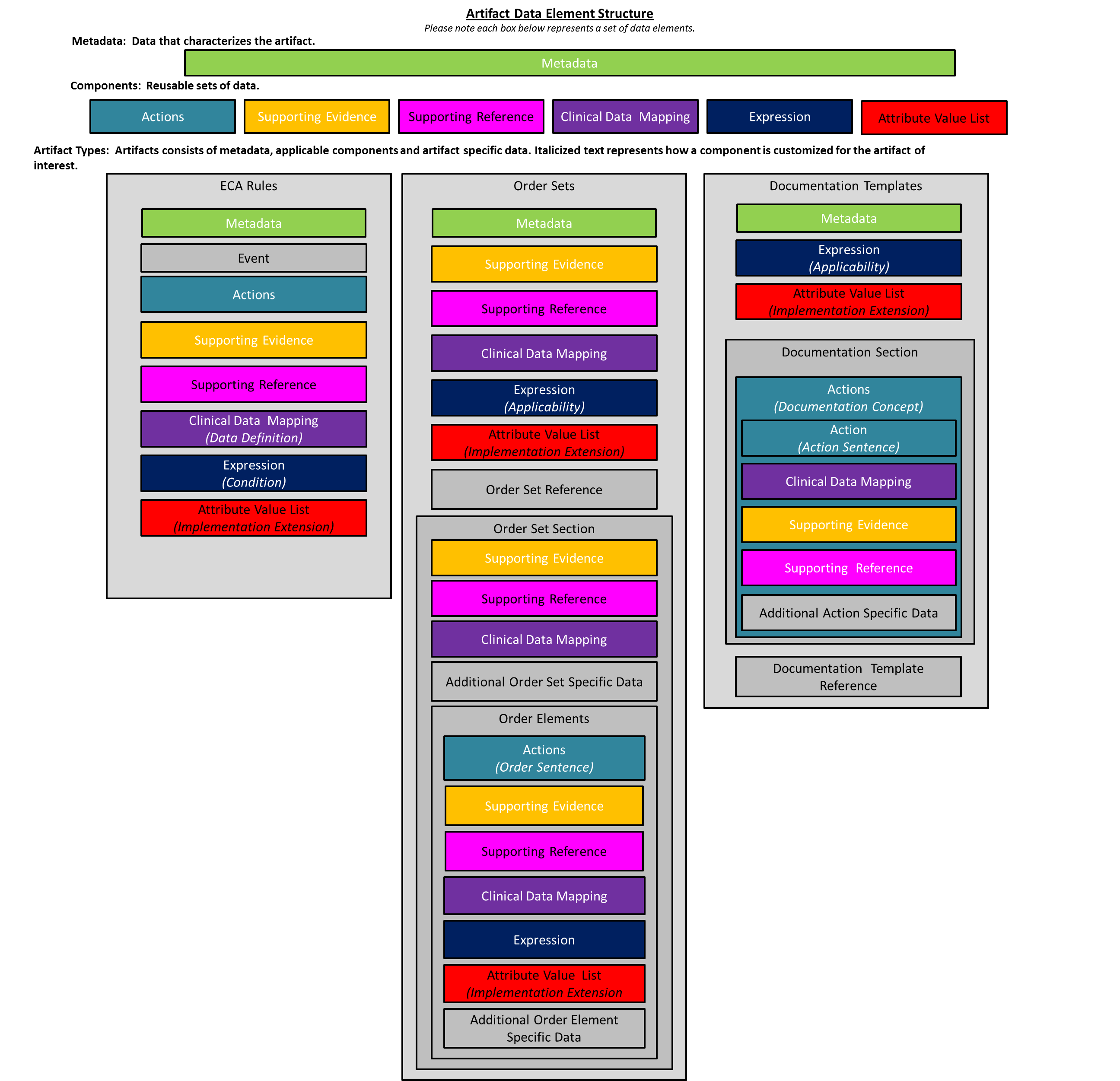
The diagram below shows how the data elements described in detail in the following sections are utilized to structure the CDS Knowledge Artifact Types. Please note each box below represents a set of data elements, each of which will be described in more detail in the following sections.

Figure . Artifact Data Element Structure

## 11.2 Metadata

These data elements included within the table below are used to characterize the CDS Knowledge Artifacts.

| **Section Name & Description** | **#** | **Data Elements** | **Data Element Descriptions** | **Cardinality** | **Additional Notes** |
| --- | --- | --- | --- | --- | --- |
| **Name:** Metadata – Identity and Provenance  **Description:** Elements that identify the artifact and its history. | 1 | Artifact Title | A descriptive label for the artifact | Single |  |
| 2 | Artifact Description | Textual description of the artifact. |  |  |
| 3 | Artifact Identifier | A unique identifier including the namespace or type of the identifier (e.g., DOI, Publisher’s proprietary id). | Potentially multiple |  |
| 4 | Artifact Contributor | An entity that contributed to the creation of the artifact. Contributors can be organizations, authors, editors & reviewers. | Multiple |  |
| 5 | Related Resource (e.g. eMeasure reference, clinical quality measure reference, dependent artifacts, other versions) | Identify resources that should be referenced. | Multiple |  |
| 6 | Source of Artifact | A resource that was used as the immediate source of knowledge for creating the artifact. For example, a clinical practice guideline, or a prior version of the artifact or a different artifact. | Multiple |  |
| 7 | Supporting Evidence | See supporting evidence reusable component. | Multiple |  |
| 8 | Artifact Documentation | Link to full reference documentation. For example, this data element can be used to reference the documentation of this artifact itself, or it may reference notes for implementing the artifact or how the artifact was created. | Multiple | This data element is used to reference the documentation of this artifact itself as oppose to where it’s derived from. |
| 9 | Publisher | Contact information for publisher, who is the responsible party. Sponsoring individual and/or organization making the artifact available for download. | Multiple |  |
| 10A | * Publisher Name | Publisher organization. | Single |  |
| 10B | * Publisher Contact Information | Contact information for publisher. | Multiple |  |
| 11 | Licensing , Usage, Restriction | Information, if any, about licenses, restrictions, or other steps necessary to access and use the artifact. | Multiple | This covers entitlement, Intellectual Property issue, etc. |
| 12 | Artifact Version | A version number for the artifact | Single |  |
| 13 | Schema Identifier | The schema that is used to structure this artifact | Single |  |
| 14 | Schema Version | Version number of the schema | Single |  |
| 15 | Artifact Status | Current status of the artifact. Possible status codes:   * Draft * Active (Date Posted) * Retired   Provides a way to communicate whether or not this is draft or final. | Single | During the harmonization phase, need to ensure that the set of status codes is mutually exclusive, and accurate with regard to the consumer. |
| 16 | Artifact history | The various lifecycle events of the artifact (noted in additional notes) over time with a date & timestamp for when the state was reached  Possible Event Codes:   * Created * Published/Active (Date Posted) * Reviewed * Retired | Multiple | Note that Date Posted is critical information for a consumer to know how current the CDS Artifact is, especially with regard to the evidence. |
| **Name:** Metadata – Scope and Coverage  **Description:** These elements should describe the context in which an artifact is used. | 17 | Artifact Type | Rule, Order Set, Documentation Template | Single | Rule implies Event-Condition-Action rules only.  For definition of these artifact types please reference the glossary found in appendix A. |
| 18 | Clinical focus | The clinical issue addressed by the artifact. For example, disease, diagnostic test interpretation, medication ordering | Multiple |  |
| 19 | Target User Role | The user types to which an artifact is targeted. For example, PCP, Patient, Cardiologist, Behavioral Professional, Oral Health Professional, Prescriber, etc. | Multiple |  |
| 20 | Patient Age Range | A patient category (demographic) for which this artifact is applicable. For example, from age X to age Y. | Multiple |  |
| 21 | Patient Gender | A patient category (demographic) for which this artifact is applicable | Multiple |  |
| 22 | Work Flow Setting | The task or activity during which the artifact can be used or applied. For example, admission, pre-op, etc. | Multiple |  |
| 23 | HIT Related Activity | The HIT function for which the artifact can be used or applied. For example, writing orders. | Multiple |  |
| 24 | Clinical Venue | The venue in which an artifact could be used. For example, Outpatient, Inpatient, Home, Nursing home | Multiple |  |
| 25 | Category | A category of artifacts to which this artifact belongs. For example, a set of interventions for meeting meaningful use stage 1 or epidemic outbreaks. | Multiple | E.g., Meaningful Use Stage 1, epidemic outbreaks, PQRS |
| 26 | Key Terms | Key terms for searching and finding specific artifact types. | Multiple | Use MeSH terms for keywords (OPTIONAL) |

Table . Metadata

## 11.3 Reusable Components

These data elements represent reusable sets of data that are can be used in any combination across a CDS Knowledge Artifact.

### 11.3.1 Actions

In order to support basic functionality for Actions within the first iteration of the standard, only Notifications and Orders will be supported initially. However, the Action constructs themselves should be built in such a way that they support extension to different action types (such as Fire Event, or Inference) in future iterations.

In addition, the Actions should support the ability to capture complex actions, in the same way that Order Sets can capture multiple actions as a group.

| **Section Name & Description** | **#** | **Data Elements** | **Data Element Descriptions** | **Cardinality** | **Additional Notes** |
| --- | --- | --- | --- | --- | --- |
| **Name**: Action (Multiple)  **Description**: This is the consequence of a positive evaluation of the clinical scenario expression. It includes a structured action that can be enacted by the user. | 1 | Action mode | Action mode describes whether a new action sentence is being added, an existing action sentence is being refined, or an existing or contemplated action sentence should be discontinued. | Single |  |
| 2 | Supporting Evidence | See supporting evidence component. | Multiple |  |
| 3 | Supporting Reference | See supporting reference component. | Multiple |  |
| 4 | Urgency | An indicator of the urgency with which the action must be executed. | Single |  |
| 5 | Action Sentence | See Action Sentence defined below | Single |  |
| 6 | Action Text | A textual description of the action to be performed. Multi-line, formattable (tabs, spaces, etc.). | Single | It is permissible for the Action Sentence to be empty, and for the Action Text to constitute the action. Such an unstructured action cannot be processed by the target system, but it can be displayed to the user who interprets it and takes the desired action. |
| **Name**: Action Sentence  **Description**: A structured description of the care action that the CDS artifacts recommend to be executed, i.e., the output of the CDS. The data elements contain the action class with the necessary parameters specified (e.g., dose of medication)  **Example:** Perform a liver function test panel after 30 days | 7 | Clinical Data Mapping | The Action Sentence includes (a) clinical actions (see Clinical Data Mapping) and (b) system actions (e.g., invoking another CDS artifact; that are not included in the clinical data mapping).  The clinical actions include:   * Substance Event– Includes medications, vaccinations, gases, blood products and other activities that fit the same output activity structure, including hydration and feeding) * Procedure– Includes surgical procedures, nursing and other allied health activities and procedures * Encounter– Including proposed encounter, referral, and admission discharge * Observation– Includes documentation, diagnosis, assessment evaluation * Diagnostic Test * Education * Goal * Supply * Message   The non-clinical actions include:   * Invoking another rule * Making an inference * Storing a record in a database   The above lists are illustrative and not comprehensive | Single | * Some of the data elements listed at left may be simply more specific instances of other elements, or combinations of several other elements. For example, Diagnostic Test is a Procedure that may produce an Observation. Nutrition can be a Procedure (feeding the patient), Education, Substance Administration (which is the superclass of Medication), or a Goal. We keep the Output Action Classes as simple and generic as possible, consistent with supporting all the different types of activities that we need to perform. * All classes should support coding the action with codes from standard terminologies. * Action classes will provide the attributes necessary to provide a structured, detailed description of the recommended action. For example, the substance administration class, will contain attributes for dose, frequency, and route of administration, etc. * Action sentences may implicitly or explicitly include flags denoting automatic execution and destinations. These will be determined during harmonization. * Actions may also require responses. * Actions may be synchronous or asynchronous. |

Table . Reusable Components - Actions

### 11.3.2 Supporting Evidence

| **Section Name & Description** | **#** | **Data Elements** | **Data Element Descriptions** | **Cardinality** | **Additional Notes** |
| --- | --- | --- | --- | --- | --- |
| **Name:** Supporting Evidence (Multiple)  **Description:** Mechanism for providing further documentation for the supporting evidence. This is OPTIONAL overall, and many fields are optional as well | 1 | Bibliographic Information | Reference to research on which the artifact is based. | Multiple |  |
| 1A | * Bibliographic Citation | Information that will allow a user to locate the source material referenced, e.g., journal, volume, pages, authors, URL. | Single | Bibliographic Citation can contain an URL. |
| 1B | * Evidence Direction of Bibliographic Citation | An indication of how the evidence in the citation contributes to the contents of the knowledge artifact, e.g., Support, Neutral, Refute. | Single |  |
| 2 | Evidence Link Information | Information that allows a knowledge artifact user to access the current evidence that supports the content provided in the knowledge artifact. | Multiple | Please note the "Linked Information" data element URL, as specified in the description, is not tied to any particular citation. |
| 2A | * LinkName | A descriptive name of the evidence source referenced | Single |  |
| 2B | * LinkText | A short description of the evidence available from the referenced source | Single |  |
| 2C | * URL to Evidence Detail | Link to information maintained by the evidence source which may include; Quality of Evidence Scheme & Quality of Evidence Score, Recommendation Strength Scheme, Recommendation Strength Score, Evidence Source. This information will be maintained by the publisher, if available. | Single |  |
| 3 | Quality of Evidence Scheme | Rating scheme for the rating quality of evidence | Single |  |
| 4 | Quality of Evidence Score | A score indicating the methodologic rigor of the studies that support the specified recommendation | Single |  |
| 5 | Recommendation Strength Scheme | An indication of the guideline developers' level of support for a given recommendation based on their confidence in the balance of anticipated benefits and costs, harms, and risks | Single |  |
| 6 | Recommendation Strength Score | A coded value that represents the recommendation strength. | Single |  |
| 7 | Evidence Link Source | The guideline, evidence review, or other document providing evidence for the care recommendations in the artifact | Multiple |  |

Table . Reusable Component - Supporting Evidence

### 

### 11.3.3 Supporting Reference

| **Section Name & Description** | **#** | **Data Elements** | **Data Element Descriptions** | **Cardinality** | **Additional Notes** |
| --- | --- | --- | --- | --- | --- |
| **Name:** Supporting Reference (multiple)  **Description:** This is a piece of data that assists a practitioner in deciding whether a given CDS artifact, section, or action is applicable based on general or specific information about the outcome of using the CDS artifact, section, or action. | 1 | Decision Support Reference Type | Type of decision support reference (e.g., guidelines from medical associations) | Single |  |
| 2 | Decision Support Reference Name | Name of decision support reference | Single |  |
| 3 | Decision Support Reference Description | More detailed information about this design support item. | Single |  |
| 4 | Decision Support Link Label | Label of hyperlink | Single |  |
| 5 | Decision Support Link | URL of hyperlink | Single |  |

Table . Reusable Components - Supporting Reference

### 11.3.4 Clinical Mapping Data

Note: The table below is intended to include some of the key data types that would be used as part of expressions throughout the knowledge artifacts.

| **Section Name & Description** | **#** | **Data Elements** | **Data Element Descriptions** | **Cardinality** | **Additional Notes** |
| --- | --- | --- | --- | --- | --- |
| **Name:** Person (Multiple)  **Description:** This is a person who is being evaluated by CDS, including at least the patient as the primary focus. May also include relatives, public health contacts, or other persons with clinical relationship to the patient.  This section focuses on the individual person; the expression language would communicate the criteria for the persons to be selected within the specifications of the artifact. | 1 | Type | A type of person that is referenced by the knowledge artifact, e.g., Patient, Relative. | Multiple | Persons for CDS purposes fall into two major groups: those who are subjects of clinical evaluation, and everyone else. The persons who are subjects of clinical evaluation include: patients, relatives for purposes of family history/genetic evaluation, public health "contacts", etc. The "other" persons are not clinically evaluated, and don't need the same depth of data elements. Therefore depending on the person type the level of data elements required will vary. |
| 2 | State | States of residence of evaluated persons that can be used to determine applicability of CDS artifact | Multiple |  |
| 3 | Zip code | Zip codes of residence of the evaluated person that can be used to determine applicability of CDS artifact | Multiple | Address data should be modeled in a way to account for international addresses. |
| 4 | Birth date/time | Specific or ranges of birth dates and times of evaluated persons that can be used to determine the applicability of a CDS artifact | Multiple |  |
| 5 | Gender | One or more gender categories of evaluated persons that can be used to determine the applicability of a CDS artifact | Multiple | Will need a coding scheme |
| 6 | Current Age | Specific age or age range of evaluated persons that can be used to determine the applicability of a CDS artifact | Multiple | May need to be expressed in minutes, days, months, and years. |
| 7 | Deceased Indicator | Indicator of whether or not the evaluated person is alive or is deceased that can be used to determine the applicability of a CDS artifact | Single |  |
| 7A | * Reason for Death | Cause of death that can be used to determine the applicability of a CDS artifact | Single |  |
| 7B | * Age at Death | Age of evaluated person at time of death that can be used to determine the applicability of a CDS artifact | Single |  |
| 8 | Preferred Language | One or more languages used by evaluated persons that can be used to determine the applicability of a CDS artifact | Multiple | Will need a coding scheme |
| 9 | Ethnicity | One or more ethnicities of evaluated persons that can be used to determine the applicability of a CDS artifact | Multiple | Will need a coding scheme |
| 10 | Race | One or more racial categories of evaluated persons that can be used to determine the applicability of a CDS artifact | Multiple | Will need a coding scheme |
| 11 | Resuscitation Status | Indicator of the resuscitation preferences of a patient. For example, comfort care only, full code/full care. Used to determine applicability of CDS artifact or action. | Single |  |
| **Name:** Insurance Information (Multiple)  **Description:** Insurance information for the person who is being evaluated by CDS. | 12 | Type | Category of insurer referenced by the knowledge artifact, e.g. Medicare, Medicaid, HSA, Private. | Single | Standard lists? |
| 13 | Insurer/Carrier | Specific insurer referenced by the knowledge artifact. | Single | This field will be addressed during implementation. |
| **Name:** Provider (Multiple)  **Description:** This section describes a care Provide. | 14 | Specialty | An area of medical practice in which a provider has been trained, e.g., neurology, cardiology. | Multiple |  |
| **Name:** Facility (Multiple)  **Description:** Location information on an entity that is providing services that can be used to determine applicability of CDS artifact. | 15 | State | States for the locations of entities providing services that can be used to determine applicability of CDS artifact | Single |  |
| 16 | Zip code | Zip codes for the locations of entities providing services that can be used to determine applicability of CDS artifact | Single |  |
| **Name:** Specimen (Multiple)  **Description:** Information on specimens that are referred to within a knowledge artifact. Please note multiple specimens can be referenced within one knowledge artifact | 17 | Specimen type | Type of specimen referenced by the knowledge artifact | Single |  |
| 18 | Specimen Code | Code used to identify the specimen referenced by the knowledge artifact. | Single | Consideration for Harmonization: As harmonization considers code sets the code set selected should address and clarify additional information about the specimen and related attributes. If a code set can’t meet these requirements then either additional elements will have to be added or the requirements will have to modified. |
| 19 | Source body site | The body site or material from which the specimen referenced by the knowledge artifact was or should be obtained | Single | May identify a very specific body site, such as a certain lobe of the lung, or may identify the source of a bodily fluid |
| 20 | Specimen Indication | Result of specimen analysis used to determine whether CDS Artifact or action in an artifact is applicable. | Single |  |
| **Name:** Encounter Event (Multiple)  **Description:** Information on encounters that are referred to within a knowledge artifact. Please note multiple encounters can be referenced within one knowledge artifact  . | 21 | Encounter Event Date Time | The date and time at which the encounter event occurred. | Single |  |
| 22 | Encounter Type | Coded value for the type of encounter being referenced by the knowledge artifact. | Single |  |
| 23 | Encounter Code | Standard coding for the encounter. | Multiple | Consideration for Harmonization: As harmonization considers code sets the code set selected should address and clarify additional information about the encounter and related attributes. If a code set can’t meet these requirements then either additional elements will have to be added or the requirements will have to modified |
| 24 | Encounter Stage | The stage of the encounter that can be used to determine the applicability of a CDS artifact or to define actions to be taken. For example, Proposed, Scheduled, Missed, Current, Complete, Refused | Single | Appointments are being treated as encounters.  This should be a tightly constrained set of values that is used to define this. |
| 25 | Encounter Setting | Clinical care source of the encounter, e.g., inpatient, outpatient, emergency department, skilled care facility, etc. | Single |  |
| 26 | Encounter event time interval | Specific or ranges of encounter timeframes that can be used to determine the applicability of a CDS artifact or to define actions to be taken. | Single |  |
| 27 | Provider Type | The type of provider performing the encounter. For example, Nurse, Physician, Physical Therapist. | Multiple |  |
| 28 | Criticality | The importance of the appointment for clinical care. The criticality of an appointment can be used to determine the applicability of a CDS artifact or to define actions to be taken | Single | For example: STAT, New, Routine |
| 29 | Repetitions | Number of times appointment to be repeated | Single |  |
| **Name:** Observation Event(Multiple)  **Description:** Information on observations that are referred to within a knowledge artifact. Please note multiple observations can be referenced within one knowledge artifact | 30 | Observation Event DateTime | The date and time at which the observation event occurred. |  |  |
| 31 | Observation Type | Coded value for the type of observation being referenced by the knowledge artifact, e.g., problem, condition, diagnosis, adverse event | Single |  |
| 32 | Observation Code | Code used to identify the observation referenced by the knowledge artifact | Single | Consideration for Harmonization: As harmonization considers code sets the code set selected should address and clarify additional information about the observation and related attributes. If a code set can’t meet these requirements then either additional elements will have to be added or the requirements will have to modified. |
| 33 | Observation Stage | The stage of the observation that can be used to determine the applicability of a CDS artifact or to define actions to be taken. | Single | Consideration for Harmonization: This should be a tightly constrained set of values that is used to define this. |
| 34 | Observation Focus | Code that identifies the focus of the observation with as much specificity as available, or as required by a template. e.g., serum potassium level, hemoglobin A1c level, smoking status. | Single | Implementation Guide will provide specifics about different observation focus areas. |
| 35 | Observation body site | The body site or material referenced by the observation that can be used to determine the applicability of a CDS artifact or to define actions to be taken e.g., “3rd finger on left hand” or “arterial blood”, etc. | Multiple |  |
| 36 | Observation time interval | Specific or ranges of observation timeframes that can be used to determine the applicability of a CDS artifact or to define actions to be taken, e.g., “for the last 3 weeks”, “when I was 2 or 3 years of age”, “right now” | Single |  |
| 37 | Observation Value | Single or ranges of observation values that can be used to determine the applicability of a CDS artifact | Single |  |
| 38 | Interpretation | Meaning of the observation or information as interpreted by a trained professional that can be used to determine the applicability of a CDS artifact | Multiple |  |
| 39 | Severity | Value or range of values for the intensity of an observation that can be used to determine the applicability of a CDS artifact | Multiple |  |
| 40 | Criticality | The importance of the observation for clinical care. The criticality of an observation that can be used to determine the applicability of a CDS artifact or to define actions to be taken | Multiple |  |
| 41 | Observation Age Range | Specific age or age range of evaluated persons that can be used to determine the applicability of a CDS artifact | Single |  |
| 42 | Adverse Event Agent | Agent that caused the adverse event that can be used to determine the applicability of a CDS artifact. | Multiple |  |
| 43 | Unconducted Reason | Indication of the reason that an observation was not conducted that can be used to determine the applicability of a CDS artifact | Multiple |  |
| 44 | Observing Provider Type | Provider type making the observation that can be used to determine the applicability of a CDS artifact or to define actions to be taken. For example, Nurse, Physician, Physical Therapist. | Single |  |
| **Name:** Procedure Event  (Multiple)  **Description:** Information on procedures that are referred to within a knowledge artifact. Please note multiple procedures can be referenced within one knowledge artifact | 45 | Procedure Event DateTime | The date and time at which the procedure event occurred. | Single |  |
| 46 | Procedure Type | Coded value for the type of procedure being referenced by the knowledge artifact. | Single |  |
| 47 | Procedure Stage | The stage of the procedure that can be used to determine the applicability of a CDS artifact or to define actions to be taken. | Single | Consideration for Harmonization: This should be a tightly constrained set of values that is used to define this. |
| 48 | Procedure code | Code that describes the procedure. Can be used to determine the applicability of a CDS artifact or to define actions to be taken. | Multiple | Considerations for Harmonization:   * As harmonization considers code sets the code set selected should address and clarify additional information about the procedure and related attributes. If a code set can’t meet these requirements then either additional elements will have to be added or the requirements will have to modified * In the current market, this is commonly represented by a CPT or HCPCS code. |
| 49 | Procedure description | Text description of the procedure. Can be used to determine the applicability of a CDS artifact or to define actions to be taken. | Single | Consideration for Harmonization: Commonly defined by a specific CPT or HCPCS code definition established by the AMA or CMS. |
| 50 | Procedure method | Description of how the procedure is provided. Can be used to determine the applicability of a CDS artifact or to define actions to be taken | Single |  |
| 51 | Approach body site | The body site on which the procedure will be conducted on. Can be used to determine the applicability of a CDS artifact or to define actions to be taken | Multiple |  |
| 52 | Target body site | The body site that the procedure will treat or test. Can be used to determine the applicability of a CDS artifact or to define actions to be taken | Multiple |  |
| 53 | Criticality | The importance of the procedure for clinical care or health status. Can be used to define actions to be taken | Single |  |
| 54 | Procedure time interval | Time interval during which the procedure should be performed. Can be used to determine the applicability of a CDS artifact or to define actions to be taken | Single |  |
| 55 | Repetition | Number of times to repeat procedure. Can be used to determine the applicability of a CDS artifact or to define actions to be taken | Single |  |
| 56 | Performing Provider Type | Provider type performing the procedure that can be used to determine the applicability of a CDS artifact or to define actions to be taken. For example, Nurse, Physician, Physical Therapist. | Multiple | Consideration for Harmonization phase: CMS has developed a set of “Acceptable Physician Specialty Types for Risk Adjustment Data Submission” with regard to Medicare Advantage or Part C program. |
| **Name:** Substance Event (Multiple)  **Description:** Includes medication, immunization, IV feeding, etc. | 57 | Substance Event Date Time | The date and time at which the substance event occurred. | Single |  |
| 58 | Substance Type | Coded value for the type of substance being referenced by the knowledge artifact. | Single |  |
| 59 | Substance Code | Code that describes the substance. Can be used to determine the applicability of a CDS artifact or to define actions to be taken | Single | Consideration for Harmonization: As harmonization considers code sets the code set selected should address and clarify additional information about the substance and related attributes. If a code set can’t meet these requirements then either additional elements will have to be added or the requirements will have to modified. |
| 60 | Substance Event Stage | The stage of the substance event that can be used to determine the applicability of a CDS artifact or to define actions to be taken. For example, proposed, ordered, administered, dispensed, undelivered. . | Single |  |
| 61 | Lot Number | Lot number of the referenced substance. | Single |  |
| 62 | Approach body site | The body site where that the substance will be administered. Can be used to determine the applicability of a CDS artifact or to define actions to be taken | Multiple |  |
| 63 | Target body site | The body site that the substance will treat or test. Can be used to determine the applicability of a CDS artifact or to define actions to be taken | Multiple |  |
| 64 | Delivery method | The manner by which the substance is delivered. Can be used to determine the applicability of a CDS artifact or to define actions to be taken | Single |  |
| 65 | Delivery route | The method for delivering the substance, e.g., oral, injection. Can be used to determine the applicability of a CDS artifact or to define actions to be taken. Can be used to determine the applicability of a CDS artifact or to define actions to be taken | Single |  |
| 66 | Delivery rate | The frequency for delivery of the substance. Can be used to determine the applicability of a CDS artifact or to define actions to be taken | Single |  |
| 67 | Dose quantity | The amount of the substance to be administered in each dose. Can be used to determine the applicability of a CDS artifact or to define actions to be taken | Single |  |
| 68 | Dosing period | The time period during which the substance should be or has been administered. Can be used to determine the applicability of a CDS artifact or to define actions to be taken | Single |  |
| 69 | Administration time interval | Proposed Time interval between administrations of the substance. Can be used to determine the applicability of a CDS artifact or to define actions to be taken | Single |  |
| 70 | Criticality | The importance of the substance event for clinical care. The criticality of a substance event can be used to determine the applicability of a CDS artifact or to define actions to be taken | Single |  |
| 71 | Dose restriction | Maximum dose to administer in a specified time interval. Can be used to determine the applicability of a CDS artifact or to define actions to be taken | Single |  |
| 72 | Dose number | The dose number in a defined series of doses to achieve a certain effect. Can be used to define actions to be taken | Single |  |
| 73 | Dosing SIG | A coded representation of dosing directions. Can be used to define actions to be taken | Single |  |
| 74 | Number of fills | Number of times a medication order was or should be repeated. Can be used to determine the applicability of a CDS artifact or to define actions to be taken | Single |  |
| 75 | Reason Not Administered | Reason why Substance Administration was not performed. May be due to patient or provider missing an appointment, or could be due to the state of patient’s health, or the lack of vaccine inventory, etc. Can be used to determine the applicability of a CDS artifact or to define actions to be taken | Single |  |
| **Name:** Supply Event (Multiple)  **Description:** Information on supplies that are referred to within a knowledge artifact. Please note multiple procedures can be referenced within one knowledge artifact | 76 | Supply Event DateTime | The date and time at which the supply event occurred. | Single |  |
| 77 | Supply Type | Coded value for the type of supply being referenced by the knowledge artifact. | Single |  |
| 78 | Supply Code | Standard codes used to identify a specific supply referenced by the knowledge artifact | Single | Something that would come from a constrained vocabulary. |
| 79 | Supply Stage | The stage of the supply that can be used to determine the applicability of a CDS artifact or to define actions to be taken. For example, Proposed, ordered, delivered, undelivered | Single | This should be a tightly constrained set of values that is used to define this. |
| 80 | Target body site | The body site that the supply was or should be used on. can be used to determine the applicability of a CDS artifact or to define actions to be taken | Single |  |
| 81 | Quantity | Amount of supplies used or recommended. The body site referenced by the goal that can be used to determine the applicability of a CDS artifact or to define actions to be taken, e.g., 4 packages of gauze bandages, 1 set youth crutches, 30 home-use catheters, etc. | Single |  |
| 82 | Criticality | The importance of the supply for clinical care. The criticality of a supply can be used to determine the applicability of a CDS artifact or to define actions to be taken | Single |  |
| 83 | Supply time interval | Specific or ranges of time for use of or dispensing of a supply that can be used to determine the applicability of a CDS artifact or to define actions to be taken | Single |  |
| 84 | Repetition | Number of times the supply was or should be repeated. Can be used to determine the applicability of a CDS artifact or to define actions to be taken | Single |  |
| 85 | Reason not delivered | Indication of the reason that a supply was not delivered that can be used to determine the applicability of a CDS artifact | Single |  |
| 86 | Supply time | Time interval when supply was or should be dispensed. Can be used to determine the applicability of a CDS artifact or to define actions to be taken | Single |  |
| **Name:**  Education /Training Event (Multiple)  **Description:** Information on education / training that is referred to within a knowledge artifact. Please note multiple education / training items can be referenced within one knowledge artifact.  For example, A smoker is identified at visit. The office has decided to provide up to 4 smoking cessation classes to all Medicare smokers identified. CDS prompts to schedule appointments for Smoking Cessation classes for next 4 weeks. | 87 | Education/Training Event DateTime | The date at which the education/training event occurred. | Single |  |
| 88 | Education Type | Coded value for the type of education being referenced by the knowledge artifact. | Single |  |
| 89 | Education Code | A code uniquely identifying the education element, such as “Smoking Cessation”, etc. | Single |  |
| 90 | Education Stage | The stage of the education/training that can be used to determine the applicability of a CDS artifact or to define actions to be taken. | Single |  |
| 91 | Education Focus | The topics that were or should be covered in an education event. Can be used to determine the applicability of a CDS artifact or to define actions to be taken | Single |  |
| 92 | Education time | Time interval during which the education or training occurred or should occur. Can be used to determine the applicability of a CDS artifact or to define actions to be taken | Single |  |
| 93 | Criticality | The importance of the education for clinical care. The criticality of an observation that can be used to determine the applicability of a CDS artifact or to define actions to be taken | Single |  |
| 94 | Repetition | Number of times the educational or training activity was or should be repeated. Can be used to determine the applicability of a CDS artifact or to define actions to be taken | Single |  |
| 95 | Educating Provider Type | Provider type delivering the education or training that can be used to determine the applicability of a CDS artifact or to define actions to be taken. For example, Nurse, Physician or Physical Therapist. | Single |  |
| **Name:** Goal (Multiple) | 96 | Focus of Goal | Target of the goal that can be used to determine the applicability of a CDS artifact or to define actions. For example, weight loss with a target of 175 lbs. to be taken. | Single | This can include current and future goals. |
| 97 | Target Body Site | The body site referenced by the goal that can be used to determine the applicability of a CDS artifact or to define actions to be taken | Multiple |  |
| 98 | Goal Criterion | A Boolean criterion that defines when the goal has been met that can be used to determine the applicability of a CDS artifact or to define actions to be taken. | Single |  |
| 99 | Goal time interval | The time period in which the goal has been or should be achieved that can be used to determine the applicability of a CDS artifact or to define actions to be taken | Single |  |
| 100 | Criticality | The importance of the goal for clinical care or health status. The criticality of an observation that can be used to determine the applicability of a CDS artifact or to define actions to be taken | Single |  |
| 101 | Goal Stage | Progress toward meeting the goal that can be used to determine the applicability of a CDS artifact or to define actions to be taken | Multiple | Consideration for Harmonization: This should be a tightly constrained set of values that is used to define this. |
| 102 | Goal Initiator | The initiator of the goal can be provider or patient. | Single |  |
| **Name:** Supporting Reference (Multiple)  **Description:** This is a piece of data that assists a practitioner in deciding whether a given CDS artifact, section, or action is applicable based on general or specific information about the outcome of using the CDS artifact, section, or action. | 103 | See Decision Support Reference Type component. | See Decision Support Reference Type component. | Single |  |
| **Name:** Related thing or entity (Multiple)  **Description:** This is a set of data elements define relationships among clinical data entities and between clinical statements. It can be used across clinical data, e.g., there may need to be a relationship defined between an encounter and a prescription | 104 | Related Thing/Entity | Names of the entities associated in the relationship, this includes the nature of the relationship. | Multiple | Clinical data elements must support the ability to define relationships with other clinical data elements. The details will be developed in the Harmonization phase. |

Table . Reusable Component - Clinical Data Mapping

### 11.3.5 Expression

Note: The expression functionality should be extensible so that particular implementations can add functionality specific to their environment while remaining within the standard format. In evaluating the standard for the expression component must allow operators & argument types to work in conjunction with one another (as an orthogonal function).

| **Section Name & Description** | **#** | **Data Elements** | **Data Element Descriptions** | **Cardinality** | **Additional Notes** |
| --- | --- | --- | --- | --- | --- |
| **Name:** Expression  **Description:** Expressions are used to unambiguously define the logic for any aspect of an artifact requiring computation of some kind to be performed.  For example, Boolean expressions, Value Set operations, Formulas, and conditions. | 1 | Expression Language Version # | Version of the expression language being utilized in the knowledge artifact. | Single |  |
| 2 | Computable Expression | This is a computable expression of operations on input elements and the value to be returned. For example, the expression may define Boolean logic to be applied and the resulting value indicating whether or not a particular action should be performed, or it may be a formula resulting in an arbitrary value used by some other expression. | Single | In general, the expression will return a value of some type, and may have any number of arguments, including zero, which are themselves expressions. |
| 3 | Expression Name | The name of the expression, allowing it to be referenced by other expressions within the artifact | Single |  |
| 4 | Expression Description | Human readable description of the expression. | Single |  |
| **Name:** Parameter  **Description:** Parameters specify additional information that will be available to an artifact or expression during evaluation. For more information refer to the Expression Reference data element defined below. | 5 | Parameter Name | Descriptive name of the parameter. | Single |  |
| 6 | Parameter Value | The value of the parameter to be used in the expression. | Multiple |  |
| 7 | Parameter Type | The form of the parameter to be used in the expression. For example, the threshold for A1c evaluations, it might be set at 6 months. | Single |  |
| **Name:** Value  **Description:** Atomic, or scalar values such as numbers, dates, and strings | 8 | Atomic or Scalar Value | A specific value used within the expression. E.g. 6.5 or “99082” | Single | Not specifying a value is valid. |
| **Name:** Request  **Description:** A request for clinical data of some specific type, and optionally for a specific set of codes and/or a date range.  This is a critical aspect of the expression requirements in that it forces the data touch points within the artifact to be conjunctive in nature, ensuring that covering queries can be answered by consuming systems, and that the data requirements for an artifact can be unambiguously determined by examining only the data request expressions it contains. | 9 | Request Type | The type of the data being requested. The request type specifies the type of information the request will return, based on the data elements specified in the Clinical Data section. | Single |  |
| 10 | Request Criteria | Criteria limiting the data being requested. See the Request Criterion data element for details. | Multiple |  |
| 11 | Request Cardinality | Allows the artifact definition to define cardinality expectations for the request. May be Single or Multiple. The default is Multiple. | Single |  |
| 12 | RequestTiming | Allows the artifact definition to define the timing of the request, either as part of the initial data requirements for artifact evaluation, or during evaluation, as part of further data requests. May be Initial or During. Initial is the default. | Single | This aspect of the expression requirements ensures that the artifact performance can be shaped dynamically by controlling the amount of information that is actually communicated.  This impacts the evaluation interface, requiring that it support an iterative evaluation approach, rather than a single evaluation. |
| **Name:** Request Criterion  **Description:** Defines a specific criterion for limiting the results of a request.  **Example:** A request may contain a limitation on the codes involved, such as the codes for a Hemoglobin A1C test, and/or a date range | 13 | Request Criterion Property Name | The name of a property the criterion will limit. | Single |  |
| 14 | Request Criterion Operator | The operator to use to limit the request. To ensure conjunctive queries, only positive relative comparison operators can be used in the criterion: (<, =, >, <=, >=, and the interval operator between) | Single | It is critical to limit the expressivity of the criterion in order to ensure that the request data can be calculated by the consuming system. This, coupled with the Timing aspect of the request is what allows control over the performance of an artifact in a stateless, real-time CDS evaluation scenario. |
| 15 | Request Criterion Argument | An expression from which the criterion value can be derived. | Single |  |
| **Name:** Operation  **Description:** Defines an operation to be performed.  **Note:** This data element defines the base requirements for all the operation categories listed below. The data element names are repeated because they are really the same data element, grouped into categories for ease of presentation. | 16 | Operator Type | The operator to use to limit the request.  There are many different types of operators which are included in sub types below. | Single | Specific operators are defined by category in subsequent elements. |
| 16A | * Logical | Defines a logical operation. For example, And, Or, Xor, Not. | Single | Logical operations should support three-valued logic semantics. |
| 16B | * Nullological | Null testing and manipulation. For examples, IsNull, IfNull, Coalesce. | Single |  |
| 16C | * Comparative | Comparative operations. For example, <, =, >, <=, >=, <>. | Single |  |
| 16D | * Arithmetic | Arithmetic operations. For example, +, -, /, \*, div, mod, ceiling, floor, power, log |  |  |
| 16E | * String Manipulation | String manipulation operations. For example, Concat, Substring, IndexOf | Single |  |
| 16  F | * Date Manipulation | Date manipulation operators should include granularity specifications, allowing date manipulation to be performed at any level of precision, day, month, year, hour, minute, second. For example, DateDiff, DateAdd, DatePart. | Single |  |
| 16G | * Date Selection | Date selection operators. For example, Now, Today, Range, RangeWithin, Date, Time. | Single |  |
| 16H | * Aggregate | Aggregate operations. For example, Min, Max, Sum, Avg, Count, First, Last. | Single |  |
| 16I | * Set Operations | Operations performed on sets of data. For example, Subset, Proper Subset, Superset, Proper Superset, Union, Intersection, Difference, Complement | Multiple |  |
| 16J | * Interval Operators | Operations on intervals. For example, Before, After, Merges, Overlaps, Contains, Begins, Ends (Allen’s operators for interval comparison) | Multiple |  |
| **Name:** Argument  **Description:** An Expression that is evaluated to provide an argument to the operation. In general, an operator may have any number of arguments, including zero. | 17 | Argument Type | The type of Expression that is evaluated to provide an argument to the operation. There are many different types of arguments which are included in sub types below. | Multiple |  |
| 17A | * Conditional | Arguments to the conditional expression, For example, if X then A else B. | Multiple |  |
| 17B | * Interval | Constructs an interval from the arguments. Intervals may be date ranges, value ranges, time intervals, etc. | Multiple |  |
| 17C | * List | Constructs a list from the arguments. For example, the elements in the list. This field may be empty. | Multiple |  |
| 17 D | * Combine | Combines two lists together. | Multiple |  |
| 17E | * Choose | Selects a specific element in a list by index. A choose argument type consists of two arguments. The first argument is the list from which the element will be chosen, the second argument is the index of the element to be chosen | Multiple |  |
| 17F | * Exists | The list to be tested. Determines whether or not a given list has any elements. | Multiple |  |
| 17G | * Filter | Filters a list based on an expression. A filter argument consists of two arguments. The first argument is the list to be filtered; the second argument is the filter criteria. | Multiple | Note that the second argument is evaluated for each element in the first |
| 17H | * Sort | Criteria that defines how the list should be sorted. | Single | This should be able to be an expression, or a simple property list.  The operation should support ascending and descending per sort criteria. |
| **Name:** Value Set  **Description:** Retrieves a set of codes maintained external to the artifact definition. | 18 | Value Set Identifier | Identifier of the value set. For example, ICD-9, SNOMED-CT, RxNorm, or other terminologies maintained external to the artifact definition. This is not the assigning authority. | Single | This should be an external reference to a value set definition. |
| 19 | * Value Set Version | Version of value set. | Single |  |
| **Name:** Expression Reference  **Description:** Provides the ability to reference expressions within an artifact definition, similar to the notion of a function call in a traditional language. | 20 | Expression Name | The name of the expression to evaluate. | Single | Expression references here are internal to the artifact definition. Although External Expressions would be nice, it has ramifications that may be beyond the scope of this iteration. |
| 21 | Argument | The arguments to the expression, if any (see argument options above). | Multiple |  |

Table . Reusable Components - Expression

### 11.3.6 Attribute-Value List

Attribute-Value lists are generic data structures which can be used to extend the current specification for specific applications. For example, if a third-party CDS content management system allows a user to customize CDS Artifact from a publisher for a particular EMR, the user may want to specify data item values to drive specific functionality in the EMR. The CDS content management system then allows for the EMR to access the customized content and process it directly, without need for further editing in the EMR. This supports a use case by which a multi-facility organization can build EMR-independent CDS artifacts, and keep the gold copy outside of any particular EMR instance. If these are used they must be an extension of a generic way to represent the artifact. The elements are not meant to be used for the existing data elements in the resulting model.

| **Section Name & Description** | **#** | **Data Elements** | **Data Element Descriptions** | **Cardinality** | **Additional Notes** |
| --- | --- | --- | --- | --- | --- |
| **Name:** Attribute-Value List  **Description:** Attribute-Value lists are used to contain data for processing a CDS Artifact by a particular application. | 1 | Attribute Name | Name of the attribute. | Single |  |
| 2 | Attribute Values | One or more values associated with the attribute. | Multiple |  |
| 3 | Attribute Type | The type of the attribute. | Single |  |

Table . Reusable Components - Attribute-Value Lists

## 11.4 CDS Knowledge Artifact Types Data Elements

### 11.4.1 Event Condition Action Rules Data Elements

| **Section Name & Description** | **#** | **Data Elements** | **Data Element Descriptions** | **Cardinality** | **Additional Notes** |
| --- | --- | --- | --- | --- | --- |
| **Name:** Metadata | 1 | See Metadata. | See Metadata. | Single |  |
| **Name**: Event  **Description:** An event that triggers or initiates the evaluation of the condition. | 2 | Event Types | Different types of event are described below in elements 3 to 8. | Single |  |
| 3 | Solicit Event | A user or an application requests that this rule be invoked. |  | The necessary data elements for Solicit Event need to be expanded after considering relevant use cases |
| 3A | * Setting | The clinical care setting (e.g., primary care clinic, home, nursing home) where the event takes place | Multiple |  |
| 4 | EHR Record Event | Events that involves the addition, deletion and update of EHR records |  |  |
| 4A | * Setting | The clinical setting (e.g., primary care clinic, home, nursing home) where the event takes place | Multiple |  |
| 4B | * Action | The action that the EHR should take (e.g. insert, delete, update) | Multiple |  |
| 5 | Workflow Event | Events that are induced by actions in the workflow process |  |  |
| 5A | * Setting | The clinical care setting (e.g., primary care clinic, home, nursing home) where the event takes place | Multiple |  |
| 5B | * Action | The workflow step that should be taken. | Multiple | E.g., access record, create prescription, submit order |
| 6 | Fixed-Time Event | Event defined by a fixed set of time points |  |  |
| 6A | * Setting | The clinical care setting (e.g., primary care clinic, home, nursing home) where the event takes place | Multiple |  |
| 6B | * Time points | The time points at which an event trigger should be generated | Multiple |  |
| 7 | Relative-Time Event | Event that occurs at a fixed time interval before or after an anchor event |  |  |
| 7A | * Setting | The clinical care setting (e.g., primary care clinic, home, nursing home) where the event takes place | Multiple |  |
| 7B | * A time interval | The time interval before or after the anchor event (e.g., +7 days or -7 days) | Single |  |
| 7C | * Anchor event | The event whose time is the fixed point against which the time interval provides the offset | Single |  |
| 8 | Periodic-Time Event | Event defined by as occurring at specific intervals |  |  |
| 8A | * Setting | The clinical care setting (e.g., primary care clinic, home, nursing home) where the event takes place | Multiple |  |
| 8B | Period description | A definition of the periodicity at which event trigger should be generated. Example: 12AM every Sunday. Most likely will involve a start time, a repeating frequency or interval, and duration. | Single | See, for example, HL7 data-type definition for precise definition. |
| **Name:** Data Definition  Patient and other clinical data required to evaluate if and how the rule and its actions apply to this patient. | 9 | Clinical Data Mapping | See Clinical Data Mapping component. | Multiple |  |
| **Name:** Condition | 10 | Logical expression | This is a computable expression of the input elements specifying when/whether the output should be enacted. | Single | * Equivalent to the logic slot in Arden or the left hand side (when) of a rule * Should contain Boolean, set, mathematical (at least arithmetic), and temporal operators. * Value set operations |
| **Name**: Action | 11 | See Actions component. | See Actions component. | Multiple |  |
| **Name:** Supporting Evidence | 12 | See Supporting Evidence component. | See Supporting Evidence component. | Multiple |  |
| **Name:** Supporting Reference | 13 | See Supporting Reference component. | See Supporting Reference component. | Multiple |  |
| **Name**: Implementation Extensions  **Description**: For storing application-specific metadata. | 14 | Attribute-Value List | See Attribute-Value component. | Single | A list of items which allows for extensible section metadata, to support application-specific needs. |
| ITEMS FOR CONSIDERATION IN FUTURE VERSIONS | | | | | |
| **Name:** Response Recommendations | 15 |  | These are data elements related to user acknowledgment, overrides, “snoozing” of reminders |  |  |
| **Name:** Expansion of expression language functionality | 16 |  | To support non-deterministic/probabilistic reasoning, natural language processing, and other desired features. |  |  |

Table . Event Condition Action Rules Data Elements

### 11.4.2 Order Sets Data Elements

| **Section Name & Description** | **#** | **Data Elements** | **Data Element Descriptions** | **Cardinality** | **Additional Notes** |
| --- | --- | --- | --- | --- | --- |
| **Name**: Metadata | 1 | See metadata | See metadata. | Single |  |
| **Name:** Supporting Evidence | 2 | See Supporting Evidence component. | See Supporting Evidence component. |  |  |
| **Name:** Supporting Reference | 3 | See Supporting Reference component. | See Supporting Reference component. | Multiple |  |
| **Name:** Applicability | 4 | See Expression component. | This element describes the clinical conditions in which this order set is applicable. | Single | Unlike the elements in the metadata, this element can be used within the clinical setting to identify order sets that are applicable to the patient. |
| **Name**: Clinical Data Mapping  **Description**:  The section includes key data types that would be used as part of expressions for the artifact.    . | 5 | See Clinical Data Mapping component. | See Clinical Data Mapping component. | Multiple |  |
| **Name**: Implementation Extensions  **Description**: For storing application-specific metadata. | 6 | Attribute-Value List | See Attribute-Value component. | Single | A list of items which allows for extensible section metadata, to support application-specific needs. |
| **Name**: Order Set Section (Multiple)  **Description**: An order set is composed of a number of sections that group together order items and/or other sections. A section can contain multiple sections. | 7 | Title | A descriptive heading for the set of orders in that section. E.g., Medications, Diagnostic Tests | Single |  |
| 8 | Order Sub Section | Repeating Order Set Section elements. | Multiple |  |
| 9 | Order elements | Specific order and related data Included in the order sub-section | Multiple |  |
| 10 | Sequence Indicator | Information indicating the placement of this order set section within the order set or the containing section | Single |  |
| 11 | Supporting Evidence | See Supporting Evidence component. | Multiple | **Optional,** you can include this at the artifact, section or element level. |
| 12 | Supporting Reference | See Supporting Evidence component. | Multiple |  |
| 13 | Selection Model | The selection option allowed for the order set, e.g., One –of-n, none-or-all and/or any. | Single | One-of-n: Pick one of a group of orders, e.g., select one antibiotic from a choice. Boolean XOR.  None-or-all: All orders must be selected together, e.g., tapered dosing. Boolean AND  Any of group: Pick zero to n -- default assumption.  Boolean OR  Avoid order: Do not pick order. Boolean NOT. For instance, ‘For subpopulation X, do not administer A’ |
| 14 | Clinical Data Mapping | See Clinical Data Mapping component. | Multiple |  |
| 15 | Expression | See Expression component. | Multiple | For the purposes of this Artifact Type, an expression to determine the applicability of the actions in this section. Optional, can be included at the artifact, section or element level |
| 16 | Implementation Extensions | See Attribute-Value component. | Single | A list of items which allows for extensible action metadata, to support application-specific needs. |
| **Name**: Order Element  **Description**: An order and related data. Multiple, per section | 17 | Supporting Evidence | See Supporting Evidence component. | Multiple | **Optional,** you can include this at the artifact, section or element level. |
| 18 | Supporting Reference | See Supporting Reference component. |  |  |
| 19 | Action (Order Sentence ) | See Actions component. | Single |  |
| 20 | Clinical Data Mapping | See Clinical Data Mapping component. | Single |  |
| 21 | Expression | See Expression component. |  | An expression to determine the applicability this action. Optional, can be included at the artifact, section or element level. |
| 22 | Clinical Venue | Optionally defines a set of appropriate venues for the item. | Multiple | There are two approaches to modeling venue relevant order sets, one is to have order sets be venue-specific, where an order set only contains order items relevant for the venue. The other is to allow the order set items to indicate relevant venues. Because the majority of elements in an order set will be common to all venues, the latter approach is more manageable because it prevents duplication of the common elements if the order set is required to be venue specific. |
| 23 | Pre-selection Status | A code that indicates the extent to which use of the order set is, optional, recommended, required: not changeable, required:changeable with reason | Single | An optional order element is unselected by default and may be selected. A recommended order element is selected by default, and may be unselected. Required:not changeable is selected by default, and may not be unselected. Required: changeable with reason is selected by default and may be unselected, but the provider must provide a reason for not ordering the item. |
| 24 | Sequence Indicator | Information indicating the placement of this order set item within the order set or section | Single |  |
| 25 | Implementation Extensions | See Attribute-Value component. | Single | A list of items which allows for extensible action metadata, to support application-specific needs. |
| **Name:**  Order Set Reference (Multiple)  **Description:**  Please note, to preserve data integrity, this field will reference another CDS Knowledge Artifact, but it would not be rendered or displayed in the artifact itself. | 26 | Order Set Reference Information | Identifier for the order set being referenced | Multiple |  |
| 26A | * Link Name | A descriptive name of the order set referenced | Single |  |
| 26B | * Link Text | A short description of the order set referenced from the link | Single |  |
| 26C | * URL | The hyperlink to access the order set reference | Single |  |

Table . Order Sets Data Elements

### 11.4.3 Documentation Templates Data Elements

| **Section Name & Description** | **#** | **Data Elements** | **Data Element Descriptions** | **Cardinality** | **Additional Notes** |
| --- | --- | --- | --- | --- | --- |
| **Name**: Metadata | 1 | See metadata | See metadata. | Single |  |
| Name: Applicability | 2 | See Expression component | See Expression component. This element describes the clinical conditions in which this documentation template is applicable | Single | Unlike the elements in the metadata, this element can be used within the clinical setting to identify templates that are applicable to the patient. |
| **Name**: Implementation Extensions  **Description**: For storing application-specific metadata. | 3 | Attribute-Value List | See Attribute-Value component. | Single | A list of items which allows for extensible section metadata, to support application-specific needs. |
| **Name:** Documentation Section  **Description:** The document template is composed of a number of sections that organize the concepts being documented. A section may have other sub-sections or have documentation concepts. | 4 | Title | A descriptive title for the section | Single | Examples of Sections: History of present illness, Physical Exam, Review of Systems |
| 5 | Subsection | Subsections of the documentation template | Multiple | GI System Review, Respiratory System Review |
| 6 | Documentation Concept | The clinical concept being documented. | Multiple | E.g., Blood pressure, History of chest pain |
| 7 | Section Cardinality | Indicator of whether one or multiple instances of this section can be created (within the same time frame). | Single |  |
| 8 | Section Frequency | An optional data element, indicating how frequently the concepts in a section or subsection should be documented. | Single | This is applicable to flowsheet type documentation, where the same elements are charted at regular intervals, e.g., vital signs are recorded every 8 hours. |
| 9 | Targeted User | The user types that should be allowed to complete this document section. For example, Nurse or Occupational Therapist. | Multiple |  |
| 10 | Selection Model | An indication of the selection options that should be applied, For example, one –of-n, none-or-all, /or any or none. | Single | One-of-n: Fill in one of a group of documentation items  None-or-all: All documentation items must be filled in together  Any of group: Any documentation items may be filled in -- default assumption.  Boolean OR |
| **Name:** Documentation Concept (Action)  **Description:** A documentation concept is a single concept that is being recorded about the patient  [Even though this is described here, a documentation concept will be modeled as an Action] | 11 | Display Label | Text that is displayed to the user | Single | Example: Chest Pain |
| 12 | Description | A description of the concept being documented. Description is different from Display Label. The former needs to be more exact. Labels might be abbreviated, and description might be spelled out. | Single |  |
| 13 | Action | See actions component. | Single |  |
| 14 | Clinical Data Mapping | See Clinical Data Mapping component. | Single | Provides a mapping of this concept to a previously entered concept in the patient’s record. This allows the response value to be populated by getting the data from the record. |
| 15 | Supporting Evidence. | See Supporting Evidence component. | Multiple |  |
| 16 | Support Reference | See Supporting Reference component. |  |  |
| 17 | Concept Code | A code from a terminology system that is equivalent of the documentation concept | Multiple | e.g. SNOMED-CT, ICD9, ICD10, LOINC code for history |
| 18 | Response Data Type | Data type of the value or the response allowed for the document concept | Single | * Date * Number * Unstructured Text * Coded Value |
| 19 | Response Range | Limits on the potential values to the responses. Specific elements would depend on the data type of the response (e.g., min-max for numbers or dates, value sets for coded types) | Multiple |  |
| 19a | * For number/date   + Min   + Max | Response range that can be used for which there is an upper limit and lower limit that can be applied to numbers or dates. | Multiple |  |
| 19b | * For coded list   + Response Item   + Response Item Code   + Response Item Render Text | Describes each item in a list with the applicable code | Multiple | 14b uses ‘Response Item Render Text’. |
| 19c | * For all   + Response Cardinality | Indication of whether single or multiple responses should be allowed | Single |  |
| 19d | * For all items   + Formula (Expression) | Computation that should be used to derived an item from other data. | Single | The formula for computing the value is written as an Expression. |
| 19e | * For all items   + Constraint Expression | An expression that specifies an arbitrary constraint on the possible values of the documentation concept | Single | The constraint is written as an Expression. |
| 20 | Display Order | The display sequence within the section in which this item is presented | Single |  |
| 21 | Concept Visibility | An expression that constrain the display of a concept. Display the concept only if the expression evaluates to true. | Single | For example, show items about pregnancy history only for women patients; show concepts based on responses to previous concepts |
| 22 | Subconcept | A subconcept is a modifier or a qualifier of the documentation concept. They have the same structure as the documentation concept. | Multiple | Example: severity, duration, quality, location, and timing are all subconcepts to the documentation concept of chest pain. |
| 23 | Related Concept Codes | Coded term (s) to describe related concepts. The codes can be used to find templates that might be related to the concept that is being documented. | Multiple | Example: In a documentation template for chest pain, if user documents that the patient has shortness of breath; the related concept can be used to identify a pertinent template for shortness of breath. This latter template will have documentation concepts about shortness of breath, e.g., pulmonary symptoms and signs. |
| 24 | Concept Frequency | An optional data element, indicating how frequently the concept should be documented. | Single | This is applicable to flowsheet type documentation. See comments under item ‘Section Frequency’ |
| 25 | Rendered Text | These elements are used to render a narrative sentence from the discrete values of the documentation concept and subconcepts. All the narrative sentences from the documentation template are stringed to form a note.  The documentation concept render text, and response item render text are combined together to form a narrative sentence. | Single per documentation concept | Rendered text is applicable for structured notes type documents.  Symptoms include chest pain and dyspnea, but no nausea or diaphoresis. The chest pain is substernal, occurs with exertion and lasts 2 – 5 minutes, with radiation to the jaw and left arm. |
| 25a | * Documentation Concept Rendered Text | Text associated with the documentation concept that is used to generate the sentence | Single | Often includes context identifying the concept being documented: ‘Symptoms include’. |
| 25b | * Response Item Rendered Text | Text associated with the response item | Single, per item | Often identical to display label, but may spell out abbreviations or include articles or other additional text. |
| 25c | * Meta Tags | The meta tags will be used to drive functionality for gender, plural, articles, etc. | Single, per item |  |
| **Name:**  Documentation Template Reference (Multiple)  **Description:**  Please note, to preserve data integrity, this field will reference another CDS Artifact, but it would not be rendered or displayed in the artifact itself | 26 | Documentation Template Reference Information | Information that allows the user to identify and locate a documentation template that is being referenced | Multiple |  |
| 26A | * LinkName | A descriptive name of the documentation template referenced | Single |  |
| 26B | * LinkText | A short description of the documentation template referenced from the link | Single |  |
| 27C | * URL | The hyperlink to access the documentation template reference | Single |  |

Table . Documentation Templates Data Elements

# 12.0 Risks, Issues and Obstacles

The following risks and mitigation actions were developed as part of the HeD Initiative Charter. Please note this list is not inclusive of all risks identified as part of the Charter.

* Insufficient “end-user” input (e.g. physicians, clinicians, technology vendors).
  + Mitigation/Response: Evaluate role and type of initiative participants; invite additional participants early in the initiative process to balance representation.
* Data reconciliation process may be negatively impacted due to a lack of value sets and terminology standards.
* Lack of generally accepted definitions for in scope artifact types (e.g. rules, eMeasure feedback, alerts, reminders, order sets, plans of care, documentation, templates, relevant data display) hinders progress.
  + Mitigation/Response: Focus on artifacts with clear definitions.
* Standards may not scale to small vendors and practices, and/or accommodate clinical practice variations.
  + Mitigation/Response: Recruit small vendors and practices to participate in the Work Group meetings and pilot efforts.
* Proposed project timeline does not reflect actual deadlines in relevant SDO Balloting.
  + Mitigation/Response: Identify support to help mitigate this issue including inviting SDO members to participate in our work group and working with SDOs on out-of-cycle balloting. Change expectations in the HeD timeline. Begin working with the SDOs ASAP.
* Proposed project timeline is significantly faster than what has traditionally been possible through volunteer effort alone.
* Progress may be slower than anticipated given the complexity of in scope artifact types.
  + Mitigation/Response: Monitor and communicate timeline, deliverables and progress frequently to all stakeholders; identify and request increased or reallocated resources (as needed).

In addition to the risks identified while drafting the initiative charter the community also identified the following considerations and risks:

* Meaningful progress requires technical expertise, an understanding of clinical processes and significant analytical and critical thinking abilities. Failure to engage and retain committed and experienced work group members could hamper the success of the project.
* The document must clearly and accurately represent the use cases to serve as a foundation for future progress in CDS harmonization and implementation.
* Different work group members speak different professional languages. (For example: to some the abbreviation IP means internet protocol, to others it means intellectual property).
  + Mitigation strategy: Clearly define terms and maintain a project glossary.
* The current extreme polarization of the federal landscape and resultant legislative flux (Accountable Care Act challenges, proposed defunding of AHRQ, postponements of HITECH, Meaningful Use 2 and ICD-10) and ongoing electoral processes creates a somewhat unstable environment for meaningful progress.
* There is a significant risk that providers won’t use CDS based on: lack of trust in the results, lack of ease of use, failure to provide relevant information, alert fatigue, and the process complicates rather than simplifies patient care.
* There is a risk that work group members represent our own interests as opposed to those of the project (ethnocentricity) rather than focusing on the end user and the patient.
  + Mitigation strategy – Ensure that the Work Group has a diversity of stakeholders and that Work Group discussions provide the opportunity for broad input across the Work Group.

# Appendices

## Appendix A: Glossary of Terms

**Clinical Decision Support (CDS):** Clinical Decision Support is a process for enhancing health-related decisions and actions with pertinent, organized clinical knowledge and patient information to improve health and healthcare delivery. Information recipients can include patients, clinicians and others involved in patient care delivery; information delivered can include general clinical knowledge and guidance, intelligently processed patient data, or a mixture of both; and information delivery formats can be drawn from a rich palette of options that includes data and order entry facilitators, filtered data displays, reference information, alerts and others. (Jerome A. Osheroff, Jonathan M. Teich, Donald Levick, Luis Saldana, Ferdinand T. Velasco, & Dean F. Sittig, 2012)

**CDS Artifact Integrator:** An organization/person/system that imports, adapts and maps CDS Knowledge artifacts to be embedded within a CDS system.

**CDS Content Developer:** An organization that produces CDS Knowledge Artifacts. Content developers will utilize the HeD Standard to make CDS Knowledge Artifacts available to the CDS Knowledge Artifact Supplier.

**CDS Knowledge Artifact:** Medical knowledge represented in a structured and encoded form to enable computer based clinical decision support.

**CDS Knowledge Artifact Repository:**  A repository where CDS Knowledge Artifacts are collected and stored for distribution/consumption.

**CDS Knowledge Artifact Supplier:** An organization/system that collects and/or distributes CDS Knowledge Artifacts.

**CDS System:** This term is used to describe any system that provides clinical decision support. Often, though not exclusively, the CDS is provided by an EHR system.

**Content Management Module:** A module that is part of the CDS system to edit, manage, and deploy/release CDS artifacts.

**Critiques and Warnings (Immediate Alerts):** Urgent requests for clarification, correction or different action - often related to an order or prescription - based on an action the user just took or data they entered. These reactive interventions prompt the user to immediately address possible errors, hazards or quality improvement opportunities related to new data or orders just entered into an information system. (Jerome A. Osheroff, Jonathan M. Teich, Donald Levick, Luis Saldana, Ferdinand T. Velasco, & Dean F. Sittig, 2012)

**Event-driven Alerts (Data-triggered) and Reminders (Time-triggered):** A common type of CDS intervention, typically an unsolicited message to a clinician about a patient's care or status that requires attention. Both alerts and reminders are not triggered by a user task, but instead raise awareness of events that are occurring throughout the care system: new highly abnormal lab results, new admissions or discharges of a physician’s primary care patients, consultant encounters, and many more. They can also detect important non-events that have not occurred in a prescribed period of time, such as failure to have a scheduled imaging study or a patient in a physician’s panel that has not had a health-maintenance visit in a long time. Fundamentally, alerts and reminders prevent errors of omission and commission, and lead to faster response to critical conditions. Typically, important data-driven alerts must reach the target user through a notification mechanism, such as paging, secure email, or appearance on a panel-wide notification screen. Lower-urgency reminders which can wait for the patient’s next real encounter can be displayed on the patient’s electronic-record facesheet. (Jerome A. Osheroff, Jonathan M. Teich, Donald Levick, Luis Saldana, Ferdinand T. Velasco, & Dean F. Sittig, 2012)

**Import:** To incorporate a CDS Knowledge Artifact into a CDS System.

**Local Adaptation:** Specifying when, where and by whom a given artifact can be used. This may include but is not limited to substitutions for local services & data elements.

**Mapping:** Mapping of data elements and actions within a CDS Knowledge Artifact to local data elements and actions within the CDS System.

**Obtain: To acquire a CDS Knowledge Artifact**

**Structural Transformations:** Translating the format from the HeD approved standard to a format that is used by the CDS System (e.g. storing it in the database schema).

**In Scope Artifact Type Definitions**

* **Event Condition Action Rule:** An ECA rule has the general syntax "on event if condition is true do action.”
  + The event part specifies the signal that triggers the invocation of the rule
  + The condition part is a logical test that, if satisfied or evaluates to true, causes the action to be carried out
  + The action part consists of execution of operations. These actions may in turn cause further events to occur, which may in turn cause more ECA rules to fire (Wikipedia), (Pissinou, et al., 1994), (Papamarkos, Poulovassilis, & Wood, 2006)
* **Document Templates:** A structured form for recording information on a patient into a set of pre-defined data slots.
* **Order Set:** a pre-defined and approved group of orders related to a particular clinical condition (e.g., hypertension treatment and monitoring) or stage of care (e.g., hospital admission to Coronary Care Unit). Often the order set consists of both diagnostic and therapeutic orders. The goals in creating order sets are to standardize care, increase compliance with best clinical practices, and facilitate the order entry process.

# Works Cited

Osheroff JA, Teich JM, Levick, D, Saldana, L, Velasco, FT, Sittig, DF, Rogers, K, Jenders, RA. Improving Outcomes with Clinical Decision Support: An Implementers’ Guide, 2nd Edition. Chicago: HIMSS Press, 2012. 323 pp