

MEMORANDUM OF UNDERSTANDING

AMONG

THE ORGANIZATIONS DESIGNATED TO MANAGE THE MAINTENANCE OF

THE ELECTRONIC DATA INTERCHANGE STANDARDS

ADOPTED UNDER THE HEALTH INSURANCE PORTABILITY

AND ACCOUNTABILITY ACT OF 1996

Preface

On August 21, 1996 the Health Insurance Portability and Accountability Act of 1996 (HIPAA) was signed into law. Title II, Subtitle F of HIPAA contains provisions for administrative simplification of the health care system. As such, it requires the Secretary of U. S. Department of Health and Human Services (HHS) to "adopt standards for transactions and data elements for such transactions."¹ To achieve the goals of administrative simplification requires a process of cooperation and coordination among a variety of organizations involved in the maintenance of the standards. To foster that administrative simplification, the signatories of this Memorandum of Understanding (MOU) agree to the following framework of cooperation with each other and HHS.

1. Purpose and Scope

The purpose of this MOU is to outline a framework of cooperation between and among HHS and the Standards Development Organizations (SDOs) and Data Content Committees (DCCs) designated by the Secretary of HHS (the Secretary) to play an active role in the HIPAA Administrative Simplification transactions maintenance process. These organizations agree to work together to manage the change request process affecting the transaction standards adopted by HHS under HIPAA. This includes all necessary and appropriate modifications to the standard implementation guidelines/manuals and documentation as well as the related data dictionaries. It also includes review of requests to add new functionality or new transactions to the HIPAA standards. This MOU documents the overall process for coordinating the review of HIPAA standard change requests among these organizations. More detail of the coordination process can be found in Annex 1. Specific information on how each SDO and DCC will handle its review can be found on each organization's Web site. The URLs for those Web sites are listed in Annex 2.

2. Guiding Principles

The signatory organizations agree to the following guiding principles for managing HIPAA Standard Change Requests:

2.1 Allow open public access. Any person or organization shall have the opportunity to submit a HIPAA Standard Change Request.

2.2 Provide for timely review. The organizations agree to establish or maintain a methodology or process that ensures timely reviews and responses to all HIPAA Standard Change Requests. Since the Secretary can promulgate new or revised HIPAA rules no more frequently than once a year, each organization's process should be designed to work within that time frame.

¹ Health Insurance Portability and Accountability Act of 1996, Title II, Subtitle F,

2.3 Cooperate and communicate. The organizations agree to cooperate and communicate with one another as each organization looks at new transactions, changes in technology, or changes in the health care industry.

2.4 Consider all viewpoints. The process allows for input and consideration of various viewpoints from health plans, providers and other entities involved in, or affected by, the HIPAA transaction rules.

2.5 Evaluate the impact of each change request. The organizations agree to consider the overall impact of the HIPAA Standard Change Request on all the HIPAA transactions. While a request may seek a change to one transaction, it is possible that the change could have an effect on other transactions.

2.6 Maintain a national perspective. The organizations agree to maintain a national perspective in satisfying the business needs of the health care industry while fostering administrative simplification.

2.7 Conform to law. All changes recommended shall be consistent with HIPAA statutory and regulatory provisions.

3. Parties to the MOU

The parties to this MOU are HHS and the DCCs and SDOs as designated by the Secretary. The DCC and SDO designees currently include the following six organizations, but may in the future include other organizations:

Accredited Standards Committee X12
The Dental Content Committee

Health Level Seven

National Council for Prescription Drug Programs

National Uniform Billing Committee

National Uniform Claim Committee

In general, DCCs are committees that provide a national forum for discussion, review and action regarding change requests to the data sets associated with health care financial and administrative transactions. The DCCs assess the global business needs and impacts of potential changes on the health care industry. The committees are comprised of a balanced representation of key national organizations that are affected by health care transactions. Their operating protocols vary, but all are open to input from the public and include a formal appeal process. Their voting structures provide balanced, proportional and accountable representation of the end users of those transactions and data sets, e.g., payors, health care professionals, institutional providers, standards development organizations, public health and research communities, etc.

In general, SDOs are organizations that develop and maintain the models, data dictionaries, structure, syntax and implementation materials for electronic transaction standards. Their operating protocols vary, but all maintain policies that meet the requirements of the American National Standards Institute for open participation and assurance of due process. Their voting structures can vary, both between organizations and at different levels within the same organization, but final voting is generally on the basis of one vote per member-in-good-standing.

4. Steering Committee

To facilitate the implementation of this MOU, the signatories to this MOU agree to designate a steering committee. Each signatory shall have a representative to the Steering Committee. Each organization shall have one vote, except HHS, which shall have a non-voting liaison role. The steering committee will communicate monthly unless there is no business to discuss.

The duties of the steering committee shall include general oversight as well as the specific duties specified in sections 5, 7, 8 and elsewhere in this MOU, which include conducting an appeals process and assessing the effectiveness of the MOU and the process it implements.

5. General Process for Requesting Changes to the HIPAA Standards

In the May 7, 1998 *Federal Register*, (Volume 63, Number 88) a Notice of Proposed Rule Making identified the initial standards for electronic transactions to fulfill the requirements of the administrative simplification provisions of HIPAA. A final rule will mandate these standards. According to HIPAA, modification to these initial standards, or adoption of additional standard electronic transactions can occur. The HIPAA Standard Change Request process outlined below is further detailed in Annex 1 of this document.

5.1 HIPAA Standard Change Requests can be submitted by anyone at any time via a designated Web site that will be available to the public. The Web site will have the forms and instructions for the public to submit a HIPAA Standard Change Request. The Web site will also contain instructions for paper submission of HIPAA Standard Change Request forms. The Web site administrator will ensure the completeness of each HIPAA Standard Change Request. The Web site administrator will batch all HIPAA Standard Change Requests monthly and ensure that all HIPAA Standard Change Request are forwarded to HHS and each of the maintaining organizations (DCCs & SDOs).

5.2 Once notified by the Web administrator, each maintaining organization will have ten business days to decide whether or not it will collaborate in the analysis and development of the HIPAA Standard Change Request.

5.3 The organizations collaborating in the analysis will have 90 days to complete a business analysis and develop a preliminary recommendation for the disposition of the HIPAA Standard Change Request. If necessary, there can be one 45-day extension.

5.4 Within 15 days after the business analysis is completed, all the collaborating organizations will review and compare their recommendations in an informal consensus process. If all the collaborating organizations agree on a single recommendation for disposition of the HIPAA Standard Change Request, then that recommendation is forwarded to the appropriate SDO to make the appropriate changes to its implementation guide(s), data dictionaries, etc. In case of disagreement, the collaborating organizations shall, to the greatest extent possible, resolve those disagreements by consultation among themselves or by development of data conditions that isolate a data change to one or more specified industry segments or circumstances. Nonetheless, if the collaborating organizations cannot reach a consensus on a solution, any collaborating organization may invoke the appeal process.

5.5 The formal appeal process requires convening the steering committee within 30 calendar days of the appeal. The steering committee will review each of the proposed solutions for the HIPAA Standard Change Request and work toward a common solution. Each organization will have one vote. A two-thirds majority of the Steering Committee will be required to move a proposed disposition forward, as described in the following section.

5.6 Once the collaborating organizations or the steering committee agree on a single disposition for the HIPAA Standard Change Request, the appropriate SDO will proceed with development of the changes necessary to

implement the disposition identified by the foregoing process. (See Section 6 of Annex 1 for details.) The resulting proposed changes to the transaction, implementation guide or other documentation will be communicated to each of the collaborating organizations for them to review and confirm that the solution satisfies the disposition recommendation. SDO proposed changes confirmed to satisfy the recommendation will then be incorporated into the appropriate documentation; SDO proposed changes not satisfying the recommendation will be referred back to the SDO for further development.

5.7 On a cycle to be determined, all the approved HIPAA Standard Change Requests will be presented to the National Committee on Vital and Health Statistics (NCVHS). (NCVHS is designated by HIPAA as an advisor to the Secretary of HHS. NCVHS may review the approved changes and may issue its own recommendations to HHS.)

5.8 HHS will assess the recommendations and initiate the HIPAA rule modifications accordingly, including the rulemaking process if required. HHS will analyze public comments received during the rulemaking process and will utilize the steering committee to solicit the consultations of the appropriate SDOs and DCCs on technical or business issues.

6. Liaisons

All signatory organizations shall establish and maintain appropriate liaisons with all other signatory organizations, either voting or non-voting.

7. Performance Evaluation

The steering committee shall review and evaluate the performance of the HIPAA Standard Change Request management system annually. Among other things, the report will indicate the number of denied requests and appeals as well as the basis for denial.

8. Term

The initial term of this MOU shall be three years. Unless otherwise agreed by the signatories, this MOU shall automatically renew for subsequent one-year periods.

9. Changes to the MOU

Changes to this MOU, including additional signatories, must be approved by three-fourths majority of the Steering Committee, and by HHS. Modifications can be made to this MOU to keep the HIPAA Standard Change Request management system aligned with industry and regulatory needs. As appropriate, the Committee will address urgent issues.

Any party to the MOU may withdraw from the MOU upon six (6) months notice to HHS and the other signatories. The steering committee shall make recommendations to the Secretary for assignment of any unmet responsibilities to other parties.

10. Signatures and Effective Date

This MOU may be signed in one or more parts. The effective date of this MOU shall be the effective date of the HIPAA transaction set final rule. The HIPAA Standard Change Request management system shall go into effect for all Change Requests received after the effective date of this MOU. For changes initiated by any of the parties prior to the effective date, those parties shall make reasonable efforts to advise all the other parties about those changes.

The undersigned organizations agree to this Memorandum of Understanding:

Accredited Standards Committee X12

By: _____ Date: _____

Dental Content Committee

By: _____ Date: _____

Health Level Seven

By: _____ Date: _____

National Council for Prescription Drug Programs

By: _____ Date: _____

National Uniform Billing Committee

By: _____ Date: _____

National Uniform Claim Committee

By: _____ Date: _____

List of Attachments

Annex 1: Details of the HIPAA Standard Change Request Management Process.

Annex 2: Web information. Annex 2 lists the URL of the Web **site** for the change request system. It includes the URLs for the Web sites of all signatories. Those sites contain additional information such as specific reference to operating protocols, membership, meeting agendas and other information that the general public would need or find useful in connection with this HIPAA Standard Change Request management system. These URLs may be changed by the organizations that control them after approval by a majority of the steering committee.

Annex 1

HIPAA Administrative Simplification Change Request Management Process

1. Designated Web Site for HIPAA Standard Change Requests

There will be a designated Web site open to the general public that has the forms and instructions for HIPAA Standard Change Requests, including access to the industry implementation guides, HIPAA data dictionaries, booklets, etc. HIPAA Standard Change Requests can be submitted by anyone at any time. While most HIPAA Standard Change Requests will be completed and submitted on-line, the Web site will also contain instructions for how to submit paper HIPAA Standard Change Requests. Throughout the process, the Web site will track each HIPAA Standard Change Request and its current status so that anyone (e.g., requestor, DCC, SDO, general public, etc.) will be able to track its progress.

The industry implementation guides, data dictionaries, booklets, etc., will be available on the designated Web site or via links to the SDO Web sites.

2. Completeness of request and determination of which organizations will review.

The designated web site administrator will review each HIPAA Standard Change Request for completeness. Incomplete HIPAA Standard Change Requests will be returned to the requestor. Properly completed HIPAA Standard Change Requests will be acknowledged and then batched at the end of the month. No later than the fifth business day of each month, the Web administrator will post the batch of HIPAA Standard Change Requests to the Web site. At the same time it will automatically notify all signatories to this MOU. Each DCC and SDO will submit to the Web site no later than the fifteenth day of the month their interest in each HIPAA Standard Change Request. They will either state that they wish to actively collaborate in addressing the HIPAA Standard Change Request or that they have no interest in the HIPAA Standard Change Request. The Web administrator will work with the steering committee (see below) to ensure that at least one organization addresses each of the HIPAA Standard Change Requests.

3. Business analyses and recommendations.

All collaborating organizations will have up to 90 days in which to do their analysis and develop their organization's business recommendation(s). Each collaborating organization shall post to the Web site pertinent information about its plans for handling the HIPAA Standard Change Request, including at least the date, place and time that the HIPAA Standard Change Request will be addressed and information on how public comments should be submitted. Each organization will allow open public input into its review and analysis of the HIPAA Standard Change Request. Meetings on the HIPAA Standard Change Request are not necessarily restricted to face-to-face meetings.

For a more complex HIPAA Standard Change Request, the collaborating organization can ask the steering committee for one 45-day extension, which is permissible. Additional extensions may only be granted by the steering committee upon presentation of compelling justification. The Web site will track the status, including all extensions and the anticipated resolution date by the organization.

At the end of the analysis period, the recommendations of the collaborating organizations will be posted to the designated Web site and the requestor will be notified.

4. Informal consensus among active participants.

Within fifteen business days after posting the recommendations, representatives from all of the collaborating organizations will compare and discuss the recommendations.

If all collaborating organizations agree on a single disposition for the HIPAA Standard Change Request, then they will document that recommended disposition and post it to the Web site as the consensus recommendation. The recommended disposition can be as simple as a yes or a no, or it can be something more complex. If all of the collaborating organizations cannot agree on a single disposition, then any dissenting collaborating organization may request a formal appeal to the steering committee. Alternatively, the dissenting collaborating organization, at its sole discretion and based on its analysis of the impact on the industry, may simply record its opposition and not request a formal appeal. If there is no appeal, the consensus recommendation will proceed to the appropriate SDO(s) for development of the changes necessary to implement the disposition identified by the foregoing process. Otherwise, the formal appeal will proceed to the steering committee. In either case, the status will be posted to the designated Web site.

If the requestor of the HIPAA Standard Change Request disagrees with the recommended solution either at the end of this informal consensus step or at the end of the formal appeal step, the requestor may invoke an appeal to the steering committee. (Requesters may also appeal at the DCC or SDO level in accordance with the protocols of those organizations.) Persons other than the requestor would not be allowed to appeal to the steering committee at these steps. They would have an opportunity to present their appeals either during NCVHS hearings or through the public comment period of the rulemaking process.

To the greatest extent possible, disagreements between collaborating organizations should be resolved by consultation between the pertinent DCCs or SDOs or by development of data conditions that isolate a data change to one or more specified industry segments or circumstances.

5. Formal appeal process.

At the DCC or SDO level, any person or entity shall have the right to appeal the outcome of a HIPAA Standard Change Request or a contrary decision made by the DCC or SDO. All such appeals must follow the procedures specified in the respective protocols of the DCC or SDO.

In case of disagreement, the collaborating organizations shall, to the greatest extent possible, resolve those disagreements by consultation among themselves or by development of data conditions that isolate a data change to one or more specified industry segments or circumstances. Nonetheless, if the collaborating organizations cannot reach a consensus on a solution, any collaborating organization may invoke the appeal process.

Appeals beyond the DCC or SDO level are restricted to only the collaborating organizations under this MOU and to the requestor of the HIPAA Standard Change Request. Other parties would not be allowed to appeal to the steering committee at these steps. They would have an opportunity to present their appeals either during NCVHS hearings or through the public comment period of the rulemaking process.

If a requestor or a collaborating organization makes a formal appeal, that person or collaborating organization will have fifteen calendar days from the date the recommended disposition is posted to the Web to submit notice of intent to appeal, and an additional fifteen calendar days to submit documentation to the steering committee to substantiate the appeal. Within thirty calendar days of receipt of the appeals documentation, the steering committee will convene to address the appeal. The steering committee will be comprised of all the organizations that are signatories to this MOU. Each organization shall have one voting representative, except HHS, which shall have a non-voting liaison

role. A two-thirds majority of the voting organizations shall be required in order to allow a HIPAA Standard Change Request disposition to proceed. The steering committee shall establish standing monthly meetings that would be canceled if there are no agenda items.

The requestor's appeal can be upheld, denied or remanded to the collaborating organizations for reconsideration. If the appeal is upheld, the original consensus disposition recommendation will be modified, posted to the Web site and forwarded to the appropriate SDO(s). If the appeal is denied, the original consensus disposition recommendation will be posted to the Web site and forwarded to the appropriate SDO(s). If the decision is to remand to the collaborating organizations, that decision will be posted to the Web and the 90-day clock for the collaborating organizations starts anew. HIPAA Standard Change Request disposition recommendations that have been entered into an appeal process will not become part of an implementation guide unless and until the disposition recommendation is overturned on appeal.

6. SDO development.

Once the disposition recommendation is cleared through the collaborating organizations, whether through the informal consensus process or the formal appeal process, the appropriate SDO or SDOs will proceed with development of a technical solution. The SDO will identify and propose changes to its transaction sets, data dictionaries, implementation guides, booklets, etc. to incorporate the recommended disposition. When completed, the SDO will post its technical solution to the designated Web site and all collaborating organizations will be notified. From the date of the posting, all collaborating organizations will have thirty calendar days to review the proposed technical solution and to render an opinion as to whether the technical solution meets the intent of the disposition recommendation. If any collaborating organization believes the SDO technical solutions do not adequately implement the disposition recommendation, it shall have 15 days to come to an informal consensus with the SDO. If consensus is not reached, the dissenting collaborating organization may invoke the formal appeal process with the steering committee, as previously described.

7. NCVHS.

HIPAA requires that the National Committee on Vital and Health Statistics (NCVHS) advise the Secretary of HHS on all changes proposed to the HIPAA administrative simplification rules. Therefore, on a cycle to be determined, all of the HIPAA Standard Change Requests approved since the previous cycle shall

be presented to NCVHS.

8. HHS and HIPAA rule making.

HIPAA requires that the Secretary of HHS adopt changes to the Administrative Simplification rules no more frequently than once a year. Therefore, on a cycle to be determined, all of the proposed transaction rule changes approved by the DCCs and SDOs since the previous cycle shall be submitted to HHS.

HHS will process the proposed changes including, if required, publishing a Notice of Proposed Rule Making (NPRM). The NPRM process includes consulting with the organizations named in the Act, drafting of the rule and clearance by the Health Care Financing Administration (HCFA), clearance by HHS and the Office of Management and Budget (OMB), publication of the NPRM in the *Federal Register*, a public comment period, analysis of the public comments, then drafting of the final rule, clearance and publication. It is anticipated that the non-policy issues HHS receives during the public comment period to the NPRM will be referred to the steering committee. The steering committee would then review the issues with its member organizations and coordinate the responses back to HHS.

Annex 2

Web site information

HIPAA administrative simplification electronic standards change requests:
www.changeHIPAA.com

Accredited Standards Committee X12: <http://www.x12.org>

Dental Content Committee: (tbd)

Health Level 7: <http://www.hl7.org>

National Council for Prescription Drug Programs: <http://www.ncpdp.org>

National Uniform Billing Committee: <http://www.nubc.org>

National Uniform Claim Committee: <http://www.nucc.org>

US Department of Health and Human Services: <http://aspe.hhs.gov/admsimp/>

National Committee on Vital and Health Statistics: <http://ncvhs.hhs.gov>