March 3, 2010

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

Re: Implementation of updated versions of the HIPAA transaction standards and ICD-10 code sets

Dear Madam Secretary:

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). This committee has legislative responsibility for making recommendations related to the Health Insurance Portability and Accountability Act (HIPAA) and has a broader mandate on national health information policy.

NCVHS recognizes that standards for the electronic exchange of administrative and clinical information are a key component to the success of health information technology initiatives. As the adoption of standards increases, there are new opportunities to ensure the accuracy and consistency of information, and to reduce administrative expenses for all parties. Encouraging health care providers, health plans, vendors, and others in the industry to use these standard transactions and code sets has been a priority of HHS for more than 10 years. Since 2003, HIPAA standards have been adopted and required to be used when exchanging a core set of administrative transactions. Now, as we move to the next version of these standards, and to continue enhancing on the investments that have been made thus far, health care providers and health plans must update some of their business processes and systems.

In January 2009, HHS published two final rules, adopting updated versions of the HIPAA standard transactions (Versions 5010, D.0 and 3.0) and one of the HIPAA code sets (ICD-10-CM and ICD-10-PCS). The updated versions of these standards correct existing technical issues, address new business needs, reduce ambiguities in interpretation and allow for more granular descriptions of the care and services provided to patients. The compliance dates for these two rules are January 1, 2012 and October 1, 2013, respectively.

Although these compliance dates are two and three years away, there is much preparation that must be done by virtually all health care organizations in order to meet these mandated dates. The need for timely preparation is further underscored by the additional simultaneous demand for resources in the implementation for Meaningful Use of Health Care IT in health care offices and facilities.

To understand how the health care industry is progressing in the implementation of Version 5010, D.0 and 3.0 and the ICD-10 code sets, NCVHS conducted two days of hearings on December 9th and 10th, 2009. The Committee heard from diverse panels of subject matter experts, including representatives from physician practices, hospitals, health plans, state Medicaid agencies and standards organizations. Testifiers were asked to address questions pertaining to planning, training, outreach, testing and strategic benefits, such as:

- How is planning being approached?
- What populations of the workforce must be trained on the new standards and code sets?
- What strategies for testing work best, based on past experience?
- What short and long term benefits should be leveraged?

Based on the testimony, it was clear that there are many different approaches to planning and training. Some of the testimony indicated progress and innovation, while other testimony described barriers and inconsistencies. Specifically, we heard the following themes:

1. The importance of adherence to published implementation dates — January 1, 2012 for 5010 and October 1 2013 for ICD-10 code sets. Adherence to the dates is considered critical for planning, testing, and synchronization across the myriad of organizations affected by these changes.

2. The heterogeneity of preparedness to meet these dates across the health care industry (providers, plans and clearinghouses). While some programs are in advanced stages of planning, others have barely begun to evaluate the requirements, due either to lack of awareness or to a belief that the dates will not be enforced.

3. The complexity of implementing ICD-10 code sets poses a greater challenge than implementation of Versions 5010, 3.0 and D.0. This is because of the vast array of processes and programs that use ICD codes, including clinical decision support systems, quality improvement programs, information systems, and administrative, billing, fraud and abuse, and other business functions within a health care organization.[1]

4. A knowledge deficit in several key areas:

[1] The committee wishes to make clear that we are addressing issues related to the differences between ICD-9-CM, ICD-10-CM, and ICD-10-PCS.

a. The complexity of the transition to ICD-10 code sets with respect to the impact on business operations, training and health professions education.
b. How and when to use the General Equivalence Mappings (GEM) for ICD-9-CM to ICD-10-CM and ICD-10-PCS.
c. The perceived need for an official, adopted, and mandated crosswalk between ICD-9-CM and ICD-10 code sets

5. The challenge for State Medicaid agencies to meet the deadlines for 5010 and ICD-10 code sets in the absence of funding and training resources and in light of issues with system procurements.

6. Timely testing between trading partners is critical to the success of implementation.

Based on the testimony, NCVHS has developed a set of eight observations and recommendations for immediate consideration and action by the Secretary. The testimony has led NCVHS to the conclusion that there is sufficient time for the health care industry to comply with the deadlines if education, planning, and testing begin without any delays (see Appendix A for a time line). Therefore, the first observation addresses the need to educate the industry about the compliance deadlines and the need to adhere to these deadlines. The rest of the observations identify issues that need to be addressed to ensure that the compliance deadlines are met. These issues include Observation 2 – Medicaid Readiness; Observation 3 – Implementation Issues; Observation 4 – Vendor Readiness; Observation 5 – Education and Outreach; Observation 6 – Mappings, Crosswalks, and Training; Observation 7 – Testing; and Observation 8 – Directory of Resources.

Observation 1. Compliance Monitoring and Timeline Adherence. When the health care industry warned that they were unable to meet the compliance deadlines for the original HIPAA 4010 and ICD-9-CM implementations, the federal government yielded to these complaints and delayed the dates for industry compliance by more than a year. Many in the health care industry believe that if they delay beginning the process for implementing the updated standards, the federal government will delay the compliance dates again. It is imperative that Department of Health and Human Services communicate now that it will enforce the compliance deadlines for these updated HIPAA transactions.

Recommendations – HHS should:

a. Reiterate in every publication, presentation and public forum, that the deadline for Versions 5010, D.0 and 3.0 is January 1, 2012, and the deadline for implementation for ICD-10 code sets is October 1, 2013. These deadlines have been established by HHS as the law, and there is no justification for changing them. HHS, through CMS, must effectively publicize its commitment to the compliance dates.
b. Highlight the implementation schedule suggested by HHS for internal testing (known as level 1 compliance) and external testing (known as level 2 compliance). Level 1

compliance is expected to be completed by December 2010, so that testing with external partners can begin in January 2011.

c. Support CMS plans to notify the industry of the timeline and consider posting industry "readiness" status on various websites
d. Support Medicare plans for testing and consider adding a third party certification for transaction compliance, including use of a neutral party such as National Institute of Standards and Technology.

Observation 2. Medicaid readiness. Several testifiers described a variety of compliance concerns regarding state Medicaid agencies. State Medicaid agencies, as health plans, are HIPAA covered entities just like commercial health plans and Medicare. Some states testified that they are having severe budget problems (large deficits) due to the economic recession. Other testifiers mentioned procurement issues, MMIS challenges and conflicting priorities. It is clear that state Medicaid agencies must be prepared for the compliance deadlines at the same time as the rest of the industry, to ensure that the value of having improved standards can be reached. Testifiers stated that over the next three years, many states will be re-procuring their claims systems, which is a cumbersome and complicated process. Some suggested that states should be permitted to extend existing contracts to avoid the re-procurement and re-purchase process. This area is important enough that NCVHS will continue to monitor Medicaid readiness through the implementation period.

Recommendations – HHS should:

a. Conduct a risk assessment of Medicaid agencies to assess readiness and risk level for compliance. This would include a survey of states to identify early adopters as well as those at risk. A mitigation strategy should be developed to ensure that the "at risk" states meet the deadlines.
b. Create a reporting format or "dashboard" (a graphical report showing implementation status) and make it publicly available on the CMS website.
c. Explore and assure adequacy of funding provided to states for necessary resource, procurement and training needs.
d. Encourage state Medicaid agencies to use a claims collection process consistent with Medicare and others in the industry. Medicare has a common edit module that may be available to states. Medicare and Medicaid leadership at CMS should pursue this opportunity internally, to determine how it could be implemented and funded.
e. Request that CMS convene the Medicaid vendor community to develop a strategy to ensure the compliance of the MMIS environment.
f. Suggest language to the States for RFPs concerning re-procurements, i.e., require Medicaid vendors to be compliant with HIPAA updated transactions and ICD-10 code sets.

Observation 3. Implementation issues with the standard transactions (5010, D.0, 3.0). As a result of the lengthy process involved in adopting updated standards, the version adopted in 2009, and created several years before that, will not be implemented until 2012. Since the first set of standards was implemented in 2003, there have been many changes in industry practice

and technology. Certainly such changes will continue to occur over the next two years. Thus, the updated standards, though newly adopted, will be four years old in 2012, and may have gaps and discrepancies with respect to current industry practices, making implementation challenging. These gaps and discrepancies must be identified and evaluated in a systematic way to ensure successful implementation. If an identified issue represents a flaw in the standard or implementation specification rather than a training problem, the standards development organization will need to address those with published errata. Several testifiers indicated that there were significant issues with the eligibility transaction in particular. While a number of other testifiers indicated that a variety of problems exist with other transactions under Version 5010, no analysis or public forum has been held to review the issues. Other testifiers expressed concern about the process of updating the standards, and reviewing change requests from industry.

Recommendations – HHS should:

a. Convene an industry meeting, as soon as feasible, to identify issues with each standard transaction, and request a formal response and action plan from the relevant standards development organization. NCVHS stands ready to assist in this process.
b. Request formal feedback from the standards organization to address issues identified by the industry, such as the specific observations about the eligibility transaction challenges.
c. Collaborate with the standards organizations to establish a streamlined, inclusive way to develop, test and adopt standards to avoid such conflicts in the future. It should be noted that this has been an ongoing recommendation from NCVHS and industry for many years.
d. Evaluate the current process and approach of DSMO[2] review and resolution of issues with standards.

Observation 4. Vendor readiness. Many testifiers questioned whether their practice management system or software health care "vendors" will be ready to support the updated HIPAA standards (transactions and code sets). The provider community has a significant dependency on these vendors because of the services the vendors provide in enabling compliance with the HIPAA standards. In particular, safety net and small providers are especially dependent on these vendors, which may be small underfunded enterprises themselves. Though vendors are not covered entities, their ability to provide compliant solutions to the provider community is critical; they too are dependent on cross walks and training being available for their work force. One testifier, the Health Information and Management Systems Society (HIMSS) offered to assist in any CMS efforts to support and monitor vendor compliance.

[2] Designated Standards Maintenance Organizations – DSMO. The organization comprised of the standards development organizations and data content committees designated to maintain the transaction standards.

Recommendations – HHS should:

a. Identify the organizations that make up the vendor community, and engage them in discussions about planning, implementation and testing at the earliest possible opportunity.
b. Include this sector in all communications and surveys to track progress and mitigate problems early.
c. Request the Office of the National Coordinator (ONC) add compliance with ICD-10 codes sets by 2013 as part of the vendor certification criteria for Meaningful Use.

Observation 5. Education and outreach (distinct from training). The transition to the updated HIPAA transaction standards (5010, D.0, 3.0) and code sets (ICD-10-CM and ICD-10-PCS) will require significant information technology and business process changes for every covered entity and their business associates. Therefore, CMS will need to communicate the significance of these changes to ensure that the health care industry understands the need to begin planning and implementation activities immediately.

Recommendations – HHS should:

a. Develop and conduct a coordinated national information campaign in collaboration with key health care industry partners.
b. Discourage the industry from implementing 5010 and ICD-10 code sets in an independent fashion; e.g. waiting for 5010 to be implemented before starting the planning for ICD-10. Planning and implementation for both 5010 and ICD-10 code sets should be done concurrently and in an integrated fashion using the recommended schedule for internal (level 1 compliance) and external (level 2 compliance) testing.
c. Articulate the benefits of moving to 5010 and ICD-10 code sets, by identifying fiscal and business advantages. CMS should identify industry partners who can help identify and promote the benefits.
d. Reiterate that the deadlines for implementation of 5010 and ICD-10 code sets will not be extended.
e. Collaborate with the health care industry to identify sources/resources for small providers to get the right information at the right level and the right time at the most reasonable cost.
f. Ensure that there is extensive communication about Medicare's own implementation plans and actions for compliance.
g. Work with national academic institutions and trade organizations to ensure that training on ICD-10 codes sets is included in medical, nursing, and allied health professions education.

Observation 6. ICD-10 code sets: Mapping, cross walks and training. When ICD-9-CM was being implemented as a standard code set, the industry had been using it for several decades and the workforce had been trained to use it. The use of ICD-9-CM existed in most internal and

external business processes and systems. With the adoption of the ICD-10 code sets, the industry faces an unprecedented workforce training challenge.

While CMS has provided information about the use of the General Equivalency Mappings (GEMs) over the past few years, testimony implied that industry needed more detailed information about how to use the HHS GEMs. In addition to general industry confusion, non-clinical providers (e.g. laboratories) have separate issues with ICD-10 code sets, because the narrative diagnoses they receive must be translated into codes. They currently are able to do this successfully with the ICD-9-CM codes, due to many years of experience, but ICD-10-CM codes require additional expertise which is not yet available. Particularly during this critical implementation period, covered entities need a guide to understand the mapping tools and how best to use them for their own practice purposes. The extent to which the ICD-10 code sets change clinical and business processes within every organization, in virtually every operation, necessitates diverse training in how to use the codes, how to interpret them, how to incorporate them into systems, fee schedules, contracts, billing forms, quality review procedures, fraud prevention etc. There is very little expertise on these code sets because they have never been used in this country; the ICD-9-CM code sets have been the only code sets used for medical billing. Resources and expertise are limited and under high demand.

Recommendations – HHS should:

a. Expand current outreach and education activities regarding the proper use of the GEMs and the risks of simply "cross walking" between ICD-9-CM and ICD-10 code sets.
b. Provide better visibility on CMS' work on MS-DRG conversion project and other activities related to replacement of ICD-9-CM within CMS data systems.
c. Provide variety of ongoing training options (e.g. web based on ICD-10 code sets, regional office expertise, etc.) to industry.
d. Provide funding to train trainers in the regional offices and in professional associations that support different segments of the health care industry.
e. Support, with financial backing, health care industry training programs on ICD-10 code sets.

Observation 7. Testing. It is critical that internal systems are tested for readiness, along with testing between trading partners to ensure that transactions can be processed. Testing must be carefully coordinated due to the huge transaction volume that must be processed between thousands of health plans and hundreds of thousands of providers, who partner with a few hundred clearinghouses.

Recommendations – HHS should:

a. Solicit information from the industry about best practices for testing strategies and share those strategies on multiple websites and within other communication strategies.
b. Identify organizations, including Medicare, which would be willing to share test scripts, and create a work group to post those scripts for public use.

c. Encourage vendors and/or clearinghouses to set test dates as early as possible and to collaborate with other early adopters.

Observation 8. Lack of central "directory" of resources for services, assistance and collaboration. Health care providers, health plans, and vendors are embarking on changes to systems and processes that are unprecedented and systemic. Though all organizations must accommodate these changes, there is no centralized resource for information sharing, best practices, or services, or centralized information or tool kits. Many entities, particularly smaller ones, often struggle to find resources and solutions, and are not able to take advantage of the skills or knowledge of larger organizations with more resources.

Recommendations – HHS should:

a. Work with industry to establish a clearinghouse for the information referenced in recommendation 8b below.
b. Support development of toolkits, checklists, lessons learned and best practices to be shared through the industry "clearinghouse" for purposes of testing, implementation, training, etc. These toolkits may need to be developed and/or organized to focus on helping specific organizations, such as safety net providers, other medical practices, hospitals, health plans, and/or vendors.
c. Encourage health plans to share best practices in ways that do not compromise proprietary information about systems and strategies.

Finally, there were several other "points of interest" from the testimony, including suggestions that HHS look into the impact of ICD-10 code sets on Long Term Care organization assessments, validate and correct errors or gaps in the Medicare companion guide, and determine how to encourage the worker's compensation and auto insurance industries to consider using the HIPAA standards, since these industries are specifically excluded in the legislation.

NCVHS believes there is an opportunity created by both the American Reinvestment and Recovery Act and the potential of Health Reform to increase adoption of health information technology tools to improve the effectiveness of the health care system. NCVHS embraces opportunities for success, while believing that there are some serious and significant challenges that must be addressed and monitored. In particular, we wish to highlight the importance of timely implementation of healthcare information standards and code sets thus ensuring interoperability of health care information. Certain actions need to happen quickly, to capitalize on the opportunities presented by the updated standards and code sets and support the goals of administrative simplification. To accomplish these goals, NCVHS recommends that HHS implement these recommendations.

NCVHS continues to stand ready to provide additional guidance or assistance to the Secretary as requested.

Sincerely,

/s/

Harry L. Reynolds, Jr.
Chairman, National Committee
on Vital and Health Statistics

cc:
James Scanlon
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1 Enc.

Appendix A: A Time Line for Moving to 5010 and ICD-10 Implementation*

	2010	2011	2012	2013
5010	• Implementation strategy in place • Define functional requirements • Develop systems • Begin internal testing	• Complete internal testing • Begin external testing with trading partners, end-to-end testing of systems	• Compliance on January 1st	
ICD-10 code sets	• Complete impact assessment • Investigate tools, e.g., GEMs • Define functional requirements • Determine implementation strategy • Complete coder training • Determine who needs training other than coders	• Complete system to accommodate ICD-10 code sets • Begin training other health professionals who work with ICD codes • Begin conversion of policies and contracts	• Continue training • Complete internal testing • Complete end-to-end testing with partners • Complete conversion of policies and contracts	• Complete external testing with partners • Complete training of all health professionals using ICD-10 code sets • Compliance on October 1st

*Time Line based on work by the American Health Information Management Association, http://www.ahima.org/icd10