

September 22, 2011

The Honorable Kathleen Sebelius
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Madam Secretary:

Re: Observations and Recommendations on the Transition to the Next Version of HIPAA Transaction Standards (Versions 5010, D.0, 3.0) and the ICD-10 Code Sets

The National Committee on Vital and Health Statistics (NCVHS) is the statutory advisory committee with responsibility for providing recommendations on health information policy and standards to the Secretary of the Department of Health and Human Services (HHS). Under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), NCVHS is to advise the Secretary on the adoption of standards and code sets for HIPAA transactions.

In January 2009, HHS published regulations adopting and mandating the use of the next version of HIPAA transaction standards¹ and the replacement of ICD-9-CM with ICD-10-CM (for diagnoses) and ICD-10-PCS (for inpatient procedures) as one of the national medical code sets to be used in conjunction with these transactions.

On December 2009, the NCVHS Subcommittee on Standards held the first in a series of public hearings aimed at monitoring industry progress towards transitioning and implementing the updated standards and code sets and identifying areas for targeted actions. At that time, the testimony led NCVHS to the conclusion that there was sufficient time for the health care industry to prepare for the transition and to comply with the established deadlines of January 1, 2012, for the updated standards and October 1, 2013, for the new ICD-10 code sets.

On June 17, 2011, the Subcommittee held a second public hearing to review the status of industry progress towards the adoption of the updated versions of the standards and code sets. We heard from over 26 individuals representing health plans, providers, clearinghouses, vendors, other government entities, State Medicaid agencies, and even the worker's compensation and property and casualty industries.

¹ ASC X12 Version 5010, NCPDP Version D.0 and NCPDP Version 3.0

In this letter, we offer observations and recommendations regarding the state of progress; the need to reinforce the deadline for compliance, to increase and accelerate industry education and outreach to promote testing the updated versions and code sets prior to implementation; the importance of preparing post-compliance contingencies to ensure business continuity and, most importantly, ensure uninterrupted delivery of quality health care services to patients.

This letter is organized into five sections 1) cross-cutting observations and recommendations, 2) observations and recommendations related to 5010, 3) observations and recommendations related to NCPDP D.0 and 3.0, 4) observations and recommendations related to ICD-10, and 5) other observations and recommendations.

As stated above, this was a well attended hearing, and included testimony from a broad spectrum of stakeholders and industry representatives. We also received additional written testimony from various stakeholders. Importantly, a number of testifiers brought forward information from targeted readiness surveys conducted by the industry. Though the number of survey participants was often small, and only represented entities that chose to respond, the information was useful. We would like to publicly acknowledge the efforts being made by industry in trying to understand and act on the needs of their constituents and in bringing this information forward to the Committee.

Based on a synthesis of the information received in both written and oral testimony, the Committee is making a series of observations and recommendations that it believes can benefit the industry at large.

1. Cross-Cutting Observations and Recommendations

- Overall, testifiers expressed concern for both 5010 and ICD-10 industry readiness.
 - There is consensus that compliance is going to be challenging, particularly for ICD-10, but that the deadlines should be maintained and met. Most concerns focused on providers (small providers in particular), and State Medicaid agencies.
- Importance of unequivocally reinforcing the deadlines for compliance.
 - The majority of testifiers were in support of reinforcing the current deadlines; and only one testifier advocated for delay.

RECOMMENDATION

- HHS should use all communication vehicles to reiterate and emphasize that the compliance dates for implementing 5010/D.0/3.0 and ICD-10 code sets are not changing.

- Concerns about multiple concurrent priorities and funding challenges.
 - Many testifiers reiterated that resources are being shared between 5010, D.0, 3.0 and ICD-10 projects; what happens to one has the potential for impacting the work effort of the other.
 - Similarly, testifiers also described how *other* competing priorities, including the requirements of the Affordable Care Act, Meaningful Use, Accountable Care Organizations, Insurance Exchanges, etc, will make the implementation of ICD-10 particularly challenging.

- Education, Communication and Outreach
 - The Committee heard that “there is never enough” when it comes to education and outreach needs for industry. According to some testifiers, many providers are still not aware of the changes that will be required, and some expect there will be a delay or that a vendor will help them achieve compliance.
 - Industry groups and associations for every covered entity type – health plans, clearinghouses and vendors in particular -- need to significantly increase their education and outreach activities over the next six months, especially for the January 1, 2012, compliance with the updated versions 5010, D.0 and 3.0.
 - There is a perception that there is “room for improvement” at CMS because many inquiries and requests for assistance or information have gone unanswered. According to several testifiers, CMS responsiveness has not been strong.

RECOMMENDATIONS

- HHS should create and deploy clearer, more direct outreach activities over the next six months, especially for Versions 5010, D.0, and 3.0 to promote testing, contact with trading partners, and identifying business change requirements.
- HHS should review and consider leveraging some of the outreach technologies, systems and tools used to promote Meaningful Use.
- HHS should coordinate awareness campaigns with the rest of the industry and consider creating a National HIPAA Awareness Month Campaign within the next three months.
- HHS should direct CMS to dedicate personnel resources and establish a more formal process to receive and respond to industry inquiries, questions, requests for guidance, and FAQ recommendations on a more timely basis. If decisions regarding certain questions or inquiries are not available, more information about the decision-making process and timetable should be made public on the CMS website.

■ Testing, Testing, Testing.

- As reported by many testifiers, testing has proven to be critical to help trading partners identify and address potential implementation issues with the transactions before going live with production systems.
- Many organizations reported they are ready for testing but can't find partners with whom to test. This is similar to the situation in 2002 when Version 4010 was implemented.
- Some initial reports from the first National HIPAA Test Day showed very low participation, particularly in certain sectors (i.e., pharmacy).
- It is clear from survey results that the last two quarters of this year, and particularly the last quarter, will see a very large rush for testing.
- Several testifiers indicated that very few entities have established a testing platform (particularly for ICD-10).
- **RECOMMENDATIONS**
 - HHS should immediately make wide-scale announcements to industry stakeholders, association contacts, and others to more strongly encourage and foster testing between trading partners.
 - Medicare and other industry stakeholders should consider making test scenarios and files more readily available to trading partners.
 - CMS and industry stakeholders should also share the results of their testing of transactions, the issues identified, and how they were (or will be) addressed.
 - HHS should build on the HIPAA National Test Day campaign and expand it to a more comprehensive, multi-part "National Campaign for HIPAA Testing", including establishing rolling "HIPAA Test Weeks" through the end of 2011.

■ State Medicaid Program Readiness

- Several testifiers expressed concerns around the readiness of State Medicaid Agencies' to use Version 5010. Some states have not yet submitted contingency plans to CMS as required.
- CMS has identified at least four states where their State Medicaid Agency will not be ready for Version 5010.
- In virtually all testimony, there were even bigger concerns about the States' Medicaid Agencies preparations to use ICD-10. In fact, according to the CMS Medicaid representative, 41 states reported medium to high risk of not being able to meet the deadline.
- **RECOMMENDATIONS**
 - HHS should establish, communicate and adhere to the deadline for submission of Medicaid contingency plans to CMS.
 - HHS should fund CMS to provide additional technical services and assistance to State Medicaid agencies to support their efforts to

plan, implement and comply with the new requirements and meet the established deadlines.

■ Planning for Business Continuity.

- Any planning efforts must include strategies to be developed in advance of the transition to the updated standards and code sets for how to handle situations after the compliance deadline when a trading partner is not ready to use the updated versions and needs an alternate compliance path.
- Testifiers support the mantra of “Don’t let the perfect become the enemy of the good” when it comes to transitioning to the updated 5010, D.0 and 3.0 standards. This is particularly important to avoid large numbers of transaction rejects and the potential of a relapse to the use of paper for claims or other transactions. A step backwards to paper claims for example, would be disastrous at this point in the evolution towards electronic transactions because health plans have eliminated or significantly reduced staffing to support that kind of paper-based workload.
- There is a perception among many covered entities that version 5010 and ICD-10 are mainly related to Information Technology (IT) or administrative processes; they are not paying attention to the critical changes in business processes and workflows that need to be implemented along with the adoption of the updated transaction standards.

○ **RECOMMENDATIONS**

- HHS should encourage industry to act responsibly and to ensure that access to timely, quality care to patients, enrollees, and consumers will NOT be adversely affected in any way by the transition to the updated versions (i.e., delays or denials of services).
- HHS should encourage industry to focus on the most critical, basic required elements of the transactions, avoid penalizing submitters and rejecting transactions due to minor errors in the early transition stages post-implementation, and wait to implement the more robust, complex portions once all initial issues have been identified and resolved.
- HHS should support Medicare in its efforts to set the example for transitional implementation and compliance.
- HHS should require Medicare to provide guidelines on advance payment policy during transition and other mechanisms to avoid disruption of services, and should require that Medicare set the example by publishing and readying such a policy.
- CMS should establish an “ombudsman” process, in collaboration with relevant and interested associations, to receive requests for assistance and/or policy interpretations. Conceivably, this could be part of the HIPAA enforcement office. Associations and industry

spokespersons would have to encourage their members to use this process.

2. Version 5010 – Observations and Recommendations

- There was some perception among testifiers that vendors of software are not ready or are not providing sufficient communication and direction.
- Testifiers are comfortable with the progress for most transactions, but agree that there is very limited use of the referral and authorization transaction. There are concerns that the transaction does not effectively represent industry business needs.
 - **RECOMMENDATIONS**
 - HHS should instruct Medicare to release data and findings from the June 15 testing event as soon as possible.
 - HHS should encourage industry to take advantage of certification programs to validate its programming and conversions to the updated versions.
 - HHS should encourage the standards organizations to do more to reach out to the user community and to formally identify, define, accumulate and, more importantly, address transaction issues as they are being found from testing and initial implementation.

3. Version D.0 and 3.0 – Observations and Recommendations

- Testing and Adoption - Several testifiers reported issues with lack of testing partners for pharmacy transactions – both D.0 and 3.0.
- Industry is dependent on successful completion of the move to D.0, to ensure the functional viability of 3.0.
 - **RECOMMENDATIONS**
 - HHS should notify NCPDP and other pharmacy groups that a more aggressive outreach and testing campaign is needed.
 - HHS should increase the amount of education, outreach, and promotion on the CMS websites specific to D.0 and 3.0.

4. ICD-10 – Observations and Recommendations

- Crosswalks and GEMs.

- Testifiers explained that there is an ongoing need, which will escalate in early 2012, to educate people on cross-walking and General Equivalence Mappings (GEMs), specifically, their purpose, roles and limitations.
- Many testifiers will not use crosswalks, but rather will do a full code conversion and use ICD-10 code sets natively.
- Some testifiers expressed concern about the “explosion’ of proprietary and vendor-provided crosswalks and their implications, and suggested that additional discussion needed to take place about how to evaluate vendors, the quality of crosswalks, and particularly the quality of the new ‘intelligence’ being built into crosswalks by vendors.
- **RECOMMENDATIONS**
 - HHS should work with associations to highlight the educational and resource information that is already available.
 - Associations should solicit feedback from constituents about the content and quality of available resources so that modifications can be made in the 2011 and 2012 calendar years.

■ Resources for ICD-10

- There are uncertainties about the availability of an appropriate number of coders in the industry -- and their geographic location – making availability of ICD-10 trainers and coders a concern for some testifiers.
- **RECOMMENDATION**
 - HHS should collaborate with an organization such as AHIMA to assess current levels of coders in the industry, the number of coders needed by 2013, and the potential gap, and should invest in expanding educational opportunities and resources to increase workforce capacity and training resources.

5. Other Observations and Recommendations

In an effort to understand broader impacts that could be attributed to the adoption of version 5010 and ICD-10 code sets, we invited representatives from other insurance industries to this hearing – specifically workers’ compensation and Property and Casualty (P&C). Given that there is often a need for health plans to communicate with other insurance carrier types, we wanted to identify potential issues that could affect providers and patients. Furthermore, the Affordable Care Act does require the Committee to consider how and if other industries might use the HIPAA standards, and if they should be required to do so. NCVHS will be holding a hearing later in 2011 on potential areas where standardization will benefit the industry, under the provisions contained in Section 10109 of the Affordable Care Act. These include the adoption of HIPAA standards by workers compensation, auto insurance and Property & Casualty. Additional recommendations in this area will be forthcoming.

- The issues associated with the implementation of 5010 and ICD-10 for workers compensation and P&C are challenging, and not unlike those for covered entities, including lack of information (such as eligibility for benefits, coverage and services) and inconsistent adoption strategies.
- There are unique circumstances associated with the business of workers compensation and P&C and how they relate to implementing 5010 and ICD-10 that require further analysis and consideration.
- The Property and Casualty industry representative discussed the impact of the Medicare Secondary Payer Mandatory Reporting requirements, and how difficult it is to comply with the requirements for certain data elements that are simply not provided to them; yet failure to comply yields significant fines.
- **RECOMMENDATION**
 - HHS should encourage workers compensation and property and casualty stakeholders to implement the transaction standards, code sets, and identifiers adopted by HIPAA, while NCVHS studies and makes further recommendations on how to move these sectors of the industry into more formal HIPAA compliance.

NCVHS has become aware that current e-Prescribing regulations require the use of the ASC X12N 835 Version 4010 standard, and that this has not been updated to conform with the requirement to use the new version 5010.

- **RECOMMENDATION**
 - HHS should make every effort to expedite the process for modifying the e-Prescribing regulations to conform with the new required national standards for administrative transactions adopted in the January 19, 2009 HIPAA regulations, so that by January 1, 2012 the industry does not have to use two different versions of the standard for the same transaction. Considering that the technical change to the e-Prescribing regulation may not be issued in time, HHS should release guidance as soon as possible, to inform the industry how to address the discrepancy in standards after January 1, 2012.

As always, NCVHS believes there are opportunities created by the use of standards, and we embrace such opportunities. However, we acknowledge that there are serious and significant challenges that must be addressed and monitored as the updated versions of the standards and code sets are implemented. NCVHS continues to stand ready to provide additional guidance or assistance to the Secretary as requested.

Sincerely,

/s/

Justine M. Carr, M.D.
Chairperson,
National Committee on Vital and Health Statistics

Cc: Data Council Co-Chairs