

HIT Standards Committee
Clinical Operations Workgroups – Task Force on Vocabulary

Tuesday, February 23, 2010, 9:00 a.m. to 4:30 p.m./Eastern Time
Omni Shoreham Hotel, 2500 Calvert Street, NW, Washington, DC

Testimony: John Quinn, SCO (Standards Development Organizations (SDO) Charter Organization)

Good Afternoon.

I have been asked here to testify on behalf of The Standards Development Organizations Charter Organization – or SCO.

Most of you also know me as the CTO of HL7 and even some of you may realize that I am actually employed by Accenture as a Senior Executive who is donated to HL7 as their CTO. I am one of the founders of HL7 dating back to 1987 and have served as its Board Chair, Technical Steering Committee Chair and now CTO.

Efforts started several years ago during the previous administration to improve healthcare, in this country – partially through the improved use of Healthcare Information Technology (HIT). As part of that effort, HITSP was created as one mechanism to deal with the challenges of creating implementation specifications for defined inter-organizational use cases. Characteristics of these efforts are that they:

- Use existing HIT interoperability Standards such as HL7, NCPDP, X12 and others;
- Use existing implementation specification from IHE
- Identify gaps that needed to be filled

Sometimes, the SDOs are seen as part of the problem. Some of the observations include:

- The approval processes are too slow – the open deliberative consensus driven process typical of ANSI certified organizations take a relatively long time.
- Standards may compete – most of the SDOs were created by different healthcare segments (e.g., provider-clinical, payer, provider-pharmacy payer, provider-dental, etc. Volunteers brought their needs to the SDOs and with little inter-SDO coordination the resulting goals and products sometimes overlapped.
- SDOs represent different vested interests but they are drawing from similar pools of sometimes scarce resources.

It has become clear that it is important that the valid, valuable and important role of the SDOs be clarified, that our collective commitment be clear, and that the complexity of the challenges and issues be explained.

In early 2008 Lee Ann Stember, CEO of NCPDP called for a meeting of US Health Care SDOs and other related organizations that was titled an "SDO Summit". I along with many others attended that meeting and two subsequent meetings that year where we expanded participation and attempted an open discussion around how we might get the US SDOs to work more cooperatively. Small projects were proposed and various objectives were discussed. After meetings in April, June and November 2008 we decided to create an organization called SCO in March, 2009. John Klimek, NCPDP Senior Vice President, Industry Information Technology, who is speaking today on behalf of NCPDP, accepted the first term as Chair of SCO. I accepted the role of chair-elect and expect to succeed him in January of next year.

The goals of SCO are to:

- Provide a basis for SDO leaders and their respective Boards to be consistent on the issues and our value proposition.
- Provide a joint, agreed upon common list of positions on SDOs, our value, contributions and current initiatives.
- Provide the basis for formal communication that can be consistent from both the SCO members and their supporting SDO press release activities.
- Provide a common basis for both formal and informal communication on key standards issues.

Key Issues that we want to address or at least clarify:

- Perception that Healthcare SDOs are not timely
- Perception that Healthcare SDOs cannot work together effectively
- Perception that there is problematic conflict by Healthcare SDO stakeholders, in terms of vested interests of the vendors, or volunteers
- Concerns that we are not working well or efficiently with HITSP and ONC
- Concerns about our resources to respond to the needs of the industry
- Concerns that certification is expensive and not a guarantee of connectivity
- Concerns that standards overlap
- Concerns about gaps in the standards

Some Key points in which we agree:

- Healthcare technology and workflow issues are difficult to solve.
- Developing and accessing subject matter expertise from the industry in creation of standards is critical.
- Timing and responsiveness of the process of reaching industry consensus takes too long and needs to be short and straight forward to achieve its stated goal.
- There is a need to identify and bridge the gaps in the overlapping work efforts in Healthcare.
- There is a need to identify and bridge the gaps among Healthcare Standards.
- There is a need and willingness for the SDOs to collaborate for the implementers.

We have spent much of the first year of SCOs existence broadening our membership and making it more inclusive as it relates to our industry and goals. We have also started some initial projects which we all agree can demonstrate value to the US Healthcare Community and, in many cases, reflects direct requests that we have received in conversation from HITSP, ONC and others.

Example projects that are in process or in discussion among SDO members today within SCO include:

- A service orientated functional profile for provider registry including stewardship roles. A follow on project would be querying for information more specific to the provider.
- Participate in and complete a recommendation document on the code set to use for Route of Administration for the HITSP use cases (electronic prescribing functions, exchange of documents, clinical research). The recommendation document will go out to the HITSP Foundations Committee, then to the SDOs for a 60-day comment period, then to HITSP Panel for approval.
- An NCPDP SCRIPT message to query; with the HL7 CCD (or ASTM CCR) that contains the patient summary information as a follow up exchange. This will involve mapping the NCPDP SCRIPT transaction with a HL7 RIM-based CCD template. The implementation guidance is being completed for submission to NCPDP.
- An HL7-WEDI-X12 collaboration to take the information in a HIPAA 837 claims transaction and map it to the HL7 RIM. The purpose is to recognize and identify the patient administrative information coming into an EHR System that was originally sourced in an HIPAA transaction and map it to the corresponding existing patient administrative information that is typically created inside of an organization through and HL7 Registration / ADT transaction. This will identify inconsistencies of static data semantic meaning and gaps that exists between the two existing environments. This is also being discussed as an experiment (along with the NCPDP SCRIPT project above) at mapping all standards data to a common reference information model.

The current members of SCO include (by category):

SDO Members	ADA, AIIM, ASC X12, ASTM, HL7, NCPDP
SDO Related Entities Members:	GS1, WEDI
Formal Observer Members:	ANSI, FHA (Federal Health Architecture), HITSP, IHE, ISO TC 215 US TAG, ONC, SSA
Pending Memberships:	NLM (SNOMED), Regenstrief Institute (LOINC)

(End of Testimony)

(Attached Additional Information)

Frequently Asked Questions

Introduction

There is clearly a need to connect the healthcare environment (doctors, hospitals, pharmacies, other providers, insurance companies, employers and patients) in better ways than we have today. This poses an opportunity to some, a challenge in many spheres and a threat to some others. The challenges arise from: the various different perspectives of the different stakeholders; educational/operational/training needs; workflow issues; modifications to the existing install base; determining a return on investment; citing the benefits; and, lack of desire to change.

The following attempts to answer some of the frequently asked questions (FAQ's) about how to do this:

What is a standard?

A standard is a commonly used and/or agreed to definition. There are standards for electricity outlets, weights and measures, time, temperature and data formats.

The earliest data format standard for transmission of the English alphabet characters was Morse Code (dots and dashes in various combinations). Today, the predominant data format for a character set in the United States is called ASCII. This character set is used in keyboards, in exchanges of data via computers, etc.

What kind of data standards exist today?

There are many kinds of standards. There are standards created by governments, vendors, industry groups and consensus bodies. Examples of government standards are an IRS tax form, an electronic tax filing format, interstate highway systems, and requirements for healthcare privacy. Examples of vendor standards are formats such as Adobe PDF or Microsoft Word Doc files. An industry group example is the financial automated clearing house (ACH) funds transfer formats. Examples of consensus body standards include standards created by standards development organizations (SDOs) such as ASC X12, HL7 (Health Level Seven), NCPDP, ASTM, and CDISC.

Do all standard development organizations use the same process?

No. However, all American National Standards Institute (ANSI)-accredited standards development organizations must follow the ANSI requirements in their processes. At an international level is the International Standards Organization (ISO). Both ANSI and ISO accredit and audit the processes of these organizations. The ANSI-accredited SDOs take very seriously the requirements of openness, balance, consideration of views, gaining industry consensus, and following procedures.

Other organizations have processes which may be more or less rigorous; they may restrict membership or avoid subjecting their standards to public review.

Is there one standard which solves all the connectivity issues in Healthcare?

There are many connectivity standards in healthcare. Some include: X12, HL7, NCPDP, ASTM, DICOM, CDISC, IHE and others. These organizations may provide expertise for a given area of healthcare, or a given level of exchange of information. There are gaps which are not covered by any of the existing standards and some overlap between the standards. In addition, there are multiple interpretations of each message/document/transaction/service of each standards organization. The organizations are working together to reduce the differences in how these are implemented. The organizations are working together to reduce the differences between the base standards, condense the options for given messages and increase the number of messages available.

Doesn't the internet and XML solve everything for us?

Truly establishing point to point connectivity requires agreement on many fronts. First, there must be agreement on a communication protocol and infrastructure. At one point this was all dial-up and leased lines, now it is the internet. Second, there needs to be agreement on character representation or encoding (this is now ASCII). Third, we need to have a common syntax structure, this is now XML. Lastly, we need to agree on common messages or services. This is also known as arriving at a common semantic base and information model. While the internet provides transportation and XML provides syntax, structure, entities still must agree on the intent of the exchange, of the data elements exchanged, of the code lists used.

Why are common semantics important?

The end goal is seamless operations of exchange of information. For this to occur, the systems must understand the meaning of the data. For example, when a consumer purchases an item with their debit card, the merchant's sales system notes the exchange; a message is conveyed moving money from the consumer's bank to the merchant's bank seamlessly. Similarly, when your primary care physician wishes for a patient to be seen by a specialist, the referral should appear seamless in the specialist's work flow and the resulting observations should also appear in the primary care physician's work flow.

Why can't we do this with just exchanging secure emails?

Secure emails are part of the picture. Secure emails do not necessarily contain structure in the text body or attachments. To reduce the amount of data entry at each end computer systems in healthcare should be able to accurately understand the intent of the exchange, and the data. This means that patient name, doctor name and other fields should be easily found by other applications – potentially with coded, structured data, which cannot be accomplished with just secure email.

Can't one big software company solve all of this?

Unfortunately, no one software company produces all the components necessary for any given enterprise, whether it is in healthcare or not. Healthcare enterprises have additional complexities which are generally satisfied by multiple unique software systems. There are varying complexities, different needs (specialty practices, large/small enterprises, clinics versus hospitals), and broad technology needs that would be difficult to be satisfied by one company.

Add to the functional requirements the differences between operating systems (Windows, MacOS, Unix) and platforms (servers, handhelds, personal computers) – it would be difficult for one software company to create one integrated solution.

Is certification important?

Interoperability is important. If one can assure interoperability without certification, then certification is not needed i.e., one is not worried that their email software will not connect to other email systems. However, without certification, how can compliance to acceptable standards be measured and assured? Certification attestations help assure connectivity before the purchase of a system.

Why can the standards development process take so long?

Sometimes the process does take long, other times it is a perception. Some standards organizations ballot changes multiple times per year; others have yearly or bi-yearly schedules. The creation of standards changes relies on industry business needs coming forward. These business needs may address current problems, or reflect future ideas. The analysis and development of the change requirements involves volunteers from the industry. These volunteers sometimes have other priorities. Sometimes meeting the business need is difficult – the problem is complicated or there are competing perspectives. Sometimes the technical standards solution is waiting for industry to determine how to build their business needs. Sometimes the standards require a new terminology, or a modification to an existing terminology.

The process of changes to the standards is governed by the *ANSI Essential Requirements: Due process requirements for American National Standards* (http://www.ansi.org/standards_activities/overview/overview.aspx?menuid=3). The ANSI-accredited SDOs take very seriously the requirements of openness, balance, consideration of views, gaining industry consensus, and following procedures.

Why does the HIPAA regulatory process for standards take so long?

Since the passage of the HIPAA regulation, three standards development organizations (SDOs) - ASC X12, Health Level Seven (HL7), and the National Council for Prescription Drug Programs (NCPDP) have worked with the Office of E-Health Standards and Services (OEHS) to propose a process of naming new versions of standards under HIPAA that is more timely and efficient for the industry. The SDOs testified to the National Committee on Vital and Health Statistics (NCVHS) in December 2005 and October 2006 and presented this paper (http://www.ncdp.org/news_hipaa_trans_current.asp#SSH). with discussion of the current problems in the process and a proposal for the future. NCVHS discussed with HHS who noted they are constrained by their interpretation of the Administrative Procedures Act. Modifications to this process would require regulatory changes.

Who are the stakeholders in the SDO process?

The standards development process includes a broad array of stakeholders, those who use the standards, those affected by the standards, those that develop the standards and those

that support the development of the standards. In the healthcare industry the stakeholders include (but are not limited to) the following:

- Providers, clinicians and their related organizations and associations (e.g. AAFP, ACP, NACDS, NCPA, AMA, ADA, etc)
- State, federal and local governments
- Payers, insurers, third-party organization and their related associations (e.g. PCMA, AMCP, BCBSA, etc)
- Volunteer members of the SDOs & paid staffs of the SDOs
- Consumers and consumer advocacy organizations
- Organizations that directly or indirectly support the SDO efforts (e.g. ANSI, CDISC,
- WEDI, HITSP, NCVHS, NUBC, NUCC, etc)
- Organizations that represent specific areas of healthcare (e.g. American Heart Association, American Health Information Management Association, Health Information Management Systems Society)

Are you involved?

Have you wondered “why can’t this be added to the standard?” or “why doesn’t someone fix this”? The questions and the answers come from the industry; it’s the implementers, the users of the systems, who bring the questions forward and help find the solutions. If you aren’t involved with a standards organization or have a voice at the table, how are the problems corrected?

What is the purpose of the SCO?

The mission of SDO Charter Organization (SCO) is to provide an environment that facilitates effective coordination and collaboration on U.S. national healthcare informatics standards development, with recognition of the international and multi-industry stakeholder implications and challenges. Its purposes include:

- To facilitate the coordination of conventions for enhanced interoperability among diverse standards development organizations in the areas of health data acquisition, processing, and handling systems.
- To communicate and coordinate when appropriate with the ISO TC 215 U.S. Technical Advisory Group (US TAG) in order to facilitate a unified representation of US standards (this is not intended to supersede any member’s existing coordination with the US TAG).

How does the SCO work with HITSP?

HITSP is a member of the SCO. In addition to working on use cases from the Office of the National Coordinator, HITSP’s Foundations Committee is comprised of SDOs and interested parties, working on collaborative items. HITSP does not create standards; the standards development organizations create standards. When HITSP recognizes a need or a gap, it is brought to the SDOs. It was recognized by SDO participants on the Foundations Committee that there needed to be executive-level support by the SDOs. While the Foundations Committee contains industry expertise, there are working items

which must be brought into the SDO's processes for delivery. There may be tough decisions that may need to be made in collaboration, which would require executive-level support.