Summary of Responses to an Industry RFI (RFI-100177a) on Monitoring Compliance with the Transactions and Code Sets, National Provider Identifier and Unique Employer Identifier Rules

Introduction

More than six years have elapsed since the mandatory date for compliance with the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Since that time, CMS has received more than 600 Transaction and Code Set (TCS) and 43 National Provider Identifier (NPI) complaints via our HIPAA complaint intake process. The total number of complaints related to TCS, NPI and Unique Employer Identifier (EIN) (hereinafter referred to collectively as the HIPAA TCS enforcement process) is small when compared with the size of the industry. However, some industry representatives believe that the extent of non-compliance is actually higher than the figures reflected in CMS' complaint enforcement statistics. In advance of the January 1, 2012 compliance date for implementing the updated transaction standards, and the October 1, 2013 compliance deadline for implementing the ICD-10 code sets, CMS intends to assess its current enforcement strategy.

On October 16, 2009 CMS published a Request for Information (RFI) to obtain public input on developing future strategies and enhancements for the HIPAA enforcement process. We solicited information on options to improve and enhance HIPAA TCS enforcement, and requested comments on seven enforcement related topics, including alternative enforcement strategies. The response period closed December 3, 2009, and we received a total of twelve responses from a combination of providers, health plans, vendors and professional associations that represent health care industry segments.

Background

Under the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996, public law 104-191, (HIPAA), HHS published on February 16, 2006 the final Enforcement Rule governing the investigation of non-compliance with the HIPAA regulations. The final rule is very specific about the Principles for Achieving Compliance at 45 CFR 160.304. It states that: (a) the Secretary will, to the extent practicable, seek the cooperation of covered entities in obtaining compliance; and (b) the Secretary may provide technical assistance to covered entities to help them comply voluntarily with the administrative simplification provisions of HIPAA. It further states at 45 CFR 160.308 that the Secretary may conduct compliance reviews to determine if covered entities are complying with the applicable administrative simplification provisions, and in 2007, CMS invoked that authority with respect to its enforcement of the Security Rule. In 2009, authority for security rule violation enforcement was transferred from CMS to HHS' Office for Civil Rights (OCR) , and CMS now has jurisdiction over Transaction and Code Set, National Provider Identifier and Unique Employer Identifier enforcement under HIPAA.

The HIPAA TCS Complaint Enforcement Process

The current HIPAA TCS enforcement process, like the OCR privacy and security process, is primarily complaint-driven. CMS receives electronic or hardcopy complaints from the public, government agencies and other covered entities. The complainant has the option to remain anonymous during the complaint process. Each complaint is reviewed to ensure that CMS has jurisdiction over the alleged TCS violation. Once accepted as a valid TCS complaint, it is investigated, typically through a request for additional information or documentation from the complainant, as well as documentation, and/or proof of compliance from the filed against entity. The outcome of each investigation often results in fairly rapid resolution of the complaint because it involves communication or misunderstanding issues. In other cases a longer term corrective action plan (CAP) must be developed by the filed against entity. This CAP must be approved by CMS, and is monitored over a specified period of time until the complainant confirms to CMS that the complaint has been resolved. Once confirmed, cases are considered closed, and both the complainant and filed against entity received notification of same.

Request for Information (RFI) Questions and Responses

Question 1

Information about the extent of the industry's non-compliance. Describe (i) key problem areas (technical vs. business); (ii) prevalence of specific TCS, NPI and EIN non compliance; (iii) patterns of non-compliance among specific transaction types; and (iv) challenges with the standards.

Responses to this question ranged from substantive issues that may impede implementation, to inherent business limitations with 4010A which likely will be corrected with the implementation of Version 5010. Most common were comments about the prevalence of companion guides that differ from the implementation guide, and industry's failure to implement all of the adopted transactions (i.e. Eligibility, Claim Status, etc.). A number of respondents commented on the HIPAA non-compliance by Medicaid agencies and the resulting administrative burden for Medicaid trading partners.

Three respondents cited the standards update process itself as a barrier to implementation. They stated that the infrequent, slow process of adopting updated standards causes standards changes to be bigger than they need to be, and further complicates synchronization with new industry developments.

Four respondents submitted lists of technical/business problem areas, including

- Plans still requiring legacy identifiers (IDs)
- Plans requiring multiple National Provider Identifiers (NPIs)
- Plans allowing Direct Data Entry (DDE) applications to be richer in data content than the electronic data interchange (EDI) standards
- Plans' poor quality and lack of compliance with the 835 transaction, such as changing the patient account number, using invalid reason and remark codes, and posting incorrect allowed dollars amounts
- Plans' requirement for the use of local codes
- The age and complexity of adjudication systems are costly to modify to accept the HIPAA standard transactions

General comments regarding barriers also included the lack of HIPAA adopted standards for acknowledgements, claims attachments and plan identifier; excessive transaction fees for pharmacy claims; and exclusion of Workers Compensation and Property and Casualty payers under HIPAA, requiring providers to use dual formats when submitting claims.

Question 2

Comments on barriers to complaints being filed and how to eliminate those barriers.

Since HIPAA's inception, it has been widely contended that there are violations of HIPAA that are not being submitted for enforcement investigation. We recognized that input was needed regarding industry's perception as to why complaints are not filed.

One provider organization respondent stated that some providers are simply unaware that a HIPAA TCS complaint enforcement process exists. Seven respondents stated that concerns about plan retaliation against providers was the main barrier to filing a complaint. They suggested that the complaint process incorporate complete complainant anonymity so that providers and plans could maintain their working relationships. However, we received three opposing responses that indicated the value of plans knowing a complainant's identity to make it easier for the plan to resolve the provider's specific problem. A separate comment suggested that CMS aggregate provider complaints so that the issues could be efficiently addressed while providing some degree of anonymity.

We received three comments indicating that CMS' lack of an approved authority for certifying compliance with implementation guides was a barrier to filing complaints.

One industry vendor pointed out that the widespread use of companion guides, and that various interpretations of perceived ambiguities in the adopted implementation guides have

created uncertainties about what the compliance requirements really are. The respondent commented that this uncertainty may be contributing to the reluctance to file complaints.

Question 3

Comments on Strengths and Weaknesses, with explanation, of the current complaint process.

Responses to the question on strengths and weaknesses of the current enforcement process were divided among confidence that the current process is working well (3 responses), and concern that the current process "has no teeth" (5 responses). One respondent commented on the ease of use of the current system, and another respondent noted that the current process permitted flexibility to negotiate solutions to complaints. Overall,, we received a greater number of responses on weaknesses rather than strengths of the current system. Some of the responses regarding the current process included:

- Compliance enforcement should be a multi-level process, such as:
  - Level I-Trading partner collaboration
  - Level II-Facilitated collaboration
  - Level III-On-site review
  - Level IV-Penalties
- The current enforcement process depends upon two parties resolving an issue, rather than invoking penalties
- Since certification is not part of the current enforcement process, the provider is left to prove his case with the payer. Complaint resolutions agreed upon by the entities may not be compliant

One professional association for health plans commented that it is critical for CMS to work closely with the industry in a collaborative approach to further adoption of the HIPAA standards.

Question 4

The usefulness of compliance reviews in identifying: (i) problem implementation areas specific to certain covered entity types; (ii) problem implementation areas specific to certain transaction types; and (iii) challenges with standards

We received six responses that favored compliance reviews, one that did not, and one that did so, but with reservations. Some of the concerns expressed included:

- Unwillingness of covered entities to provide information on a voluntary basis
- The need to collect data for review versus privacy concerns

- Entities that could provide valuable information, such as banks, value-added networks and sponsors, are not covered entities and would not be included in compliance reviews
- Without a standard for Acknowledgements, the collection of data may be inconsistent
- Navigating the business relationships among entities under compliance reviews may be a challenge

Among the respondents who supported compliance reviews, there was agreement that compliance reviews would assist in identifying and addressing compliance issues and promote standards implementation. Comments that favored compliance reviews included:

- Compliance reviews would target specific transactions
- Compliance reviews prior to implementation of new transactions could increase overall industry compliance
- Results of compliance reviews should be published
- If done correctly, compliance reviews could be a significant improvement over what is done today

Question 5

The methods that could be employed to execute the compliance reviews, including the process for identifying entities to review.

We recognize that the methods employed for compliance reviews are integral and important to the compliance review process. We requested responses on this subject in order to learn about industry experience, and received comments from five respondents on suggested ways to identify potential entities for review. These included:

- Use industry surveys and volumes of error data to identify entities for review
- Implement standard Acknowledgements to gather data on transaction rejections for entity selection criteria
- Include proof of concept and testing to selected entities for review
- Identify entities for review according to random sampling and entity size

Question 6

Recommendations for the logistics for conducting compliance reviews.

We understand that compliance reviews typically are conducted through a variety of different venues, or a combination thereof. For this reason, we requested input from the industry on any logistics that may have proven effective. We received logistics recommendations from five respondents.

- Contract with clearinghouses to randomly sample inbound and outbound transactions for quality control, analyses and reporting
- Automate processing with validation software
- Present results to an expert review panel for evaluation
- Permit compliance parties to have input on venue, such as face-to-face meetings, videoconferencing, conference calls, etc.

Question 7

Any alternative enforcement strategies

We received the most number of responses to this question. While Question 3 provided responses about some of the strengths and weaknesses of the current enforcement process, the responses to this question provided some recommendations for alternative enforcement strategies, and suggestions for reinforcing the strengths of the current system.

- Reach out to relevant trade organizations to foster understanding of the enforcement process with their members
- Allow X12 interpretations of the implementation guides to be binding, and require covered entities to publish their current compliance status with the transactions and code sets
- Solicit public feedback on compliance from providers and vendors
- Establish a compliance certification authority for CMS
- Validate front-end transactions
- Conduct compliance audits that certify health plans both syntactically and functionally
- Capture live transactions

We also received suggestions that were not relevant and/or exceeded CMS' HIPAA enforcement authority. These included

- Implement standard payment rules
- Implement a HIPAA standard code-editing system
- Reduce reimbursements for non-compliant entities
- Give state governments enforcement jurisdiction
- Share monies collected from fines and penalties with the administrative agency and the injured parties

ANALYSIS

Identifying Goals, Gaps and Solutions for the HIPAA Enforcement Process

In a perfect HIPAA world, all HIPAA covered entities would be fully compliant with all of the adopted standards, and conduct all HIPAA standard transactions seamlessly, leaving an enforcement process that addressed only the exception rather than the rule. In those few exceptions, complainants could submit their grievances quickly and easily, without fear of retaliation. Complaints would be collaboratively investigated and resolved timely, and CAPs would demonstrate measurable progress toward expeditious compliance. It is this ultimate goal that the HIPPA TCS enforcement process strives to achieve. Some aspects of the process, such as ease of filing a complaint, and collaborative investigation, already exist. In other areas, responses to the RFI helped to identify gaps that indicate additional work is needed.

We have categorized these gaps as follows:

- Improvement in the reporting of non-compliance with the HIPAA transactions and code sets;
- improvements to the existing enforcement process; and
- The need to make the complaint enforcement process more proactive.

Improve reporting of HIPAA non-compliant transactions and code set violations

Within our enforcement process, we know of only one case of alleged plan retaliation against a complainant; that complaint was investigated, but never validated. However, we are aware through informal stakeholder feedback that there may be a significant gap in our reporting, and that retaliation may occur more frequently than our records indicate, simply because instances of non-compliance and/or retaliation are not necessarily reported to us. While oftentimes it is easier to resolve a complaint when both parties are known to each other, we believe that continuing to offer the option of anonymous submissions helps to reassure complainants who remain concerned about possible plan retaliation that their valid HIPAA TCS complaints can be addressed without fear of retaliation.

We believe that more and better outreach and education regarding the enforcement process will encourage those with legitimate HIPAA transaction and code set complaints to report the violations, stressing to them the very viable option of remaining anonymous throughout the enforcement process; the ease in which complaints can be submitted on-line; and making the ASET tool's availability more widely known throughout the industry.

Improvements to the Existing Enforcement Process

Regarding our existing enforcement, we propose to maintain the current complaint submission process, but work toward resolving what we consider to be gaps in our existing enforcement process. These gaps include the sometimes protracted length of time between the initial complaint filing and final resolution; better monitoring of CAP progress toward complaint resolution; and as appropriate, better use of civil penalties for non-compliance.

Regarding our existing enforcement, we would maintain the current complaint enforcement process, but work toward shortening both response and CAP implementation timeframes. For example, if an initial violation notification letter and subsequent requests for additional documentation sent to a filed-against entity (FAE) each ask for a response within 30 days, the enforcement process can extend for many months. An increased complaint caseload will only exacerbate these timelines, so we likely will review our requirements relative to allowable and reasonable response time. CAPs take even longer. Currently, the amount of time approved for CAP completion is based upon the type of violation, the corrective action requirements, and its approval by the Enforcement Team. For some CAPS, this may mean years before a TCS complaint is fully resolved. For future CAP completions, we may develop more expeditious CAP timelines that limit the compliance period for specific responses and/or implementations.

While we work collaboratively with both complainant and filed-against entity to resolve violation issues in both these instances, we also recognize that we must balance the need for reasonable timing to allow an FAE to make revisions to systems/processes, with the need for expedient closure, which benefits both parties. We may also ask the FAE to provide additional documentation demonstrating timely progress toward compliance, and monitor that progress more closely. In some instances, we have received reports from FAEs that they are making progress toward compliance under a CAP, only to discover as the CAP deadline nears that the progress previously reported was exaggerated and that the FAE would not be able to meet the CAP deadline, necessitating an extension. We need to employ additional tools, including compliance audits if necessary, to determine the veracity of reported progress made toward compliance. If evidence of timely progress toward compliance is not forthcoming, or if the initial CAP expires with no resolution, then we will fully exercise our authority under HIPAA to assess penalties of $100 per person per violation, up to $25,000 per person per standard violation in a calendar year.

Respondents also expressed desire for CMS compliance certification, front-end validation of files, and CMS designation of an authority for the X12 implementation guides.

It is apparent from the feedback that we received that the industry is not aware of the validation tool that is part of the ASET electronic complaint system. While we consider this a

valuable tool, we acknowledge that it only provides validation of transaction compliance at a very basic level. Also, this tool is only accessible if one enters the ASET system to file a complaint. However, there are many commercially-available, front end testing tools available to industry. While we provide the ASET tool for top-level validation as a value-added feature, testing in this instance is ancillary to our main focus on enforcement, and we do not preclude industry's use of other available transaction testing mechanisms. However, we will consider making the availability of the validation tool on ASET more prominent in our outreach and education efforts, ensure that the ASET tool is Version 5010 compliant, and request that if used, the ASET tool results be included in any complaint documentation that is subsequently submitted.

Inherent in this discussion is the need for outreach and education on the ASET system itself, its, validation tool and its functionalities; the steps in the complaint process, and what both complainants and FAEs should expect relative to each phase of the process from submission to final resolution; information on as yet to be established criteria for compliance audit reviews; and best practices and lessons learned regarding HIPAA TCS compliance. Initially, the most expeditious way to conduct this outreach is through our CMS and ASET websites, but we also will explore other opportunities to partner with the industry to push this information out to all interested parties.

We also may consider partnering with the applicable standards development organizations (SDOs) on implementation guide interpretations that are enforcement and/or complaint related, and determine the authority/feasibility under which such interpretations could be binding.

Make the compliance process more proactive

From the Version 4010A complaints submitted through our current HIPAA enforcement process, most common among these are failures to implement all or certain of the adopted transactions. It is our observation that plans are reactive rather than proactive in their approach to adopting the Version 4010A complete suite of standard transactions, reporting oftentimes that "no one has requested" specific transactions, such as eligibility and claim status, as a reason for non-compliance even though the compliance date for the transactions was October, 2003. HIPAA states that a health plan is required to have the capacity to accept and/or send (either itself, or by hiring a health care clearinghouse to accept and/or send on its behalf) a standard transactions that it otherwise conducts but does not currently support electronically. The final rule also states that if an entity requests a health plan to conduct a transaction as a standard transaction, the health plan must do so. Health plans appear to react only when a transaction is requested, versus having the ability to respond using the adopted standard when any of the transactions for which a standard has been adopted is requested.

Plans should stand ready and able to conduct transactions using the adopted standards for all transactions for which the Secretary has adopted a standard, not just those for which a request has been received, or those standard transactions which may be more "convenient" than others to conduct. We need to improve and expand our outreach and education, specifically to the plans, so that they have a fuller understanding of the requirements and CMS' expectations relative to standards adoption.

Other compliance issues we have identified through our enforcement experience involve issues regarding acceptance of, or additional requirements made by, plans relative to use of a provider's NPI; whether or not an entity performs as a health plan and is therefore, a HIPAA covered entity; and the inability of state Medicaid agencies to conduct standard transactions. We recognize that state Medicaid agencies face challenges such as funding and resources, and rollouts of new Medicaid Management Information Systems (MMIS). However, states have various federal resources available to them, and we are working to identify both their current issues with possible Version 4010A non-compliance, and monitor their progress relative to preparations for Version 5010 and ICD-10 code set conversion.

Version 5010 and HIPAA Standards Adoption

We anticipate that the transition to Version 5010 will be much smoother for those entities that have already successfully implemented Version 4010A. However, based upon our enforcement of Version 4010A, we expect a significant increase in complaints for Version 5010. Some entities may in reality be implementing these transactions as new transactions, rather than just upgrades, because they have not yet fully adopted Version 4010A. Some respondents noted that the inability to quickly adopt new HIPAA standards due to the required rulemaking process created a "bottleneck" and was a barrier to compliance, yet it appears that some covered entities are not yet Version 4010A compliant even after all these years. There are instances where we have relied upon backward compatibility of updated standards to their previous versions as a mechanism through which to speed up the standards adoption process. Going forward, the administrative simplification provisions of health care reform legislation may result in a streamlining of this process, placing even more emphasis on the health care industry of the need to be current on HIPAA standards compliance.

Compliance Audits

We believe that adding compliance audits to the TCS enforcement process would yield valuable information that would help inform more widespread industry compliance. Although criteria for the number of audits and selecting audit candidates has not yet been determined, we may consider auditing entities that have a history of non-compliance based on the number of complaints filed against it, as well as highlight entities that demonstrate best compliance

practices. Entity type, geographic location and size could also be considered for selection criteria. Once criteria are established, we plan to publish it on our website. We also intend to publish de-identified audit information and outcomes on our website, and use this information to assist non-compliant entities with achieving compliance, as well as develop lessons learned and education information from entities that have already achieved compliance. We believe that the best approach to determining the feasibility and usefulness of compliance audits is to conduct a pilot project to "road test" various approaches to compliance audits, and apply those lessons learned to a permanent compliance audit program.

CONCLUSION

We appreciate the respondents for bringing many of these issues to our attention. We anticipate that there will be more and different complaint issues relating to Version 5010 implementation. With the emphasis of the American Reinvestment and Recovery Act and Administrative Simplification requirements for checking eligibility and filing claims electronically, and compliance certification requirements under the Patient Protection and Affordable Care Act (PPACA), we see the need for a robust enforcement process that extends beyond the current complaint-driven filing and resolution system, that improves the timing of resolution of enforcement cases, and that adds value to the industry relative to HIPAA TCS compliance . Going forward, we will first address potential changes and enhancements to the existing enforcement process as previously discussed in this document. Concurrently, we will undertake an analysis of the process for initiating compliance audits, including establishing criteria for audit entity selection, timing, and necessary resources, and develop a pilot project to test our assumptions.

Appendix A

List of Respondents to RFI

America's Health Insurance Plans

American Association of Healthcare Administrative Management

American Medical Association

Axiom

Blue Cross Blue Shield Association

Catholic Healthcare West Grassroots Advocacy

Deloitte Consulting LLP

Healthcare Billing and Management Association

Tampa General

Veterans Health Administration

Whicker, Jim

Xifin