National Committee on Vital and Health Statistics
Subcommittee on Standards and Security

December 8, 2005

ASC X12 Comments on Backward Compatibility and Predictable Migration of Standards

Good morning. My name is Alix Goss. I am the Director of Health Care Standards for the Washington Publishing Company where my responsibilities include Accredited Standards Committee X12 (X12) standards development work and health care consulting. I am currently the Chair of X12's Insurance Subcommittee. On behalf of X12, I am a member of the Designated Standards Maintenance Organization (DSMO), National Uniform Billing Committee, National Uniform Claim Committee and Health Information Technology Standards Panel. Today, I am presenting the X12 views on the important topic of "Updating HIPAA Standards".

Flow of testimony:

1. Current World
2. Experience to date and Lessons Learned
3. Recommendations

Current world

Health Care standards are currently mandated by the Administrative Simplification provisions of the 1996 HIPAA law, followed by federal rulemaking in 2000 and 2003. Distinct implementation guide specifications are named in federal regulations as HIPAA standards, for example, the ASC X12N 835—Health Care Claim Payment/ Advice, Version 004010 and Addenda.

Industry stakeholders via the mandated DSMO or SDO processes can request changes to the HIPAA standards. Additionally, X12 has a request for interpretations portal from which change requests are sometimes derived. Changes are vetted through an extensive process within X12. This process includes: a) assessing the business need of a requested change, b) discussing potential impacts to trading partners, and c) determining whether existing functionality or a new method is needed to support the business need. These steps occur in multiple layers within X12's open, consensus-based process.

Once changes are agreed upon within the X12 and DSMO environments, they are incorporated into an upgraded version of the implementation specification. The upgraded version is then put forward for industry review and comment per the X12 process. The outcome of the X12 public comment period results in a final version of the upgraded implementation specification being approved. The final version of the upgraded implementation specification is submitted into the DSMO process.

Assuming both the DSMO and NCVHS processes go smoothly, first the DSMO process results in testimony to the National Committee on Vital and Health Statistics (NCVHS) recommending adoption. Second, at the conclusion of public testimony, the NCVHS sends a letter to the Department of Health and Human Services recommending adoption.

The combination of all the steps above is intended to and in reality thoroughly satisfies the requirements in 45 CFR §162.910. These require the Secretary to consider a recommendation for a proposed modification to an existing standard, or a proposed new standard, only if the recommendation is developed through a process that provides for the following:

1. Open public access.
2. Coordination with other DSMOs.
3. An appeals process for each of the following, if dissatisfied with the decision on the request:
    a. The requestor of the proposed modification.
    b. A DSMO that participated in the review and analysis of the request for the proposed modification, or the proposed new standard.
4. An expedited process to address content needs identified within the industry, if appropriate.
5. Submission of the recommendation to the National Committee on Vital and Health Statistics (NCVHS).

Experience to date and Lessons Learned

Standards development work is driven by industry needs. It is an iterative process resulting in improved standards being produced that meet business' evolving needs. The development work is staffed by dedicated, hard working industry volunteers – savvy and selfless individuals whose companies pay to be members of SDO's such as X12, pay for them to attend meetings, and who, individually and collectively, donate many hours each year to the standards development process.

X12 has been developing standards since 1979 and addressing the electronic messaging needs of industries such as transportation, government, and finance with more than 300,000 companies worldwide using the X12 electronic data interchange (EDI) standards in daily business transactions. Our history demonstrates that our iterative, open, consensus based process meets the needs of many industries.

As a part of X12, the Insurance Subcommittee's (X12N's) process for implementation guide specification development is a well documented and vetted process that includes a public comment period *freely* open to anyone who wishes to comment. We promote and encourage all industry stakeholders to review and comment on implementation guide specifications in development.

Development work is iterative, building on prior efforts to incorporate current needs of the industry. Iterative development is a fundamental characteristic of standards and implementation guide specification activities.

With HIPAA, standards and implementation guide specification activities have become more time consuming, in that much more work has to be completed to get the implementation guides adopted by the federal process. Specifically, the federal rule making steps dictated by the Administrative Procedures Act (APA) and various Executive Orders (*e.g.*, 12866) – which X12N supports by (a) preparing additional materials to be used by the federal government in their rule making processes, (b) reviewing and commenting on Notices of Proposed Rule Making (NPRM), and (c) supporting the federal government in responding to technical comments received in response to NPRM comments from others. X12 does all of this even though the NPRM comment period is an additional comment period to the public comment period already managed by X12.

To date, the only real life example of making modifications to HIPAA standards is the version 004010 addenda process. The process to produce and adopt the addenda, referred to as the 'fast track process', took two years to complete (February 2001 to February 2003). The goal of the fast track process was to provide industry changes considered critical to effectively implement the HIPAA standards mandated in 2000 which were based on implementation guides developed in the 1998 timeframe.

Below is a summary of the fast track process:

1. Widely-distributed announcements were made that changes to the HIPAA guides could be submitted to the DSMO process as part of the ability to update the standards during the first year in accordance with the final HIPAA Transactions and Code Sets rule: 45 CFR 160 §160.104(b).
2. In February 2001, all change requests to be considered for an addenda specification had to be submitted to the DSMO.
3. The industry submitted 239 change requests.
4. X12N produced a draft addenda specification and held their public comment period in early spring of 2001.
5. In accordance with the X12N development process, informational forums were held on the outcome of the X12N public comment period and finalized the changes to the draft addenda during the June 2001 X12 meeting.
6. X12N submitted the addenda through the DSMO and NCVHS processes.
7. In May 2002, HHS issued a notice of proposed rule making (NPRM) with the addenda specification to obtain industry comments in their public comment period.
8. In the summer of 2002, HHS passed approximately 100 comments to the DSMO for review of requested changes submitted in the NPRM comment period. X12N worked with the DSMO on the requested changes and made further modifications to the addenda specifications.
9. In August and September 2002, X12N held another public comment period on the latest version of the addenda.

10. In October 2002, X12N held informational forums on the results of public comment periods and a vote to approve the addenda as final. The addenda were approved for publication.
11. The addenda final rule was published in the Federal Register in February 2003.
12. X12N's public comment period in August-September, 2002, was the final comment period of the three – calling into some question any real need of a federally driven comment period for modified specifications.

At times, there was a difficult dynamic in syncing up government direction and industry consensus achieved in X12N's public comment review and resolution process. Through extensive collaboration and X12N's focus on the big picture needs of the industry, the addenda specifications were finalized.

The addenda process came into play in order to have a rapid fix to implementation problems recognized with the original 004010 mandate. A so-called rapid fix process taking two years is indicative of how long a theoretical normal process will take.

Since the first HIPAA standards were adopted, X12N has processed thousands of requests for changes received via the DSMO and SDO processes. The reason for the volume of changes is found in the amount of time between adopted versions, changing business environments, and more industry focus on the health care standards. We have finalized version 004050 and are in the latter part of our 005010 development cycle.

Throughout the initial HIPAA adoption and normal development cycles, X12N has been actively engaged in discussion with our Designated Standards Maintenance Organization (DSMO) partners, plus the Office of E-Health Standards and Services. The discussion has been "how can we create a predictable and efficient process for adopting future HIPAA standards", with the goal of identifying ways to shorten the length of time it takes to adopt modifications to the HIPAA standards. To date, these discussions have not borne fruit.

The importance of a predictable cycle is that it provides the industry with the information necessary to effectively plan, budget and allocate resources required to implement changes to the HIPAA standards. In other words, predictability in a maintenance process supports the goals of administrative simplification.

To fulfill the Administrative Simplification provisions, Health and Human Services (HHS) issued the proposed Transaction and Code Set Rule. This proposed rule set forth 10 principles which must be met for a standard to be adopted. Four of the 10 principles are particularly applicable to today's discussion:

a. The first principle states "Improve the efficiency and effectiveness of the health care system by leading to cost reductions for or improvements in benefits from electronic HIPAA health care transactions. This principle supports the regulatory goals of cost-effectiveness and avoidance of burden."

b. The fourth principle states “Have low additional development and implementation costs relative to the benefits of using the standard. This principle supports the regulatory goals of cost-effectiveness and avoidance of burden.”

c. The fifth principle states “Be supported by an ANSI-accredited standards developing organization or other private or public organization that would ensure continuity and efficient updating of the standard over time. This principle supports the regulatory goal of predictability.”

d. The tenth principle states “Incorporate flexibility to adapt more easily to changes in the health care infrastructure (such as new services, organizations, and provider types) and information technology. This principle supports the regulatory goals of flexibility and encouragement of innovation.”

From our extensive analysis and discussions within X12, with our DSMO partners, and the Workgroup for Electronic Data Interchange (WEDI), two repeating themes have emerged. First, the standards development process is able to produce iterative work products on an established schedule by managing a volunteer workforce in producing specifications reflective of the industry’s evolving needs. Second, the Federal Rule making structure is not currently designed to provide a predictable schedule.

You may be wondering “why” the current federal rule making structure is counter to predictability and efficiency. Simply put, it is the present complexity and unpredictability of the steps and time associated with getting from HHS’s receipt of an NCVHS recommendation for adoption of a modification to the point of Final Rule issuance mandating the modified standard.

It has been estimated that HHS may *very* optimistically be able to have a two-year cycle to produce a notice of proposed rule making, hold a public comment period and produce the final rule. Keep in mind that the HHS cycle is after the SDO, DSMO and NCVHS cycles. X12N’s development cycle for health care related specifications, including public review periods, is currently on a repeating two year schedule. The DSMO and NCVHS steps can be completed in less than 1 year. This brings us to an absolute best-case scenario of 5 years from initial development to final rule adoption. It does not take into account unexpected issues or distractions – such as the industry requesting a new version or feature in the NPRM comment period resulting in the federal rulemaking process being stalled by a segment of the industry pushing for a different solution than what was approved by the industry via the SDO or DSMO processes.

There are two items not accounted for in the timeline above. First is the time associated with developing a cost benefit analysis on new versions of implementation specifications being proposed for adoption. This new activity is the result of OESS indicating cost benefit information is needed to move into an NPRM process. To accomplish this goal, X12N will produce additional documentation in the form of qualitative narratives on the scope of changes in a new specification compared to the

previously mandated one. This documentation will be used by WEDI in surveying the industry to obtain more specific cost benefit information. This activity has already taken place for the version 004050 835 remittance advice specification. X12N and WEDI have learned from the 004050 835 experience and are working on how to handle the 005010 cost benefit assessments. The second item not factored into the timeline is piloting transactions before adoption. Determining the process for piloting transactions – and finding interested participants – needs additional discussion to achieve consensus. We recommend NCVHS hold hearings on this topic.

Recommendations:

From our experience to date, we offer the following recommendations:

Backward compatibility as defined in the e-prescribing final rule states “Backward compatible means that the newer version would retain, at a minimum, the full functionality of the version previously adopted in regulation, and would permit the successful completion of the applicable transaction with entities that continue to use the previous version.”

First, to ensure a full understanding of the final rule preamble, we recommend NCVHS request the Office of General Counsel to provide documentation explaining the legal basis, precedent and justification for the e-prescribing final rule comment that might permit waiving of the notice and comment steps in backward compatible situations. In particular, this request is focused on understanding the basis for the final rule preamble text of “When determining whether to waive notice and comment and whether to incorporate by reference multiple existing versions, we would consider the significance of any corrections or revisions to the standard as well as whether the newer version is ‘‘backward compatible’’ with the previously adopted version.” We are trying to understand ‘why and on what basis does the government believes that a backward compatible standard can be adopted without formal rule making?’; as opposed to the process currently used for adoption of all new and modified HIPAA implementation specifications.

Second, based on the information we have today, we do not recommend pursuing the concept of backward compatibility for HIPAA transactions.

The preamble of the e-prescribing final rule describes what we would term ‘forward compatible’ rather than ‘backward’ compatible; in that the compatibility concept is directed at future standards containing the same base functionality provided in the previously adopted version. However, for the purposes of today’s testimony, we will use the e-prescribing rule term.

The backward compatibility concept as currently defined would prevent any functionality from being removed from specifications even when the industry must have functionality removed or changed. For instance, 005010 functionality modifies

provider information to meet National Provider Identifier (NPI) needs and is not backward compatible with 004010A1.

Implementation specification development evolves faster than HIPAA mandates occur. The development process occurs because industry needs are changing. Voluntary adoption of a new specification does not achieve standardization because it undermines the goals of administrative simplification to achieve consistency and avoidance of burden. For instance, permitting the industry to have a new and old version of a standard in play for an undefined and extended period of time will result in coordination of benefit (COB) complexities. This will occur because different trading partners will submit different data sets of information and trading partners downstream from an initial claims submission may or may not receive all the information necessary to process a COB claim.

Functionality in a new version of a specification cannot be guaranteed to be the same as a previous specification version due to industry needs or change requests received by the SDO or DSMO change request processes. The DSMO process provides the industry with the mandated vehicle for requesting any and all changes. Backward compatibility requirements negate the mandate of the DSMO process to effectively maintain the HIPAA standards.

The concept of backward compatibility is counter to the iterative standards development process. As noted before, a fundamental characteristic of standards work is to evolve a standard based on industry needs. We learn from industry's prior implementation efforts resulting in modified guidance or function within a specification.

The concept of backward compatibility is a great concept, but it is not always realistic. Rather than backward compatibility, are we really trying to address a migration path for moving the industry forward to newer specifications? We believe this is the crux of the issue that needs to be resolved and the remaining recommendations will focus on this.

We recommend eliminating the Federal Notice of Proposed Rule Making process for the modifications to existing HIPAA standards. Reasons for this recommendation are as follows.

The goal of administrative simplification is to achieve efficiency and effectiveness through the adoption of standards for the electronic transmission of certain health information. Being able to support modified standards every 5 years is insufficient for meeting the needs of the evolving health care world. We need to support industry needs in a more agile method than currently exists. X12 is working hard to have new implementation specifications generated in a routine cycle. The result is new specifications being available in a considerably shorter timeframe for adoption if we did not have a federal notice and comment period required.

By having the federal comment period in play, portions of the industry are not participating in the standards development public comment process. This means the industry input is not being effectively managed, resulting in the potential for additional delays to standards adoption. The federal comment period could result in another version of a specification being generated and cycled through the entire SDO process, thus further delaying adoption of modified standards.

We propose that when the SDO issues their public comment period announcement, the government shall publish corresponding notices in the Federal Register and through its HIPAA and other applicable list-servs. Part of the notice shall indicate that no NPRM comment period will occur for the SDO's implementation specifications, and the industry shall submit their comments through the SDO public comment period. If the government believes that there will also be policy items requiring public comment, it shall indicate that these are not included in the SDO materials, but will be included in an NPRM specifically dedicated to policy issues. We believe any policy decisions necessitate the proposed rule making public comment period.

With recommending the elimination of the comment period during the notice of proposed rule making, we also recommend a final rule with comment be generated as part of the adoption process to ensure standardization. The industry appears to need the security of a final rule before they are willing to implement a new HIPAA standard.

These recommendations approach HIPAA standards adoption like the current process for routine code set updates that are permitted without formal rule making. We would like to see the HIPAA law modified to permit modifications to an adopted standard to occur without notice and comment rule making. If this is not feasible, then we request education on why.

We recommend adopting modifications to HIPAA standards that define a specific migration approach and timetable so that only one version is supported within the industry after the migration time has completed.

The approach to conversion and overlap between versions is extremely critical to implementation success. The only time two versions would be supported is during the migration timeframe. Maintaining one version addresses the administrative simplification principles of eliminating undue burden and promoting cost-effectiveness. Allowing an old version to be maintained indefinitely permits trading partners to delay migration, which negatively impacts data flow, such as in COB exchanges.

In January 2004 WEDI held hearings to obtain industry feedback on the implementation efforts of the Transaction and Code Set regulations. It was very clear from the testimony that future transitions need to have a staggered approach to roll-out by covered entity. There was an overwhelming agreement on the flow of adoption by covered entities:

1. Payers transition first to enable stable systems, complete companion guides and effective communication with their trading partners, then
2. Clearinghouses transition either in tandem with payers or immediately thereafter, and
3. Providers would be last to implement – thus minimizing the burden on the most populous type of covered entities.

Sequencing of transactions by function should also be staggered in the future. Claims should not have been first, some say. Many referenced the eligibility transaction as being a good place to start. Volume of future changes need to be assessed and controlled to manage the impact to the industry.

Finally, we recommend continuing the Federal Notice of Proposed Rule Making process for adopting new HIPAA standards.

This concludes my remarks on behalf of X12. Again, thank you for this opportunity to testify on the important topic of upgrading HIPAA standards.