

September 20, 2013

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

Re: Findings from the June 2013 NCVHS Hearing on Current State of Administrative Simplification Standards, Code Sets and Operating Rules

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). 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. The Patient Protection and Affordable Care Act (ACA) [Sec. 1104. (g)(3)] enacted on March 23, 2010, calls for NCVHS to assist in the achievement of administrative simplification to “reduce the clerical burden on patients, health care providers, and health plans.”

Each year the Committee holds industry hearings in June to evaluate and review the standards, code sets, identifiers and operating rules adopted under HIPAA and ACA, and determine whether there is a need for updating and improving any of these standards and operating rules.

The Committee is pleased to present in this letter findings from our June hearing. The letter summarizes first a series of common themes across the various topics covered during the hearing, followed by findings, observations and recommendations on each of the main topics discussed.

Significant changes have been taking place in terms of number, scale, pace and timing over the past three years – implementation of ASC X12 version 5010, NCPDP version D.0, Operating Rules, Meaningful Use – and a number of transformative changes are coming – care delivery reform, payment reform, insurance exchanges, ICD-10 code sets implementation, next phases of Meaningful Use. Implementation strain remains a constant theme, as the industry continues to cope, embrace and adapt to these changes, let alone

understand and achieve the overall benefits and value, and the true efficiency and effectiveness improvements from a clinical and administrative standpoint.

The Committee presents several observations and recommendations which focus on the following key points.

- Staying the course on ICD-10 code sets compliance deadline. It is paramount that HHS remains steadfast and commits to the October 1, 2014, deadline for ICD-10 code sets transition.
- Emphasis on education, outreach and guidance activities. HHS should further provide succinct and practical guidance, assistance and support to the industry, particularly to smaller health care organizations, for upcoming major mandates such as ICD-10 code sets. Implementation and adoption of these mandates and changes often take multiple years.
- Defining a Roadmap for Standards. Mandates typically have post implementation issues, if not suffering delays or incomplete implementation and adoption. Delays or incomplete implementation from one mandate often impacts subsequent mandates, e.g., HIPAA 5010 is a pre-requisite for ICD-10 code sets implementation. Due to competing mandates, priorities, changing standards and evolving policies, it is imperative for HHS to rationalize the pace, scope, scale and timing of critical HHS / CMS initiatives.

The following observations are drawn from the testimonies that reflect these challenges and opportunities.

Status of ICD-10 Code Sets Planning, Testing and Implementation

Testimony we heard during the hearing contained a clear, consistent and strong message of the following points:

- The October 1, 2014, deadline for compliance with the adoption of ICD-10 code sets should not be modified. Larger health plans and provider organizations are reportedly on track, but small and medium size providers and facilities remain a challenge.
- Testing – both end-to-end and content-based – remains the single, most important preparation step for the remaining 12 months. Strong concerns were expressed regarding the recent announcement by the Medicare Fee-for-Service program that they will not be conducting end-to-end testing with trading partners.
- Access to the ICD-10 code sets-based version of the CMS Hierarchical Condition Categories (HCCs) being used by Medicare to model capitation payment adjustments is critical, as is finalizing cross-walk tools and

intensifying education and outreach, particularly to small and medium-size health care organizations, and sharing ICD-10- related health plan payment policies in advance with trading partners.

- There are still concerns among providers about correct code selection, payment equivalencies, clinical documentation and potential loss of productivity.
- ICD-10 code sets should be aligned with the implementation of the EHR Incentive Program, the EHR certification program, and the use of SNOMED-CT for codifying and exchanging clinical information between electronic health record systems.
- Clearinghouses and practice management vendors will play a significant role in supporting provider-payer communication of ICD-10 coded transactions. And there are concerns about the degree of preparedness of these entities to appropriately support their provider and payer trading partners.

Recommendation 1: HHS should continue to emphasize its intent NOT to change the current deadline for compliance with ICD-10 code sets of October 1, 2014.

Recommendation 2: CMS should establish and publicize a series of realistic and actionable interim testing milestones to be achieved during the remaining 12 months before the October 1, 2014, compliance deadline.

Recommendation 2.1: CMS should clarify and communicate that its Medicare-Fee-For-Service Program has a testing strategy that will ensure a smooth transition to ICD-10 code sets.

Recommendation 2.2: CMS should encourage clearinghouses and vendors to communicate their ICD-10 code sets testing and transition plans more explicitly and clearly to their trading partners. Providers should be encouraged to demand access to such plans.

Recommendation 2.3: CMS should support and actively participate in the Healthcare Information and Management Systems Society (HIMSS) – Workgroup on Electronic Data Interchange (WEDI) ICD-10 National Pilot Program, establish high-level criteria for readiness, leveraging the pilot programs currently underway, and provide readiness guidance and framework for smaller and medium size entities.

Recommendation 2.4: CMS should reassess Medicaid ICD-10 preparedness and help address the disparity in readiness across Medicaid programs, since state Medicaid programs impact local adoption of major changes such as ICD-10 code sets.

Recommendation 2.5: CMS should work with HHS partners to explore the possibility of leveraging Department-funded education and training centers (e.g., Centers of Excellence, or ONC's Regional Extension Centers) to help reach smaller practices and develop targeted education and outreach activities related to the transition, testing, and adoption of ICD-10 code sets.

Recommendation 3: CMS and the health plan industry should disseminate their ICD-10-related claim payment policy guidelines aimed at clarifying payment equivalency when moving from ICD-9 to ICD-10 code sets.

Recommendation 3.1: CMS should share its Medicare and Medicaid ICD-10- related payment policies with the industry; private payers should do the same.

Recommendation 3.2: CMS should share with the industry, as soon as possible, the ICD-10-based Hierarchical Condition Categories (HCCs).

DSMO Report and Status of Current Version of Transaction Standards (5010, D.O, 3.0)

The Designated Standards Maintenance Organizations (DSMO) is an important industry-led process established to identify and address issues with existing standards, as well as collect, review and process requests for changes to those standards, for possible adoption in future versions. The DSMO report also serves to advise the Committee as to the need for adoption of new versions of standards and implementation specifications that are necessary to permit compliance with existing or new laws or regulations.

One of the most important elements of this year's DSMO report was the confirmation that a formal recommendation for adoption of the next version of

HIPAA transaction standards is not likely to come to the Committee until sometime in mid- to late-2015 for possible adoption and implementation.

Recommendation 4: HHS should work with the DSMO to inform the industry that the current version of the transaction standards (5010, D.0 and 3.0), in effect since January, 2012, is not expected to change until sometime in 2017 or later.

This constitutes an important milestone to be included in the standards roadmap being developed by the Committee.

The transition to version 5010, D.0 and 3.0 transaction standards took place in January 2012, with enforcement date extended to July 2012, and compliance with these versions has been largely achieved. Providers, payers, clearinghouses and other trading partners are now sending and receiving administrative transactions electronically using these new versions of the standards, with no reports of issues with respect to the technical specifications and use of the standards.

Still, industry estimates show that approximately 80% of the providers have successfully moved to 5010, while 20%, mainly small providers, continue to use the previous version (4010). They are achieving compliance via the use of “translator” tools and/or clearinghouse services, which provide cross-walking capabilities between the two standard versions.

However, with the adoption and implementation of ICD-10 code sets by October of 2014, there will be significant ramifications for those entities continuing to use the 4010 standard, as 4010 does not support the use of the new ICD-10 code sets. Assignment of medical codes by a provider is based upon clinical notes contained in the patient’s medical record. No translator tools currently can crosswalk between ICD-9 and ICD-10 codes, nor are clearinghouses allowed to change a provider-submitted ICD-9 code to an ICD-10 code. It is important for these providers to transition to 5010 now, to avoid possible claim processing and reimbursement disruptions. Failure to transition to 5010 may result in inaccurate, untimely, or non-payment situations that may adversely affect the delivery of, and access to care in local communities where providers and payers are still using 4010.

Recommendation 5: HHS should work with the industry to identify current 4010 users and develop a targeted outreach campaign explaining the implications for not migrating to 5010 in advance of the adoption of ICD-10 code sets.

With respect to pharmacy transactions, there were strong calls for action on needed enhancements to the current standard for pharmacy claims. The Committee already acted on this issue and submitted a separate recommendation in a letter to the Secretary on June 21, 2013.

Several testifiers noted the need to adopt standards for the electronic *Acknowledgement* transactions. Industry feedback continues to consistently highlight the critical role and the many benefits that adoption and consistent use of standardized Acknowledgements will bring to the industry.

Recommendation 6: HHS should act upon the NCVHS recommendations on standards for Acknowledgement transactions as communicated in the NCVHS letters to the Secretary dated September 22, 2011, and September 21, 2012, as soon as possible.

Status of Development and Implementation of Operating Rules

Under ACA, Operating Rules were added as a new set of standards to advance administrative simplification. This new set of standards complements the other six major components of health care standardization: transaction standards, implementation specifications, code sets, identifiers, and privacy and security.

The first set of Operating Rules, for eligibility and claim status transactions, went into effect January 1, 2013. The second set of Operating Rules, for electronic remittance advice (claim payment) and electronic funds transfer will go into effect January 1, 2014. The third set of Operating Rules, for all remaining transactions (claims, claim attachments, prior authorization, enrollment, and premium payment) are to be evaluated by the Committee next year for possible recommendations for adoption.

The most significant findings and observations on Operating Rules from the June hearing included:

- The authoring entity for operating rules, the Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules for Information Exchange (CORE), has undertaken a significant number of activities over the past few years related to planning, developing, vetting, testing and finalizing operating rules, and will continue to build awareness and expand industry involvement, support implementation, test adoption, conduct ongoing maintenance and identify future operating rules.

- Compliance status with the first round of operating rules is strong among commercial health plans and some clearinghouses. Provider adoption is facing challenges around available technical and business resources, coordination with multiple trading partners, inconsistent use, and varying entry levels. Organizations are reporting value with the use of the first round of operating rules.
- With respect to the second set of operating rules, entities completing the first round of operating rules were well underway with implementing the second set, while other organizations are either at an early awareness or planning stage as they move towards compliance.
- There were also concerns expressed by testifiers regarding the degree to which covered entities are actually conducting and using the underlying transactions (eligibility and claim status) to which operating rules apply. According to the testimonies, smaller providers and health plans are not using these transactions to improve efficiency, relying instead on manual processes. This is due to reliance on practice management system vendors, implementation cost for system and process changes, and lack of resources and expertise to evolve their practices.
- Another concern raised by testifiers was the negative impact that non-HIPAA covered entities, such as practice management system vendors, have on the adoption of HIPAA standards by providers, by failing to incorporate the required standards into their products.
- Testifiers also identified issues and challenges with the process for developing and maintaining operating rules.
- Regarding the third set of operating rules, CAQH CORE is currently surveying the industry to identify needs for operating rules for each of the remaining transactions, will provide an update on the status of development to the Committee by the end of the year, and intends to submit any recommended operating rules during the first quarter of 2014.
- CAQH CORE is also committed to continue to work to expand industry involvement, support industry investment and measurement of benefits and value, and refine and improve implementation support and the process of development and maintenance of operating rules, based on industry feedback.

Recommendation 7: HHS should consider designing and implementing targeted assistance and outreach programs directed at smaller providers to improve their understanding of the importance of using HIPAA transactions and operating rules.

Recommendation 8: HHS should work with NCVHS, CAQH CORE, and industry stakeholders to make a more comprehensive assessment of 1) the level of adoption and use of operating rules; 2) the value and benefits of adopting Operating Rules that apply to

multiple transactions that comprise business processes, rather than establishing Operating Rules on a transaction by transaction basis, so that end-to-end administrative and business processes are optimized, and 3) the relationship and opportunities offered by operating rules to support health reform.

2013 WEDI Report

We are very pleased to learn about the efforts that WEDI is undertaking to develop a new industry report this year, on the occasion of the 20th anniversary of the landmark 1993 WEDI Report, which paved the way for the development of the 1996 HIPAA Administrative Simplification Law. We applaud this effort, led by the Honorable Louis W. Sullivan, MD, former Secretary of HHS, who spearheaded the development of the 1992 report and the creation of WEDI.

We believe this report will help identify concrete ways to accelerate the attainment of the goals and benefits of administrative simplification and standardization, as well as new areas to achieve more efficient and effective health care system processes and information exchanges, within the context of new care delivery and payment reform.

The Committee will continue to collaborate closely with WEDI on this important effort.

Impact of the Health Insurance Exchange (HIX) capabilities on standards

The HIXs or Marketplaces have profoundly changed the business rules and processes between the FFM (Federal Facilitated Marketplace), or the state exchanges, and the health plans. As the current HIPAA 5010 transactions are being used, albeit with adjustments to how they are applied in the Marketplace environment, we will need to review and monitor the implications that new electronic information exchanges needed to support HIXs will have on current and future standards, specifically around enrollment, premium payment, eligibility, quality reporting, bundled payment, and other forms of payment reform.

Concluding Comments

The health care industry is experiencing major transformative changes as a result of the confluence of various national, regional and local initiatives, including the Affordable Care Act, adoption of electronic health records and the

Meaningful Use program, implementation of national messaging and vocabulary standards for clinical exchanges, establishment of regional health information exchanges, and adoption of new administrative standards, including new versions of HIPAA transactions, operating rules, ICD-10 code sets, and Health Plan ID.

NCVHS recognizes the challenges that the industry faces today and will experience over the coming years to adjust to these transformative changes, and will continue to work with the Secretary and industry stakeholders to develop and advance a 2020 vision and a roadmap for E-Health standards. We will continue to support your efforts to increase adoption of standards and operating rules that help move the industry forward with technology to achieve greater efficiency.

Sincerely,

/s/

Larry A. Green, M.D. Chairperson,
National Committee on Vital and Health Statistics

Cc: HHS Data Council Co-Chairs