

September 21, 2012

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

Re: Findings from NCVHS Hearings on Administrative Simplification in June 2012 – an Update on Health Care Administrative Transactions

Dear Madam Secretary,

The National Committee on Vital and Health Statistics (NCVHS) is a statutory advisory committee with responsibility for providing recommendations on health information policy and standards to the Secretary.

The Committee is pleased to present findings from a recent hearing with industry held in June of this year, during which we heard from industry experts on a wide range of issues, including:

- Lessons learned after the first six months of implementation of new versions of HIPAA transactions (version 5010, D.0 and 3.0)
- Industry feedback on the proposed delay in the compliance date for ICD-10 code sets
- Industry readiness for the implementation of the first set of operating rules to support standard transactions
- Concerns about end-to-end testing and the certification process as it applies to the implementation of the standards and operating rules and the new penalties under the Affordable Care Act (ACA)
- An update from the Designated Standards Maintenance Organization (DSMO)
- Issues about a new voting infrastructure in the dental code content committee; an overview of the innovative work with unique device identifiers from the FDA and the State of California; and finally, health plan perspectives on the compliance certification process required to be established under the ACA

Though the topics were diverse, several themes were consistent across all of them. Industry is at a tipping point in the midst of accelerated changes and

complexity. Succeeding in this environment requires innovative and effective ways of stakeholder collaboration, convergence, cooperation, communication, transparency and testing.

Furthermore, as industry is spending significant resources to meet the mandates, it is looking for a greater focus on prioritization and timing of adoption of these changes. Ultimately, the goal is to achieve these changes in a way that will provide maximum benefit, while minimizing disruptions to the provision of care.

This letter summarizes first some of the most significant findings and observations on each of the topics covered during the hearing, followed by a discussion on common themes and recommendations to the Department of Health and Human Services (HHS) for action.

A. 5010, D.0 and 3.0 – Issues, Approaches to Solutions and Lessons Learned

During this portion of the hearing we heard testimony from providers, health plans, clearinghouses, vendors and billing services, the pharmacy industry, Medicare (fee-for-service), and WEDI.

Overall, after the first six months of implementation of the new version of HIPAA transactions, the industry is still adjusting and working towards achieving full compliance. Some of the most salient issues cited in testimony included:

- Delayed availability of software prior to the compliance date
- Delayed testing, and not full, end-to-end testing done prior to the compliance date
- Inconsistency in testing done prior to compliance
- Publication of Errata documents by the SDO, which impacted implementation

All transition issues identified and reported thus far seem to relate exclusively to interpretation and implementation of the standards rather than issues associated with the adopted standards per-se. Most issues would have been able to be addressed if full, end-to-end testing had been done well in advance of the compliance date. In the pharmacy sector, almost all organizations have successfully moved to the new version (D.0) of their transactions.

The approach used in the regulations of allowing both the current and the new versions of the transaction standards to be used concurrently during a one-year transition period prior to compliance was reported to be very valuable.

However, experience showed that while important testing was done during the transitional year, it was not widespread, nor was it done sufficiently in advance of the compliance deadline to avoid many of the issues that occurred after the compliance date. They would have been avoided with earlier, more thorough testing.

Opportunities and changes to be considered, as reported by testifiers, include the:

- Benefit of having a central, objective location to log transition, testing and implementation issues similar to what OESS and WEDI organized during the first enforcement discretion period (this is not just for transactions, but also for code sets, identifiers, operating rules, etc.) to augment the problem identification and resolution process
- Value of adopting and consistently implementing the Acknowledgment transactions, which would address many of the issues encountered in the rejection/re-submission process
- Importance of establishing more detailed milestones for the transition period that are spread out throughout the entire period (for example, focusing first on syntax compliance, then on rules for existing content, then on new content)
- Increased emphasis on testing early, fully and often
- Expanded educational opportunities before and during transition period

A key message from testifiers was for CMS and NCVHS to consider looking at the entire process for adopting and implementing standards and operating rules and to define a new roadmap that takes into account appropriate sequencing, timing, and understanding the impact of other mandates (including, but not limited to Meaningful Use and Health Reform).

It is important to emphasize that there were no reports made about direct patient care being affected by issues with the transition.

B. Operating Rules for Eligibility and Claim Status – Preparing for Implementation

On January 1, 2013, the first set of operating rules for two HIPAA transactions (eligibility and claim status) will become effective. Generally, testifiers reported that while some organizations are well into their preparation plans for compliance (mainly, those that have already voluntarily adopted the operating rules now required under regulations), many in the industry are only at the assessment level, and not moving as fast as necessary for a successful transition to the new rules by the compliance date. Delays in compliance with

the new version of the transactions are making matters more difficult. Some of the most significant concerns noted included:

- Practice management systems may experience challenges meeting the connectivity and performance rules
- Providers that have not yet completed their full transition to 5010 for those two transactions (in other words, are not yet using the eligibility and claim status transactions in Version 5010)
- Domino effects - delays completing the transition to 5010 will have an effect on implementing the new operating rules
- System level issues exist, including the lack of coordinated networks of people that should connect all relevant components of the organization responsible for implementing the operating rules
- Implementation level issues exist, including the impact on workflows, revenue cycle, and cost and resources
- There is a lack of reaching out to the highest executive levels in organizations to make them aware of, and emphasize the value of, the benefits and savings of the new operating rules

Where to focus on in the coming six months:

- Testing: send a strong message that testing of the new operating rules should have started already, and that testing should continue through the remainder of the year
- Outreach: consider a high-level communication from HHS (via CMS) to industry CEOs/CIOs regarding the upcoming requirements, as well as more systematic and frequent communications from CMS to the industry regarding the upcoming requirements, transition periods, testing milestones and compliance dates
- Monitor: consider establishing a web-based voluntary registration process to identify and document the status of entities' efforts towards compliance with the new rules
- Coordination: health plans (including Medicare and Medicaid) should have a consistent message regarding testing and implementation of the new operating rules

C. ICD-10 Code Sets: Strategies and Recommended Milestones to Achieve a Successful Transition

The main purpose of this portion of the hearing was to identify concrete milestones to be achieved between now and the compliance date that would help ensure a successful transition to the updated code sets. The industry's assumption, given the Spring 2012 proposed rule from HHS, was that there would be a one-year delay in the compliance date. We were pleased to see that

on August 24, 2012, HHS did publish a final rule, announcing an extension of one year, to October 1, 2014.

Across the board, testifiers emphasized the importance of HHS and the industry to: 1) stay the course by ensuring that no more delays on the deadline would be considered; 2) maintain the momentum of the process; 3) minimize disruptions in the business of delivering care, and 4) emphasize that the additional year will provide extra time to plan, prepare, and execute end-to-end testing of systems and processes, as well as to prepare people in the organization for the change. Other observations made were that HHS should:

- Develop a single strategic plan and roadmap for an orderly transition to ICD-10 code sets
- Support the development and implementation of trading partner testing pilots, with documented outcomes shared broadly
- Announce and execute a freeze on code changes well in advance of the final compliance date
- Continue to develop and release the crosswalks and maps among ICD-10 code sets and other code sets, including ICD-9-CM and SNOMED
- Consider convening a group of organizations representing key stakeholders that can serve as early adopters during the transition period, and as a forum to identify and address issues early in the process
- Promote the establishment of test scenarios and test methods, including sample test data sets for use by industry to ensure clinical consistency and financial neutrality.

D. Dental Code Set Updates and Considerations

The current HIPAA designated code set used in electronic dental data interchange is the Code on Dental Procedures and Nomenclature, commonly known as CDT or Current Dental Terminology (CDT). For the past ten years, the code set has been maintained by the Code Revision Committee (CRC), supported by the American Dental Association (ADA) and involving key major stakeholders.

The original agreement that ADA had with stakeholders to operate the CRC expired in June, 2011, and since then, ADA has instituted a series of changes to the CDT review process, including dissolving the CRC and forming a new Code Advisory Committee (CAC). Dental health plan representatives argued that the new CAC shifted the previous voting balance between providers and payers to an increasingly controlled provider structure. They noted that under the new CAC, the ADA made several modifications to the CDT, including revisiting codes that had been rejected by the previous CRC, as well as introducing new submissions that would eliminate many existing code

descriptors, a critical component of the code set that helps providers understand what elements of care a procedure code represents.

The ADA also decided to begin updating the CDT annually, rather than every two years, a change that may increase costs for its adoption and use, as noted by the dental health plan testifiers. One additional concern noted in testimony was the lack of rigorous scientific and objective criteria for the evaluation and approval of new codes introduced into the CDT.

Dental health plan testifiers recommended that NCVHS review and provide further oversight over the governance and the openness of the process of reviewing, adopting and incorporating new codes into CDT. At the hearing, testimony was offered by ADA (and corroborated by others) that important adjustments to the changes instituted since 2011 to the code committee were being made in the past month, and that additional participation, representation, and openness in the process were being considered. It was recommended that NCVHS closely monitor the implementation of these new changes and request a report from the ADA and dental health plan representatives by the end of the year. Furthermore, it was suggested by testifiers that NCVHS look into the maintenance process of all HIPAA-named standard code sets to ensure openness and transparency in the processes, and that documented business needs and sound evidence be considered when identifying, reviewing, adopting and incorporating new codes into these code sets.

E. ACA Health Plan Compliance Certification

The ACA requires that health plans file a statement with HHS by December 31, 2013, certifying that the health plan's data and information systems are in compliance with the adopted standards and operating rules for eligibility, claim status, health care claim payment, and electronic fund transfer transactions. Health plans must file a second statement by December 31, 2015, certifying that their data and information systems are in compliance with the adopted standards and operating rules for health care claims, enrollment, premium payment, referral authorization, and claim attachment transactions. Compliance certification statements will be required thereafter for any revised standard or new standard adopted by no later than the date of compliance.

The purpose of this portion of the hearing was to hear perspectives on the compliance certification process overall, the methods/mechanisms that should be used to fulfill such certification, any supporting documentation needed, and the expectations needed to ensure that business associates of the health plan are complying with the applicable compliance certification requirement.

Overall, testifiers agreed that the compliance certification process should be kept as simple, practical and operationally efficient as is possible. Attestation of compliance supported by sample reports was suggested as the preferred, primary method to be used. External voluntary validation and certification through known and well-recognized organizations (i.e., accreditation bodies, operating rules certifiers, HIPAA external testing organizations, etc.) were also suggested. The Secretary, under discretionary authority, can designate independent organizations that conduct certification for some or all areas required. These services would be available for use on a voluntary basis by health plans and their business associates.

Defining key terms will also be critical, including readiness, end-to-end testing, compliance, etc. Key indicators of readiness, as suggested by one association, could include:

- Completion of all practice management system upgrades;
- Confirmation of successful testing with direct submission carriers;
- Confirmation of successful testing with clearinghouses where applicable;
- Confirmation of successful production submission of claims (837); and
- Confirmation of successful retrieval of the claims' associated remittance (835).

There were also strong concerns expressed at the fact that this requirement only applies to health plans and not other covered entities subject to compliance with the same standards and operating rules. It was suggested that HHS consider mechanisms to bring in the other covered entities, including strongly encouraging voluntary compliance certification.

With respect to the requirement that documentation be provided showing completed end-to-end testing, it was suggested that CMS should 1) clarify that this is intended to apply to testing with trading partners and that it not be required with each and every trading partner but with a sample of trading partners, 2) provide documentation guidelines that focus on simple interchange reports documenting such testing, 3) consider publishing a high level testing schedule example to serve as guidance for health plans and to emphasize to the entire industry the importance of early planning and testing.

F. Common Themes Across Hearing Panels

While the hearings covered a variety of topics, the Committee identified a series of key common themes, observations and recommendations. They include:

- **Roadmap.** Need to develop a strategic plan and a road map for adopting and implementing standards and operating rules in a coordinated,

sequential, timely, efficient, and cost-effective manner. The Committee believes that the time has come to step back and look at how all the current and upcoming health IT initiatives (including those related to administrative simplification, quality measurement, payment reform, meaningful use, and health reform) need to fit appropriately into a comprehensive, overarching strategy and plan, rather than continuing to address items and components on a fragmented basis. Priorities should be driven by values and benefits, and not by prescribed dates.

Recommendation 1: CMS should convene a listening session with key stakeholders to discuss the development of such a roadmap.

- **Collaboration, Coordination, Openness, Transparency.** Across the board, these four principles consistently resonated during the hearings. Every effort should be made to ensure that in the development, assessment, adoption, implementation and evaluation of standards, these core principles are met.

Recommendation 2: Incorporate these four principles into the roadmap for future standards work.

- **Testing.** This step in the planning and preparation for implementation continues to be mentioned as the most critical one to achieve. Yet, testing is not consistently executed and is usually not planned effectively, or given sufficient time to be fully completed prior to the compliance date, to allow it to identify and correct fatal, critical or significant errors or issues.

Recommendation 3a: Consider requiring testing as part of the transition steps towards the implementation of new standards and operating rules. Standards and operating rules must meet testing requirements and documentation of such testing (findings and results) must be made available to the industry.

Recommendation 3b: HHS should convene an industry working session to discuss and define a more effective and formal testing plan, including establishing a mechanism for the industry to report testing start-up and progress, and share experiences and issues identified during the testing process, as well as more effective mechanisms for timely monitoring of testing work being done during the transition period.

Recommendation 3c: Specific to ICD-10 code sets, CMS should expeditiously promote the establishment of test scenarios and test methods, including sample test data sets for use by industry to ensure

clinical consistency and financial neutrality. *NCVHS looks forward to receiving reports on the status of ICD-10 code set testing on a regular basis.*

- **Education and Outreach.** Need to enhance communication, education and outreach efforts to all industry sectors. Need more “how to” and real technical assistance rather than just awareness and informational.

Recommendation 4: *CMS should increase industry-oriented communication programs and collaboration initiatives, which are needed to increase access to technical assistance and encourage development of industry resources to resolve implementation challenges early in the process. Outreach should be targeted to help safety net providers and small entities with limited resources.*

- **Acknowledgments.** As demonstrated through testimony provided during this and previous hearings, the Acknowledgment transaction is a critical component of the complete cycle of electronic data interchange in health care, and adopting and implementing the standards for this transaction are imperative.

Recommendation 5: *HHS should adopt the NCVHS recommended standards for Acknowledgments as soon as possible.*

- **Monitoring.** With an expanded suite of transactions, standards, operating rules, code sets, identifiers, and privacy and security requirements, monitoring the progress, successful implementation, industry issues, and ultimately the value and benefits derived from these requirements are critical functions that need to be accomplished more systematically.

Recommendation 6: *Secure funds to enable CMS to conduct a professional industry-wide assessment of adoption and use of the full suite of standards and operating rules (baseline followed by post-implementation comparisons in 2014 and 2016).*

- **Enforcement.** CMS/OESS should enforce what is in the regulations by conducting sample pro-active compliance assessments of each covered entity types, and should validate that appropriate pre-implementation testing is being done satisfactorily.

Recommendation 7: *Fund CMS/OESS sufficiently to both conduct an adequate sample of compliance audits in accordance with its authority, and use the findings to develop and implement outreach and education*

programs to address specific industry implementation challenges with standards and/or operating rules.

In summary, the Committee believes that the emerging **convergence** of clinical and administrative data, transactions and standards provides tremendous opportunities to further harmonize data and better coordinate adoption and implementation. This will continue to improve industry adoption of changes and optimize the value of these initiatives.

As always, we continue 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: HHS Data Council Co-Chairs