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Apelon Inc.
Response to: Health IT Standards Committee Clinical Operations Working Group
Questions on vocabulary subsets and meaningful use

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Apelon, Inc. is honored to provide input to the Clinical Operations Workgroup of the Office of the National Coordinator's Health I T Standards Committee regarding Vocabulary considerations on terminology value sets. Apelon has been involved in the development and provision of health care terminology content, terminology tooling, and standards for many years. We were instrumental in the development of the NLM Unified Medical Language System (UMLS) and have directly, or indirectly through the use of our tools, helped build and manage multiple health care terminologies including SNOMED CT, the Veterans Health Administration's NDF-RT, NCI's Thesaurus, Metathesaurus and BiomedGT, among other international, national and local terminologies and systems. We provided interoperability services to two of the NHIN prototypes and participate in a number of RHIOs and HIEs. We have worked with many users on the complex activity of deploying and managing terminologies to meet the ongoing needs of shared health care systems – a process we call Terminology Asset Management[SM]. Our personnel serve in leadership roles on numerous national and international standards committees including HL7, IHTSDO, HITSP, CCHIT and Canada Health Infoway.

Apelon is in agreement with the focus and direction of HHS and the ONC that semantic interoperability is a crucial element of the value proposition for deploying health care information technology. While non-standard electronic data capture within closed systems can be helpful, well-defined common terminology is required to access common knowledge resources and external clinical data. Supplying the infrastructure to meet this need has driven decades of work in the standards and application interoperability space. Clearly, given the pace of adoption, this is a complex activity that has required substantial work to obtain important consensus agreements on operational models that support data and knowledge sharing. But to date much of the focus of this work has been on what we call "the information model" (the structure of shared data) with varying degrees of attention and therefore less success in the equally important area of "the terminology" that must fit inside this model. It is time to address that deficit.

Over the past couple of years as the information models, complex as they may be, have reached some consensus and implementers have started the hard work of applying standards within real operating systems, thereby highlighting the unsolved "terminology problem". This meeting provides good evidence of that recognition. And, just as consensus through standards activities and joint collaborative efforts (plus regulatory guidance) have helped firm up common approaches to the information model, we feel that similar activities are needed for shared terminology.

1) Who should determine subsets and/or value sets that are needed?

Value sets are collections of concepts for use in specific data model elements within implementable specifications for data sharing, access, or reporting, so value sets are always crafted with a context of use in mind. The details of what specific information needs to be communicated in each element of the model are best known by the developer of the specific requirements to be met by the implementable specification. This "contextual alignment" can occur at any point in the process: from the initial crafting of a general information model (such as a domain analysis model) through defining a specific local implementation of a common model. We call this process "binding", where specific concepts are selected as acceptable when sharing clinical data (or looking to access clinical information sources). Information models can be built, discussed and shared prior to such binding by describing in a general way "the kinds of concepts we expect to be used" for the data elements included in the information model. In HL7 this is embodied in what is called "the concept domain." Because model developers can use a concept domain to give implementers guidance on what should be included when a value set is "bound" for actual implementation, the two activities have traditionally been separated. We believe this has led to problematic disconnects between what the information model can appropriately carry and what the value set creator specifies for actual implementations. The result can be semantic (and often functional) mismatches between different implementing systems. It has even resulted in unimplementable models where no one is sure what the modeler really meant. Therefore, we believe that model developers (including quality measure developers) must participate in specifying value sets are needed across sharable information models.

Subsets are collections of concepts that are recognized as being useful in *general* ways. Value sets may then draw from these subsets for targeted uses with the knowledge that the agency defining the subset understands and has already agreed to the general uses noted in the subset definition. While such guidance may not always be needed, when subset metadata clearly identifies expectations for reporting requirements (such as quality measure specification, and regulatory guidance) it can be appropriate for organizations (who are not model developers) to participate in defining the content of these general subsets.

But to be clear, the specific value sets that are used in implementable specifications must be acceptable to the clinical model developers who are directly involved in the expected behavior of the semantic data exchange. As an example, a US regulatory body could define a subset of reportable clinical diseases drawn from SNOMED CT, and that subset could be used in defining a specific value set for reporting resistant bacterial infections occurring in Intensive care units.

2) Who should produce subsets and/or value sets?

Because value sets exist to have common collections of accepted representations of clinical meaning, value sets must be produced in environments that support collaborative discussion and consensus. While it is true that value sets which only serve to exchange information between two business partners can be created by just those two organizations, the greatest value will come from those produced in an open and transparent way by public organizations that service multiple interests. Standards Development Organizations (HL7, ANSI, NCPDP, DICOM, CDISC, LOINC, IHTSDO, etc.) are suited for this role (although many have not currently embraced this role). However, the capability is not limited to SDOs. Other open collaborative organizations that choose to follow set guidelines for the creation and exchange of consensus value sets should be encouraged, organizations such as AHRQ US Health Information Knowledgebase (USHIK), The National Cancer Institute (NCI) and the National Quality Forum (NQF). What will be important for this to succeed is that publishing organizations should follow an approved, well-documented, and transparent value set development and maintenance process; provide value sets with commonly defined metadata and support access and interactions via a common set of APIs. In this way we will develop a federated matrix of value set producers that meet certain standards and have common interface protocols.

Subsets can also be produced by the same organizations in collaboration with regulatory or other organizations dependent on data exchange. It is important to require that subsets serve as a starting point for value set creation but subsets are not defined with the same tight alignment to data model exchange and can not be assumed to be “implementable” in general. Also, organizations that see benefit in participating in the development of either subsets or value sets but are not “acceptable producers” should be expected to work with a producer organization and not strike out on their own.

3) Who should review and approve subsets and/or value sets?

Apelon does not have any recommendations on specific organizations for approval or review, but we recommend a process that allows a broad perspective on proposed subsets and value sets. In most cases, these artifacts will get attention from those directly affected implementation and it is through real use

that valuable feedback will occur. To accomplish this, we would like to see web-based registries and repositories where interested organizations can obtain, review and comment on the available artifacts as defined by developers. If we have learned one thing through the advent of the Internet and social systems, it's that users are very good at identifying value and need. But note that we do not suggest that only a single registry and repository be created. It is unclear that one single location is the only solution and would prefer an approach that supported independent developers to create, maintain and promote such artifact systems. A federated solution such as this will require a common model for accessing subset and value set metadata and common exchange mechanisms (based on standards such as HL7 Common Terminology Services – CTS 2), so that the integration of consistent, semantically interoperable terminology elements can occur in an open and transparent way.

4) How should subsets and/or value sets be described, i.e., what is the minimum set of metadata needed?

Metadata is critical for searching, sharing, authorship, quality assurance, versioning and maintenance of content. This will need to represent that value sets and subsets can be defined *Intensionally* (by rules) and *Extensionally* (by enumeration) and track what data model artifacts use a particular value set is important. ISO has provided some guidance on metadata elements, as has HL7 International. We believe that a thorough analysis of existing standards (Dublin core, ISO 1179 and new work such as the IHTSDO RefSet metadata and ISO/CEN15699:2009) represents additional work but such a review will provide valuable guidance of the appropriate minimum metadata set needed.

5) In what format(s) and via what mechanisms should subsets and/or value sets be distributed?

Apelon suggests that an Internet-based process that supports multiple developer-oriented distribution points using a common metadata set with defined access APIs would be important.

6) How and how frequently should subsets and/or value sets be updated, and how should updates be coordinated?

Apelon only suggests that updates need to occur on well-defined schedules (so they can be depended on) and those schedules be dictated by use requirements (medication lists are more frequently updated than billing codes).

7) What support services would promote and facilitate their use?

Apelon suggests that the value of a distributed approach to developing and hosting subsets and value sets requires easy access to training and re-usable development artifacts. NHIN Connect is beginning to demonstrate the value of

this approach and we see the same, or perhaps more benefits, for sharable terminology value sets. A predictable, consistent infrastructure is important to implementers so that terminology can be consistently incorporated by organizations without deep terminology expertise.

8) What best practices/lessons learned have you learned, or what problems have you learned to avoid, regarding vocabulary subset and value set creation, maintenance, dissemination, and support services?

Having worked with many clients, including governmental, pharmaceutical, and quality management organizations to implement terminology systems, Apelon and our clients are convinced that managing terminology requires a complete terminology asset management program where dedicated resources and a well defined set of process are fully capitalized to address all activities. Developing complete value sets is a time-consuming activity and it is the completeness that characterizes a useful and implementable value set. The following are key elements of success:

- Defining useful, well-vetted terminology artifacts is serious business that justifies budget-line attention with ongoing funding.
- Utilizing a transparent, well defined set of processes allows stakeholders to fully understand how they will participate and what they will get in return.
- Semantic intent must be understood to create useful value sets. Therefore, useful subsets or value sets cannot be crafted without the direct interaction of those with "skin in the game." For example, developing value sets for quality measures requires direct participation by quality measure developers.
    - Development of value sets must occur in collaboration with the model developer to cleanly align the information model with the concepts needed within the value sets.
    - Involvement of implementers is critical; just because you can find a way to say something doesn't mean it can be captured within a reasonable system or workflow.
- The widespread use of SNOMED CT as the "terminology of choice" has helped create a common focus for terminology use and development, but successful use requires an incremental process that builds towards utilization of SNOMED CT expression semantics to support post-coordination. To whit: use of SNOMED CT requires eventual incorporation of expressions.

- Encode only to a level of detail needed for the required computable semantic interchange. Exchange of clinical data exists to support clinician-to-clinician communication as its *primary* purpose. An exchange that has detailed free text with encoded information that carries some, but not all of the clinical meaning, is perfectly reasonable.

9) Do you have other advice or comments on convenience subsets and/or value sets and their relationship to meaningful use?

Convenience subsets, particularly those based on empirical analysis of terminology use such as the SNOMED CT CORE and the LOINC frequency subset, are likely to be a useful type of subset. The problem with associating meaningful use criteria with subsets is that actual implementations – the functionality that will form the basis for demonstrating "meaningful use" – will not be tied to subsets but will be tied to implementing value sets. So at best there will be a degree of indirection where the implemented value set will have to draw from a subset. It is likely that meaningful use criteria that are linked directly to accepted and implemented standards (such as is done by Canada Health Infoway) will be easier to measure and result in better understanding (but perhaps more resistance).

We would not see any significant usefulness in "convenience value sets".

10) What must the federal government do or not do with regard to the above, and/or what role should the federal government play?

1. Apelon suggests that the federal government role should be to provide a strong common infrastructure through definition of implementable standards that allow capable terminology value set providers to create independent but federated terminology services. This will require a consistent approach to metadata and a common set of terminology deployment resources.

2. Governmental adoption of a few selected terminologies focuses our collaborative attention on those key terminologies. Use of SNOMED CT as the "general purpose clinical reference terminology" is an important public good but for SNOMED CT to be truly useful requires commitment of:

    a. Continued support for international collaboration in the improvement and usability of the terminology.

    b. Clear guidance on implementable use of concept expressions in:

        i. Value set definitions,

        ii. Clinical reporting including quality measures, and

        iii. Data exchange.

Use of concept expressions (post-coordination) is the core value of SNOMED CT and governmental adoption of this will be a key enabler.

3. The government should function as an exemplar large integrated organization where it follows the approaches outlined and deploys commonly accessible value sets to support semantic interoperability within government agencies (VHA-DoD) and with appropriate trading partners. Once again, the NHIN Connect model serves well.