

July 5, 2016

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

Re: Recommendations for the Electronic Health Care Attachment Standard

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, implementation specifications, code sets and identifiers for the HIPAA-named transactions.

On February 16, 2016 NCVHS held a hearing on the Electronic Health Care Attachment Standard. In this letter, we provide a summary of the findings, observations and recommendations to adopt a set of updated electronic health care attachment standards. We are also consolidating relevant recommendations made in our past three letters on the subject (March 2, 2012, June 21, 2013 and September 23, 2014), so that a complete set of final recommendations about this important transaction can be considered at this time.

In summary, we recommend that DHHS consider the following actions:

- Adopt one standard definition of the “Attachment” transaction, and establish the scope of the transaction.
- Adopt a set of mature, implementable electronic standards for the health care industry to execute the Attachments transaction.
- Define a series of transaction process requirements, including consistency with adopted privacy laws and regulations.
- Take an incremental, flexible implementation approach in no less than five years inclusive of rulemaking.
- Broaden the testing, education, outreach and compliance efforts.
- Ensure alignment of the Attachment standard’s regulatory requirements with those adopted for use with Electronic Health Records under the Office of the National Coordinator (ONC) for Health Information Technology’s 2015 Edition Certification of Health Information Technology program (i.e., Meaningful Use) and the Medicare Access

I. Background

Section 1173(a)(2)(B) of HIPAA identified the “health care claim attachment” as one of the transactions for which electronic standards were to be adopted. Although a proposed rule was published in 2005, a final rule was not adopted, due in part to concerns with the standard’s maturity and the users’ ability to adopt them. By 2010, Section 1104 of the Patient Protection and Affordable Care Act (ACA) calls for the Secretary to publish final regulations adopting a comprehensive national standard, including implementation specifications and operating rules for health care claim attachments.

Since 2010, NCVHS has held three hearings on the Attachment standard (November, 2011, February, 2013, and June, 2014). The findings of these hearings and NCVHS recommendations from these hearings were included in three separate letters to the Secretary.¹ Attachment-related recommendations from these letters included:

- Take an incremental, flexible approach to the adoption of attachment standards, implementation specifications and operating rules.
- Adopt the definition of attachments as the “supplemental documentation needed about a patient(s) to support a specific health care-related event (such as a claim, prior authorization, referrals, and others) using a standardized format.”²
- Attachment-related transaction standards should be applied to claims, prior authorization, referrals, care management, post-payment audits, and any other administrative processes for which supplemental information is needed.
- Attachment standards should be defined to include three types of transactions – query, response, and acknowledgment.
- Regulations should not define specific standards or methods of transport as the only ways for exchanging attachments.
- Adopted standards should support submission of structured and unstructured data.
- The attachment transaction process should support solicited and unsolicited attachment situations.
- Regulations should strongly emphasize applicability of minimum necessary privacy requirements.
- Data that is already part of the original transaction for which an attachment is being generated should not be requested again in an attachment.
- Chained attachment requests should only be permitted in limited situations.

¹ NCVHS letter to Secretary Kathleen Sebelius, March 2, 2012. Health Care Claim Attachment Standards
NCVHS letter to Secretary Kathleen Sebelius, June 21, 2013. Attachments Standards for Health Care
NCVHS letter to Secretary Kathleen Sylvia Burwell, September 23, 2014. Health Care Claim Attachments

² *ibid*

- Future operating rules for attachments should address infrastructure and technical needs.
- Collaborate with the industry on implementing a testing program for attachments prior to the compliance date, as well as on education and outreach.
- Regulations should consider special needs of the pharmacy industry, where attachments are used for prior authorization but not for claims payment.

A. Overview of the Attachment Transaction and Standards

Attachments are intended to focus on clinical data for additional information required to support and adjudicate a claim. Benefits for using attachments beyond claim adjudication include improved care coordination, facilitation of transitions of care by moving clinical data across health care settings, support care management, enhance quality reporting and support of alternative health care payment models.

The attachment standard represents collaboration between two Standards Development Organizations – the Accredited Standards Committee (ASC) X12 and Health Level Seven International (HL7). ASC X12 provided the existing Provider/Payer Electronic Data Interchange (EDI) Communication Channel while HL7 provided the Clinical Data Architecture (CDA). Logical Observation Identifiers Names and Codes (LOINC) codes identify or tag each request type. Attachments can be structured or unstructured. Structured documents are defined by an HL7 CDA Standard which requires the Consolidated Clinical Data Architecture (C-CDA) R2.1 Header and the block text for each populated section.

The C-CDA is the vehicle to submit additional information required to adjudicate a claim. The implementation guidelines specify how to create an unstructured document consisting of a C-CDA set of metadata in the header and an unstructured body containing the clinical record, and specifies structured and coded requirements for different types of clinical notes. The LOINC classifies documents by type and applies unique standard codes. A selection of these codes, housed in the National Library of Medicine Value Set Authority Center (VSAC) is used with the C-CDA. In addition to clinical document types, LOINC contains high level codes for administrative document types.

Dental payers may require supporting documentation before adjudicating dental claims. The American National Standard/American Dental Association Standard No. 1079 for Standard Content of Electronic Attachments for Dental Claims describes the content for electronic claims attachments to payers. The dental standard describes uses for SNODENT[®] terminology and International Statistical Classification of Diseases and Related Health Problems diagnostic codes.

Benefits for using the attachment transaction include cost reduction and saving opportunities as identified by the Mayo Clinic. In their pilot testing, they identified savings in mail room staff time, pre-reading staff time sorting letters and routing, billing staff time reviewing paper requests and copying data, postage, and a 25-30 day delay elimination in receiving payment. The Mayo Clinic implemented electronic attachments utilizing the ASC X12 275 transaction and

the HL7CDA R2. By analyzing high volume and high cost requests, the Mayo Clinic identified the business need to send an operative report as an unsolicited attachment when complications occurred or additional surgeons were required for a surgical procedure. Results of the project showed reduced staff time, decreased costs with paper processes, and receipt of payment approximately 30 days sooner. The challenges found were: providers and payers' EDI staff have limited or no experience with HL7 standards, multiple HL7 documents needed to be referenced, HL7 documentation was not easily interpreted, significant HL7 education as well as and technical assistance was needed.

Other industry partners shared benefits from attachment usage. Costly, manual paper claims and attachment processing have moved States to adopt ASC X12 EDI standards and to mandate the type of services billed that require an attachment for payment. States that have adopted attachment rules require the ASC X12/005010 Health Care Claim 837 "PWK segment" be annotated based on services being billed or the claim is rejected. The States' attachment rules also contain acknowledgment requirements that the payer notifies the submitter of a pending claim status using the ASC X12/005010X214 Health Care Claim Acknowledgment (277CA).

HIPAA non-covered entities also require the attachment transaction to support the level of services billed as part of the "Clean Claim" rules. In 2008, the Worker's Compensation Attachment Standards was established as part of the National Workers' Compensation Electronic Medical Billing and Payment Guide. Subsequent to 2008, the electronic attachment solutions has expanded beyond Property and Casualty and now includes the Group Health Industry. One testifier indicated that some payers are reporting 15 – 30 percent administrative savings due to front end attachment edits and providers are reporting an average 75 percent increase for first time clean claim submission with an average 30-50 percent administrative savings.

Testifiers were unanimous in recommending the adoption of the attachment standard. Many cited previous NCVHS recommendations to HHS to adopt the attachment standard.^{3 4 5 6} Stakeholders indicated that greater efficiency in processing claims would be achieved through the use of the attachment standard. The standard was described as benefitting workflow, supporting changes in technologies, and providing consistency and uniformity. Testifiers agreed that the standard supports unsolicited and solicited attachments for prior authorizations, referrals, notifications and post-adjudicated claims. Testifiers stated that the attachment standard provides consistent content and format, provides for automation and provides a mechanism to expedite routing. However, concern was raised that providers are confronted with different and varying proprietary approaches from payers for supplying the additional information.

³ NCVHS Letter to Kathleen Sebelius, March 2012, Claims Attachments

⁴ NCVHS Letter to Kathleen Sebelius, June 2013, Attachment Standards for Health Care

⁵ NCVHS Letter to Kathleen Sebelius, May 2014, Findings from the February 2014 NCVHS Hearing

⁶ NCVHS Letter to Sylvia Burwell, September 2014, Findings from the June 2014 NCVHS Hearing

B. February 16, 2016 Hearing

The purpose of the February 16, 2016 hearing was to gather industry input regarding an updated set of finalized, proposed attachment standards and code sets. Specifically, the objectives of the hearing were to:

- Understand the new developments and current status of proposed standards and code sets for claim attachments.
- Review and validate the business needs and use cases for claim attachments.
- Explore the use of attachment standards for other health care transactions, such as prior authorization and post-paid claim audits.

NCVHS heard presentations by HL7, ASC X12 and LOINC for the proposed attachment standard. In addition, twelve oral testimonies were presented and over sixteen written testimonies were submitted from the health care industry representing providers, health plans, vendors, clearinghouses, associations, public programs (Medicare, Medicaid), federal agencies, standards development organizations, and consultants.

One of the most significant findings from the February hearing was the general consensus across testifiers regarding the need to move forward with the adoption and implementation of the recommended attachment standards. These standards have been updated since the versions recommended by NCVHS in its June, 2013 letter to incorporate more explicit and better defined conformance statements for covered entities implementing the standard.

NCVHS reviewed testimony and formulated its recommendations utilizing the criteria that formed the basis of the questions posed to the testifiers. The criteria centered on identifying if the proposed attachment-related standards and code sets:

- Meet the industry's business need/use/problem resolution?
- Decrease cost and/or administrative processes?
- Are flexible/agile to meet changes in technology and/or healthcare delivery systems?
- Can be operationalized?
- Can be enforced?

NCVHS also looked at other factors to evaluate the degree to which the adopted standards were meeting the overall goal of administrative simplification. These included:

- *Completeness*: Does the standard or operating rule provide the complete information necessary to execute the transaction and achieve the business purpose?
- *Efficiency*: Does the standard or operating rule decrease resource utilization and the time to perform the transaction function?
- *Complexity*: Do the standard or operating rule requirements exceed the healthcare industry's cost and resource capacity resulting in limited or non-implementation?
- *Flexibility*: Does the standard or operating rule allow for interim updates and can it adapt to changes in technology and health delivery models?

- *Consistency*: Is the standard or operating rule able to be implemented in the same manner across all healthcare entities?
- *Effectiveness*: Does the standard and operating rule solve the business need?
- *Ambiguity*: Does the standard or operating rule result in differences in interpretation and in implementation?

In addition to these criteria, specific questions were posed to the Standards Development Organizations and stakeholders to consider for the proposed attachment standard:

- The degree of industry input into the development,
- Relationship to existing standards,
- Impact of adoption,
- Benefits of their adoption and
- Their recommendation for adoption.

Based on our review of the oral and written testimony from the February hearing, as well as materials from previous hearings and other industry evidence, we conclude that the standards and policy recommendations we are making in this letter do meet the industry’s business needs, improve administrative efficiency and reduce administrative burden, are flexible and agile to meet future technology developments and health system changes, are mature, adoptable and enforceable. NCVHS also believes that the standards being adopted meet the other evaluation criteria (completeness, efficiency, complexity, flexibility, consistency, effectiveness, and ambiguity). Accordingly, we make the following recommendations, which represent a consolidated, comprehensive and updated set of recommendations from all our previous letters and the findings from the February, 2016 hearing. Together, they form the basis for our final, complete set of recommendations to the Secretary on this important topic of Attachments.

II. Adoption of a Standard Definition and a Set of Mature, Implementable Standards for the Attachment Transaction

Recommendation 1: Adopt One Standard Definition of Attachment

NCVHS recommends that the definition of “attachment” to be adopted in regulations should be the definition proposed in previous NCVHS recommendations as “any supplemental documentation needed about a patient(s) to support a specific health care-related event (such as a claim, prior authorization, referrals, and others) using a standardized format.”⁷

Recommendation 2: Adopt the Standards for Attachment Query, Response, and Acknowledgment

The standards noted below should be adopted for each of the following three types of attachment-related transactions: 1) Query (the electronic solicitation of an attachment); 2)

⁷ *ibid*

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 3: Adopt the Recommended Standards

NCVHS recommends the adoption of the following standards for attachment-related transactions:

- Query (Request) for Attachments:
 - ASC X12N 277 Health Care Claim Request for Additional Information (for all claim-related attachment requests) (*)
 - ASC X12N 278 Health Care Service Review – Request for Review and Response – Response (for non-claim-related attachment requests) (*)

- Response – Submission of an Attachment: Message Content/Format:
 - HL7 CDA R2 – Consolidated CDA Templates for Clinical Notes R2.1
 - HL7 Attachment Supplement Specification Request and Response Implementation Guide R1

- Acknowledgment:
 - ASC X12 Acknowledgment Reference Model (ARM)
 - ASC X12C Implementation Acknowledgment for Health Care Insurance (999) (*) and ASC X12 TA1 Acknowledgment Segment (Appendix to the 999) (*)
 - Acknowledgment standard (ACK)

- 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. HIPAA Panel Solicited and Unsolicited Lists.

() For all of the above X12 transactions, the Secretary should consider adopting the HIPAA version that will be expected to be in effect by the time these transactions are mandated.*

Recommendation 4: Adopt Additional Standard for Attachment Response

- NCVHS recommends that the Secretary adopt the HL7 Implementation Guide for CDA Release 2: Additional CDA R2 Templates – Clinical Documents for Payers – Set 1 as an additional, acceptable standard for the submission of attachments-related information, in support of CMS’ electronic submission of Medical Documentation (esMD).

Recommendation 5: Identify Standards for Routing/Envelope of an Attachment

NCVHS recommends that the Secretary adopt the following standards to support the electronic routing of attachment transactions. These standards should be the ones to be used by trading partner covered entities when a routing or envelop method is needed, and as agreed upon by trading partners. Not all attachment queries may need these routing/envelope standards, thus, they should *not* be required to be used in all exchanges. Routing/Envelope:

- ASC X12N 275 Additional Information to Support a Health Care Claim or Encounter (*)
- ASC X12N 275 Additional Information to Support a Health Care Services Review

() For these X12 transactions, the Secretary should consider adopting the HIPAA version that will be expected to be in effect by the time these transactions are mandated.*

HHS should allow for alternative recognized standard envelope and transport options to transmit attachments to accommodate existing and future transport technologies⁸.

Recommendation 6: Define Structured and Unstructured Data

We recommend that the submission of structured and unstructured data in an attachment be defined by the implementation specification contained in the standard for *message content* and the *attachment type value set* recommendations 3, 5, 7 and 8.

Recommendation 7: Adopt Attachment Standards – Pharmacy Industry

We recommend the adoption of the following standard for prior authorization attachment-related transactions applicable to the pharmacy industry. As noted above, the pharmacy industry attachments are primarily used for prior authorization and not for claims.

- HHS should name the NCPDP SCRIPT Standard Version 2016071 Prior Authorization transactions as the adopted standard for the exchange of prior authorization information between prescribers and processors for the pharmacy benefit.

Recommendation 8: Adopt Attachment Standards – Dental Industry

We recommend the adoption of the American National Standard/American Dental Association Standard No. 1079 for Standard Content of Electronic Attachments for Dental Claims.

III. Defining Key Transaction Process Requirements and Providing Additional Guidance for the Implementation of the Attachment Transaction

Recommendation 9: Transaction Process to Support Solicited and Unsolicited Transactions

We recommend that the transaction process support both solicited and unsolicited models for attachment request/submission. The specific situations for which unsolicited attachments are expected by payers should be clearly identified in trading partner agreements (TPAs) and, in the future, in operating rules. Supporting TPA pre-defined unsolicited attachments avoids uncertainty

⁸ ONC “Interoperability Standards Advisory” <https://www.healthit.gov/sites/default/files/2016-interoperability-standards-advisory-final-508.pdf>

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 10: Avoid Duplication and Chain Requests

Data, other than identifying information, that are already part of the original transaction (i.e., the health care claim), and that are supposed to be included in the original transaction associated with an attachment must not be permitted to be requested again in an attachment. Similarly, chained attachment requests (continuous follow-up requests of attachments after a first attachment has been requested and satisfactorily fulfilled) should not be permitted either, except in limited circumstances when information in one attachment establishes a legitimate business need for requesting follow-up supportive documentation.

Recommendation 11: Conform to Privacy and Minimum Necessary Requirements

We recommend that the Secretary strongly emphasize in regulations the need for covered entities to conform to minimum necessary requirements under the HIPAA Privacy Rule, when executing attachment transactions. Thus, a covered entity should only request and submit attachments when there is a valid, permitted, treatment payment or health care operations purpose for such request. Requesters of attachment information should not ask for, and senders of attachments should not send more than what is minimally necessary to achieve the valid purpose for which the transaction is being conducted.

Recommendation 12: Additional Guidance for Implementing the Attachment Standard

The Standards Development Organizations should:

- Evaluate the need for a larger size limit to accommodate lengthy attachments submitted by diagnostic entities (e.g., genetic tests).
- Ensure that instructions for information required on claims attachments are clear.
- Create a quick reference guide.
- Provide a single source for the industry to download the necessary documents.
- Require health plans to communicate to the provider that additional information is required as soon as the need is identified.
- Ensure requests for attachments are in one request and are limited to information not found on a claim required to adjudicate the claim.
- Ensure that adequate operational testing is done to validate the standard's data content requirements before turning on production usage of attachments.
- Require the inclusion of header that describes the document and establishes the context of the body of the document.
- Require that the body content can accommodate both structured and unstructured documents.
- Require that the body of an attachment contains only minimally necessary and clinically relevant information.

- Ensure that testing has demonstrated that data content and infrastructure requirements can be operationalized by all health care entities.
- Define structured and unstructured documentation.
- Define authentication requirements.
- Ensure health plans identify and publish situations that require attachment information so providers can submit these proactively as unsolicited attachments.
- Collaborate with the health care industry to agree upon minimum necessary requirements to ensure patient confidentiality, privacy and security of attachment information.

IV. Taking an Incremental, Flexible Implementation Approach

Recommendation 13: Utilize Flexible Adoption and Implementation Approach

NCVHS recommends that the Secretary identify the areas where attachment-related transaction standards can be used. These includes 1) claims; 2) prior authorization; 3) referrals; 4) care management; 5) post-payment audits; and (6) any other administrative processes for which supplemental information is needed.

We also recommend that adoption and implementation of the attachment standards be done incrementally and in a flexible manner, starting with requiring the use of the recommended attachment standards in connection with the health care claim. Use of the attachment standards for all other transactions where supplemental information is needed should be encouraged. HHS 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.

We further recommend the following additional adoption and implementation elements be considered:

- An effective implementation date of no less than two years from the publication of the Attachment Standard Final Rule, including any necessary sub-regulatory guidance, conformance or testing tools and any other guidance necessary to successfully implement the Attachment standard.
- Predictability in the adoption of the attachment standard, in relation to other possible mandates and requirements. Testifiers indicated that timetables appear to be set without consideration of the range of mandated requirements and the adoption of standards that often coincide with the need to implement other mandated requirements. Predictability should include:
 - Providing a timeline indicating when regulations are expected to be published.
 - Utilizing a staggered approach for implementing the attachment standard including publishing each implementation date.

- Publishing the Notice of Proposed Rulemaking (NPRM) and the subsequent final rule in a timely manner and are not delayed or prolonged resulting in regulations that are outdated or ineffective.

V. Broadening the Testing, Education, Outreach and Compliance Efforts

Recommendation 14: Provide Testing, Communication, Education and Outreach

NCVHS recognizes that testing has been done on the attachment standard and implementation of the standard has been on a voluntary basis. However, we recommend that HHS work with the industry to implement additional implementation testing for attachments, to ensure a successful transition prior to the compliance data.

Testifiers also agreed that increased education and knowledge on the use of the attachment standard (including code sets) is needed. The need for education was also expressed at the June 2015 NCVHS Review Committee hearing. In the subsequent letter to you on February 29, 2016⁹, we provided industry-wide recommendations that we believe apply to the attachment standard as well. Consequently, NCVHS recommends a broad education effort.

The *Healthcare Industry, Standards Development Organizations, and HHS* should work together to ensure that:

- Stakeholders have access to and are educated on the Attachment Standard. This would include intended benefits and other considerations to support greater implementation and standardization of use such as:
 - Providing a timeline indicating when regulations are expected to be published.
 - Front-end edits by clearinghouses and payers can quickly identify and report back to providers claim errors or deficiencies so they can be promptly addressed and the claim submitted correctly improving processing timeliness.
 - Accelerated turnaround times resulting in better use of staff and resources.
- Instructional materials are prepared and maintained with multi-stakeholder involvement and are clear, concise, consistent and relevant.
- Guidance on the use of the HL7 C-CDA for Attachments is given to payers and providers.

Recommendation 15: Publication of a Notice of Proposed Rule

We recommend that the Secretary consider publishing an expedited Notice of Proposed Rule Making (NPRM) adopting the recommended standards, rather than an Interim Final Rule, or a Final Rule, considering the length of time that has elapsed since the previous NPRM was published and the technology advances made since then.

⁹ February 29, 2016 letter to, Sylvia M. Burwell, Secretary, Department of Health and Human Services, from the National Committee on Vital and Health Statistics (NCVHS), Findings from Administrative Simplification Hearing.

VI. Alignment with other National Initiatives

Recommendation 16: Ensure alignment with the Electronic Health Record (EHR) Incentive Program and the Medicare Access CHIP Reauthorization Act of 2015 (MACRA)/Merit-Based Incentive Payment System (MIPS).

NCVHS recommends that HHS charge the Office of the National Coordinator (ONC), the CMS Innovation Center and the other applicable areas within HHS and CMS to ensure that (1) the claim attachment standards and associated data and transport requirements do not conflict with health data interoperability program requirements and road maps of other HHS programs, and (2) to the extent possible, ensure that all programs use the same connectivity and interoperability infrastructure. Specifically, that these program areas ensure that providers, payers and other industry stakeholders are not obligated to establish and maintain different standards-based infrastructures for different programs that require the exchange of similar data (for example, Meaningful Use in the EHR Incentive Program, the forthcoming MACRA/MIPs program, the Accountable Care Organizations (ACO) Value Based Purchasing Programs and the CMS eSMD Post-Payment Audit Program). NCVHS believes that it is important to ensure that basic e-infrastructure for administrative simplification align as well as possible with the rapidly developing connectivity requirements for moving patient clinical data¹⁰.

Conclusion

In summary, the healthcare industry's adoption and implementation of administrative simplification standards and operating rules has presented many benefits and challenges. Numerous hearings on attachments have provided an opportunity for NCVHS to learn about the successes as well as the barriers to successful implementation. The industry feedback indicates it is time to adopt attachment standards. Thank you for consideration of the recommendations in this letter. NCVHS remains available to answer any questions and will continue to support your efforts in the promotion and expansion of administrative simplification.

Sincerely,

Walter G. Suarez, M.D., M.P.H., Chairperson,
National Committee on Vital and Health Statistics

Cc: HHS Data Council Co-Chairs

¹⁰ HHS interoperability road map. <https://www.healthit.gov/sites/default/files/nationwide-interoperability-roadmap-version-1.0.pdf>