**Health eDecisions**

**Value Sets and Terminology**

**Implementation Guide**

***(HeD VST IG)***

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# BACKGROUND

Health eDecisions (HeD) is an ONC-sponsored project that was launched with the intent of defining and harmonizing standards for clinical decision support (CDS) interoperability. For more information about HeD, visit <http://wiki.siframework.org/Health+eDecisions+Homepage>.

During the Harmonization phase of HeD, several sub-working group (SWG) initiatives were launched, one of which includes the Terminology and Value Sets sub-working group (**TVS SWG**) whose objective was to identify value sets or coding systems (terminologies) and map these to data elements used by **HeD CDS artifacts**.

# PURPOSE

The purpose of this document is to:

* provide guiding principles for aligning existing value sets or coding systems to data elements in CDS Artifacts.
* provide the user community with guidance on how to read and interpret aligning activity outcomes for use in CDS systems.

# GOAL

The goal of the alignment activity is to establish common language, represented by existing coding systems and value sets, for all data elements used within CDS systems. Consistent use of common language is key prerequisite to semantic interoperability between CDS systems.

Gaps that are identified during alignment or implementation process will be used to optimize comprehensiveness and accuracy of value sets and coding systems.

# TARGET AUDIENCE

The target audience includes:

* the HeD community which includes but is not limited to document editors and reviewers.
* the HL7 community members who will evaluate the CDS Knowledge Artifacts proposal on upcoming HL7 ballots.
* the user community (implementers) who will implement alignment outcomes in their CDS systems.

# DELIVERABLES

There are two (2) deliverables associated with HeD Value Sets and Terminology working Group (HeD VST WG):

1. “Health eDecisions - Value Sets & Terminology-Bound Fields” (**HeD VST**) **spreadsheet** document located at the [following S&I Framework website](https://docs.google.com/spreadsheet/ccc?key=0AkVg6OcD6S5NdElOTndjOGhpaEF6UmlfTm05OGVYdWc#gid=0).
2. “Health eDecisions Value Sets and Terminology Implementation Guide” document (this document)



# GUIDE FOR IMPLEMENTERS

## General Guiding Principle

Consistent implementation of HeD CDS artifacts along with associated coding systems and value sets is the key to enabling the creation, exchange and meaningful use of artifacts by participating CDS systems. To achieve complete compliance with published HeD specifications, implementers need to adopt coding systems and value sets identified in HeD VSTspreadsheet when exchanging CDS-related data elements whenever content is exchanged. This is particularly important *outside of their proprietary systems, that is, with other organizations*.

In case where the defined standard value set content does not satisfy the needs of vendor’s CDS or EHR systems, implementers are encouraged to document the gap and provide feedback to the HeD Value Set and Terminology sub-Group (VST WG). Implementers of CDS artifacts may, depending on conformance requirements, use proprietary or non-standard coding systems and value sets *when there is a gap* in the HeD recommendations. However, implementers are advised that such use may prevent semantic interoperability between participating CDS systems. HeD VST WG recommends following approach when gaps are identified:

1. Explore whether existing coding systems (CS) and value sets (VS) from the table below (“*Value Set and Coding Systems resources*”) address the gap, and provide recommendation to VST WG in form of a feedback on the use of appropriate CS/VS to close the gap.
2. When existing coding systems and value sets do not address thegap, use proprietary or non-standard coding system, and provide VST WG with a list of values (examples).

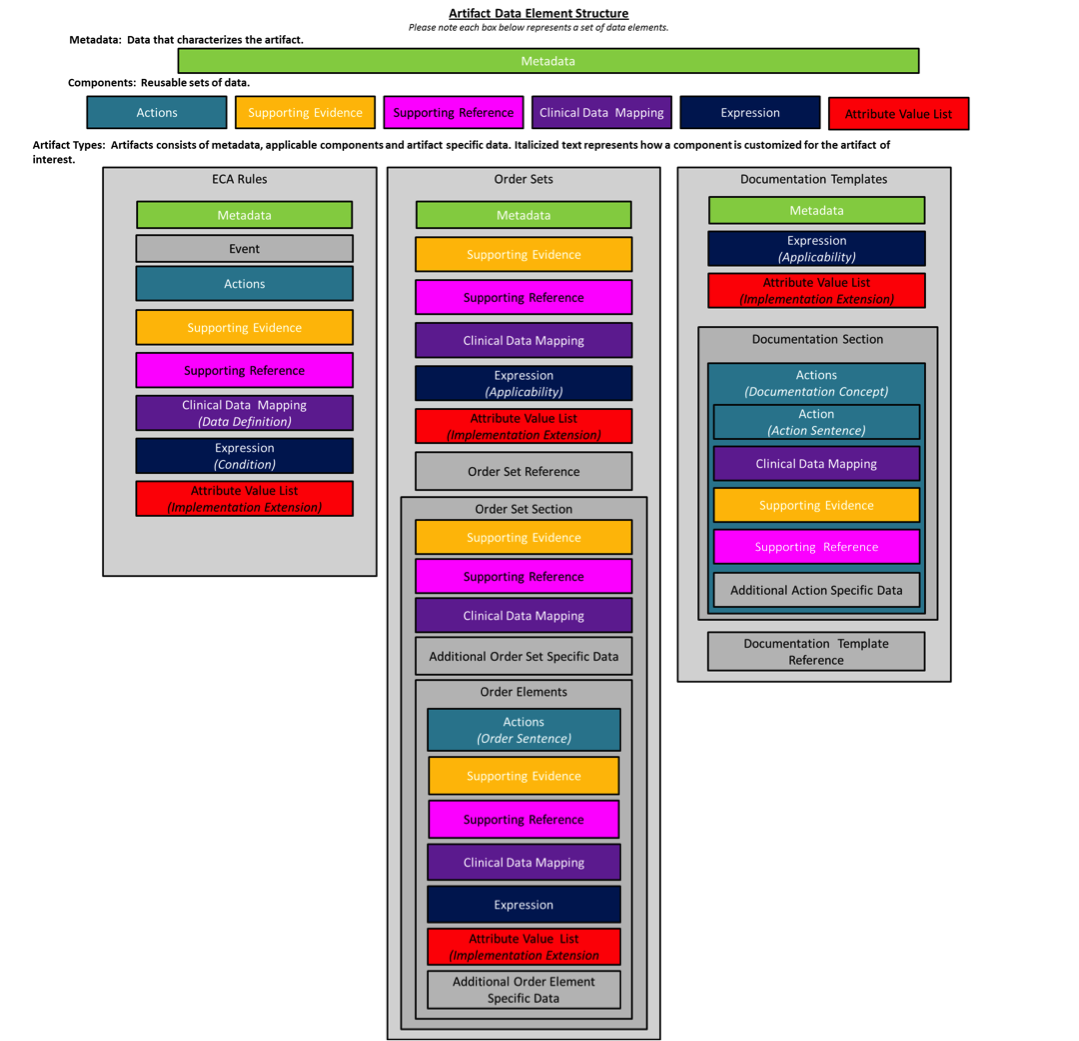
CDS and EHR vendors may not be constrained to use HeD-compatible value sets when not exchanging CDS artifacts outside a closed environment, although they may choose to do so voluntarily if desired and where applicable. The HeD approach may allow CDS vendors and EHR vendors to continue usage of their own proprietary terminologies, value sets, data models, expression languages, etc. and only defines specifications for the exchange of CDS knowledge artifacts.

## Prerequisite Resources

Implementers are strongly encouraged to review resources listed below. These resources provide necessary background that facilitates implementation of value sets and coding systems for CDS artifacts.

### HeD Artifact Sharing Use Case (document)

HeD Artifacts Sharing Use Case document, available at the [following S&I Framework website](http://www.google.com/url?q=http%3A%2F%2Fwiki.siframework.org%2Ffile%2Fview%2FSIFramework_HeD_UC1_CDSArtifactSharing_v1.0.docx%2F371583300%2FSIFramework_HeD_UC1_CDSArtifactSharing_v1.0.docx&sa=D&sntz=1&usg=AFQjCNFTG8Ay6aRhNTsxdNJQwa_DDjMRrw), lays out specific Use Case that was developed in support of HeD initiative in initial stages of HeD project. It is the fundamental driver of all HeD-related activities and derivatives. It is helpful to review Figure 6. “*Artifact Data Element Structure*” diagram on page 18 (also see below).



### HL7 Implementation Guide: Clinical Decision Support Knowledge Artifact Implementation Guide, Release 1 (document)

CDS Knowledge Artifact Implementation Guide document, available at the [following S&I Framework website](http://wiki.siframework.org/file/view/implementation_guide_working_final_032513_lse_uploaded.docx/417790778/implementation_guide_working_final_032513_lse_uploaded.docx), provides an overview and key steps on how to implement all components of CDS knowledge artifacts produced by HeD initiative. Implementers are strongly encouraged to review at the least Section 1 through 3 of this document to obtain general understanding of HeD Initiative and key concepts.

### vMR (Virtual Medical Record) model (document)

Virtual Medical Record (vMR) for Clinical Decision Support (CDS), available at the [following HL7 website](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=270), is a data model for representing clinical data relevant to CDS. The vMR encompasses data about a patient's demographics and clinical history, as well as CDS inferences about the patient (e.g. recommended clinical interventions).

Metadata from vMR were included in HeD alignment activity to ensure optimal coverage of all data elements that may be exchanged between CDS systems. Note that metadata from both versions of vMR (v1 and v2.0) are included in the spreadsheet.

### Value Set and Coding Systems resources

These resources represent standards developing organizations such as IHTSDO and Regenstrief institute that develop standardized terminologies such as SNOMED CT and LOINC (respectively). Resources also represent various organizations such as National Library of Medicine’s (NLM) Value Set Authority Center (VSAC) that maintain value sets.

The following table includes a ranked order of preferred value set sources that were utilized during alignment process. Equally, table provides list of sources that user community is strongly encouraged to become familiarized with to facilitate implementation of HeD artifacts.

|  |  |  |
| --- | --- | --- |
| **Resource Type** | **Value Set** | **URL** |
| **Value Sets** | HITSP c80 v2.0.1 (pdf) | <http://www.hitsp.org/Handlers/HitspFileServer.aspx?FileGuid=1d34ed96-351f-4f00-9a84-3e2da455315e> |
|  | VSAC | <http://vsac.nlm.nih.gov/> |
|  | CDC-PHIN/VADS | <https://phinvads.cdc.gov/> |
|  | USHIK | <http://ushik.ahrq.gov/> |
|  | C-CDA (by Kai Heitmann) | <http://art-decor.org/art-decor/decor-valuesets--ccda-> |
| **Coding Systems (Terminologies)** | SNOMED CT | <http://www.ihtsdo.org/snomed-ct/> |
|  | ICD-9-CM | <http://www.cdc.gov/nchs/icd/icd9cm.htm> |
|  | ICD-10-CM | <http://www.cdc.gov/nchs/icd/icd10cm.htm> |
|  | CPT | <http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/cpt.page> |
|  | LOINC | <http://loinc.org/> |
|  | RxNorm | <http://www.nlm.nih.gov/research/umls/rxnorm/> |
|  | NDC | <http://www.fda.gov/drugs/informationondrugs/ucm142438.htm> |
|  | NDF-RT | <http://www.pbm.va.gov/NationalFormulary.aspx> |
|  | CDC CVX | <http://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=cvx> |
|  | CDC MVX | <http://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=mvx> |
|  | HL7 v3 Vocabularies | <http://www.hl7.org/v3ballotarchive/v3ballot2012may/html/infrastructure/vocabulary/vocabulary.html> |
|  | HL7 v3 InfoButton | <http://www.hl7.org/documentcenter/public_temp_2CF86F06-1C23-BA17-0C118DC5184B88FB/standards/dstu/V3IG_INFOBUTTON_DSTU_R4_2013JAN.pdf> |
|  | MeSH | <http://www.nlm.nih.gov/mesh/> |

Value Set OIDs should be preferentially selected from HITSP if available. Value sets that have gone through a review process and have been deemed useful (e.g., value sets that have been defined as part of ARRA Meaningful Use) should be preferentially used.

### OID Registry

An OID is a globally unique ISO (International Organization for Standardization) identifier. Implementers can learn more about OIDs at the [following HL7 web site](http://www.hl7.org/oid/index.cfm).

In **HeD VST** **spreadsheet**, OID is used to uniquely identify a Value Set or Coding System that is aligned to a data element. Providing OID simplifies search for and use of the appropriate coding system/value set. For example:

* OID **2.16.840.1.113883.6.96** uniquely identifies **SNOMED CT** coding system.
* OID **2.16.840.1.113883.3.88.12.3221.6.8** uniquely identifies **Problem Severity Value Set”** in Table 2-67 of HITSP c80 v2.0.1 document.

From a practical perspective, while SNOMED CT represents *human readable* name of a coding system or a value set, OID represents its *machine readable* identifier.

### HeD Pilot Tools webpage

[HeD Pilot Tools webpage](http://wiki.siframework.org/HeD+Pilot+Tools) available at S&I Framework website is designed to provide implementers with core materials relevant for implementation of CDS artifacts, including the HeD VST spreadsheet.

Implementers are strongly encouraged to use “Comments” section of the webpage to provide feedback to document their implementation experiences and provide input into future versions of HeD specifications.

## HeD VST Spreadsheet

The “Health eDecisions - Value Sets & Terminology-Bound Fields” (**HeD VST**) **spreadsheet** is derived from all data elements within the existing HeD XML schema and all data elements from the vMR XML schema. HeD Vocabulary working group extracted data elements from both HeD and vMR schemas to ensure maximum coverage for data elements required to support CDS artifacts. Notwithstanding, the HeD XML schema is the source of truth and supersedes the “Health eDecisions Schema Value Sets & Terminology-Bound Fields” spreadsheet in the event of any discrepancy in data elements.

The **HeD VST** **spreadsheet** document represents work-in-progress deliverable that vocabulary *domain experts* in VST WG use to *map* specific value sets or coding systems to data elements in CDS artifacts. The excel document also represents a reference document that *implementers* of HeD CDS artifacts use to *identify* value sets or coding systems that are *aligned* to data elements in CDS artifacts.

### HeD VST Spreadsheet Structure Overview

HeD VST spreadsheet contains five (5) worksheets. The first sheet named “Terminology and Value Set Master” is the most relevant to both mappers and implementers since it contains the alignment between data elements and coding systems and value sets. The second worksheet named “DE stats” contains a pivot-table representation of the data in the first sheet and is used primarily by mappers to efficiently access statistical data about Data Elements that aid in alignment activity. The remaining worksheets represent historical data and should therefore not be used.

For the purposes of clarity, whenever there is a reference to “worksheet” or “spreadsheet”, what is meant is ***always*** the “Terminology and Value Set Master” ***(first worksheet)*** within HeD VST spreadsheet!

In the first spreadsheet, each CDS artifact data element is listed in its own row. There are multiple columns which contain a description, a designation of whether a value set should be defined for that coded data element, proposed values, value set metadata (if appropriate), notes, and various other fields. The column headers should be fairly intuitive, and the metadata fields contain mouseover descriptions, so they will not be defined in this document. The following sections will outline sections of the spreadsheet that are relevant to implementers.

### Overview of Data Elements and Sources

The following table provides and overview of all CDS artifact data elements, their sources, their total numbers, and which of the total data elements were aligned to value sets or coding systems (*Note that “Data Element” column from below table corresponds to* ***Column B*** *in spreadsheet*):

|  |  |  |  |
| --- | --- | --- | --- |
| **Data Element Source** | **Data Element (*Column B*)** | **Total Number** | **DEs aligned to coding systems/value sets** |
| **HeD schema** | Attribute Value List | 3 | 0 |
|  | Clinical Mapping Data | 106 | 24 |
|  | Documentation Templates Data Elements | 37 | 1 |
|  | ECA Rules Data Elements | 28 | 1 |
|  | Expression | 22 | 1 |
|  | From Schemata | 9 | 9 |
|  | Metadata | 31 | 13 |
|  | Order Sets Data Element | 29 | 2 |
|  | Reusable Components | 7 | 2 |
|  | Supporting Evidence | 17 | 2 |
| **vMR schema** | vMR 1.0 Clinical Statement CD Elements | 68 | 68 |
|  | vMR 2.0 Clinical Statement CD Elements | 30 | 30 |
| **Total** |  | **387** | **157** |

Implementers should note that data elements from above table were aligned to coding systems and value sets *where appropriate*. For example, Clinical Mapping Data Element ***targetBodySite*** is aligned to the Table 2-71 Body Site Value Set developed by HITSP C80: Table 2-71 Body Site Value Set (OID: 2.16.840.1.113883.3.88.12.3221.8.9). In contrast, most Expression data elements such as ***Request Cardinality*** are not aligned to any terminologies or value sets. In general, Clinical Mapping Data, Metadata and vMR Clinical Statement CD Elements represents ~75% of all aligned data elements.

### Spreadsheet Columns Relevant for Implementers

Spreadsheet contains numerous columns that assisted HeD Vocabulary experts in their alignment activity. Many of these columns (especially those after column ***P***) are still work in progress. Implementers need to focus on only following columns to efficiently and timely identify codings systems and value sets relevant for implementation.

**Items identified in bold blue color represent the core focus of the alignment activity. For implementers, these will be the most important fields for reference.**

|  |  |
| --- | --- |
| **Column (Name) and Description** | **Intended Use** |
| (B) Section Name & Description 1 | Identifies Metadata, applicable components and artifact specific data extracted from HeD XML schema, as well as Data Elements extracted from vMR XML schema. |
| (C) Section Name & Description 2 |  |
| (E) Reviewed by Team | Identifies those spreadsheet rows that were reviewed by HeD Vocabulary Working Group members. Generally, implementers should focus on those data rows that have ***any value except “no value”.*** |
| **(F) Data Element** | **Identifies DATA ELEMENT used within CDS artifact.** |
| (I) Description | Describes Data Element in further details, such as intended use and exemplary values. Description is derived from the XML schema document. |
| **(K) Proposed Values** | **Identifies ALIGNMENT associated with the aforementioned DATA ELEMENT.**  Proposed values can be either a value set or a coding system.   * For *coding systems*, this column contains:   + **Coding System Name** (E.g. SNOMED CT)   + **OID** associated with Coding System (E.g. 2.16.840.1.113883.6.96)   + **specific code and code description**, where applicable (E.g. "Priorities" (272125009) and descendents) * For *value sets*, this column contains:   + **Value Set Name** (E.g. HITSP 80: Table 2-71 Body Site Value Set, MU Patient Reason Value set)   + **OID** associated with Value Set (E.g. 2.16.840.1.113883.3.88.12.3221.8.9)   Note: Some Data Elements can be aligned to more than one coding systems or value sets that either overlap or complement each other.  For example, data element “manufacturer” is aligned to CDC MVX and FDA NDC coding systems that provide *complementary* coverage. Similarly, data element “problemCode” is aligned to ICD-9-CM, ICD-10-CM and SNOMED CT coding systems that provide *overlapping* coverage. |
| (P) Notes for internal discussion | These notes provide implementers with an overview of evolution of alignment activity. Vocabulary WG members used this column to indicate candidate coding systems and/or value sets for initial (preliminary) alignment and to indicate challenges and discrepancies during alignment process. Notes also contain rationale for choosing one coding system/value set over another. |

## Feedback Mechanism

Feedback is instrumental mechanism that implementers can use to improve the usability of aligned data elements. For example, vendors who identify gaps in coverage of coding systems or value sets are encouraged to document these gaps and communicate them to the HeD working group. Vendors are also encouraged to propose coding systems and value sets that addresses identified gaps. Lastly, implementers may also use feedback mechanism to request further clarification or guidance on how to implement aligned value sets and coding systems.

Feedback can be provided at the following S&I Framework website <http://wiki.siframework.org/HeD+Pilot+Tools>. Feedback will be monitored on a regular basis and, where required, HeD Terminology experts will be engaged to assist implementers with their feedback.

# ALIGNMENT GUIDING PRINCIPLES

The following sections explain guiding principles that VST WG used in aligning vocabulary codes and value sets to CDS artifact data elements. The guiding principles for aligning coding systems and value sets to data elements are in line with vocabularies and value sets recommended by the CMS Blueprint for eMeasure Specifications[[1]](#footnote-0) (Table 9-5).

## Value Set Use Case

If a value set is defined for HeD, then the value set must be used in order for end users to be considered conformant with HeD. Therefore, a valid use case should exist before a value set is defined for a data element.

## Coded Data versus Free Text

When there is general agreement across stakeholders regarding the semantic meaning of coded concepts (regardless of the actual descriptions) as well as in the importance of exchanging these defined concepts, it is worthwhile to encode a value set. An example is the concept of Frequency for substance administration. There would be unanimous agreement that 1x/day, 2x/day, 3x/day, etc. would make sense as coded values, even though there may be variation in the way these concepts are described (e.g., QD, BID, TID, QID).

On the other hand, if a shared consistency of the concepts that comprise a value set is not important, it may be better to NOT define a value set for that data element. An example is the concept of named departments within a hospital. Due to different departmental structures across healthcare organizations, it may not make sense to try to capture all of the different departmental concepts because of differences in granularity which may result in overlap of concepts, gaps for some organizations, and irrelevant coded values for others, resulting in little benefit from an attempt to determine a common set of agreed-upon representative concepts.

## Proposed Values for Value Sets

In general, if a data element is to be populated by concepts drawn from more than one code system, each code system-specific set of concepts should be maintained in its own value set. This means that a grouping value set will need to be created for the data element, and this in turn would link, or “group,” the code system-specific sub-value sets together. Situations requiring grouping value sets such as these fall into two categories:

1. *Overlapping*: When multiple alternative code systems each independently represent the scope of meaning necessary for the data element. For example the use of SNOMED CT and ICD-10 for problems (see *problemCode* data element in the spreadsheet). In this case the scope of semantic meaning may be slightly different when reviewing the unique ideas included in the two sub-value sets. However, the expectation is that the overall scope of the semantic coverage should be as similar as possible given the code coverage for each code system.
2. *Complementing*: When the required scope of meaning for a data element is best met by combining non-overlapping sets of concepts drawn from multiple code systems. For example, to represent drug concepts that may cause adverse events, codes are needed from RxNorm and NDF-RT. Therefore each must be managed in a separate but non-overlapping value set. In this case the scope of semantic meaning is represented by the union of ideas in both sub-value sets.

Value set authors need to keep in mind that use of multiple code systems for a single data element complicates interoperability and should be avoided. Situations such as this will be rare as the expectation is that a value set represents concepts that are used in the model in a similar manner; alignment across code systems will be required for union sets that require multiple code systems to be useful. In some cases of *complementing* multi-code system grouping value sets, the linked data element is actually representing multiple similar ideas, but each idea type may have different code system requirements and likely different implementation needs in systems (if not in the CDS representation).

## Intension versus Extension

When possible, value sets should be built by intension rather than by extension. For example, if there is a need to describe drugs within a class, it would be preferable to define a value set at the class level rather than provide a list of each individual drug because the list of drugs may change over time, and it would be preferable to simply refer to the drug class with the expectation that the terminology source will be appropriately updated over time.

## Create complete value set purpose statements

Any value set *must* have a complete textual description of the intended meaning of the scope and membership of the value set - a description of the *semantic space* for the value set. This may be very similar to the description of the meaning of the data element but will often focus on the targeted subsections used from the included code systems - particularly if more than one code system is needed to complete the value set.

## Defining the meaning of member concepts

For value sets that include user-defined phrases when no standard code system concepts exist, a textual definition for the proposed phrase *must* be included so subsequent users can understand the intended meaning of the proposed concept. In addition the code system in which the proposed concept should be found must also be included.

# DOCUMENT HISTORY

|  |  |  |
| --- | --- | --- |
| **Date** | **Contributor** | **Action** |
| 11/6/2012 | Victor Lee | Document creation. Inserted Background, Document Structure, Guiding Principles, and Document History sections. Defined 4 guiding principles. Asking for community input. |
| 11/8/2012 | Rob McClure | Changed and added some sections. Changed heading format. |
| 11/9/2012 | Victor Lee | Added “Preferred Terminologies and Value Sets” section. |
| 11/14/2012 | Victor Lee | Added discussion about purpose of value set definition in the Background section. |
| 11/16/2012 | Victor Lee | Renamed document from “HeD Terminology and Value Sets Guidance” to “Health eDecisions Schema Value Sets and Terminology Guidance”. Incorporated revisions to wording based on SWG review and comment. Becky Angeles and Victor cleaned up offline version for HL7 ballot submission. |
| 1/15/2013 | Victor Lee | Added HL7 to “Preferred Terminologies and Value Sets” table |
| 3/12/2013 | Mark Roche | Added CPT, ICD-9-CM, ICD-10-CM, NDC, NDF-RT, MeSH, CDC CVX and CDC MVX to “Preferred Terminologies and Value Sets” table |
| 3/25/2013 | Mark Roche | Created a copy of the original document intended only for mappers. The entire document was repurposed to explicitly act as implementation guide to both mappers and implementers. Added goal section to stress the importance of use of standardized coding systems and value sets. Identified key knowledge prerequisites for reading implementation guide and spreadsheet - inserted: reference to HeD Use document and IG, Data Element Artifacts schema, references to vMR. Added Overview of Data Elements and Sources section and two tables within. Formatted table that includes terminology and value set resources in 2 groups: value sets and coding systems (terminologies). Added Feedback section. Added Acronym section. Reread the document to ensure consistency in use of following concepts: HeD CDS artifact, data element/metadata, and HeD Value Sets and Terminology working group. |
| 4/1/2013 | Mark Roche | Resolved comments and suggestions from 03/29 HeD Terminology WG call. Added clarification that conformance to HeD specifications requires implementation of all aligned valuse sets and coding systems. |
| 4/5/2013 | Rob McClure | Minor edits and suggestions |
| 4/8/2013 | Mark Roche | Minor edits based on suggestions from the group. Further clarified feedback process with respect to addressing gaps. |

# ACRONYMS

* **IG:** Implementation Guide document (this document)
* **TVS SWG**: Terminology and Value Sets sub-Working Group is a working group within Health eDecision initiative tasked with aligning HeD CDS artifacts to standardized coding systems and value sets
* **HeD VST spreadsheet (aka. spreadsheet)**: “Health eDecisions - Value Sets & Terminology-Bound Fields” spreadsheet represents an outcome of alignment activity performed by TVS SWG. It servers as the document that implementers use to identify coding systems and value sets for each data elements within HeD CDS artifacts.

1. Centers for Medicare & Medicaid Services. “*A Blueprint for the CMS Measures Management System, Version 9.1, December 2012 Health Services Advisory Group, Inc.*”. Available at: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/MeasuresManagementSystemBlueprint.html>. Accessed April 7, 2013. [↑](#footnote-ref-0)