

Proposed Health Care Clinical Attachments

Background:

The Health Insurance Portability and Accountability Act (HIPAA) of 1996 (Section 1173(a)(2)(B)) identified electronic "Health Care Claims Attachments" as a transaction for which a standard was to be adopted. A proposed rule was published in 2005, but a final rule was never published due to questions about the maturity of the standards being recommended for adoption and concerns regarding the ability of potential users to implement the standards. In 2010, Section 1104 of the Patient Protection and Affordable Care Act (the ACA) directed the Secretary of Health and Human Services (HHS) to publish final regulations adopting national standards, implementation specifications and operating rules for Health Care Claims Attachments no later than 1 January 2014, with a compliance date no later than 1 January 2016.

On 14-15 June 2016, National Committee on Vital and Health Services (NCVHS), the statutory advisory committee responsible for providing recommendations on health information policy and standards to HHS, held their full committee meeting and presented their draft recommendations to HHS for the adoption of a clinical attachment standard. Please note, while originally called "Health Care Claims Attachments" the health care industry has shifted toward the phrase "Clinical Attachments" to reflect the broader usage of the standard for purposes including but not limited to claims, referrals, and requests for pre-authorization. Furthermore, on 5 July 2016, NCVHS submitted their recommendation letter to HHS recommending the following actions in adopting the standard:

- Adopt one standard definition of the "Attachment" transaction, and establish the scope of the transaction.
- Adopt a set of mature, implemental 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 CHIP Reauthorization Act of 2015 (MACRA)/Merit-Based Incentive Payment System (MIPS).

What is a Health Care Clinical Attachment?

In this context, the term "attachment" refers to any supplemental documentation needed to support a specific health care related event. Clinical Attachments are expected to include a specifically defined set of extracts from the medical record such as an x-ray, lab result, operative report, etc., needed to support the processing of a claim, request for referral/pre-authorization, etc. Clinical Attachments can be solicited or unsolicited. The extract may be designed to respond to a particular request from a payer (a solicited attachment) or proactively fulfill a documentation requirement that has historically

been requested by the payer (unsolicited attachment). Clinical Attachments should be limited to clinical or medical administrative information about the patient to whom the service was rendered or requested, including the dates of service and orders that produced the clinical data.

A solicited clinical attachment would be based on a request submitted by the health plan/payer to the provider, while an unsolicited clinical attachment would be submitted by the provider along with the associated claim or request for referral/pre-authorization based on a common agreement between trading partners. It is expected that most clinical attachments will be done in a solicited manner.

What are some of the expected benefits of the Health Care Clinical Attachments standard?

The goal of a standard for Health Care Clinical Attachments is to make the process of submitting and adjudicating health care claims and requests more efficient by providing structured, standardized electronic data to payers. By doing so, a receiver will have the data necessary to increase the rate of automated adjudication and processing, and thus reduce the administrative overhead necessary to process their transactions (i.e. claims, pre-authorizations, etc.). Providers are expected to benefit by faster claim adjudication and request processing.

As the rate of automated adjudication increases and human intervention decreases, senders will be able to better predict the successful adjudication and processing of their transactions. When providers are aware in advance of the need to provide additional information to support a health care transaction, they may, at their discretion, submit the attachments with their initial transaction.

This will result in a much shorter and more predictable turnaround, and will reduce the amount of time and effort necessary to respond when requests for additional information are made. A second significant benefit is the reduction of a very manual, paper driven process that exists today. If this data can be gathered and submitted electronically, senders will no longer have to manually retrieve and copy records and prepare paper (sometimes many pages of paper) attachments for the receiver. With electronic exchanges of clinical attachments an expectation is for a return on investment in the utilization of people resources, paper and postage.

Who will be required to use the Health Care Clinical Attachment standard?

The 2005 Health Care Claims Attachments Notice of Proposed Rule Making (NPRM) imposed requirements on all private sector health plans, government health plans (including Medicare, State Medicaid programs, the Military Health System for active duty and civilian personnel, the Veterans Health Administration, and Indian Health Service programs), all health care clearinghouses, and all health care providers that choose to submit or receive health care clinical attachment transactions electronically. Note: The Military Health System is not required to send/receive electronic clinical attachments.

What standards have been recommended for adoption in a Health Care Clinical Attachments Final Rule?

Industry Stakeholders, including standards development organizations and federal health advisory groups collaboration efforts have helped shape NCVHS's recommendations to HHS on which a standards should be adopted in a Final Rule. According to the aforementioned 5 July 2016 NCVHS letter to HHS,

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the below standards have been recommended for adoption for attachment-related transactions. These transactions are considered to be the envelope that would carry the clinical content or attachment:

- Query (Request) for Attachments :
 - X12N 277 Health Care Claim Request for Additional Information (for all claimrelated attachment requests)
 - 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:
 - Health Level 7 (HL7) Clinical Document Architecture (CDA) R2 Consolidated CDA Templates for Clinical Notes R2.1
 - HL7 Attachment Supplement Specification Request and Response Implementation Guide R1
- Acknowledgement
 - X12 Acknowledgement Reference Model (ARM)
 - X12C Implementation Acknowledgement for Health Care Insurance (999) and X12 TA1 Acknowledgement Segment (Appendix to the 999)
 - Acknowledgement standard (ACK)
- Attachment Type Value Set: Logical Observation Identifier Names and Codes (LOINC) developed and maintained by the Regenstrief Institute, Inc., LOING c/o Center for Biomedical Informatics. HIPAA Panel Solicited and Unsolicited Lists.

Lastly, for all of the above X12 transactions, NCVHS recommended the Secretary adopt the HIPAA version that will be expected to be in effect by the time these transactions are mandated.

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What does the data flow model for solicited and unsolicited clinical attachments look like?

The following diagram depicts what has previously been envisioned as the data flow models for solicited and unsolicited health care clinical attachments using the X12N 277/275 transactions:

