

June 21, 2013

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

Re: Attachments Standards for Health Care

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.”

Background

In 1996, HIPAA, Section 1173(a)(2)(B), identified a health 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, due in part to questions about the maturity of the standards being recommended for adoption and the ability of users of the standards to implement them. Section 1104 of ACA now directs the Secretary to publish final regulations adopting national standards, implementation specifications and operating rules for health care claim attachments no later than January 1, 2014, with a compliance date no later than January 1, 2016.

The NCVHS Subcommittee on Standards held a hearing on attachments on November 17, 2011 to begin gathering current information regarding industry practices, priorities, issues and challenges. Testimony addressed the status of development of standards and implementation specifications, and the identification of organizations interested in serving as authoring entities for attachment operating rules. Major observations were summarized in the Committee’s letter of March 2, 2012 but it was the Committee’s conclusion that

it was premature to make formal recommendations regarding adoption of any standard, implementation specification, or operating rule associated with attachments. In summary, testimony revealed strong industry support for adoption of useable standards for attachments consistent with those being used for exchange of clinical information under other national programs and initiatives. Testimony also called for reducing the number and type of attachment requests. The Committee also learned of successful pilot demonstration of the value of standards-based electronic exchange of attachments.

On May 5, 2012, we recommended that the Committee on Operating Rules for Information Exchange (CORE) be designated as the authoring entity for claim attachments.

On February 27, 2013 we held a second hearing on the topic to discuss 1) the policy, business, and technical approaches to attachments in their various forms and purposes; 2) the status of development of standards, implementation specifications and operating rules and the degree to which they are ready for adoption and use; and 3) associated business issues and milestones to be defined in order to achieve a successful planning, transition and implementation of attachments. Testifiers represented various stakeholder representatives, including providers, health plans, public programs, clearinghouses, standards development organizations, standard coding groups, CORE, and WEDI.

This letter summarizes the common themes from the hearing, the most significant observations, and a series of recommendations to the Department of Health and Human Services (HHS) for action.

Common Themes

Three overarching themes were observed during this hearing, which are consistent with some overarching themes we have observed during our hearings for the past year:

- **Convergence:** The theme of the emerging convergence of administrative and clinical information is central to the consideration of standards for attachments. The attachments regulation is unique in that it is one of the first major opportunities to bridge clinical and administrative health care data and information exchange through standards. The regulation provides the opportunity to build on existing infrastructure in both clinical and administrative spheres, while allowing for future innovation. It also provides an opportunity to support payment reform and population health.

- **Need for a Roadmap:** With the number of upcoming health care initiatives, it is essential that there be a roadmap to support and enable adoption of clinical and administrative information exchange standards. Optimizing the costs, efforts, and timing of these initiatives can result in better returns and better value to the industry.
- **Continuous Collaboration:** SDOs and ORAOs (Operating Rules Authoring Entities) need to continue aligning their standards and operating rules and collaborating closely. This will be especially important in the development and adoption of attachment standards and future operating rules.

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

Observations

There was significant consistency in the testimony regarding the scope, adoption, and implementation of the standards for attachments. Most importantly, there was consensus that the main goal for establishing a standard for electronic attachments should be administrative simplification, and more specifically, the seamless electronic exchange of clinical and other medical and administrative information between providers and payers to support payment and health care operations functions. There were a host of other items that were in alignment across all of the presentations.

- **Scope and definition of Attachments.** There is consensus that discussions, recommendations and adoption of standards should no longer be limited to “claim attachments” but rather be more inclusive of any kind of attachment with administrative or clinical information. Attachments refer broadly to the exchange of additional information between parties using administrative and financial transactions.
- **Purpose of Attachments.** The business purpose for when attachments are needed, and which cannot be fulfilled with data already included in other transactions must be clearly defined. Consistency across payers and providers in the situations that elicit the need for an attachment should be encouraged.

- **Privacy, Security and Minimum Necessary Information.** Covered entities and their business associates must be mindful of the need to meet current privacy and security regulations, in particular minimum necessary requirements (making reasonable efforts to disclose only the protected health information that is reasonably necessary to achieve the purpose of the disclosure). Health plans should be mindful of identifying specific permitted purpose for requesting attachments and only requesting the minimum amount of information needed to achieve the purpose of such requests. Similarly, providers should be mindful of only sending attachments (solicited or unsolicited) consistent with minimum necessary requirements. Covered entities must also balance the relationship between the increased interest and need from payers to obtain clinical information in support of payment and operations (such as health care management functions) and the need to apply minimum necessary criteria to requests for attachments.
- **Balance.** Several testifiers commented that new regulations must balance the desire to establish mandated standards with the need to avoid strict, inflexible prescriptiveness, in this evolving area of the industry. The regulators need to be aware of other initiatives to ensure consistency and minimize competition, conflict, redundancy, and cost. In the case of attachments, it would be important to be mindful of Meaningful Use Stage 3 standards requirements, so that the versions of adopted standards are consistent and synergistic. Allowing industry to leverage an existing infrastructure is important to avoid unnecessary expenditures for system replacements or revisions.
- **Avoid duplication.** Testifiers stressed the need to avoid duplicating data and data requirements. For example, when data are already part of a transaction, such as a claims transaction, they should not be requested again as part of an attachment. Existing transactions, transaction standards, and data requirements should be followed and enforced to minimize the need for, or possible overuse, of attachments.
- **Education.** Active outreach to promote awareness across all stakeholders will be paramount to the success of adopting and implementing attachment standards.
- **Benefits and outcomes.** The adoption of standards for the exchange of attachments between providers and payers addresses a very costly and inefficient process currently done via paper, fax, mail, and other non-electronic, non-standards-based methods. Using consistently electronic health data exchange standards with codified data that can be machine-processed will increase process efficiencies, reduce processing errors or delays, improve controls on fraud and abuse, and, overall, improve the

business processes that support patient care, as reported by testifiers and demonstrated through industry pilots on attachments.

- **Maturity of Standards and Adoption and Use by Industry.** The standards for exchanging clinical and other medical and administrative supportive information under consideration for attachments have evolved and matured to a point that they now have been adopted as a requirement of the EHR Incentives Program (Meaningful Use) and the EHR Standards and Certification Criteria associated with the program.
- **Applicability.** Nothing in the recommendations that follow is intended to mandate the use of attachments. As with all other HIPAA-related transactions, covered providers are not required by regulation to conduct transactions or to conduct them electronically. If they choose to conduct attachment transactions electronically, or if they are required to do so under provider- trading partner agreements, then they would be required to use the adopted standards. Other covered entities are required to be ready to conduct HIPAA-related transactions electronically (and this would include attachments), using the adopted standards.

Recommendations

We are pleased to offer a number of recommendations to the Secretary for the development of a rule to adopt standards for electronic attachments. It is important to consider the following general concepts about the attachment transactions:

- Attachment transactions generally apply to exchanges between providers and payers (with or without the involvement of a clearinghouse), although there are some instances in which attachments may apply to exchanges between providers (for example, between a pharmacy and a prescriber).
- Attachments have several layers where standards can be defined and applied, including:
 - The message content, containing the actual clinical information being requested, and which includes the message format and vocabulary/terminology
 - A coding mechanism to identify consistently the type of attachment being exchanged
 - The ‘envelope’ or external data layer in which the clinical message content is wrapped
 - The method by which the information will be sent (the transport mechanism)

- The business rules layer that will define various attachment parameters to support the migration from paper to electronic exchange over time

Following are our recommendations for your consideration.

- **Recommendation 1.** Conduct an overarching review of the adoption of standards for clinical and administrative processes, in light of the various programs currently underway (i.e., Meaningful Use, HIPAA/ACA Administrative Simplification, Health Reform, Medicare and Medicaid Program Integrity, and others) and develop a roadmap that will phase in at appropriate times and in the most effective sequence various standards for related health information exchanges. Furthermore, the complexity, pace and scope of changes require us to rethink how these standards are evolving and applied, taking into account the industry's diversity, agility and flexibility to promptly adopt them. We believe that to fulfill the information needs of the future efficiently, administrative transactions such as claims, eligibility, prior authorizations and attachments, to name a few, will need to be evaluated, and we feel this is the right time for government, the industry and standard development organizations to begin looking at this long-term review and modification effort.
- **Recommendation 2.** Take an incremental, flexible approach to the adoption of attachment standards, implementation specifications and operating rules, and transition period for industry adoption within the roadmap noted above. This includes naming an initial attachment transaction type to comply with by January 1, 2016 as specified in ACA (for example, for claims), and appropriately sequencing the naming of the other attachment transactions. This should also include identifying the key building blocks, the base standards, core attachment components and priority purposes. The overall cost and efforts expected for the industry to adopt all elements of attachments at once can be significant and come at a time when many other requirements on covered entities and stakeholders will converge. The Department should also consider working with the industry to identify and define a series of milestones to be achieved during the transition period towards the compliance date that can be included in the regulations.
- **Recommendation 3.** Depending on the timing of the attachments rule, the Office of the National Coordinator for Health IT and CMS should make every effort to align their rules, such that the adoption of electronic attachments could support the next stage of EHR certification criteria (Stage 3 meaningful use). This would be a precedent for the convergence of clinical and administrative information, systems and operations.

- **Recommendation 4.** The definition of attachment that we recommend to be adopted is “supplemental documentation needed about a patient(s) to support a specific health care-related event (such as a claim, eligibility, prior authorization, referrals, and others) using a standardized format.”
- **Recommendation 5.** The areas to which attachment-related transaction standards should be applied include claims, eligibility, prior authorization, referrals, care management, post-payment audits, and any other administrative processes for which supplemental information is needed.
- **Recommendation 6.** Attachment standards should be defined for three types of transactions: 1) Query (the electronic solicitation of an attachment); 2) Response (the electronic submission of an attachment); and 3) Acknowledgment (the electronic confirmation of the receipt of the query and submission of an attachment transaction).
- **Recommendation 7.** The following standards for attachment-related transactions are proposed for adoption. These standards are a composite of the standards that were recommended by industry and should be included in a Notice of Proposed Rule Making (NPRM), per Recommendation 17 below.
 - Message Content/Format:
 - HL7 Implementation Guide for CDA Release 2: IHE Health Story Consolidation, DSTU Release 1.1 (US Realm) Draft Standard for Trial Use, July 2012
 - HL7 Attachment Specification: Supplement to Consolidated CDA Templated Guide, Release 1, May, 2013
 - Attachment Type Value Set:
 - Logical Observation Identifier Names and Codes (LOINC) developed and maintained by the Regenstrief Institute, Inc., LOINC® c/o Center for Biomedical Informatics.
 - Routing/Envelope (*):
 - X12 275 Additional Information to Support Health Care Claim (**)
 - X12 275 Additional Information to Support Health Care Service Review (**)
 - Request for Attachments:
 - X12 277 Health Care Claim Request for Additional Information (for all claim-related attachment requests) (**)
 - X12 278 Health Care Service Review – Request (for non-claim-related attachment requests) (**)
 - Acknowledgment:
 - X12 TA1 and 999 (**)
 - Pharmacy Prior Authorization:

- Pharmacist initiated prior authorization for drugs/biologics:
 - NCPDP Telecommunication Standard
- Prescriber initiated prior authorization for drugs/biologics:
 - NCPDP Script
 - X12 278 Health Care Services Review

() The routing protocol noted above is not required when trading partners agree to use other routing/envelope mechanisms.*

*(**) For X12 transactions, the Secretary should consider adopting the same version that may be proposed to be adopted for other HIPAA-related transactions at the time of compliance implementation with the attachments requirements.*

- **Recommendation 8.** The regulations should not define specific standards or methods of transport as the only ways for exchanging attachments. Standards being adopted should be agnostic of the transport selected by trading partners to exchange attachments, so as not to preclude or inhibit innovation. However, the regulations should remind covered entities of the importance of following reasonable and appropriate administrative, physical, and technical security policies and procedures when using and disclosing attachment information.
- **Recommendation 9.** The standards being adopted should support the submission of both structured and un-structured data, according to the specifications contained in the standard for message content and attachment type value set recommended above. Every effort should be made to maximize the use of structured data recognizing the efficiency gains in subsequent processing.
- **Recommendation 10.** The attachment process should support both solicited and unsolicited attachment situations, as we recommended in 2004 when we first wrote to the Secretary in support of electronic attachments. The specific situations for which unsolicited attachments are expected by payers should be clearly identified in trading partner agreements (TPAs). Supporting TPA pre-defined unsolicited attachments avoids uncertainty and ambiguities in expectations from payers to providers, and allows the provider to have greater control over his or her workload. Requests and submissions of attachments for unspecified purposes should not be permitted.
- **Recommendation 11:** The regulations should strongly emphasize the applicability of minimum necessary privacy requirements. The regulations should also emphasize that covered entities are not permitted to disclose

protected health information without having a valid, permitted purpose for such disclosure. In other words, requesters of information should not ask for, and senders should not send more than what is minimally needed. We recommend that the Office for Civil Rights be engaged in defining guidance for covered entities regarding the applicability of privacy and security requirements to the request and submission of attachments, while acknowledging the changing face of health care technology, and the power of attachments to improve health care delivery, quality of care and administration.

- **Recommendation 12:** Data, other than identifying information, that are already supposed to be included in the originating transactions for which an attachment is being requested must not be permitted to be requested again in an attachment. The regulations should clearly remind covered entities to follow the implementation specifications and/or operating rules of the transactions and to avoid duplicating exchange of information beyond what is necessary to appropriately re-associate or link transactions.
- **Recommendation 13.** Chained attachment requests (the continuous follow-up requests of attachments after a first attachment has been requested and fulfilled) should not be permitted, except in limited circumstances when information in one attachment creates a legitimate business need for requesting additional supportive documentation.
- **Recommendation 14.** Support the industry's development of operating rules for attachment transactions that address the infrastructure and technical needs across industry sectors, such that the use of companion guides is minimized or restricted to service information and other limited plan specific guidance.
- **Recommendation 15.** Work with the industry to implement a testing program for attachments, during the transition period prior to the compliance date.
- **Recommendation 16.** Collaborate on education and outreach with all sectors of industry. The opportunity for using electronic attachments in the clinical and administrative setting to reduce costs and improve care is dramatic.
- **Recommendation 17.** While we heard a strong, consistent message regarding these recommendations noted above, we recommend that the Department consider publishing an expedited Notice of Proposed Rule Making (NPRM) rather than a Final Rule on attachments, considering 1) the length of time and changes in technology that have occurred since the

original NPRM was published in 2005 and, 2) the scope of attachments we are recommending to be covered.

- **Recommendation 18.** The regulations should take into account the specialized needs of the pharmacy industry where attachments are used for ‘prior authorization’ but not used for ‘claim attachments’.

At this point we are not in a position to make any recommendations regarding the adoption of operating rules for claim attachments, as they have not been developed yet by the industry. We expect to evaluate this in early 2014 and will communicate with the Department as to whether there are standard operating rules to be recommended for adoption at that time.

NCVHS recognizes the important process improvement and efficiency opportunities between providers and payers that can be achieved by leveraging the use of standards-based electronic attachments. We also understand the significant and costly changes the industry is facing with several recent and upcoming major shifts, such as Meaningful Use, ICD-10 code sets, Health Insurance Exchanges, ACA provisions, and others. We encourage a prudent and practical approach for the adoption of electronic attachments so that the industry can better manage implementation risks, and optimize the value of this important capability.

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