September 23, 2014

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

Re: Findings from the June 2014 NCVHS Hearing on Health Care Claim Attachments

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 (DHHS). Under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), NCVHS advises the Secretary on the adoption of standards and code sets for the HIPAA transactions. The Patient Protection and Affordable Care Act (ACA) (Sec. 1104 (b) 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, NCVHS holds industry hearings on standards, code sets, identifiers and operating rules adopted under the HIPAA and the ACA to evaluate the need for updates and improvements to any of these standards and operating rules. NCVHS is pleased to present in this letter, findings on Health Care Claim Attachments from our June 2014 hearing. This letter summarizes common themes across various topics covered during the hearing, followed by findings, observations and recommendations on specific topics.

Background

Section 1173(a)(2)(B) of the HIPAA, identified a health care claim attachment as one of the transactions for which electronic standards were to be adopted. A proposed rule was published in 2005, but a final rule was never adopted. Section 1104 of the Affordable Care Act directs the Secretary to publish final regulations for the adoption of a national standard for health care claim attachments.

The NCVHS Subcommittee on Standards held hearings in November, 2011 to gather information about industry priorities, practices, perspectives regarding

attachments including business and technical issues, challenges and opportunities. At that hearing, testimony addressed the status of the development of standards and implementation specifications, and the identification of organizations interested in serving as authoring entities for attachment operating rules. Observations from the June 2011 hearing were summarized in the NCVHS letter of March 2, 2012 indicating strong industry support for adoption of useable standards for attachments consistent with those used for exchange of clinical information. However, testifiers called for reducing the number and type of attachment requests. The letter concluded that it was premature to make formal recommendations regarding adoption of any standard, implementation specification, or operating rule regarding attachments.

On February, 2013 we held a second hearing on attachments. Our June 21, 2013 Letter to the Secretary summarized observations and themes from the February hearing, and provided detailed recommendations regarding attachments including:

- There should be convergence in the clinical standards being adopted under the Meaningful Use program and the administrative standards being recommended for health care claim attachments.
- Taking an incremental approach to the adoption of attachment standards.
- Providing a definition of attachments to be "supplemental documentation needed about a patient to support a specific health care-related event (such as a claim, eligibility, prior authorization, referral, and others) using a standardized format".
- Three types of transactions for which there are attachment standards should be adopted (Query, Response, Acknowledgment).
- Specific standards to be adopted include HL7's Consolidate CDA Release 1.1 and Attachment Supplement Release 1; Logical Observation Identifier Names and Codes (LOINC); X12 275 Additional Information to Support Health Care Claim and Health Care Service Review; X12 277 Health Care Claim Request for Additional Information; X12 278 Health Care Service Review Request; X12 TA1 and 999 Acknowledgments; and NCPDP Telecommunication Standard (for pharmacists initiated prior authorization) and NCPDP Script standard (for prescriber initiated prior authorization).
- Regulations should not define specific standards or methods of transport for this transaction.
- Adopted Standard should support both structured and unstructured message content, as well as solicited and unsolicited attachment situations.
- Regulations should strongly emphasize the applicability and need to comply with minimum necessary privacy requirements

■ Operating Rules should be developed accordingly.

June, 2014 Hearing

A follow-up hearing was held in June, 2014 to assess the status of the development of the standards and operating rules, and the need to consider any changes being done that would impact our recommendations from 2013. The main themes and observations from this hearing were as follows:

- There continued to be strong industry support for the adoption of national standards for attachments.
- Concerns were expressed with respect to the lack of standardized business practices and operating rules related to attachments.
- A new set of standardized HL7 implementation specification for attachments has been developed to support Medicare-specific business and program policy needs for Electronic Submission of Medical Documentation (esMD).
 - o This new set of implementation specification could create an additional burden on EHR developers and implementers due to its requirement to provide specific coded explanations (referred to as "null flavors") for when a submitter is not providing requested information.
 - o There are challenges that these new specifications and requirements for data submission would create for covered entities' ability to comply with minimum necessary privacy requirements.
- A new version of the originally recommended HL7 standard (Consolidated CDA Release 2, replacing the NCVHS recommended Release 1.1) is being developed and is expected to be completed and published by early 2015.
- Both the new Medicare-sponsored implementation specifications and Consolidated CDA Release 2 have not yet completed the standards development process for balloting and publication, and are not yet finalized as formal HL7 standards. This is expected to be completed by early 2015.
- There are concerns with the level of maturity of the standards being considered for adoption.
- There are concerns with the overall level of readiness of the health care industry to adopt health care attachments.
- Consideration should be given to the importance of establishing and utilizing standardized Operating Rules for attachments, along with the technical information exchange standards.
- There is a need to move slower and progressively, rather than faster and comprehensively, given where the health care industry is with the implementation of other national requirements (ICD-10, Meaningful Use, Health Reform, and others).

- There is a need to allow for flexibility in the electronic exchange of attachment-related information, while the industry gains experience with these new standards.
- Consideration should be given to the importance of providing adequate and sufficient industry lead time to test, transition and implement any new attachment standard and operating rule.
- Testifiers also opined on the importance that operating rule development for attachments be aligned with meaningful use and the health insurance marketplace/exchanges requirements.

Recommendations

Considering our previous detailed recommendation on attachments, and in light of the new themes and observations from our June, 2014 hearing, NCVHS recommends the following:

Recommendation 1: At this juncture, given that the next version of the standards for attachments (i.e., Consolidated CDA Release 2 and Medicare-sponsored HL7 implementation specification for attachments) has not yet been finalized, NCVHS stands on all its June 21, 2013 recommendations to the Secretary.

o NCVHS considers it premature to recommend the new standards currently under development at this point. NCVHS believes that once these standards have completed their full standards development cycle and have been formally published as finalized standards by HL7, they will merit being reviewed for adoption as national standards.

Recommendation 2: In our June 21, 2013 letter we recommended adopting standards for a broad application of attachments which included claims, eligibility, prior authorization, referrals, care management, post-payment audits, and others. In this letter we are refining those recommendations by limiting the initial implementation to health care claims attachments, for which the HL7 standard has defined a template (e.g., hospital discharge summary, operating notes, ambulance runs).

Recommendation 3: Implementation of these standards should be aligned with the implementation of Stage 3 Meaningful Use Program, as much as possible, to facilitate a common, consistent transition to the new standards on both EHR and Administrative and Financial Systems.

Recommendation 4: Due to the complexity of health care claim attachments, HHS should work with the industry to implement a series of pilots addressing various types of covered entities and business situations where health care claim attachments are needed, to develop and document best practice before a universal rollout.

Closing Comments

NCVHS recognizes the challenges that the health care industry faces today and will continue to experience over the coming years as they adopt health care standards and operating rules. NCVHS will continue to support your efforts to increase the adoption of these standards and operating rules that help move the industry forward with technology to achieve greater efficiency. NCVHS plans to hold additional hearings on health care attachments in the coming months to continue to evaluate and reassess the status of development of attachment standards and operating rules.

Sincerely,

/s/

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

Cc: HHS Data Council Co-Chairs