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HIT Standards Committee

Vocabulary Task Force

Re: September 1st & 2nd , 2010 Meeting

Dear Vocabulary Task Force;

ASC X12 is submitting the following responses to the questions as requested by Judy Sparrow on behalf of the Task Force dated August 19th, 2010.

ASC X12, chartered by the American National Standards Institute (ANSI) in 1979, develops electronic data interchange (EDI) standards and implementation guides for national and global markets, and includes among its membership standards development experts from health care, insurance, transportation, finance, government, supply chain, and other industries.

ASC X12 appreciates the opportunity to provide input. The theme of our comments surrounding the subsets and /or value sets used to report health data, must consider the following three things:

- The business/use case should be the driver for what subset and /or value set is developed and maintained.
- The subset and /or value set MUST be “implementable”. It has been our experience that it is important to be mindful of the processes and staff at the entry point of the health data. If it is too complex, the use of that data will be compromised.
- Don’t re-invent processes to develop and maintain the subsets and /or value sets used in health data when organizations and processes exist today. An effort should be made to have a single maintainer for each subset and/or value set used to report health data.

Overall questions:

1. *What are the requirements for a centralized infrastructure to implement “one-stop shopping” for obtaining value sets, subsets, and vocabularies for meaningful use?*

X12 Response:

The centralized location must be a neutral entity. The centralized location must contain a repository able to support value sets, subsets and vocabularies from the data content creation committees and standards organization. The centralized repository must contain minimum metadata set which is defined as the codified value, any associated definition(s), version, dates of codes (when added, modified, or deleted), status, and the organization responsible for maintenance. The centralized repository must support real time web services, subscription/publication, and other means of computer to computer distribution. The centralized repository must provide the general public access to Print, downloadable human readable formats, and electronic batch downloads for automatic consumption by systems. All formats must support version, dates of codes (when added, modified, or deleted), and status, which should be incorporated into the metadata for this subset and /or value set. The centralized repository must be easy to search and retrieve information with clear and concise information concerning version, and the organization responsible for the maintenance of the value sets. The ability for the system to record information requestors, including contact information, so the content owners are able to push notifications to information requestors when the values change. The system must provide a mechanism for the user to subscribe to a value set and provide the ability for the content owners to be able notify information requestors of changes.

2. *Which requirements or functionalities are urgent, i.e., absolutely required to support “meaningful use”?*

X12 Response: Assuming the centralized organization and repository have been identified, it is X12’s position in order to support meaningful use, the minimal functionalities required would be the value set, subset ,definition, organization of record, the version or versions to be implemented, and a link to access the information from the organization of record.

Which would be most useful immediately?

X12 Response: Search functionality to find the value set would be the most useful to assist the implementers. If possible to have automatic links and downloads from the organizations of record, would be desired. The ability for the system to record information requestors, including contact information, so the content owners are able to push notifications to information requestors when the values change.

What would be a staged approach over time to get to the desired end state?

X12 Response: Coordination with the content creation organization of record. If

this is a standards organization, understanding the versioning and maintenance of the organization of record, working with the SDO Charter Organization (SCO) collaboratively to populate the centralized repository, while preserving the independent standards processes. Each organization would be responsible to populate the metadata per the agreed to value set, subset and definitions. The end state must provide a mechanism for the user to subscribe to a value set to enable the content owners the ability to notify information requestors of changes.

Detailed Questions

3. Where are you using value sets and subsets?

X12 Response: ASC X12 is one of the content creation organization/standards organization, creating value sets, subsets and definitions utilized across multiple industries, Health Care being just one.

For what domains?

X12 Response: While ASC X12 supports multiple industries. With regard to Health Care, ASC X12 supports multiple domains within healthcare such as, Dental versus Medical, financial versus clinical, ambulatory versus institutional.

How many value sets and subsets?

X12 Response: ASC X12 maintains value sets for our standard across versions of the standard. ASC X12 maintains the value sets and subsets required for the implementation of the standard (across versions) which exponentially increases the number of value sets and subsets. At this time it would difficult to provide an exact number given the timeframe for this response.

4. In your experience with creating, disseminating, updating and/or using value sets, subsets, and entire vocabularies, what works and what does not work?

X12 Response: ASC X12 has had extensive experience in creating, maintaining and disseminating value sets, subsets and vocabularies. For value sets and subsets that change frequently, it is imperative the value sets not be tied to a specific version of a standard. ASC X12 has maintained code lists as part of our standards process and has a very mature process for codes which are internal to our standard. Our development process adheres to the American National Standards Institutes procedures, which is required to be a recognized standards body. ASC X12 is also able to support external codes sets within our standard, which are maintained by organizations other than ASC X12, such as ICD-x, ,CPT-X, CDT-x , NDC etc.. It should be noted that our experience in the creation of external code lists either by ASC X12 or other organizations do not force new versions of the standards and expedite the implementation and adoption process while reducing the overall costs of implementation and maintenance.

5. What human resources does it take to implement and manage value sets, subsets, and entire vocabularies? Informaticists? Clinicians? IT people? How are you organized?

X12 Response: ASC X12's experience is that a varied cross section of resources are needed to maintain and implementable value sets. Such a "team" would include content experts representing all possible users of the value set including resources such as clinicians and policy makers, informaticists, application IT personnel, and implementers -including IT Vendors. If any one group or domain dominates the creation of a particular value set, then the goal of creating an implementable value set is compromised. Details concerning ASC X12's organizational structure is located at: <http://www.x12.org/x12org/about/procdrs.cfm>

6. What national resources and services could be leveraged to reduce the level of effort required for local implementations ?

X12 Response: ASC X12 develops standards which are implemented by organizations nationally. For Health Care, the HIPAA legislation created national implementation for the industry. While this national implementation approach minimizes local implementation issues, ASC X12 believes this question raises an underlying issue, the need for a strong central presence to be the arbiter of what is the acceptable industry standard for a business need to be filled by a value set. As the industry has already experienced, it is hard enough to implement and maintain new versions of value sets without dealing with competing standards. (i.e. HIPAA rules mandate use of ICD-9 and soon ICD-10 for reporting diagnoses). The task would be immeasurably more complicated if there was a competing value set for different standards development organizations to choose from.

What is the irreducible minimum of local work at an implementation site, or within an organization or system?

X12 Response: To address the question of what is the irreducible minimum of local work at an implementation would be difficult, however, without the arbitrator organization, the local work effort at an implementation site could potentially increase exponentially.

7. What is your maintenance process?

X12 Response: The ASC X12 body comes together three times each year to develop and maintain EDI standards. Each release is published by the X12 Secretariat. The maintenance process is documented in detail within ASC X12's foundational documents. (described below) These documents can be located at: <http://www.x12.org/x12org/about/procdrs.cfm>

ASC X12-Approved and Published Procedures:

Organization and Procedures Manual (OPM) - The OPM describes the organization and function of ASC X12, its officers, its subcommittees and task groups. It also describes the X12 Secretariat and its role. A glossary defines terms used in the OPM. Participants, membership and meetings are described. The processing of American National Standards, conducting appeals and other administrative matters are also described.

ASC X12 Standing Documents - The ASC X12 Steering Committee approves X12 Standing Documents, except those dealing with procedures.

Standing Document 1: ASC X12 Administrative Policies & Procedures
This publication provides clarification of policies that are not defined in detail in the OPM and which are not standards development and maintenance procedures.

Standing Document 2: Operations Manual; Development and Maintenance Procedures for Standards, Interpretations, Guidelines and Technical Reports (SD2)

SD2 contains the detail-level procedures for developing and maintaining standards, interpretations, guidelines, technical reports and American National Standards. A glossary provides definitions of the terms used in SD2. An appendix contains forms for:

- submitting new work
- Submitting changes to existing work
- tracking the progress of work
- changing a vote
- withdrawing a project (new or published).

In addition, guidelines for preparation of subcommittee minutes, document control numbering instructions, a checklist for conducting an Open Forum for discussion and resolution of ballot disapproval votes, sample ballots and comment response letter instructions are included.

How do you manage updates?

X12 Response: The Standard has one major release each year, with two smaller updates. The release and update follow the ASC X12 Trimester Meetings. Implementation instructions which identify subsets are incorporated into the implementation guides. Within ASC X12, the Health Care documents, like the HIPAA mandated documents, are moving toward establishing a two year publication schedule for revisions to the documentation. These documents are based on a

specific version of the standard. They contain both value sets and subsets.

8. What metadata do you maintain and how do you maintain versioning?

X12 Response: The ASC X12 body comes together three times each year to develop and maintain EDI standards. Each release is published by the ASC X12 Secretariat. Implementation specifications based on the ASC X12 Standard are published as the documents are completed. As previously stated, these are moving to a two year publication schedule.

9. Is there a difference between versioning for clinical documentation vs. versioning for reported measures, i.e., when do you go live with a change in the EHR vs. when do you use the new version for measures?

X12 Response: Not applicable.

10. How do you manage versioning in clinical decision support vs. changes in value sets?

X12 Response: This is an application issue, people who implement our standard fully understand our versioning. X12 is consistent in the manner in which we version our standard and implementations of our standard. ASC X12 has been developing standards for over 31 years.

11. How does an application know which value set is for which purpose? How is the specific context for a value set maintained at the message data element level of specificity? How is the English language intent of the value set context documented and maintained?

X12 Response: These tasks are normally done by the applications vendors. Standards messages and/or transactions indicate what value sets are used for various types of reporting in context to the message or transactions structure and definitions and implementation specifications. These are then interpreted by the applications that use this information in context to the application usage. English translations of codes sets, should normally reference the codes definition of the code value, which will provide the English translation or guidance for the translation

12. What are lessons learned about web links vs. storage of the vocabulary or other artifact in a physical repository?

X12 Response: Whether the value sets are available via a web link or storage, one lesson ASC X12 has learned, it is necessary to retain older versions to understand time dependent information, such as archived information or when a translation function is needed. For example, ICD-9 to ICD-10 does not always translate 1 to 1 upward or downward.

13. How do you manage distribution of updates to multiple sites?

X12 Response: Not applicable. ASC X12's Secretariat publishes in multiple formats, including print, digital downloadable format as well as an electronic human readable

format (.chm file or .pdf). Please note, the information requestor organization may share information among their owned facilities, when license or copyright permits.

14. Where is local customization appropriate and how much customization is acceptable?

X12 Response: This would not normally be permitted within Healthcare.

15. How do you manage distribution of updates with local variations and optionality? Unique subsets? Local mappings?

X12 Response: Not applicable. ASC X12 does not distribute codes with local variations or optionality.

16. What has to be local in an EHR implementation vs. what can be external in a vocabulary repository?

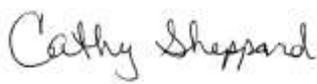
X12 Response: Not applicable to X12, this would be more of an issue for application developers rather than X12.

What functions are required that users have not yet appreciated?

X12 Response: No response at this time.

ASC X12 appreciates the opportunity to present this information to the task group.

Sincerely,



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