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| Health eDecisions |
| Clinical Decision Support Guidance Service  (Use Case 2) |
|  |
| **April 4, 2013** |
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# 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, has developed 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 Interest, 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 Cases
* The information flows that must be supported by the data exchange
* The types of data and their specifications required in the data exchange

A Use Case is the foundation for identifying and specifying the standards required to support the data exchange and for developing reference implementations and tools to ensure consistent and reliable adoption of the data exchange standards, and is therefore written with individuals working toward these outcomes as the primary audience.

# 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 Clinical Decision Support (CDS) interventions can be implemented via:

* Standards to structure medical knowledge in a shareable and executable format for use in CDS (Use Case 1: “CDS Artifact Sharing”), and
* Standards that define how a system can interact with and utilize an electronic service that provides helpful, actionable clinical guidance (Use Case 2: “CDS Guidance Service”)

Note: References to “Initiative” within this document refer to the Health eDecisions Initiative and its work products, including both Use Cases unless otherwise specified. “Use Case” is the narrower term used to describe either the “CDS Artifact Sharing” Use Case or the “CDS Guidance Service” Use Case.

## 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 the repeated import and update of CDS artifacts into CDS systems as well as the export to support maintenance of the artifacts (Use Case 1) and the consumption of CDS interventions through a web service (Use Case 2).

# 3.0 Scope of Use Case 2

This Use Case defines the requirements for the interfaces for sending patient data and receiving CDS guidance. This Use Case has one scenario: Requesting Clinical Guidance from a CDS Guidance Supplier.

Note: The following list of functional interaction types were among those considered by the Health eDecisions community in developing this Use Case. It is neither a comprehensive list of all interaction types that may be addressed with this document, nor is it meant to be a strict floor used for the detailed evaluation of all components of this document.

Potential Functional Interaction Types:

* Drug Dosing Calculation
* Immunization Forecasting
* Disease Management
* Quality Measure Evaluation
* Transition of Care Support
* Prediction Rule Evaluation – APACHE score, AHRQ Pneumonia Severity Index, etc.
* Severity of Illness Assessment – Charlson index, etc.

## 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 utilization of data through 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 CDS. 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.

The purpose of 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 or implemented. 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 supports 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 (“CDS Artifact Sharing”), interoperability relates to the exchange of those artifacts (e.g., order sets, rules, and documentation templates) that are required for a system to deliver CDS. In this second Use Case, interoperability relates to the exchange of information that allows the delivery of the results derived from the execution of CDS. This Use Case addresses a scenario in which a system sends information on a specific patient to a CDS Guidance Supplier that provides conclusions and recommendations to facilitate decision-making by the clinical user.

Please note, only the second Use Case (CDS Guidance Service) is defined within this document.

## 3.2 In Scope

* Semantically Interoperable Data Exchange Interface Definitions for Sending Patient Data to a CDS Guidance Service and receiving CDS guidance in return
* Format of the Patient Data Input and Clinical Context to Service (format of the CDS Guidance Request)
* Format of the CDS Guidance (output from CDS service)
* Requirements to support Service Transactions, Transport & Security
* Stateless Transactions

## 3.3 Out of Scope

* Workflow Integration in the CDS Guidance Requestor’s system
* User Presentation
* Direct Interaction with the User
* How the Guidance Integrator will utilize the information
* Deciding what guidance is subscribed to
* Authoring, Creation and Maintenance of CDS Knowledge used to produce the clinical guidance
* Internal workings of the CDS services supplier
* Stateful Transactions

## 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.  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, and academic health systems. |
| Patients/ Consumers | 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 professional standards of conduct, maintain those standards and oversee its membership, develop and publish peer reviewed evidence based guidelines and “White Papers” directed at providing and improving quality of healthcare services delivered and represent the profession 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, and Accreditation Association for Ambulatory Health Care. |
| 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 vendors may include developers, resellers, integrators, operators and others who facilitate access to CDS services via their product. |
| CDS Service Provider | An organization that provides Clinical Decision Support services. These services could include, for example, the provision of terminology alignment services (localizing terms in CDS service output for use in an EHR/EMR/PHR).  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 may or may not interact with a CDS Service Provider for such CDS services. |
| EHR/EMR/PHR Service Provider | An organization that operates an EHR, EMR or PHR System and manages its access to CDS services. An EHR/EMR/PHR Service Provider might or might not be the Provider Organization in which a Healthcare Professional works. |
| CDS Healthcare Researchers | Individuals who use healthcare information to develop the guidance that is used in a CDS service, 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 service outputs. |
| 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, and Ancillary Medical Service Providers. |

Table 1: Communities of Interest

# 4.0 Value Statement

Health information technologies (HIT) 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 new, timely, and person-centered knowledge into care delivery.

Standardized expressions of CDS 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 patient safety
* Improved efficiency, cost benefit, and provider and patient satisfaction
* Improved patient engagement
* Reduced latency for incorporating new clinical knowledge and evidence-based guidelines into clinical practice
* Ultimately, improvement in the health of the population

Focusing the S&I Framework community on CDS 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 (Use Case 1 only)
* Each intervention will be represented by a standardized expression of a recommendation that can be accessed by EHR system developers and users to simplify the process of incorporating recommendations into EHRs
* CDS Services can interact with EHRs and/or other HIT 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

* The CDS Guidance Requestor determines when to make a guidance service call.
* This is a stateless CDS service. For purposes of obtaining guidance, the CDS Guidance Requestor should NEVER assume that the service is stateful or able to utilize historical requests to provide guidance. However, the CDS Guidance Supplier may store the data for auditing and other operational reasons.
* The CDS Guidance Supplier provides sufficient requirements to the CDS Guidance Requestor for the CDS Guidance Requestor to determine the data that must be sent to the supplier during a guidance request.
* The CDS Guidance Supplier is responsible for verifying the unique response IDs to ensure that CDS Guidance Requestors can communicate unambiguously with the service and that the meaning of the response ID is consistent for historical and current CDS interactions.
* The role of the CDS Service Integrator and the associated functions (such as implementation) are handled outside of this Use Case, prior to the CDS Guidance Requestor sending a request.
* User agreements (trust relationships) are in place between the Guidance Requestor and Guidance Supplier, if required.
* The CDS Guidance Requestor is responsible for *not* sending identifiable protected health information unless the appropriate agreements are in place to do so.
* If a CDS Guidance Supplier receives identifiable protected health information that it expects (based on user agreements), then it will comply with legal and regulatory requirements for privacy and security for all relevant jurisdictions (including, but not limited to, HIPAA, state-level requirements, etc.).
* The CDS Guidance Supplier will make clear its policy for retaining or sharing any data received from the CDS Guidance Requestor, and it will comply with this stated policy.
* These transactions may be conducted in either a synchronous or an asynchronous manner.

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

* Patent and intellectual property protections are addressed by participants.
* 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.
* Conformance to the standards/solution described in this Use Case may occur directly between a CDS Guidance Requestor and CDS Guidance Supplier, or through an intermediary party (e.g., for interface, model, or terminology mapping).
* Conformance will be addressed further by subsequent phases of the S&I Framework and may be specified at multiple levels, e.g., at the interface, model, and terminology levels.

# 6.0 Pre-Conditions

* The CDS Guidance Requestor’s system is pre-configured to identify triggers to request clinical guidance.
* The CDS Guidance Requestor’s system is pre-configured to receive the clinical guidance data and integrate it into the system.
* The CDS Service Integrator is able to identify the type of CDS Guidance Service for specific scenarios (e.g., immunization reminders).
* CDS Service Integrator is able to identify the end-point address for making the request for CDS Guidance.
* The CDS Guidance Requestor’s system is aware of and able to supply the input parameter values (the clinical information and context).
* The CDS Guidance Requestor’s system is able to map to/from the terminology and content format standards specified in the standards selected by the Health eDecisions Initiative, either natively or by way of a third party (which might be the CDS Guidance Supplier itself).
* The CDS Guidance Supplier is able to formulate non-guidance components of the response (such as error messages).
* The CDS Guidance Requestor is able to properly process the defined non-guidance components of the response (such as errors in submitted data, additional information required, etc.). This would include things such as notifying technical staff of operational / data format errors, and notifying the end user, if appropriate, of the need for additional data.

# 7.0 Post Conditions

* The CDS Guidance Supplier has sent the Guidance or error message to the CDS Guidance Requestor’s system.
* The CDS Guidance Requestor’s system has received the Guidance or error message sent by the CDS Guidance Supplier.
* The Guidance or error message returned by the CDS Guidance Supplier is available for display and/or action within the CDS Guidance Requestor’s system.

# 8.0 Actors and Roles

## 8.1 In-Scope Actors

| **Role** | **Actor** | **System** | **Core Functions** |
| --- | --- | --- | --- |
| CDS Guidance Supplier | CDS Service Vendor, CDS Service Provider | CDS Service | * Receives Patient and Context Data * Evaluates the data * Returns guidance |
| CDS Guidance Requestor | User or Automated System | CDS Guidance Requestor’s System (e.g., Clinical Workflow System) | * Consumes a service * Sends patient data * Makes service call * Receives guidance |

Table 2: In-Scope Actors and Roles

## 8.2 Out-of-Scope Actors

| **Role** | **Actor** | **System** | **Core Functions** |
| --- | --- | --- | --- |
| CDS Service Integrator:The role of the CDS Service Integrator and the associated functions are handled outside of this Use Case, prior to the CDS Guidance Requestor sending a request | Technical Engineer on Behalf of the CDS Guidance Requestor’s System | CDS Guidance Requestor’s System (e.g., Clinical Workflow System) | * Enables CDS Service within system |

# 9.0 Use Case Diagrams

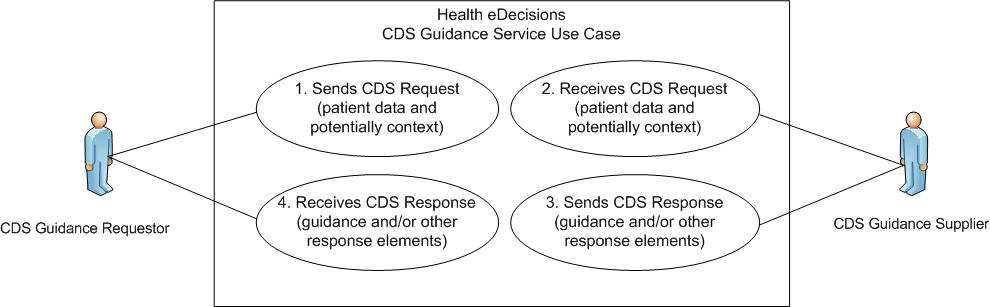


Figure 1: Use Case Diagram

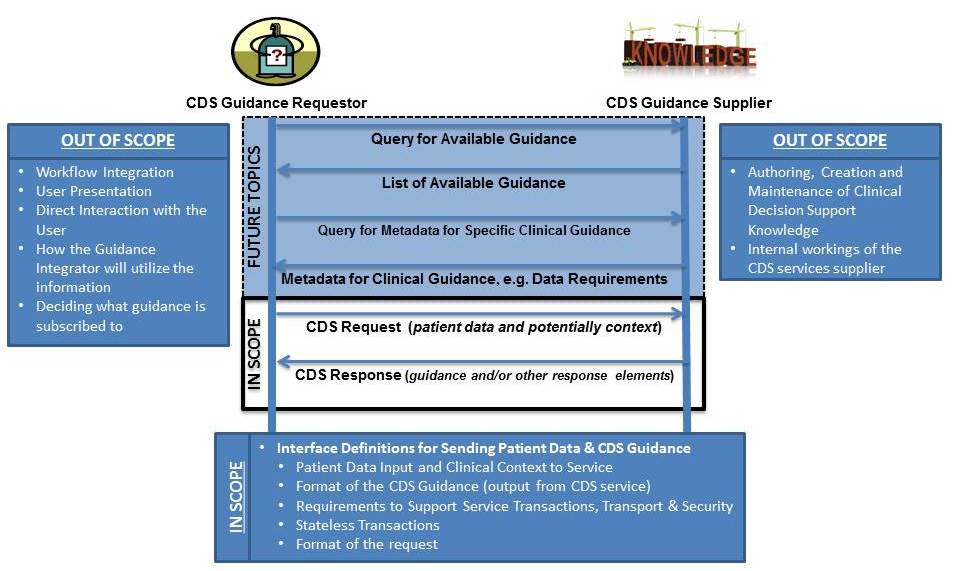


Figure 2: Context Diagram

# 10.0 Scenario

CDS Guidance Requestor Submits CDS Guidance Request

## 10.1 User Story

The user of a system (such as a clinical workflow system) (CDS Guidance Requestor) would like to receive clinical guidance for a particular patient or the system automatically determines the need for clinical guidance based on clinical observations. In order to obtain this information, the CDS Guidance Requestor generates one or more guidance requests, which are sent to the CDS Service Vendor (CDS Guidance Supplier). The request includes patient clinical data as well as potentially contextual information such as the user role and type, the encounter setting, and the type and/or scope of CDS guidance being requested. This request may or may not include a specific time point to use for the evaluation.  The CDS Guidance Supplier will evaluate temporal logic against the specified evaluation time point. If an evaluation time point is not furnished, then the CDS Guidance Supplier will use the current time in its system. This evaluation time point may be in the past (for instance, as of the end of an evaluation period or calendar year), or it may be in the future (such as the time of the patient’s next appointment). For example, if a CDS Guidance Requestor wishes to request guidance a day prior to outpatient visits for performance reasons, it may request an evaluation to be done using the date and time of the appointment as the evaluation time point.  Similarly, a CDS Guidance Requestor wishing to evaluate patients for a quality measure may request an evaluation to be done using a date required by the quality measure, such as December 31st of the previous year.  Finally, to conduct regression batch testing, a CDS Requestor may wish to use static test cases along with a static evaluation time point, so that the CDS evaluation results do not unintentionally change over time as the date changes.

The CDS Guidance Supplier receives and processes the request. The CDS Guidance Supplier returns the clinical guidance and/or other response elements (e.g., error messages) for each request to the CDS Guidance Requestor. This information is then made available to the end user.

## 10.2 Activity Diagram



Figure 3: Activity Diagram

### 10.2.1 Base Flow

| **Step #** | **Actor** | **Role** | **Event/Description** | **Inputs** | **Outputs** |
| --- | --- | --- | --- | --- | --- |
| 1 | User or Automated System | CDS Guidance Requestor | Generates a CDS Guidance Request | Patient Clinical Data, Contextual Information (User Role & Type, Encounter Setting, Type and/or Scope Of CDS Being Requested, Time for Evaluation) | CDS Guidance Request |
| 2 | User or Automated System | CDS Guidance Requestor | Sends the CDS Guidance Request to the CDS Service Vendor | CDS Guidance Request | CDS Guidance Request |
| 3 | CDS Service Vendor | CDS Guidance Supplier | Receives the CDS Guidance Request | CDS Guidance Request | CDS Guidance Request Data Ready for Processing |
| 4 | CDS Service Vendor | CDS Guidance Supplier | Processes the CDS Guidance Request | CDS Guidance Request Data Ready for Processing | CDS Response (Clinical Guidance and/or Other Response Elements) |
| 5 | CDS Service Vendor | CDS Guidance Supplier | Sends the CDS Response to the User or Automated System | CDS Response (Clinical Guidance and/or Other Response Elements) | CDS Response Details |
| 6 | User or Automated System | CDS Guidance Requestor | Receives the CDS Response | CDS Response Details | [End Process] |

Table 3: 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** |
| --- | --- | --- | --- | --- | --- |
| 1 | CDS Guidance Requestor’s System (e.g., Clinical Workflow System) | Sends | CDS Request (Patient Data and Potentially Contextual Information) | Receives | CDS Service |
| 2 | CDS Service | Sends | CDS Response (Clinical Guidance and/or Other Response Elements) | Receives | CDS Guidance Requestor’s System (e.g., Clinical Workflow System) |

Table 4: Information Interchange Requirements

### 10.3.2 System Requirements

| **System** | **System Requirement** |
| --- | --- |
| CDS Guidance Requestor’s System (e.g., Clinical Workflow System) | * Generate a CDS Request with Patient Data and Potentially Contextual Information * Receive a CDS Response Containing Clinical Guidance and/or Other Response Elements |
| CDS Service | * Process a CDS Guidance Request Containing Patient Data and Potentially Contextual Information * Generate a CDS Response with Clinical Guidance and/or Other Response Elements |

Table 5: System Requirements

## 10.4 Sequence Diagram

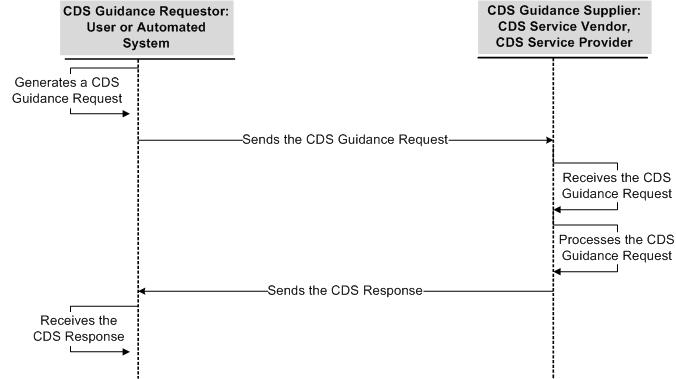


Figure 4: Sequence Diagram

# 

# 11.0 Dataset Requirements

The following tables include the data requirements necessary to support the functionality described within this Use Case document.

## 11.1 Clinical Data Elements

| **Clinical Data** | | | | | |
| --- | --- | --- | --- | --- | --- |
| Note: The table below is intended to include some of the key data types that would be used as part of the input data to the CDS Guidance Service, as well as part of the output from the CDS Guidance Service. | | | | | |
| **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. | 1 | Type | A type of person (e.g., Patient, Relative) | Single | 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 | Evaluated Person ID | The evaluated Person’s unique identifier, normally used for internal implementation tracking purposes. Does not need to be the evaluated Person’s "real" identifier, although it may be used for that purpose. | Single |  |
|  | 3 | Address | Location information for the evaluated person | Single | Address data should be modeled in a way to account for both US and international addresses to the level of specificity required by a use case |
|  | 4 | Birth date/time | Specific or ranges of birth dates and times of evaluated persons | Single |  |
|  | 5 | Gender | One or more gender categories of evaluated persons | Single | Will need a coding scheme |
|  | 6 | Current Age | Specific age or age range of evaluated persons | Single | 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 | Single |  |
|  | 7A |          Reason for Death | Cause of death | Single |  |
|  | 7B |          Date of Death | Date of evaluated person's death (used to calculate age of death for a more accurate value) | Single |  |
|  | 8 | Preferred Language | One or more languages used by evaluated persons | Multiple | Will need a coding scheme |
|  | 9 | Ethnicity | One or more ethnicities of evaluated persons | Multiple | Will need a coding scheme |
|  | 10 | Race | One or more racial categories of evaluated persons | Multiple | Will need a coding scheme |
|  | 11 | Resuscitation Status | Indicator of the resuscitation preferences of a patient (e.g., comfort care only, full code/full care) | Single |  |
| **Name:** Insurance Information (Multiple)  **Description:** Insurance information for the person who is being evaluated by CDS. | 12 | Type | Category of insurer (e.g. Medicare, Medicaid, HSA, Private) | Single | Standard lists? Will need a coding scheme |
|  | 13 | Insurer/Carrier | Specific insurer/carrier name | Single | This field will be addressed during schema development |
| **Name:** Provider (Multiple)  **Description:** This section describes a care provider. | 14 | Specialty | An area of medical practice in which a provider has been trained, e.g., neurology, cardiology. | Multiple | Will need a coding scheme |
| **Name:** Facility (Multiple)  **Description:** Location information on an entity that is providing services. | 15 | Address | Location information on an entity that is providing services | Single | Address data should be modeled in a way to account for both US and international addresses to the level of specificity required by a use case |
| **Name:** Specimen (Multiple)  **Description:** Information on specimens. Please note multiple specimens can be referenced. | 16 | Specimen Code | Code used to identify the specimen referenced in the input or output data | 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. |
|  | 17 | Source body site | The body site or material from which the specimen referenced in the input data was obtained, or where the specimen referenced in the output data 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 |
| **Name:** Encounter Event (Multiple)  **Description:** Information on encounters that are referenced. Please note multiple encounters can be referenced. | 18 | Encounter Event Date Time | The date and time at which the encounter event occurred. | Single |  |
|  | 19 | Encounter Type | Coded value for the type of encounter | Single |  |
|  | 20 | 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 |
| . | 21 | Encounter Stage | The stage of the encounter (e.g., 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. |
|  | 22 | Encounter Setting | Clinical care source of the encounter, e.g., inpatient, outpatient, emergency department, skilled care facility, etc. | Single |  |
|  | 23 | Encounter event time interval | Specific or ranges of encounter timeframes | Single |  |
|  | 24 | Provider Type | The type of provider performing the encounter (e.g., Nurse, Physician, Physical Therapist) | Multiple |  |
|  | 25 | Criticality | The importance of the appointment for clinical care | Single | For example: STAT, New, Routine |
|  | 26 | Repetitions | Number of times appointment to be repeated | Single |  |
| **Name:** Observation Event (Multiple)  **Description:** Information on observations that are referenced. Please note multiple observations can be referenced. | 27 | Observation Documentation Date Time | The date and time at which the observation event was recorded in the medical record | Single |  |
|  | 28 | Observation Type | Coded value for the type of observation (e.g., problem, condition, diagnosis, adverse event) | Single |  |
|  | 29 | Observation Code | Code used to identify the observation | 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. |
|  | 30 | Observation Stage | The stage of the observation | Single | Consideration for Harmonization: This should be a tightly constrained set of values that is used to define this. |
|  | 31 | 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. |
|  | 32 | Observation body site | The body site or material referenced by the observation (e.g., “3rd finger on left hand” or “arterial blood”, etc.) | Multiple |  |
|  | 33 | Observation focus time interval | Specific or ranges of observation timeframes (e.g., “for the last 3 weeks”, “when I was 2 or 3 years of age”, “right now”) | Single |  |
|  | 34 | Observation Value | Single or ranges of observation values | Single |  |
|  | 35 | Interpretation | Meaning of the observation or information as interpreted by a trained professional | Multiple |  |
|  | 36 | Severity | Value or range of values for the intensity of an observation | Multiple |  |
|  | 37 | Criticality | The importance of the observation for clinical care | Multiple | Consideration for Harmonization: vMR R2 uses "importance" for adverse events and "criticality" in other cases |
|  | 38 | Observation Age Range | Specific age or age range of evaluated persons | Single |  |
|  | 39 | Adverse Event Agent | Agent that caused the adverse event | Multiple |  |
|  | 40 | Adverse Event Status | The state of the effects of this adverse event. E.g., active, inactive, resolved. | Single |  |
|  | 41 | Unconducted Reason | Indication of the reason that an observation was not conducted | Multiple |  |
|  | 42 | Observing Provider Type | Provider type making the observation (e.g., Nurse, Physician, Physical Therapist) | Single |  |
| **Name:** Procedure Event (Multiple)  **Description:** Information on procedures that are referenced. Please note multiple procedures can be referenced. | 43 | Procedure Event DateTime | The date and time at which the procedure event occurred. | Single |  |
|  | 44 | Procedure Type | Coded value for the type of procedure | Single |  |
|  | 45 | Procedure Stage | The stage of the procedure | Single | Consideration for Harmonization: This should be a tightly constrained set of values that is used to define this. |
|  | 46 | Procedure code | Code that describes the procedure | 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. |
|  | 47 | Procedure description | Text description of the procedure | Single | Consideration for Harmonization: Commonly defined by a specific CPT or HCPCS code definition established by the AMA or CMS. |
|  | 48 | Procedure origination mode | The mode the order was received (such as by telephone, electronic, verbal, written). This describes 'how' the communication was done as opposed to dataSourceType which specifies the 'where' and 'from'. | Single |  |
|  | 49 | Procedure method | Description of how the procedure is provided | Single |  |
|  | 50 | Approach body site | The body site on which the procedure will be conducted on | Multiple |  |
|  | 51 | Target body site | The body site that the procedure will treat or test | Multiple |  |
|  | 52 | Criticality | The importance of the procedure for clinical care or health status. Can be used to define actions to be taken | Single |  |
|  | 53 | Procedure time interval | Time interval during which the procedure should be performed | Single |  |
|  | 54 | Lockout Interval | The amount of time that must elapse after a PCA demand dose is administered before the next PCA demand dose can be delivered (e.g., 10 minutes) | Single |  |
|  | 55 | Repetition | Number of times to repeat procedure | Single |  |
|  | 56 | Frequency | The interval in between events. For instance, TID, BID, q8h, etc. | Single |  |
|  | 57 | Performing Provider Type | Provider type performing the procedure (e.g., 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. |
|  | 58 | Origination mode | The mode the order was received (such as by telephone, electronic, verbal, written). This describes 'how' the communication was done as opposed to dataSourceType which specifies the 'where' and 'from'. | Single |  |
|  | 59 | PRN Reason | Indication for the proposed procedure such as shortness of breath; things like "SpO2 less than x%" should be addressed as a PRN Instruction (because it is difficult to enumerate a value set for these instructions) rather than a PRN Reason. | Multiple |  |
|  | 60 | Comment | A comment, instruction, or note associated with the proposal. The type specifies the type of comment (e.g., 'Provider Instruction', 'Patient Instruction', 'Reason for Procedure', 'Consult', etc...) and the value of the comment represents the free text value. | Multiple |  |
|  | 61 | Diet Qualifier | Diet proposals may be fully precoordinated in a terminology or specified by type only and allowing the nutrients (eg, specification of calories, carbohydrates, protein, fat, sodium, potassium, etc.) to be post-coordinated. | Multiple |  |
|  | 62 | Diet Qualifier Type | The type of nutrient that this diet contains. Nutrient types include: carbohydrates, lipids and fats, salts such as Sodium or Potassium, fibers, and also fluids. | Multiple |  |
|  | 63 | Amount | The quantity of nutrient or bound to consider for this diet. For instance, 40mg, <40mg, 30mg<x<60mg, etc… | Multiple |  |
|  | 64 | Qualifier | Not all nutrients will be given using physical quantities. A fat may be specified as 'Low Fat', 'No Animal Fat', etc... Other examples include: 'Ketogenic 3:1 Ratio', 'Consistent Carb Low (1200-1500 Kcal'), etc... Note that fluid consistencies may also be specified as the qualifier of a Nutrient whose type is 'Fluid'. E.g., Honey Thick Liquids, Nectar Thick Liquids, Pudding Thick Liquids, Other | Multiple |  |
| **Name:** Administrable Substance (Multiple)  **Description:** Material of a particular constitution that can be given to a person to enable a clinical effect. Can have component administrable substances | 65 | Form | The physical form of the substance as presented to the subject. E.g., tablet, patch, injectable, inhalant. | Single |  |
|  | 66 | Manufacturer Code | The code for the organization that produces the substance. | Single |  |
|  | 67 | Strength | The concentration of the substance. E.g., 250 mg per 5 ml. | Single |  |
|  | 68 | Brand Code | A code describing the product as a branded or trademarked entity from a controlled vocabulary. | Single |  |
|  | 69 | Substance Generic Code | A code describing the product as a substance produced and distributed without patent protection. | Single |  |
|  | 70 | Diluent | A fluid base (sometimes called a "base solution") into which an additive is mixed in order to prepare IV fluids for patient administration; the diluent is an inactive ingredient | Multiple |  |
|  | 71 | Additive | An active ingredient that is mixed with a diluent; the diluent enables intravenous delivery of the additive to a patient | Multiple |  |
| **Name:** Substance Event (Multiple)  **Description:** Includes medication, immunization, IV feeding, drip, etc. | 72 | Substance Event Date Time | The date and time at which the substance event occurred. | Single |  |
|  | 73 | Origination mode | The mode the order was received (such as by telephone, electronic, verbal, written). This describes 'how' the communication was done as opposed to the 'where' or 'from'. | Single |  |
|  | 74 | Substance Code | Code that describes the substance | 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. |
|  | 75 | Substance Event Stage | The stage of the substance event (e.g., proposed, ordered, administered, dispensed, undelivered) | Single |  |
|  | 76 | Lot Number | Lot number of the referenced substance. | Single |  |
|  | 77 | Approach body site | The body site where that the substance will be administered | Multiple |  |
|  | 78 | Target body site | The body site that the substance will treat or test | Multiple |  |
|  | 79 | Delivery method | The manner by which the substance is delivered | Single |  |
|  | 80 | Delivery route | The method for delivering the substance (e.g., oral, injection) | Single |  |
|  | 81 | Delivery rate | The frequency for delivery of the substance | Single |  |
|  | 82 | Dose Type | The kind of dose (e.g. initial, loading, maintenance, single) | Single |  |
|  | 83 | Dose quantity | The amount of the substance to be administered in each dose | Single |  |
|  | 84 | Loading Dose | The initial amount of an analgesic to be administered at one time. | Single |  |
|  | 85 | Demand Dose | A dose of an analgesic given upon request often through an action such as pressing a button to activate a pump | Single |  |
|  | 86 | Timing | Relative to another event | Single |  |
|  | 87 | Dosing Period | The time period during which the substance should be or has been administered | Single |  |
|  | 88 | Dosing Period Importance | Together with Dosing Period, identifies the frequency of substance administration. Dosing Period identifies the periodicity of doses within a specified timeframe, which is often 24 hours, whereas Dosing Period Importance identifies whether doses should be equally spaced within that timeframe. | Single |  |
|  | 89 | Lockout Interval | The amount of time that must elapse after a PCA demand dose is administered before the next PCA demand dose can be delivered (e.g., 10 minutes) | Single |  |
|  | 90 | Administration time interval | Proposed Time interval between administrations of the substance | Single |  |
|  | 91 | Valid Administration Time Interval | Acceptable time for administering the substance. Distinct from Administration Time Interval in that this time includes acceptable but suboptimal administration times. This is an important aspect of immunizations, which have recommended and acceptable/valid timeframes for administration that can differ. | Single |  |
|  | 92 | Criticality | The importance of the substance event for clinical care | Single |  |
|  | 93 | Dose restriction | Maximum dose to administer in a specified time interval | Single |  |
|  | 94 | 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 |  |
|  | 95 | Dosing SIG | A coded representation of dosing directions. Can be used to define actions to be taken | Single |  |
|  | 96 | Number of fills | Number of times a medication order was or should be repeated | Single |  |
|  | 97 | Infuse Over | Represents the actual time the medication is infused. Note the difference between infuseOver and duration. An orderable may call for infusing a patient TID for an hour each time over a duration of 5 days. | Single |  |
|  | 98 | Comment | Further information related to a substance order captured as free text |  |  |
|  | 99 | 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. | Single |  |
| **Name:** Body Site (Multiple)  **Description:** A location on an EvaluatedPerson's body. E.g., left breast, heart. | 100 | Body Site Code | A location on an EvaluatedPerson's body. May or may not encompass laterality. E.g., lung, left lung. | Single |  |
|  | 101 | Laterality | The side of the body, from the EvaluatedPerson's perspective. E.g., left, right, bilateral. | Single |  |
| **Name:** Supply Event (Multiple)  **Description:** Information on supplies that are referenced. Please note multiple procedures can be referenced. | 102 | Supply Event DateTime | The date and time at which the supply event occurred. | Single |  |
|  | 103 | Supply Code | Standard codes used to identify a specific supply | Single | Something that would come from a constrained vocabulary. |
|  | 104 | Supply Stage | The stage of the supply (e.g., Proposed, ordered, delivered, undelivered) | Single | This should be a tightly constrained set of values that is used to define this. |
|  | 105 | Target body site | The body site that the supply was or should be used on | Single |  |
|  | 106 | Quantity | Amount of supplies used or recommended (e.g., 4 packages of gauze bandages, 1 set youth crutches, 30 home-use catheters, etc.) | Single |  |
|  | 107 | Criticality | The importance of the supply for clinical care | Single |  |
|  | 108 | Supply time interval | Specific or ranges of time for use of or dispensing of a supply | Single |  |
|  | 109 | Repetition | Number of times the supply was or should be repeated | Single |  |
|  | 110 | Reason not delivered | Indication of the reason that a supply was not delivered | Single |  |
| **Name:**  Education /Training Event (Multiple)  **Description:** Information on education / training that is referenced. Please note multiple education / training items can be referenced.  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. | 111 | Education Type | Coded value for the type of education | Single |  |
|  | 112 | Education Code | A code uniquely identifying the education element, such as “Smoking Cessation”, etc. | Single |  |
|  | 113 | Education Stage | The stage of the education/training | Single |  |
|  | 114 | Education Focus | The topics that were or should be covered in an education event | Single |  |
|  | 115 | Education time | Time interval during which the education or training occurred or should occur | Single |  |
|  | 116 | Criticality | The importance of the education for clinical care | Single |  |
|  | 117 | Repetition | Number of times the educational or training activity was or should be repeated | Single |  |
|  | 118 | Educating Provider Type | Provider type delivering the education or training (e.g., Nurse, Physician or Physical Therapist) | Single |  |
| **Name:** Goal (Multiple)  **Description:** A clinical end or aim towards which effort is directed. | 119 | Focus of Goal | Target of the goal (e.g., weight loss with a target of 175 lbs. to be taken) | Single | This can include current and future goals. |
|  | 120 | Target Body Site | The body site referenced by the goal | Multiple |  |
|  | 121 | Goal Criterion | A Boolean criterion that defines when the goal has been met | Single |  |
|  | 122 | Goal time interval | The time period in which the goal has been or should be achieved | Single |  |
|  | 123 | Target Goal Value | The metric whose achievement would signify the fulfillment of the goal. E.g., 150 pounds, 7.0%. | Single |  |
|  | 124 | Criticality | Urgency or importance of the goal. May reflect the threat to the patient's health that this goal addresses (e.g., critical, moderately important) | Single |  |
|  | 125 | Goal Stage | Progress toward meeting the goal | Multiple | Consideration for Harmonization: This should be a tightly constrained set of values that is used to define this. |
|  | 126 | Goal Initiator | The initiator of the goal can be provider or patient. | Single |  |
| **Name:** Supporting Resource (Multiple)  **Description:** A resource such as information or tool regarded by the artifact supplier as relevant to a provider’s decision to use a particular artifact, section, or action or to facilitate the execution of the CDS recommendation or action. It may include information describing contraindications as well as supporting information, or it may simply be information that is less definitive than Supporting Evidence. It also may be a tool such as a dose calculator or a risk calculator. | 127 | See Decision Support Resource Type component. | See Decision Support Resource Type component. | Single |  |
| **Name:** Related Clinical Statement or Relevant 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 | 128 | Related Clinical Statement or Relevant 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. |
| **Name:** Imaging (Multiple)  **Description:** A proposal for an Imaging Order. For instance, Chest Radiograph - PA and Lateral. | 129 | Contrast | Specification of whether contrast should be administered as part of the imaging study (e.g., Yes, No, Per Radiology) | Single |  |
|  | 130 | Contrast Route | Specification of the route of contrast (e.g., Oral, IV, Per Radiology) to be given as part of an imaging proposal | Single |  |
|  | 131 | Contrast Type | Specification of the kind of contrast (e.g., Barium, Gastrograffin) to be given as part of an imaging proposal (e.g., Barium, Gastrograffin) | Single |  |
|  | 132 | Isolation Code | Specification for type of precautions that should be taken when in proximity to the patient. For instance, Airborne Precautions, Contact Precautions, Droplet Precautions, Standard Precautions. | Single |  |
|  | 133 | Portable Exam | Designation of whether or not the imaging procedure should be performed at the patient's bedside (Yes) or if the procedure can be conducted in the location of the performing department (No) | Single |  |
|  | 134 | Stressor | Type of physiologic or pharmacologic stress that will be subjected to the patient during the imaging procedure (e.g., Adenosine, Dipyrdomole, Persantine, Thallium, Cardiolite, Dobutamine, Treadmill) | Single |  |
|  | 135 | Transport Mode | Specification of how a patient will be moved from their hospital room to the performing department | Single |  |
| **Name:** Laboratory (Multiple)  Description: A proposal for a laboratory test. | 136 | Test | The laboratory test | Single |  |
|  | 137 | Collection Method | Specification of how the laboratory specimen should be obtained | Single |  |
|  | 138 | Special Handling | Special instructions on how to handle a laboratory specimen (e.g., 'Keep on ice') | Multiple |  |
|  | 139 | Suspected Pathogen | The pathogen or pathogens that are felt to be the most likely cause of the patient's condition that led to the laboratory procedure proposal. For instance, Staphylococcus, Streptococcus, Pseudomonas, Neisseria. | Multiple |  |
| **Name:** Respiratory Care (Multiple)  **Description:** Order proposals that encompass supplemental oxygen (eg, nasal cannula, face mask), BiPAP/CPAP, and mechanical ventilation. While these are vastly different respiratory care concepts, the associated data elements can be constrained through templates. | 140 | EPAP | Expiratory positive airway pressure, often expressed in cmH20 in the United States. Example: 5 cmH2O | Single |  |
|  | 141 | fiO2 | Fraction of inspired oxygen, expressed as a percentage (e.g., 100%.) | Single |  |
|  | 142 | Inspiratory Time | Specification of the duration of the positive airway pressure applied by a mechanical ventilator (e.g., 1 second) | Single |  |
|  | 143 | IPAP | Inspiratory positive airway pressure, often expressed in cmH20 in the United States (e.g., 10 cmH2O) | Single |  |
|  | 144 | Isolation Code | Describes the kinds of precautions that should be taken for the patient. Values include: Airborne Precautions, Contact Precautions, Droplet Precautions, Standard Precautions, Neutropenic (Reverse) Precautions | Single |  |
|  | 145 | Oxygen Delivery Method | Describes how oxygen will be delivered to a patient (e.g., Nasal Cannula, Hood, Face Mask, Non-rebreather Mask) | Single |  |
|  | 146 | Peak Flow Rate | Specification of the maximum allowable rate of airflow delivered by a mechanical ventilator (e.g., 60 L/min) | Single |  |
|  | 147 | Peak Inspiratory Pressure | Specification of the maximum airway pressure allowed to be delivered by the ventilator in order to prevent barotrauma, applies to volume-controlled ventilation modes (e.g., 35 cmH2O) | Single |  |
|  | 148 | PEEP | Positive end expiratory pressure, the alveolar pressure above atmospheric pressure that exists at the end of expiration, often expressed in cmH20 in the United States (e.g., 5 cmH2O) | Single |  |
|  | 149 | Pressure Support | Specification of the additional amount of pressure that is added to a mechanical ventilation mode, often CPAP mode. Not to be confused with pressure control ventilation mode (e.g., 500 mL) | Single |  |
|  | 150 | Respiratory Rate | Number of machine-delivered breaths per minute, in the context of mechanical ventilation, expressed as breaths/minute (e.g., 14 breaths/minute) | Single |  |
|  | 151 | spO2 Range | Target oxygen saturation, expressed as a percentage. For instance, 95-100% | Single |  |
|  | 152 | spO2 Titration | Titration instructions to achieve target oxygen saturation. An example might include: "Titrate oxygen to maintain SpO2 > 93%" | Single |  |
|  | 153 | Tidal Volume | Volume of air delivered with each machine-delivered breath, often expressed in mL in the United States (e.g., 500 mL) | Single |  |
|  | 154 | Ventilator Mode | Primary setting on a mechanical ventilator that specifies how machine breaths will be delivered to a patient (e.g., Assist Control (AC), Synchronized Intermittent Mandatory Ventilation (SIMV), Pressure Support Ventilation (PS or PSV), Pressure-Regulated Volume Control (PRVC)) | Single |  |

## 11.2 Context Data Elements

| **Context** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Section Name & Description** | **#** | **Data Elements** | **Data Element Descriptions** | **Cardinality** | **Additional Notes** |
| **Name:** Clinical Context   **Description:** Elements that identify the source of the CDS request and the type of clinical care in which the clinical guidance will be applied. | 1A | Initiating Organization Name | The entity initiating the request | Single |  |
|  | 1B | Initiating Organization ID | Identifies for the organization initiating the request | Single |  |
|  | 1C | Initiating Organization Address | Physical address, phone, and email for the initiating organization | Single | Will define these elements based on the vMR |
|  | 2A | Initiating Person | Person initiating the request | Single |  |
|  | 2B | Initiating Person ID | Identifier of the person initiating the request | Single |  |
|  | 2C | Initiating Person Role | Type of clinician initiating the request, e.g., physician, nurse | Single |  |
|  | 2D | Initiating Person Address | Physical address, phone, and email for the initiating person | Single | Will define these elements based on the vMR |
|  | 3A | Receiving Organization Name | Facility where the clinical guidance will be used | Single |  |
|  | 3B | Receiving Organization ID | Identifier for the receiving organization | Single |  |
|  | 3C | Receiving Organization Address | Physical address, phone, and email for the receiving organization | Single | Will define these elements based on the vMR |
|  | 4A | Receiving Person Name | Individual who will be using the clinical guidance | Single | Could be used to incorporate user preferences for the use of the clinical guidance |
|  | 4B | Receiving Person ID | Identifier for the receiving person | Single |  |
|  | 4C | Receiving Person Role | Type of clinician who will be using the clinical guidance, e.g., physician, nurse, patient | Single |  |
|  | 4D | Receiving Person Address | Physical address, phone, and email for the receiving person | Single | Will define these elements based on the vMR |
|  | 5A | Initiating Care Setting Type Description | Name of the type of care setting where guidance request is initiated | Multiple |  |
|  | 5B | Initiating Care Setting Type Code | Code for the type of care setting where guidance request is initiated | Multiple |  |
|  | 6A | Receiving Care Setting Type Description | Name of the type of care setting where guidance will be used | Multiple |  |
|  | 6B | Receiving Care Setting Type Code | Code for the type of care setting where guidance will be used | Multiple |  |
|  | 7A | Task Context Name | The name of the task that the user will be performing when using the clinical guidance | Multiple |  |
|  | 7B | Task Context Code | Code representing the task | Multiple |  |
|  | 8 | Encounter Type | Identifies the type of encounter with as much specificity as available, or as required by a template. E.g., outpatient encounter, outpatient cardiology encounter. | Single |  |
|  | 9 | Attribute | A user-specified attribute for this class. The field 'attribute' supports user-defined attribute extensions for clinical concepts. | Multiple |  |
|  | 10A | Artifact of Interest Name | Description of the artifact of interest | Multiple |  |
|  | 10B | Artifact of Interest Identifier | Identifier for the artifact of interest | Multiple |  |
|  | 11A | Recipient Language | Language in which the response should be sent in | Multiple |  |
|  | 11B | Recipient Language Code | Code representing the language | Multiple |  |
|  | 12 | Reference Time for Evaluation | The date and time when the clinical guidance will be used, e.g., the date and time of an upcoming patient appointment | Single |  |
|  | 13 | Request Date Time | The date and time when the request is made | Single | This may be linked to the Request ID |
|  | 14 | Request ID | Identifier generated by the requestor for this instance of the request. It is the requestor's  responsibility to ensure that this identifier is unique within the scope of the organization. | Single | This may be linked to the Request Date Time |

## 11.3 Supporting Evidence Data Elements

| **Supporting Evidence** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Section Name & Description** | **#** | **Data Elements** | **Data Element Descriptions** | **Cardinality** | **Additional Notes** |
| **Name:** Supporting Evidence (Multiple) | 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. |
| **Description:** Information regarded by the artifact supplier as strong indications for the correctness or adequacy of the the actions defined in the artifact. | 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 |          LinkLabel | 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 | This is not patient specific recommendation strength. |
|  | 6 | Recommendation Strength Score | A coded value that represents the recommendation strength. | Single | This is not patient specific recommendation strength. |
|  | 7 | Evidence Link Source | The guideline, evidence review, or other document providing evidence for the care recommendations in the artifact | Multiple |  |

## 11.4 Supporting Resource Data Elements

| **Supporting Resource** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Section Name & Description** | **#** | **Data Elements** | **Data Element Descriptions** | **Cardinality** | **Additional Notes** |
| **Name:** Supporting Resource (multiple) | 1 | Decision Support Resource Type | Type of decision support resource (e.g., guideline from medical association, meta-analysis, systematic review, randomized controlled trial, retrospective analysis) | Multiple | HeD may wish to consider the following resources when developing the terminology for this data element.  MeSH: Publication Formats http://www.nlm.nih.gov/cgi/mesh/2013/MB\_cgi?mode=&index=23665  MeSH: Study Characteristics http://www.nlm.nih.gov/cgi/mesh/2013/MB\_cgi?mode=&index=23667 |
|  | 2 | Decision Support Resource Name | Name of decision support resource | Single |  |
| **Description:** A resource such as information or tool regarded by the artifact supplier as relevant to a provider’s decision to use a particular artifact, section, or action or to facilitate the execution of the CDS recommendation or action. It may include information describing contraindications as well as supporting information, or it may simply be information that is less definitive than Supporting Evidence. It also may be a tool such as a dose calculator or a risk calculator. | 3 | Decision Support Resource 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 |  |

## 11.5 Actions Data Elements

| **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) | 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 |  |
|  |  |
| **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. | 2 | Supporting Evidence | See supporting evidence component. | Multiple |  |
|  |
|  | 3 | Supporting Resource | See supporting resource 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 related to 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 | 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). | 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. |
|  | The clinical actions include: |          All classes should support coding the action with codes from standard terminologies. |
| **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) |          Substance Event– Includes medications, vaccinations, gases, blood products and other activities that fit the same output activity structure, including hydration and feeding) |          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. |
|  |          Procedure– Includes surgical procedures, nursing and other allied health activities and procedures |          Action sentences may implicitly or explicitly include flags denoting automatic execution and destinations. These will be determined during harmonization. |
| **Example:** Perform a liver function test panel after 30 days |          Encounter– Including proposed encounter, referral, and admission discharge |          Actions may also require responses. |
|  |          Observation– Includes documentation, diagnosis, assessment evaluation |          Actions may be synchronous or asynchronous. |
|  |          Diagnostic Test |  |
|  |          Education |  |
|  |          Goal |  |
|  |          Supply |  |
|  |          Message (could be a warning, such as "patient is due for immunizations, but no information was furnished telling whether or not the patient has an allergy to eggs.") |  |
|  | 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 |  |
| **Name**: Order Set Section (Multiple) | 8 | Title | A descriptive heading for the set of orders in that section. E.g., Medications, Diagnostic Tests | Single |  |
|  | 9 | Order Sub Section | Repeating Order Set Section elements. | 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. | 10 | Order elements | Specific order and related data Included in the order sub-section | Multiple |  |
|  | 11 | Sequence Indicator | Information indicating the placement of this order set section within the order set or the containing section | Single |  |
|  | 12 | Supporting Evidence | See Supporting Evidence component. | Multiple | **Optional,** you can include this at the artifact, section or element level. |
|  | 13 | Supporting Resource | See Supporting Resource component. | Multiple |  |
|  | 14 | 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’ |

## 11.6 Attribute-Value List Data Elements

| Attribute-Value lists are generic data structures which can be used to extend the current specification for specific applications. 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 | 1 | Attribute Name | Name of the attribute. | Single |  |
|  |
| **Description:** Attribute-Value lists are used to contain data for processing a CDS Artifact by a particular application. | 2 | Attribute Values | One or more values associated with the attribute. | Multiple |  |
|  | 3 | Attribute Data Type | The data type of the attribute. | Single |  |

## 11.7 Response Metadata Data Elements

| **Response Metadata** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Section Name & Description** | **#** | **Data Elements** | **Data Element Descriptions** | **Cardinality** | **Additional Notes** |
| **Name:** Response Metadata  **Description:** Metadata used to link the CDS Guidance Request with the CDS Guidance Response | 1 | Response ID | The Response ID is defined by the Guidance Supplier, whereas the Request ID is defined by the Guidance Requestor, so the Request ID is only unique when considered with the Initiating Organization ID | Single | Assumption: The CDS Guidance Supplier is responsible for verifying the unique response IDs to ensure that CDS Guidance Requestors can communicate unambiguously with the service and that the meaning of the response ID is consistent for historical and current CDS interactions. |
| 2 | Request ID | Identifier generated by the Guidance Requestor for this instance of the request. It is the Guidance Requestor's responsibility to ensure that this identifier is unique within the scope of the organization. | Single |  |

## 11.8 Exceptions Data Elements

| **Exceptions** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Section Name & Description** | **#** | **Data Elements** | **Data Element Descriptions** | **Cardinality** | **Additional Notes** |
| **Name:** Exception (Multiple)  **Description:** Data elements for conveying information pertaining to exceptions | 1 | Exception | This element describes any error conditions that arose during processing of the request. | Multiple |  |
| 1A | Exception Source | The source of the error (e.g., HeD, CDS Service). Codes within a specific source will be unique. | Single |  |
| 1B | Exception Code | A unique identifier that can be associated with the kind of error that occurred. | Single |  |
| 1C | Exception Message | A description of the error that occurred. | Single |  |
| 1D | Exception Level | An indicator intended to assist the person receiving the error in determining where to direct troubleshooting efforts. The following levels are defined:  DATA - Data: The error is related to the data being sent as part of the request. This type of error would typically be something that an end-user could correct, such as a missing data value or an out-of-range value.  KB - Knowledge Base: The error is related to an incorrect or invalid knowledge base definition. This type of error would typically be something that a content author would be required to correct.  CONN - Connectivity: The error is related to connectivity with one or more components within the system. This type of error would typically be something that the service administrator could correct.  SECURITY - Security: The error is related to improper authentication or insufficient authorization of the request.  SYSTEM - System: The error is an internal or unexpected error, such as an internal engine or compiler error. This type of error would typically be something that would require further diagnostics and possibly development effort to correct. | Single |  |

# 12.0 Risks, Issues and Obstacles

The following risks and mitigation actions were developed through research and dialogue with the community, beginning with those risks identified as part of the HeD Initiative Charter.

* Use Case may not align with industry and federal priorities.
  + Mitigation/Response: Participants in the HeD Initiative include industry and federal thought leaders and representatives from various projects and organizations specializing in CDS (HL7 Clinical Decision Support Workgroup, OpenCDS, etc).
* Insufficient “end-user” input (e.g. physicians, clinicians, technology vendors). Originally included in the list of risks for Use Case 1, this risk applies to Use Case 2 as well.
  + Mitigation/Response: Continue to evaluate role and type of Initiative participants; invite additional participants as needed to balance representation. Incorporate feedback relevant to Use Case 2 from the Use Case 1 pilots. Ensure that the pilots for Use Case 2 include representation from all major stakeholder groups.
* Use Case scope may be too narrow to be valuable. While ancillary services to enable the automatic discovery of available CDS guidance and the required format and data elements for each type of guidance have been discussed, they were not included in the initial scope.
  + Mitigation/Response: Reviews and input from the HeD participants, the HL7 CDS Workgroup, and others have been obtained in order to identify the components seen to deliver the most value for the least complexity and effort, thereby facilitating maximum adoption among the user community.
* Another standard or Initiative may already meet Use Case scope. This risk is exemplified by the concerns about HQMF raised during the balloting of Use Case 1.
  + Mitigation/Response: Participants in the HeD Initiative also participate in or have participated in other related projects/Initiatives and will recognize if this is beginning to become an issue. HL7 balloting and the pilots will provide another check.
* Use Case scope may not be attainable through existing standards or extensions to existing standards.
  + Mitigation/Response: Given the richness of the existing standards this risk is low. As needed HeD will engage with the relevant SDOs to suggest changes or extensions via normal channels.
* Standards adopted/developed may not scale to small vendors and practices, and/or accommodate clinical practice variations. Originally included in the list of risks for Use Case 1, this risk applies to Use Case 2, as well.
  + Mitigation/Response: Recruit small vendors and practices to participate in the Workgroup meetings and pilot efforts. Reduce scope on the requirements for local mapping so that there is an option for such services to be provided by other vendors.
* Use Case scope and supporting standards may not provide sufficient flexibility to allow for future growth.
  + Mitigation/Response: The workgroup has made conscious efforts to use language within the Use Case that does not preclude users from going above and beyond the requirements outlined within the document. Piloting with common use scenarios and potentially future rounds of specification and standardization could help to mitigate this risk.
* Use Case scope and supporting standards may not be well defined enough to promote interoperability.
  + Mitigation/Response: Continue to ensure that a balanced community of stakeholders is actively involved within the S&I Framework, SDOs, and other stakeholder organizations, and that these organizations are evaluating the work products for accuracy as well as usefulness in promoting interoperability. Piloting with common use scenarios and potentially future rounds of specification and standardization could help to mitigate this risk.
* Proposed project timeline does not reflect actual deadlines in relevant SDO Balloting. Originally included in the list of risks for Use Case 1, this risk applies to Use Case 2, as well.
  + Mitigation/Response: Identify support to help mitigate this issue including inviting SDO members to participate in our workgroup and working with SDOs on out-of-cycle balloting. Begin working with the SDOs ASAP.

In addition to the risks identified while drafting the Initiative charter the community also identified the following considerations and risks: (Originally included in the list of risks for Use Case 1, these apply to Use Case 2, as well.)

* 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 workgroup 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 workgroup members speak different professional languages. (For example: to some the abbreviation IP means internet protocol, to others it means intellectual property).
  + Mitigation/Response: 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 may be perceived as creating a somewhat unstable environment for meaningful progress.
  + Mitigation/Response: Such a flux increases demand for efficient and safe systems. CDS will be part of the solution. Systems without robust CDS may be flawed and lacking (and unsafe).
* 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.
  + Mitigation/Response: This can be addressed with education and examples of sites where CDS is working and productive. The inclusion of supporting evidence with results may address concerns about the validity of alerts and recommendations made.
* There is a risk that workgroup members represent our own interests as opposed to those of the project (ethnocentricity) rather than focusing on the end user and the patient.
  + Mitigation/Response: Ensure that the Workgroup has a diversity of stakeholders and that Workgroup discussions provide the opportunity for broad input across the Workgroup.
* There is a risk of failure to achieve industry-wide consensus on the common functional interaction types that must be pre-configured in order for pre-conditions to be met. For example, CDS Guidance Suppliers may all decide to provide Immunization Forecasting, but CDS Guidance Requestors may actually be more interested in Prediction Rules. If this were the case then the value of this Use Case would fail to live up to its full potential.

# Appendices

## Appendix A: Health eDecisions Initiative 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)

**Asynchronous:** A style of communication that allows for multiple actions from one party at a time without requiring an action from the other party in response in order to proceed.

**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**

**Stateful:** The opposite of stateless, this term describes a service that is able to utilize historical request to provide guidance.

**Stateless:** In the context of CDS, a term to describe a service that does not utilize historical requests to provide guidance (i.e., data is not stored between transactions). Statelessness does not imply that information about historical requests cannot be used for audit or operational improvement purposes.

**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).

**Synchronous:** A style of communication that is single-threaded, allowing for only one action at a time and blocking future actions until the first is complete.

**In Scope Artifact Type Definitions (Use Case 1)**

* **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.

## Appendix B: Topics for Future Consideration

The S&I Framework Health eDecisions community has identified several topics that should be considered for future efforts. The community decided to proceed with the scope as outlined above because the transactions described were seen to deliver the most value for the least complexity and effort, thereby facilitating maximum adoption among the user community. These items were scoped out of this Use Case for various reasons (some transactions will require changes to the Assumptions, Pre-Conditions, Post-Conditions, and/or Data Elements), but it was agreed that they would augment the functionality described within this document and would be topics worthy of development by the S&I Framework or another organization seeking to improve CDS Guidance Services.

* Query/response for available guidance
* Query/response for metadata requirements
* Iterative approach for additional data requirements
* Chained requests where the Guidance Supplier becomes a Guidance Requestor and consolidates the response it receives into the response it provides to the original requestor
* Tools for mapping guidance to local codes
* Implementation Guidance and the role of the CDS Guidance Integrator
* Natural Language Processing (NLP)

## Appendix C: Other Resources

The Health eDecisions CDS Artifact Sharing (Use Case 1) document and supporting materials may be accessed from the S&I Browser (<http://sibrowser.siframework.org/>). The direct link to the Use Case document download is: http://sibrowser.siframework.org/siclient/view?type=artifact&id=b3f1c2b0-626e-4c28-91fb-5c79e9d461bc&name=SIFramework\_HeD\_UC1\_CDSArtifactSharing\_v1.0.docx