Proposal for the Modification of the HIPAA Transaction Implementation Specifications Adoption Process

This document provides discussion of improvements in the process of adopting HIPAA transaction standards to meet the needs of the health care industry

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1. EXECUTIVE SUMMARY

Health care industry stakeholders have struggled to understand the impact of the Health Insurance Portability and Accountability Act (HIPAA) since its inception. The legislation is complex and is further hampered by its own rigid processes.

Standards Development Organizations (SDOs), with voluntary industry participants, try to address these challenges by actively engaging in the development of implementation specifications. These specifications represent the knowledge, consensus, and approval of the industry members.

However, the ability for the SDOs to be responsive to industry needs is greatly impaired by the regulatory process and its subsequent impact on standards adoption.

This paper examines the current process for adopting modifications to already adopted transaction standards, summarizes findings, and proposes ways to improve the adoption process to make it more efficient to modify existing standards.

This document was prepared by representatives of the Standards Development Organizations:

Accredited Standards Committee (ASC) X12
Health Level Seven (HL7)
National Council for Prescription Drug Programs (NCPDP)

1.1 Inefficiencies in the Current HIPAA Adoption Process

Health care industry representatives find the current HIPAA process to be inefficient for a number of reasons, primarily:

1. Constraints from the regulatory and Administrative Procedures Act (APA) processes
2. Length of time from industry approval to implementation of new versions
3. Modifications being made to ***approved*** implementation specifications
4. Lack of predictability in the process
5. Pilot testing as a possible requirement step
6. Lack of industry understanding of the cyclical process at the SDO
7. Not enough industry input at the time of SDO standards development (it's too late once an NPRM is published), and
8. Lack of agreement on how often the industry wants to move to a new version versus market need for making that change

1.2 Recommendations to Streamline the Current HIPAA Adoption Process

A few improvements to the current process will result in an implementation specification adoption process in which consensus-based standards could be developed, maintained, approved and implemented in an acceptable timeframe. These key modifications are as follows:

1. As part of the SDO process, industry input must take place early in the development and approval of the implementation specification. The Federal Register notice and the SDO processes alert the industry to this opportunity.
2. Through strong industry cooperation, all technical public comments must be collected at one time – while the implementation specification is being developed and approved -- thus eliminating the need to "re-open" already published implementation specifications.

3. An industry impact survey of materially affected parties should be conducted by WEDI and be a part of the NCVHS review/approval/recommendation steps.
4. The Federal Register Final Rule must provide the adoption and implementation timeframe.

1.3 Next Steps

Upon near completion, the document was shared with the Designated Standards Maintenance Organizations (DSMO) Steering Committee and with the WEDI Board of Directors for their comments. Comments were reviewed but they may not have all been incorporated. The document was reviewed within SDO appropriate entities (for example Board or review committee) prior to final completion.

This document was shared with the DSMO Steering Committee and WEDI Board of Directors upon completion.

The SDOs presented testimony to the National Committee on Vital and Health Statistics (NCVHS) in October 2006, which was a follow up to the SDOs' December 2005 testimony on this subject. After the October 2006 testimony, minor modifications were made to the document, and the document can be shared with the industry.

Although much initial analysis has been completed, the SDOs must finalize the analysis and implement the changes to each of their internal processes to synchronize with this proposal. When the regulatory reforms are finalized, the changes in this proposal will be implemented by the SDOs.

2. GUIDANCE TO THE READER

2.1 Implementation Specification Terminology

Each organization has its own naming conventions for its documents, many of which are adopted under HIPAA (standards, implementation guides, specifications, additional information specifications, technical reports, etc.). For the purposes of this document, the term “implementation specification” is used.

2.2 Modification versus a New Standard

This proposed process would be used for modifications to already adopted HIPAA implementation specifications for the naming of a newer version of the implementation specification. This paper does not address the process of adopting new HIPAA standards, code sets, or policy issues. See Section 2.4 “*Out of Scope*” for additional details.

2.3 SDO Essentials

SDOs that are accredited by the American National Standards Institute (ANSI) must follow the *ANSI Essential Requirements: Due process requirements for American National Standards* (www.ansi.org). There are requirements that the SDO must demonstrate and they must provide accountability of balance, consensus, due process, and other principles. ANSI allows latitude in the specific implementation scheme and therefore each SDO may have different process steps to accomplish these same principles.

Each SDO is a **voluntary industry** body, with administrative support. The industry that participates in the development of implementation specifications is responsible for the products created. Implementation specifications represent the knowledge, consensus, and approval of the industry participants. The SDO is comprised of volunteer membership that is interested in developing and promoting healthcare information technology standardization.

Any materially affected party may participate, vote on ballots and submit comments on work products.

2.4 Out of Scope

While *new* implementation specifications for new transactions/messages are not in scope for this document, it is expected that *new* implementation specification*s* introduced under HIPAA (versus modifications to existing implementation specifications/new versions) will either follow the same process as proposed below, or create a more detailed process that ensures public input and comment opportunity, but again allow the SDO’s and industry to work through the details of this process and do not require the NPRM course of action.

Also, when considering adoption of new implementation specifications, it will likely be more important to encourage and support industry pilots prior to adoption of the implementation specifications. The need for this will have to be evaluated on a case-by-case basis; the WEDI survey tool might be an appropriate place to solicit industry feedback on the need for pilots.

2.5 Acronyms

Frequently used terms are as follows:

Acronym	Description
ANSI	American National Standards Institute
SDO	Standards Development Organization
X12	Accredited Standards Committee X12
NCPDP	National Council for Prescription Drug Programs
HL7	Health Level Seven
DSMO	Designated Standards Maintenance Organizations
WEDI	Workgroup for Electronic Data Interchange
NCVHS	National Committee on Vital and Health Statistics
OESS	Office of e-Health Standards and Services
NPRM	Notice of Proposed Rule Making
APA	Administrative Procedures Act

3. OVERVIEW

Standards Development Organizations (SDOs) have been actively engaged in the world of HIPAA for nearly a decade and believe we must seize the opportunity to improve the process of adopting HIPAA standards to meet the needs of the health care industry. This document provides a summary of lessons learned and recommendations to achieve efficiencies in producing and adopting modifications to existing HIPAA transaction standards.

Since 2002, industry stakeholders have struggled to understand the impact of the Health Insurance Portability and Accountability Act (HIPAA) on health care implementation specifications development and deployment. An identified early need was education on the impact of HIPAA. Later, as modifications to implementation specifications were brought forward by the industry, education about the Administrative Procedures Act (APA) was necessary. It was explained to the DSMO representatives that, the APA had a direct impact on the Federal Government's ability to quickly adopt modifications to HIPAA implementation specification transactions, as well as new implementation specifications. The ability for the Standards Development Organizations to be responsive to industry needs is greatly impaired when it comes to implementation specifications adopted under HIPAA.

The SDOs along with the Workgroup for Electronic Data Interchange (WEDI) began writing a whitepaper in 2002. Originally, the paper intended to offer solutions to the problem of industry needs for faster adoption and implementation of modifications to and new HIPAA transaction implementation specifications. Eventually, after the authors of the paper began to learn more about the regulatory process and it's impact on standards adoption, and after many revisions to the paper, it was determined that the APA and the regulations were clearly the "problem" in getting implementation specifications to the industry faster. At this point, the focus of the paper changed to make it an educational tool. Ultimately, work on the paper ceased and the SDO representatives as part of the DSMO, tried to determine workable solutions.

Over the past several years the SDOs worked to develop various solutions to streamline the process for bringing forward new implementation specifications for HIPAA adoption and modifications to those already adopted. This included going back to the "drawing board" multiple times for reasons such as not fitting within the parameters of the APA and or federal regulatory process. It appeared the APA and the regulatory processes were intractable without Congressional alteration.

As recently as December 2005, the SDO's testified to the National Committee on Vital and Health Statistics (NVCHS) with options for a "streamlined" process. In parallel to these efforts the SDOs are also addressing this issue through legislative means. With these activities in mind, this document proposes a "joint SDO" agreed upon solution for bringing forward modifications to adopted HIPAA implementation specifications.

4. PROBLEMS WITH THE EXISTING HIPAA TRANSACTION IMPLEMENTATION SPECIFICATIONS ADOPTION PROCESS

The healthcare industry brings forth business needs and the SDOs develop and maintain healthcare implementation specifications to respond to those needs. Working within the regulatory environment (specifically HIPAA), the SDOs are unable to bring new balloted/approved (developed through an ANSI approved, open consensus based process) standards to the industry fast enough to meet the aforementioned needs. This is not speculation, but indeed has been recognized throughout the industry since the adoption of transaction implementation specifications under HIPAA in 2002. The problem continues to grow.

Acknowledging this problem in 2002, the affected SDOs (ASC X12, NCPDP and HL7) have worked collaboratively with HHS to attempt to reach a resolution. Problems identified include:

1. Constraints from the regulatory and APA processes
2. Length of time from industry approval to implementation of new versions
3. Modifications being made to ***approved*** implementation specifications
4. Lack of predictability in the process
5. Pilot testing as a possible requirement step
6. Lack of industry understanding of the cyclical process at the SDO
7. Not enough industry input at the time of SDO development (it's too late once an NPRM is published), and
8. Lack of agreement on how often the industry wants to move to a new version versus market need for making that change

A high level discussion of each of these problem areas is provided below and is followed, in section 4.9, by the *"Current HIPAA Implementation Specifications Adoption Process – Current Process Timeline".*

4.1 Constraints from the Regulatory and APA Processes

Provisions of the Administrative Procedure Act (APA) that are included in the Freedom of Information Act at 5 U.S.C.552, requires agencies to publish in the *Federal Register*:

- Substantive rules of general applicability
- Interpretive rules
- Statements of general policy
- Rules of procedure
- Information about forms
- Information concerning agency organization and methods of operation.

Generally, the rule making process has ten steps. In some cases, statutory provisions that are agency specific or subject matter specific impose more stringent or less stringent requirements. In some cases, more stringent requirements are imposed by agency policy. The ten general requirements are:

1. Initiating Events
2. Determination whether a rule is needed
3. Preparation of proposed rule
4. Office of Management and Budget (OMB) review of proposed rule
5. Publication of proposed rule (NPRM)
6. Public comments to NPRM
7. Preparation of Final Rule
8. OMB Review of Final Rule

9. Publication of Final Rule
10. Congressional Review Period

Under the APA provisions (5 U.S.C. 553) rules may be established only after proposed rulemaking procedures (steps three through six) have been followed, unless an exemption applies. The following are exempted:

- Rules concerning military or foreign affairs functions
- Rules concerning agency management or personnel
- Rules concerning public property, loans, grants, benefits, or contracts
- Interpretive rules
- General statements of policy
- Rules of agency organization, procedure, or practice
- Non-significant rules for which the agency determines that public input is not warranted
- Rules published on an emergency basis.

Even if an exemption applies under the APA provisions, other statutory authority or agency policy may require that proposed rulemaking procedures be followed. However, if rulemaking is exempt from the proposed rulemaking procedures under the APA provisions **or under statutory authority, an agency may promulgate a final rule omitting steps three through six.**

Under the current HIPAA laws, HHS (CMS) has determined that they must follow all nine steps of the APA when promulgating a new Standard and Implementation Specification; and when updating or modifying an already adopted HIPAA Standard and/or Implementation Specification. CMS has a more stringent rule making process, which is described within this document. (See section *"Appendix B. The Regulatory Process"* for more detail on the steps of regulatory process.) But, the basic steps shown above are all included. If everything goes exactly to plan, we estimate the **APA process alone** takes approximately 5 years to complete - that is, until implementation is completed and the compliance date is met.

The problem HHS' interpretation creates for updating or modifying an already adopted HIPAA standard and/or Implementation Specification is the commenting process of the NPRM, which significantly extends the time to adopt such changes and creates unnecessary burdens to the SDO and the industry. Why? At this point in the adoption process (the NPRM) the updated or modified Standard and/or its Implementation Specification have been finalized and published by the SDO. For an SDO to change the Standard or Implementation Specification as a result of comments received during the NPRM (step 6 above), the SDO would be required to make such changes in yet another new version of the Standard or Implementation Specification, which may require CMS to issue yet another NPRM when the new version is ready. The newer version could include other changes as a result of ongoing development activities of the SDO and the industry. This creates the potential for comments from this new NPRM to generate still more revisions to the standard or Implementation Specification thus creating an endless loop prohibiting implementation. Moreover, if the revised Standard and Implementation Specification should get implemented after the second NPRM, it would only be after significant additional time was spent at the SDO level revising, re-balloting, and taking additional public comments during their development process (could take up to 12-18 months for the SDO to complete), all of which is added to the 5-year schedule to complete just the APA process steps. Our goal is to eliminate the need for steps three through six (identified above).

See section *"Appendix B. The Regulatory Process"* for more detail on the steps of regulatory process.

The SDOs have discussed modifications to the APA processes with HHS multiple times. Despite offering possible alternatives to the current process that would offer fewer constraints due to the regulatory processes, we were unable to arrive at a solution.

This document does not address any regulatory requirements for cost-benefit analysis. The SDOs recommend HHS work with WEDI to ensure the HHS cost-benefit analysis requirements are met.

4.2 Length of Time from Industry Approval to Implementation of New Versions

The analysis done in several iterations repeatedly concluded that the regulatory adoption process takes far too long after the implementation specification has been approved by the industry via the SDO process. Our analysis also examined the SDO process (steps/length of time) and concluded that it is **not** the SDO process that needs to be addressed in order to bring implementation specifications to the industry faster.

Initial estimates by the SDO suggest that from the time a healthcare organization requests changes to a "HIPAA adopted" implementation specification either through the DSMO Change Request System, or via the SDO's data maintenance process, it takes a minimum of **5 years** before that implementation specification is used under the law (the full change request process). This estimate assumes the regulatory process will work as scheduled (which has not yet happened) and equates to approximately 5 years allocated for the rulemaking process. There are examples where the rule making process has exceeded these time frames. The current timeline is unpredictable and unacceptable for today's changing health care related information needs. Demonstrative examples include:

1. The recent Notice of Proposed Rule Making (NPRM) for "claims attachments standards" under HIPAA. The NPRM was expected (and even drafted) in 1998, and finally published in late 2005.
2. The NPRM expected to obtain public comment about issues in the pharmacy industry for billing of supplies and professional pharmacy services that were first identified in 2001 has yet to be published.
3. In some situations, workarounds had to be identified and agreed upon because existing versions did not support industry needs and the regulatory process would take too long after the new solution was approved. For example
    a. ASC X12N 837 I - Insured's birth date – a "standard default" birth date of 01/01/2001 needed to be used in a given situation.
    b. NCPDP Version 5 Editorial Document, which was created to address questions, clarifications, corrections to the Telecommunication Standard.

Because the time lapse between the filing of the DSMO Change Request and the NPRM being published with requested changes may be months or years, more recent changes will need to be included to meet industry needs, but may require another review cycle through the APA. This begins an endless cycle.

Congressional awareness of the timing issue is observed by the number of bills on health information technology. Of late, bills with a focus on ICD-10 adoption are tied to the need to update the HIPAA mandated 4010A1 X12N implementation guides to version 5010 and an updated version of the NCPDP Telecommunication Standard. Specifically, House Resolution (HR) 4157 articulates the need for more timely and predictable processes. The next "versions" of the X12 standards and the NCPDP standards are also proposed to be legislated for use because the rulemaking process is too lengthy for their modifications as well as being too lengthy for supporting the ICD-10 data needs. If the process provided a more timely response to industry needs, legislating new versions would not be necessary. The SDOs testified to this problem before the NCVHS in December of 2005.

4.3 Modifications Being Made to Approved Implementation Specifications

There is an **underlying industry assumption** that based on public comments received through the NPRM process, the published version of the implementation specification may be opened and updated and republished in order to accommodate changes requested by the NPRM comments.

This assumption poses serious concerns in the following areas:

1. Revisions to an approved implementation specification.
2. Adjudication of comments received during an NPRM.
3. Multiple versions of an implementation specification underway concurrently.

4.3.1 Revisions to an Approved Implementation Specification

Currently, modifications requested through the NPRM public comment process are sent to the SDO for SDO/industry consideration. The underlying assumption that modifications might be made without a formal ballot/approval process is contrary to the requirements of ANSI. If the SDO were to take the changes through the formal ballot/approval process again, as is initially done with the original implementation specification, a new version/release would be created. Then HHS may need to issue a new NPRM because a different version/release was being adopted. This begins an iterative process from which there is no end as comments are received from each NPRM.

The best approach is clear; the comments must be received during the SDO's development of the implementation specification and during the formal ballot/comment approval period of the document, not after the document is approved.

4.3.2 Adjudication of Comments Received during an NPRM

Some comments received during the NPRM process may not be implementable in the currently published version. This is because for some SDOs the base standard does not support the requested functionality. Revisions to an SDO's implementation specification will need to occur within the SDO defined processes and balloting timeframe, which can:

1. Extend the timeline for completion of industry requested changes.
2. Result in a new version being named in the Final Rule.

Other comments may impact the already published and approved implementation specification. The iterative cycle of SDO implementation specification development intentionally accommodates industry requests into subsequent versions of implementation specifications.

In the current NPRM process, the SDO may submit comments that include the revisions incorporated in the newer version. Depending on the breadth of changes, HHS may determine that a new NPRM cycle is needed or may deem the changes to be manageable enough to warrant adoption of the newer SDO version. If a new NPRM cycle is chosen, an endpoint may not occur due to the continuation of the newest needs brought forth by the industry, again illustrating how the cycle could become un-ending.

4.3.3 Multiple Versions of an Implementation Specification Underway Concurrently

By the time the NPRM commenting process is held on a proposed new version for HIPAA adoption, the SDO with industry input typically has produced another iteration (a newer version) of the implementation specification.

It is extremely difficult for the SDO to go back to potentially years-old implementation specifications making their way through the regulatory process, modify them based on NPRM comments, and then try to incorporate these comments into the new implementation specifications already underway. The most effective use of limited industry volunteer resources requires that the SDO's focus on updating one version of the implementation specifications – the most current - and not go back and modify already approved documents.

4.4 Lack of Predictability in the Process

Predictability of the transaction implementation specifications adoption process under HIPAA has been a topic of discussion since the passage of the law in 1996. Many in the industry have strongly supported the need for a schedule for upgrading the HIPAA adopted implementation specifications. Knowing the process and associated timetables enables covered entities to more effectively manage their budgetary planning and allocation of resources for competing projects. Establishing a reasonable, predictable maintenance cycle for HIPAA adopted transaction implementation specifications has not been feasible to date, in large part due to the unpredictability of the Federal Rule Making process.

This is a topic that the SDOs have discussed with the Office of e-Health Standards and Services (OESS) multiple times. Despite offering possible alternatives to the current process that would enable more predictability from the regulatory side, we were unable to arrive at a resolution.

4.5 Pilot Testing as a Possible Step

While pilot testing of a draft implementation specification is a desirable goal, it is recognized that many factors must be in place to execute a pilot. If the industry feels a pilot is necessary due to significant changes, the SDOs will support the pilot to the best of their ability, but the testing must be done within the SDO timeline of public commenting (and prior to closing any ballots), approval, and publishing. Items such as funding, management, participants, and scope are outside of the SDO processes.

Due to the type of modification and industry requirement, not all draft implementation specification modifications would need a pilot test.

4.6 Lack of Industry Understanding of the Cyclical Process at the SDO

Within each SDO, there is a cyclical process of industry modifications, consensus building and solutions, approval processes, and publication. The process is consistent in the steps. Balance may sometimes be difficult between the immediate need for an industry request and the consensus-building process. Further balance must be weighed between immediate requests and the implementation timeframe of the industry.

We note that there have been comments about the slowness of the SDO process. Sometimes these comments are warranted due to the voluntary nature and workload of the organization and perhaps because of the lack of participation of subject matter experts on a particular issue or because of the process that must be executed to reach consensus by the industry. Other times these comments are simply an indication of lack of education throughout the industry as it relates to the SDO and regulatory processes.

Even though the aforementioned may be true, the SDO still contend that, in the context of HIPAA, the regulatory process timeframe far exceeds that of the SDO and it is, as described above, completely unpredictable in terms of its initiation and length.

4.7 Not Enough Industry Input at the Time of SDO Development (it's too late once an NPRM is published)

It appears there are multiple reasons for this. One, the industry might not be aware of the development or the importance of participation within the SDO. Two, there is a concern that, because the industry focuses on commenting during the NPRM process, the development and review of an implementation specification is less than important until after the SDO approval process has taken place. There is also the negative impact of the long delays on both SDO development and public comment participation. We cannot foster an attitude that there is no need to participate as the development process unfolds, i.e. "you can always undo that later". These perceptions must be rectified.

It is important for the industry to discuss the business requirements together and determine a consensus-based, balanced decision early in the SDO development process, not once the document has been published. The comments that currently occur at the NPRM time must occur in the SDO requirements phase of the development of the implementation specification.

4.8 Lack of Agreement on How Often the Industry Wants to Move to a New Version versus Market Need for Making that Change

It has been difficult to determine whether the industry wants changes made often, to react to business needs, or less frequently, so change does not occur too often. What is the balance? Would the adoption of a new version of an implementation specification every two years be soon enough? Is this too soon? If so, what is appropriate? Is it determined by designated "year increments" or market demand, or something else entirely?

The industry needs to consider the timeline for support of multiple versions during transition periods. The SDOs recognize and acknowledge this issue, but believe that the industry needs to reach consensus on how to best proceed. This is an industry decision, not an SDO decision.

4.9 Current HIPAA Implementation Specifications Adoption Process – Current Process Timeline

Experience has shown us that the current process for naming a new version of an implementation specification or a new implementation specification under HIPAA is not timely or predictable, thus rendering it unworkable for the industry. The following is an example of the flow of a new version of an existing implementation specification to be named in HIPAA and provides some <u>approximate</u> timeframes from request of the change to actual adoption.

The industry development of an implementation specification timeframe through the SDO has not been assigned dates (Steps C1-C2). It is recognized that the industry brings forth requests for modifications of implementation specifications over a period of time and the voluntary industry participants review and prepare the modifications for a next version/release. The timeline is activated once the SDO with industry input determines a version/release will move forward and prepares the ballot/public comment period.

For the purposes of this timeline, assume the industry submitter requested a change in 2005 or 2006.

The industry discussed the requested changes during 2005-2006 (Step C1-C2). The SDO ballot/approval process vetted the version during 2007-2008. From 2008 to 2013 most of the steps are regulatory/process steps. From the time of the beginning of the requested change to the DSMO (Step C7) to the actual adoption (Step C24) may take over five (5) years (2008-2013).

Step C20 is of concern because the published, industry approved implementation specification is subject to modification based on public comment, which may not represent an open industry process. For Step C20 see section "*Modifications to Approved Implementation Specifications".*

	Action in Current Process Timeline	**Typical Duration in business days (approximate)**	**Date (illustration Only)**
C1	The industry through the SDO process reviews change requests and works them according to their schedules.		
C2	The amount of time to develop of a new version/release of an implementation specification is determined by volume of changes, technical difficulties, voluntary effort, possible SDO coordination, etc. This is iterative.		
C3	At some point, the Industry participants via SDO determine it is time to request new version be named in HIPAA and begin the SDO approval process. (Start date forced on this example to provide a starting point.)	40	Start Date: 01/01/2007
C4	SDO balloting/approval processes occur including public comment periods. Any materially affected party may vote on ballot or submit a comment.	120	
C5	SDO reconciles ballot or comments and finalizes scope of changes to implementation specification. This duration may be impacted by variations in process, number of comments received, and complexity of the implementation specification being reconciled.	200	
C6	SDO publishes new version implementation specification.	20	
C7	Industry files DSMO Change Request to request new version through SDO.	1	
C8	DSMO Process (to review the Change Request and collaborate on a recommendation). (This does not include a request for a 45-day extension.)	100	Start Date: 06/17/2008
C9	DSMO prepare recommendation to NCVHS Subcommittee on Standards and Security and gets on docket with WEDI	10	
C10	WEDI prepares survey on Benefit Analysis Report	20	
C11	WEDI Survey is open for industry responses	40	
C12	WEDI provides survey findings	10	
C13	NCVHS Subcommittee on Standards and Security schedule session and hears testimony on request from DSMO and WEDI	20	
C14	NCVHS writes, approves recommendation letter	30	
C15	HHS receives letter	1	
C16	HHS writes NPRM and clears through all departments (clearance process may re-start repeatedly)	400	
C17	HHS publishes NPRM in Federal Register	5	
C18	Public Comment Period (30, 60, 90 days)	60	
C19	SDO, DSMO works with OESS on technical public comments	90	
C20	SDO discusses the comments received and determines next steps (see section *"Modification to Implementation Specifications"* concern)	40	
C21	HHS writes final rule and clears through all departments (clearance process may re-start repeatedly)	400	
C22	HHS publishes final rule	1	
C23	Congressional Review Period	60	
C24	HIPAA New Version Implementation Date (not less than 180 days)	180	End Date: 01/30/2013

5. CHANGING HIPAA TRANSACTION IMPLEMENTATION SPECIFICATIONS ADOPTION PROCESS – OUTLINE NARRATIVE

The recommendation is for an implementation specifications adoption process under HIPAA whereby consensus-based standards are developed, maintained, approved and implemented in an acceptable timeframe. The recommendation proposes some important tenets.

1. Industry input takes place early in the development and approval of the implementation specification as part of the SDO process. The Federal Register notice and the SDO processes alert the industry.
2. The proposal supports collecting all technical public comments at one time – while the implementation specification is being developed and approved, thus eliminating the need to "re-open" already published implementation specifications.
3. An industry impact survey would be conducted by WEDI and be a part of the NCVHS review/approval/recommendation steps.
4. The Federal Register Final Rule provides the adoption and implementation timeframe.

With these modifications, the timeliness and length of time for adoption are optimized and the volunteer industry participation is at the beginning of the process, yielding more efficient use of limited volunteer resources.

5.1 Proposed Improved Process Concepts

1. SDOs receive change requests (via SDO process or Designated Standards Maintenance Organizations Change Request System. (DSMO CRS))
    a. Input/questions/comments about an implementation specification are addressed through the SDO development environment (meetings/conference calls/emails/list serves). Further input takes place during the public review/ballot/approval processes. (Steps P1–P2, and P7-P8)
    b. The ANSI consensus process conducted by the SDO must be accepted as the primary vehicle for industry involvement and input regardless of SDO membership. SDO processes include public comment periods, which provide ample opportunity for the industry to comment and participate in these changes as they are being developed by the industry within the SDO. (Steps P1-P2 and P7-P8)
    c. HHS will publish notice in the Federal Register of SDO work beginning on new versions. This is intended to reach the widest possible audience, as **industry's input is imperative at the development and approval stages of implementation specification development process**.
    d. Modification logs from one ballot/approval version of the implementation specification to the next requested version will be kept by the SDO and included in the ballot/approval process review documents.
    e. The DSMO will reconcile change requests to the modification logs to verify changes have been made where recommended.
2. Industry participants via SDO determine it is time to request new version be named in HIPAA (upon approval). (Step P3)
    a. This is the "go to" version so industry is involved in the change requests, the determination that the version be put forward under HIPAA, and in the balloting/approval process.
3. SDO notify HHS of new version approval process (ballot, approval). (Step P5)
4. HHS will announce the SDO ballot period through their far-reaching federal list serves. (The SDO announces through their normal means.) (Step P6)

5. SDO balloting/approval processes occur. (Step P7-P8)
    a. Members and any materially affected party may vote on ballot regardless of SDO membership.
    b. Ballot/approval process includes public comment periods - whether through ballot process (may include new ballot and then recirculation ballot based on negative comments) or other steps.
    c. DSMO will provide their review and will provide comments at this time as well.
    d. Ballot/approval documents will include modification log.
6. SDO publishes new version implementation specification. (Step P9)
7. SDO prepares Benefit Analysis Report for WEDI. (Step P10)
8. DSMO Process (Step P-11)
    a. The industry via the SDO process files a DSMO Change Request. (Step P11.1)
    b. The DSMO process for organizations to review the Change Request and collaborate on a recommendation. (Step P11.2)
    c. DSMO prepare recommendation to NCVHS Subcommittee on Standards and Security. (Step P11.3)
9. WEDI prepares survey on Benefit Analysis Report. (Step P12) – this is in tandem with DSMO Process.
    a. Establish a formal process for WEDI to execute surveys for each version request brought forward. An assumption that perhaps in time this will become somewhat "cookie cutter" in the information to be obtained to prepare the survey and the questions asked. (Step P12.1)
    b. Survey is open for industry responses. (Step P12.2)
    c. WEDI provides survey findings to DSMO and SDO. (Step P12.3)
10. NCVHS Subcommittee on Standards and Security schedules session and hears testimony on request from DSMO and WEDI. (Step P13)
    a. NCVHS will provide notice to the public and a reasonable opportunity for public testimony at a hearing on such modification, addition, or new version. (It should be noted that this step could extend depending on the amount of information NCVHS hears in public testimony which would require follow up. The expectation is most of the industry discussion will have taken place during the development of the implementation specification, during ballot/approval processes, and during the WEDi survey.)
11. NCVHS writes, approves recommendation letter. (Step P14)
12. HHS receives letter. (Step P15)
13. HHS takes action. (Step P16)
    a. Within 90 days of submission of the letter from NCVHS, the Secretary either shall reject the recommendation and return it to the Committee with his or her reasons for rejection, and shall cause notice of the rejection and such reasons to be published in the Federal Register, or shall accept the recommendation. (Step P17)
    b. In the event the Secretary shall accept the recommendation, he or she shall promulgate the new standard in a final rule within 60 days of his or her decision to accept the recommendation, with new version implementation date 180 days from Final Rule. (Step P18)
14. Congressional Review Period. (Step P19)
15. Implementation timeframe. (Step P20)

5.2 Proposed Improved Process Timeline

The following proposes a timeline based on H.R. 4157.

This example attempts to illustrate the naming of a new version of an implementation specification under HIPAA timely and predictable for the industry. The following is an example of the flow of a new version of an existing implementation specification to be named in HIPAA and provides some approximate timeframes from request of the change to actual adoption.

The industry development of an implementation specification timeframe through the SDO is not assigned dates. It is recognized that the industry brings forth requests for modifications of implementation specifications over a period of time and the voluntary industry participants review and prepare the modifications for a next version/release. While it may be argued that the SDO process can take months or years, it is important to note that the industry is involved in this development. The timeline is activated once the industry determines a version/release will move forward and prepares the ballot/public comment period.

For the purposes of this timeline, assume the industry submitter requested a change in 2005 or 2006.

The industry discussed the requested changes during 2005-2006 (Step P1-P2). In early 2007, the industry is notified via HHS that a version/release is being prepared for ballot/approval. (It is hoped the industry is involved in the 2005-2006 discussions, but the 2007 notification is an alert.) In 2007, the industry via the SDO notifies HHS that a new version/release of the implementation specification will be going through ballot/approval process for industry comments. In 2008 the new version of the implementation specification is published. In 2008, a WEDI survey may occur. By 2009, the final rule notification is published and the industry prepares for implementation. From the time of the beginning of the requested change to the DSMO (Step P11) and WEDI Survey (Step P12) to the actual adoption (Step P20) may take less than two (2) years (2009-2010).

	Action in Proposed Improved Process Timeline	Typical Duration in business days (approximate)	Date (illustration Only)
P1	The industry through the SDO process reviews change requests and works them according to their schedules.		
P2	The amount of time to develop of a new version/release of an implementation specification is determined by volume of changes, technical difficulties, voluntary effort, SDO coordination, etc. This is iterative.		
P3	At some point, the Industry participants via SDO determine it is time to request new version be named in HIPAA and begin the SDO approval process. (Start date forced on this example to provide a starting point.)		Start Date: 01/01/2007
P4	Industry requests SDO notify HHS to consider a new version for HIPAA	10	
P5	SDO notify HHS of new version approval process (ballot, approval)	30	
P6	HHS publish notification of ballot/approval process and timeline	30	
P7	SDO balloting/approval processes occur including public comment periods. Any materially affected party may vote on ballot or submit a comment – includes modification log (DSMO CRS and SDO requested changes)	120	
P8	SDO reconciles ballot or comments and finalizes scope of changes to implementation specification. This duration may be impacted by variations in process, number of comments received, and complexity of the implementation specification being reconciled.	200	
P9	SDO publishes new version implementation specification	20	
P10	SDO prepares Benefit Analysis Report for WEDI	20	
P11	DSMO Process		
P11.1	Industry files DSMO Change Request to request new version.	1	Start Date: 08/08/2008
P11.2	DSMO Process (to review the Change Request and collaborate on a recommendation). (This duration does not include a request for a 45-day extension.)	100	
P11.3	DSMO prepare recommendation to NCVHS Subcommittee on Standards and Security and gets on docket with WEDI	10	
P12	WEDI Benefit Analysis Report Process		Start Date: 08/08/2008
P12.1	WEDI prepares survey on Benefit Analysis Report	20	
P12.2	WEDI Survey is open for industry responses	40	
P12.3	WEDI provides survey findings to DSMO and SDO	10	
P13	NCVHS Subcommittee on Standards and Security schedule session and hears testimony on request from DSMO (CRS) and WEDI (Benefit Analysis Report)	20	
P14	NCVHS writes, approves recommendation letter	30	
P15	HHS receives letter	1	
P16	HHS takes action	90	
P17	HHS rejects recommendation and publishes rejection in Federal Register	20	
P18	HHS approves recommendation and publishes final rule	60	
P19	Congressional Review Period	60	
P20	HIPAA New Version Implementation Date (not less than 180 days)	180	End Date: 06/15/2010

6. APPENDIX A. SDO PROCESSES

SDOs follow general processes to develop, ratify, and publish their documents. SDOs that are accredited by the American National Standards Institute (ANSI) must follow the *ANSI Essential Requirements: Due process requirements for American National Standards* (www.ansi.org). There are requirements that the SDO must demonstrate and provide accountability of balance, consensus, due process, and other principles. ANSI allows latitude in the specific implementation scheme therefore; each SDO may have different process steps to accomplish these same principles.

In general, the SDOs perform the following steps for a document to be approved for publishing for use in the industry.

1. SDOs receive change requests from the industry via an SDO process for submitting enhancements or via the DSMO Change Request System website.
2. Industry participants via SDO based meetings/conference calls etc discuss the change requests, determine actions on the requests and then do the necessary work to accommodate the request.
    a. Some changes may be easily incorporated into a next version.
    b. Some changes may require industry outreach/discussion/research to determine solutions.
    c. Some changes may require modifications to be implemented to the SDO's underlying implementation specification.
3. SDO publishes a draft version of the implementation specification for consideration.
4. SDO notifies industry of public review / ballot and timeframe.
5. Any materially affected party may vote on ballot.
6. SDO performs voting - balloting/approval processes occur.
7. Auditing is performed on voting to verify balance and whether approval percentages have been reached.
8. Any negative votes are considered by the SDO in open process. SDO documents deliberation and outcome steps.
9. The ballot process includes appeal steps by negative voters or any affected party.
10. SDO attempts to resolve any appeals.
11. The SDO will usually obtain approval of implementation specification from highest level in SDO (e.g. Board, Technical Committee).
12. SDO publishes implementation specification.

7. APPENDIX B. THE REGULATORY PROCESS

This information was supplied by OESS. All timeframes are approximate and extremely variable.

7.1 Step One - Initiating Events

Approximate Timeframe: 1-2 months

Statutory mandates
Recommendations from other agencies, external groups, states, federal advisory committees
Agency reviews event and determines administrative approach.

7.2 Step Two - Issue Development

Approximate Timeframe: 6 months, depending on the number and impact of issues)

Identify individual issues
Develop proposed positions and get approval

7.3 Step Three - Rule Develop NPRM

Approximate Timeframe: 3 months (depending on the number and impact of provisions)

Develop draft preamble, regulation text, and impact analysis

7.4 Step Four - Clearance Process in CMS

Approximate Timeframe: 4 months May repeat multiple times

Circulate for clearance within agency
Receive comments/clearance
Revise as necessary; re-circulate for clearance until all agree (indeterminate time)
Agency signoff

7.5 Step Five - Departmental Clearance

Approximate Timeframe: 2 months or more May repeat multiple times

CMS forwards to Department
Circulate for clearance among Departmental components
Receive comments/clearance
Revise as necessary; recirculate for clearance until all agree (indeterminate time) (note: if “significant” changes due in Department clearance, must return to CMS clearance)
Secretary signoff

7.6 Step Six - OMB Clearance

Approximate Timeframe: 3 months May repeat multiple times

Forward package to OMB
Initial briefing for OMB staff
OMB review
OMB comments

Revise package as necessary for OMB approval
OMB approval

7.7 Step Seven – Federal Register Publication

Approximate Timeframe: 1 month (depending upon urgency of regulation)

Package forwarded to Federal Register
On display at Federal Register (for 24-48 hours)
Publication in daily Federal Register (usually 4th Friday of the month)
Public comment period begins (usually 60 days)

7.8 Step Eight – Response to Public Comments

Approximate Timeframe: Varies with the number of public comments and issues

Review public comments
Identify and summarize issues
Develop responses
Prepare issue papers on major issues
Present to Department
Get Departmental Clearance

7.9 Step Nine – Prepare Final Rule through Step Thirteen - Federal Register Publication of Final Rule

Approximate Timeframe:

For final rule, repeat 8.3 to 8.7 for final rule and use same time periods.

7.10 Step 14 – Congressional Review Period

Approximate Timeframe: 2 months

Respond to requests and inquiries from Congress (may include briefings)