

Submitter : Mr. James Schuping
Organization : WEDI
Category : Health Care Provider/Association
Issue Areas/Comments

Date: 01/19/2006

GENERAL

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See Attachment

CMS-0050-P-78-Attach-1.DOC

CMS-0050-P-78-Attach-2.DOC

Workgroup for Electronic Data Interchange (WEDI)
Proposed Rule on
Standards for Electronic Claims Attachments
CMS-0050-P

WEDI Recommendations Adopted by the WEDI Board of Directors

I. STANDARDS ISSUES

Calls for the adoption of X12 and HL7 standards, including versions that utilize LOINC as the appropriate code set to identify attachment requests and responses. This section includes discussion on: Clinical Document Architecture (CDA), Attachment Types, and Content & Structure Issues.

1. Adoption of X12 and HL7 Standards that Utilize LOINC

Issue: The NPRM calls for the adoption of X12 and HL7 Standards that utilize LOINC as the appropriate code set to identify attachment requests and responses. The NPRM is asking whether these standards including LOINC are the appropriate standards that should be adopted for the Claim Attachment.

Recommendation 1: WEDI agrees with the NPRM approach for using standards developed by X12 and HL7 along with the LOINC code for the business purpose of a claim attachment.

Recommendation 2: WEDI supports the adoption of the Human Decision Variant and the Computer Decision Variants mentioned in the NPRM for electronic claims attachments. Both variants should be acceptable – not favoring one over the other.

Recommendation 3: We recommend that the content of the BIN segment does not have to be validated for the data that is not being used.

Recommendation 4: We recommend that CMS ask the Standards Development Organizations (SDOs) to provide guidance on receiving imperfect transactions - such as the content in the BIN 01.

Issue: In the regulation text section 162.1920(d) Standards of the NPRM - the phrasing for use of the BIN segment is not quite accurate.

Recommendation 5: WEDI recommends the following changes:

Original Text

“Response information may be free text, scanned documents, or an embedded, document within the BIN Segment of the response transaction”

WEDI Suggested Text:

"In accordance with the HL7 CDA, response information may be expressed as free text, scanned documents, or an embedded document with the BIN segment."

2. Overview of Clinical Document Architecture

Issue: The NPRM is seeking comment on whether to name HL7's CDA Release 1 versus Release 2 as the standard.

Recommendation 6: WEDI recommends moving to CDA Release 2, assuming there is a pilot that successfully uses Release 2. WEDI recommends, pending successful results of the pilot, that HL7 make the necessary changes to the HL7 implementation guide and Additional Information Specifications (AIS).

Anticipated benefits for using CDA Release 2 are as follows:

- a) Improvements in the technical consistency among all new HL7 standards including some of the following: Genomic Reporting; Adverse Event Reporting; and the Care Record Summary used for Continuity of Care.
- b) Increase consistency and compatibility with the code being developed for Electronic Health Records (EHR) for standard and other applications based on CDA.
- c) Improves the ability to use "off the shelf" software being developed by various health care vendors.
- d) Enhances the technology used for validating the computer-decision variant of attachments (when this is required)
- e) Conforms with U. S. Federal Consolidated Healthcare Informatics initiative
- f) Providers who implement EHRs would benefit from CDA release 2 because they could take advantage of commercial off-the-shelf software (COTS) solutions in their EHRs to create the electronic attachments.

Recommendation 7: WEDI recommends that CMS provide the industry 12 months notice as to which release will be specified in the final rule to allow adequate time for vendors and covered entities to prepare for implementation, especially those who might be early adopters. Entities need time for planning and budget process, testing and deployment.

3. Electronic Claims Attachment Types

Issue: The NPRM is seeking to identify whether the six attachment types are the right ones or whether there are other types of attachments that should be considered for adoption.

Recommendation 8: WEDI recommends the six attachment types proposed in the NPRM be adopted as standards because they are still significant and important for claims adjudication.

Recommendation 9: WEDI recognizes that there are overlaps between data elements that are in some of the attachment types as well as in the claim standards. WEDI recommends that the different standards organizations undertake a process for reviewing the overlapping data elements. Some of the overlapping occurs in the Ambulance and Therapy attachment types.

To eliminate the possibility of duplication of effort in the industry, WEDI recommends that CMS clarify that if the data is provided in the claim that it not be duplicated as an attachment

Recommendation 10: WEDI recognizes there are other types of attachments that could be beneficial. WEDI supports the process adopted by HL7 for outreach and development of new attachments.

4. Attachment Content and Structure

Issue: NP RM is seeking to validate whether the 64 MB size limit per BIN segment is sufficient for providers, clearinghouses, and health plans.

Recommendation 11: WEDI notes that a correction is needed to the preamble. The preamble should indicate that the 64 MB reference is per BIN segment and not per the 275 Transaction set.

Recommendation 12: WEDI recommends that the 64 MB not become a maximum limit. As technology evolves, so will the need for flexibility in adopting a size limit that can match the imaging or documentation developments of health care. Recommendations should be made as to best formats and the usage of technology and software to reduce transmission size.

5. Acknowledgements and Error Reporting

Recommendation 13: WEDI recommends the 275 Implementation Guide (IG) be changed to remove the use of the 102 transaction. WEDI recommends the reference in the 275 IG be changed to recommend the use of the X12 999 for syntax errors, and the use of the X12 824 TR3 to acknowledge both the X12 and HL7 content. This is consistent with the WEDI Acknowledgements PAG recommendations.

Recommendation 14: WEDI recommends that acknowledgements for claims attachments be consistent with the “WEDI Acknowledgement Recommendations for ASC X12N Implementation Guides,”

II. STANDARDS MAINTENANCE

1. Modification to Standards

Issue: The federal regulatory process for the adoption of new standards is lengthy. So too is the maintenance process to existing standards. Are there alternatives to existing processes that would yield a more timely and responsive methodology for these standards?

Recommendation 15: WEDI supports improving the regulatory process and will convene industry stakeholders including the DSMO and SDOs to address this issue.

2. Managing Changes to LOINC and the Implementation Guides

Issue: The implementation guides for the claim attachment standards references a subset of LOINC. How will health care acquire the educational materials pertaining to LOINC? Additionally, as changes to LOINC are made, will the standards reflect these changes and will the industry be prepared to adjust to these changes?

Recommendation 16: WEDI recommends that the Final Rule state a clear process on how to access the LOINC codes used for the HIPAA specific code set.

Recommendation 17: WEDI recommends that the Final Rule state a clear understanding of the maintenance and update to LOINC including the update schedule.

Issue: Because LOINC is adopted as a Medical Code Set, the regulation needs to clarify which LOINC codes are used in each of the AIS documents. There is a concern that absent this clarification, entities may attempt a legalistic position that any LOINC code may be used for any attachment.

Recommendation 18: WEDI recommends the regulation be clarified as follows:

- 1) Those AIS documents that contain static content (for example, Ambulance, Emergency Department, Rehabilitation, and Medications) the regulation must be clear that only the LOINC codes enumerated in AIS are allowed.
- 2) Those AIS documents that reference the LOINC database, the regulation should clarify that only the LOINC class as described in the LOINC

database (such as Laboratory or Clinical Reports) defined for those AIS is allowed.

III IMPLEMENTATION

1. Implementation Timeline

Issue: HIPAA regulations typically call for implementation 26 months after the final rule. Is this timeline feasible? Should there be a national roll-out plan? Would it be beneficial for staging the approach for certain attachment types?

Recommendation 19: WEDI recommends that 26 months is insufficient, an important step is the piloting of the CDA Release 2.

Recommendation 20: WEDI recommends the length of time after the effective date be as described in the proposed rule, however, WEDI recommends the final rule be published as soon as possible and the effective date of the final rule be 1 ½ years after its publication. This would provide a total of 3 ½ years. WEDI proposes the additional time in acknowledgement of the significant development work required.

2. Clearinghouse Perspective

Issue: The NPRM is seeking comments on a national roll-out plan and whether clearinghouses should go first.

Recommendation 21: WEDI recommends that a WEDI sub-workgroup on claims attachments explore and develop a national roll-out plan. And, that the industry supports a WEDI proposed national roll-out plan.

Recommendation 22 : WEDI recommends that clearinghouses are not required to implement first.

3. Industry Needs

Issue: Healthcare organizations have indicated assistance would be needed in implementing the attachment transactions.

Recommendation 23: WEDI identified the following items that would be useful tools to aid implementation.

- Education – overview of the transactions
- Education – process at providers, payers and vendors
- Education – LOINC codes, their use and interpretation

- Education – what resources and skills are needed to implement this
- Better education outreach to providers, payers, and vendors
- Using regional groups, such as WEDI's regional affiliates
- CMS being the sponsor and/or source of education, use of Medlearn
- CMS and WEDI links on other web sites, such as DMERC, other associations or sites that providers and payers typically use
- CMS site to link to other sites
- Education to Federal Intermediaries
- Information on vendor readiness; possible third vendor forum
- Internet for communication – pressure to have CMS use it
- CMS put together an interoperability center to use for testing for free, so parties can do testing without having to wait for an available trading partner
- Mapping between SNOMED and LOINC code set – federally sponsored and maintained.[crosswalk work is being done at the HL7 ASIG]

IV BUSINESS PROCESS

1. Solicited vs. Unsolicited Attachments

Issue: NP RM proposes that the request for claim attachment information would be a single iteration process to allow a single request (277) with the provider responding with a complete set of information to answer the request. NPRM asks for comments on the workflow implications.

Recommendation 24: WEDI recommends that health plans endeavor for completeness of the request by asking all known questions at the initial request, with the understanding that further questions may be asked based on information contained in the initial response.

2. Unsolicited Attachments

Issue: The NPRM indicates that unsolicited attachments could continue if “instructions” between health plan and provider exist.

Recommendation 25: WEDI suggests replacing the term “instructions” with the term “prior arrangement or experience.”

Recommendation 26: A provider, based on prior arrangement and/or experience with a health plan, may send unsolicited attachments until a health plan either issues advance instruction to clarify its requirements or explicitly instructs the provider that attachment is not required for the type of claim in question. If the plan instructs the provider that an attachment is not required but resumes requesting the attachment, the provider may resume sending an unsolicited attachment.

3. Other Business Use of Attachment Standards

Issue: Is it permissible to use the attachment standard for purposes other than claims adjudication? (Includes request for comment on Post-adjudication and trading partner agreement)

Recommendation 27: WEDI recommends that the regulation should not disallow health plans from collecting information via claims attachment process for purposes other than the purposes defined in this rule - such as, post-adjudication. WEDI suggests removing the requirement that this can only be done using trading partner agreements.

Recommendation 28: In section 162.1910(a)(2) the regulation text describes a workflow that is not recognized by the SDOs nor is supported by these standards. WEDI recommends that this workflow be stricken from the regulation text.

4. Coordination of Benefits

Issue: The NPRM indicates that when multiple health plans are involved in the adjudication of a patient's claim (coordination of benefits process) that each health plan would submit their own claim attachment request for information. Seeking comments on whether the primary health plan should forward the responses they receive to the secondary or tertiary health plan.

Recommendation 29: WEDI recommends that Payers who receive attachment information should not be required to send it onto the subsequent payers.

V. Clarifications

1. Other Procedures/Processes for Verifying Information

Recommendation 30: WEDI recommends the following changes for the second paragraph on page 56012: "The use of the standard electronic health care claims attachments would not preclude the health plan from using other processes or procedures to verify the information reported in the attachment documentation." WEDI recommends that CMS strike the word "verify" and replace with "clarify" - the remainder of the statement remains the same.

Recommendation 31: WEDI recommends that the WEDI PAG convene a discussion with the assistance of CMS to answer clarification requests cited below:

Clarification Request 1:

WEDI requests clarification that if a health plan does not have a current business model that sends requests for additional information (electronic or hardcopy), does the health plan have to use the 277 RFI if a provider requests it to be used?

Example, the health plan uses the unsolicited business model, thus publishing the criteria for the providers in advance and expecting the 275 with the claim.

Clarification Request 2:

Some health plans currently use a business process that will deny a claim for a reason of “needing additional clinical information”, i.e. needing information that would be in a claim attachment. Can that process continue? Or, does the request for that information now have to come through a 277 RFI? If this process can continue, how does the provider know what additional information to submit?

Clarification Request 3:

WEDI requests clarification on the issue of routing. Could a provider request use of the 277 be different for different claim attachment types, such as the routing of the request or the use of a 277 for one type of attachment but not other types? We see no need for this practice to separate handling of the 277 requests.

VI. PRIVACY

1. Impact to Privacy

Issue: Implications of minimum necessary provisions to the attachment transactions.

Recommendation 32: Request guidance for the following scenarios:

1. Payer has received a claim attachment but did not receive the claim. Today, payers may be storing an image and then return the paper original, or shred it, or file it.
2. Payer to payer COB if the attachment is sent on to the subsequent payer. What are the implications of privacy rule?
3. Plan requests specific questions, and providers send scanned documents with more than minimum information, since it is in a scanned document since it is on the same page.
4. If request does not specify a timeframe using a LOINC modifier, how far back does the provider go? Today, if it is not defined, then some providers only send the information related to that episode of care.
5. Payer receives claim and attachment, but the patient is not covered by that health plan. Today, they print out and return the information to the provider.

Recommendation 33: WEDI recommends that a requirement for providers to black out sections of a document that includes more than the minimum necessary information will be costly and would inhibit widespread adoption of this variant of the electronic claims attachments.

VII. IMPACT ANALYSIS

Issue: Are the citations related to the cost & benefits findings appropriate and realistic? Should we urge HHS to seek funding for a cost-benefit study? Where HHS specifically solicits input or data, please come prepared to share that data. Can we connect this or point out the relationship to the NHIN initiatives for funding, since claims attachments use clinical information standards?

Recommendations 34: WEDI recommends that CMS include the cost-benefit results from the Empire Medicare Services pilot in preamble of the final rule.

Recommendations 35: WEDI recommends that it is important to have funding options for initial implementation of these transactions. WEDI points out the relationship these standards have to the NHIN initiatives since the claims attachments use clinical information standards. Furthermore, WEDI urges HHS to also provide funding for a cost-benefit study

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*Partnering for Electronic Delivery
of Information in Healthcare*

January 18, 2006

The Honorable Michael Leavitt
Secretary of Health and Human Services
440D Hubert Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Leavitt,

In its advisory role under the Health Insurance Portability and Accountability Act (HIPAA), The Workgroup for Electronic Data Interchange (WEDI) provides input from its broad-based industry membership on issues related to Administrative Simplification that it believes merit review and consideration by the Secretary and by the National Committee on Vital and Health Statistics (NCVHS).

On October 24-25, 2005, WEDI conducted a Policy Advisory Group (PAG) Forum to address the Standards for Electronic Health Care Claim Attachments NPRM (CMS-0050-P). The PAG provided a forum for healthcare industry stakeholders to convene and discuss in detail issues relating to regulatory provisions and implementation specifications for the Claim Attachments NPRM. The outcome of the discussions was a set of PAG recommendations for ensuring a smooth transition to and industry compliance with the final Claim Attachments rule so that the benefits of this part of Administrative Simplification can be realized. The recommendations were reviewed subsequently and, with minor modification, approved by the WEDI Board of Directors on November 18, 2005. As WEDI recommendations, and on behalf of the WEDI Board of Directors, I send them to you for your review and consideration.

WEDI appreciates the opportunity to work with the Department of Health and Human Services, especially with the staffs of the Office of HIPAA Standards that is responsible for implementation of Administrative Simplification regulations.

Jim Schuping, Executive Vice President and CEO of WEDI, or I would be pleased to answer any questions pertaining to WEDI's Claim Attachment recommendations, which are enclosed herein.

Sincerely,

Mark McLaughlin
Chairman, WEDI

cc: WEDI Board of Directors
Dr. Simon Cohn; Chair, NCVHS

Submitter : Mr. Frank Pokorny
Organization : Dental Content Committee of the ADA
Category : Other

Date: 01/19/2006

Issue Areas/Comments

GENERAL

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The Dental Content Committee (DeCC) of the American Dental Association has prepared comments on CMS-0050-P. A cover letter and the DeCC comments are in an attachment to this "General Comment", submitted on January 19, 2006.

This entry is submitted by the DeCC Secretariat on behalf of the committee.

CMS-0050-P-79-Attach-1.RTF

January 19, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-0050-P
PO Box 8014
Baltimore, MD 21244-8014

RE: HIPAA Administrative Simplification: Standards for Electronic Health Care Claims
Attachments – 45 CFR Part 162 – (File Code CMS-0050-P)

Dear Sir or Madam:

The Dental Content Committee of the American Dental Association (DeCC) is the deliberative body sponsored and chaired by the American Dental Association (ADA), that has been established in accordance with the administrative simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) to cooperate in the maintenance of the standards adopted under HIPAA. On August 17, 2000, the Secretary of the Department of Health and Human Services designated the “Dental Content Committee of the American Dental Association” as a Designated Standards Maintenance Organization (DSMO) pursuant to Section 162.910 of the final rule titled “Standards for Electronic Transactions.” (See 65 *Fed. Reg.* 50312 and 50373 [August 17, 2000]).

The (DeCC) has prepared comments on the proposed rule concerning Standards for Electronic Health Care Claims Attachments as published in the Federal Register on September 23, 2005 (Volume 70, Number 184, Page 55990). These comments are contained in the following pages, and the committee is pleased to offer them for consideration as part of the Notice of Proposed Rule Making public comment process. The DeCC is comprised of representation from organizations representing dental practitioners, dental third-party payers and other organizations concerned with health care electronic commerce standards. DeCC members believe that the proposed rule will have significant implications for all sectors of the dental care community as well as the health care community at large.

Please direct any questions concerning this submission to the DeCC Secretariat, Mr. Frank Pokorny, Senior Manager, Dental Code Standards and Administration, telephone 1-312-440-2752, e-mail pokornyf@ada.org.

Sincerely,

Frank Pokorny

Frank Pokorny
DeCC Secretariat
Senior Manager, Dental Codes Standards and Administration

cc: DeCC Executive, Member Representatives, Alternates and Secretariat Staff

CMS-0050-P: Standards for Health Care Claims Attachments NPRM
 Comments from the Dental Content Committee (DeCC)

#	Page #	Section	Comment
1.	55993	A. DEFINITIONS	<p>The DeCC is in agreement with the definitions of the terms listed in the preamble of the proposed rule. These same definitions should be repeated in Section 162.1900 of the regulation text.</p>
2.	55993	2. Implementation Guides in the HIPAA Regulations	<p>In implementation of previous standards, one of the ongoing issues has been lack of synchronization between request and response transactions. An example in the current set is the missing Procedure Code Qualifier in the 275 2000A REF segment where the code qualifier of 'AD' for the dental codes is not present (P. 74). It is, however, present in the 277 transaction 222E SVC segment (page 98). Further, there is inconsistency in the code qualifier identification between the 275 and 277 for the same segments.</p> <p>Recommendations:</p> <ol style="list-style-type: none"> 1) The Qualifier HC should be used consistently between the 275 and 277, instead Code Qualifier HC is used in the 277 and CPT is used in the 275. 2) The implementation guide be subject to exhaustive review and revision to ensure that all references to professional, institutional and dental claims are correct (e.g., by their presence or absence) before the Guide is adopted as a standard under Section 162.1920 of the proposed final rule (page 56024 of the NPRM).
3.	55993	2. Implementation Guides in the HIPAA Regulations	<p>The 277 Implementation Guide implies that the transaction is relevant to all HIPAA standard claim transactions (837P, 837I and 837D) and includes dental procedure codes as valid for use in the 277 (e.g. Page 98). However, there are several instances where a specific reference to dental is missing. For example; 1) Note on Page 22 should also include reference to a dental claim, not just professional claim; 2) Note 1 on Page 77 should state that the segment is not needed for dental, in addition to the existing exclusion of professional claims.</p> <p>Recommendation: The implementation guide be subject to exhaustive review and revision to ensure that all references to professional, institutional and dental claims (e.g., applicable/not applicable) are correct before the Guide is adopted as a standard under Section 162.1915 of the proposed final rule (page 56024 of the NPRM).</p>
4.	55994	B. EFFECTIVE DATES	<p>The DeCC finds the timeframe outlined to be marginal for the implementation of the claims attachment transaction. Although the NPRM states that covered entities have already implemented other X12 transactions and set up the business agreements for translator services, submission and receipt protocols, and testing, such mass implementation of the core HIPAA standard transactions has not taken place in the small or solo practice sector. Members of this sector include dentists and physicians.</p> <p>The proposed standard is set forward as a "second-round" HIPAA transaction standard, which presumes that most of the technical infrastructure and supporting processes should already be in place to accommodate a new standard transaction. However, we note that the proposed rule incorporates data content (e.g., LOINC) that is likely unfamiliar to significant portions of the health care community. It is uncertain whether the implementation period can successfully accommodate necessary education on such matter.</p>

CMS-0050-P: Standards for Health Care Claims Attachments NPRM
 Comments from the Dental Content Committee (DeCC)

#	Page #	Section	Comment
			<p>The committee recognizes that the Electronic Claims Attachment Project through Empire Medicare Services was able to implement and conduct claims attachment transactions within a six-month period of time. As this project was much more limited in scope, we question whether it is an accurate bellwether of the health care community's ability to implement the proposed transactions within the timeframe specified in the rule.</p> <p>Please note that the DeCC supports the WEDI SNIP Claims Attachment Workgroup efforts in developing an implementation plan for the industry related to this standard.</p>
5.	55995	1 Overview of Extensible Markup Language (XML)	<p>This section acknowledges that "...XML is a relatively new technology." and further states that "...XML has been adopted by most major companies in information technology as the basis for obtaining interoperability...." These two comments cast further doubt on the ability for significant portions of the health care community to adopt the proposed standard within the proposed 24 month implementation period before compliance is mandatory.</p> <p>The Dental Content Committee supports the adoption of XML for health insurance transactions because tools to create, exchange and read the transactions are readily available and will simplify the development of required software. However, the dental industry has very limited experience with the use of XML in practice management, clearinghouse and plan systems. Health care companies, and the individual practitioners who make up most of our market, will be treading new ground with such a new architecture. Small entities will face additional costs to implement the proposed transactions.</p> <p>We encourage HHS to develop an overall implementation strategy to enable all covered entities to implement the claims attachments standards without disrupting business operations. This strategy must include pilot tests to expand the knowledge base for and industry experience with the use of XML in claims attachment standards prior to requiring all covered entities to adopt it.</p>
6.	55995	2. Overview of Clinical Document Architecture	<p>The DeCC concurs with moving to CDA Release 2.0, versus the current Release 1.0, assuming that there is an adequate pilot of Release 2.0 that demonstrates acceptable functionality. It is our understanding that the following are benefits of CDA Release 2.0:</p> <ul style="list-style-type: none"> • More technical consistency with all new standards coming from HL7 including, but not limited to genomic reporting, adverse event reporting, and the care record summary used for continuity of care. • More consistency with code being developed by EHR developers (vendors and users) for standard and other applications based on the CDA • More ability to use off-shelf software being developed by health care vendors • Improved technology for validating computer-decision variant instances of attachments (when this is required) • Compliance with the U.S. Federal Consolidated Healthcare Informatics initiative
7.	55996	4. Transactions for Transmitting Electronic Attachments	<p>The DeCC strongly supports the use of structured, as opposed to unstructured, content in electronic data interchange and we believe that the HL7 standards provided such structure. We note that the language regarding Binary Data (BIN) segments does not specify that it conveys the HL7 CDA standard as discussed in "3. How XML Is Applied Within the Clinical Document Architecture." It should be made clear that the</p>

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			<p>HL7 standards are to be used in the BIN segment.</p> <p>What is not clear is whether imaged data and text, for example, could be in the BIN segment without the CDA structure. These clarifications are necessary with each reference to BIN segments throughout the proposed rule.</p>
8.	55996	5. ELECTRONIC CLAIMS ATTACHMENTS TYPES	<p>The DeCC believes that the six proposed attachment types: Ambulance Services, Emergency Department, Rehabilitation Services, Clinical Reports, Laboratory Results and Medications, are the most frequently requested by health plans and there are currently no others that are equally or more pressing for the health care community.</p> <p>Further, the DeCC strongly recommends that prior to consideration of additional attachment types a large scale survey be done in the health care industry to determine the perceived need for additional types of claims attachments, the anticipated frequency with which additional standard attachments would be used, and the anticipated costs and savings related to implementation of electronic claims attachment transactions.</p>
9.	55996	5. ELECTRONIC CLAIMS ATTACHMENT TYPES	<p>The DeCC desires to express its interest in the adoption of attachment standards to support the claim adjudication process. As the vast majority of attachments for dental claims are radiographs, which are not included in the proposed standard, we encourage the Secretary HHS to develop an interim final rule for comment and investigation prior to the promulgation of final standards. This would help ensure that the resulting attachment transaction can adequately address the needs of the dental benefits industry without undue confusion, or operational or financial burden, on practitioners, payers and clearinghouses</p>
10.	55997	6. FORMAT OPTIONS (Human vs. Computer Variants) for Electronic Claims Attachments	<p>The DeCC strongly support the flexibility being allowed in the proposed rule for using either the human or computer decision variant options of the HL7 CDA. We agree with the human variant option's provisions for transmission of scanned or imaged documents as well as narrative text. What is not clear is any provision for transmission of radiographs (DICOM standard) or photographic images (digital or otherwise). If these items are not within the scope of the proposed six types of attachments, that must be noted.</p>
11.	55998	7. COMBINED USE OF DIFFERENT STANDARDS Through Standard Development Organization (SDO) Collaboration	<p>The DeCC strongly supports the use of standards for electronic data interchange, versus non-standard approaches. We support the collaborative efforts of HL7 and X12 in developing the format and content of the transactions in this proposed rule.</p>
12.	55999	1. Electronic Health Care Claims Attachment vs. Health Care Claims Data	<p>The DeCC agrees with the statement "Electronic health care claims attachments must not be used to convey information that is already required on every claim." Duplicate transmission of data brings no additional value to the proposed transaction and places an additional administrative burden on both the originator and recipient of the transaction.</p>

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			Further, claims attachments must remain as an exception and not become a rule with each claim. We see the Data Content Committees (NUCC, NUBC, and DeCC) having responsibility for examining and recommending claim data requirements as well as data best included in an attachment.
13.	55999	2. SOLICITED VS. UNSOLICITED ATTACHMENTS	The DeCC believes that use of unsolicited claims attachments provides for more efficiency in the claims adjudication process, and agrees that such transactions be sent only when there is a prior arrangement (or standard) that is consistent between all providers and all payers.
14.	55999	3. Coordination of Benefits	The DeCC see the potential of the standard claims attachment to facilitate the COB process, and we support the preamble's language that states that any secondary health plan would send an attachment request separate from a request made by the primary health plan. This statement should be reiterated in the regulatory text.
15.	55999	4. Impact of Privacy Rule	<p>The DeCC believes that the Department of Health and Human Services (HHS) should provide more formal guidance on the relationship between a claims attachment's data content and the HIPAA Privacy regulation's concept of "minimum necessary" information. As written this portion of the regulatory preamble makes some 'good-faith' assumptions, e.g., "...health plans or health care providers may exercise discretion as to whether the information should be provided or requested in the transaction..." and "A health care provider may rely, if such reliance is reasonable under the circumstances, on a health plan's request for information, or specific instructions for unsolicited attachments, as the minimum necessary for the intended disclosure."</p> <p>We believe there needs to be a balance between the patient's right to privacy and the ability for the provider to respond to a request for additional information, specifically as it relates to the use of scanned documents within the attachment. In addition, the NPRM does not address the recipients' maintenance of the data and use of the data under which the rule applies. We recommend that all data on a single scanned page that contains required attachment information should be deemed to fall within the minimum necessary requirements of the Privacy rule.</p>
16.	56000	6. Connection to Signatures (Hard Copy and Electronic)	The DeCC believes that signature information should be conveyed in the same manner as on the claim (837) transaction, the signature on file indicator or by applicable HL7 CDA standards. If necessary, an image of the signature could be included within the attachment transaction envelope.
17.	56000 0	6. Connection to Signatures (Hard Copy and Electronic) [HL7 suggested response]	<p>We concur that there is no interoperable standard for electronic signatures. The term electronic signature is broadly understood to include a variety of technical approaches that vary in technological complexity and forensic accountability. Some representative technological approaches include:</p> <ul style="list-style-type: none"> (a) simply transmitting a data field that indicates that the sender has a "wet" signature on file (b) simply transmitting a data field that indicates that an authenticated user of an electronic has performed an overt act that would serve as a "signing ceremony" (c) transmitting an image of a document, or a portion thereof, that includes a wet signature (d) strongly authenticating a computer user and using digital signature

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			<p>technologies to record the electronic act of signing a document and associate it with the electronic document itself in a manner that allows subsequent verification that only the authorized signer could have performed the act of signing and the electronic document has not been subsequently altered.</p> <p>The choice of approach depends on the specific business use, applicable legislation and governmental regulations and the policies of the parties exchanging electronically signed documents.</p> <p>We further concur that there is an important business requirement to share signatures electronically as information in support of a healthcare claim. The signature that must be shared is often not the signature of the author of the electronic attachment document. For example, a consent signature is generally that of the patient or the patient's agent and a rehabilitation plan may include the signatures of multiple providers not all of whom are the authors of the plan.</p> <p>The <signature_cd> element of CDA Release 1 is only defined for case (b), above, and only describes the signature of the author of the CDA document.</p> <p>It is important that the standard for additional information in support of a claim support multiple approaches to signature so that the correct approach may be chosen that is practical, cost-effective and consistent with the federal, state and local legislation, regulations and policy. For example, there are regulatory and practical concerns that rule out approaches (a), (b) and (d) for consent forms, since policy makers have indicated that a "wet signature on file" is not adequate and it is unlikely that the person providing the signature will usually be an authenticated user of a healthcare provider's electronic system, much less a strongly authenticated user.</p> <p>We would propose, therefore, that the final rule and commentary either be silent on electronic signature or indicate that individual attachments should specify the approach to electronic signature appropriate to the business needs for that attachment</p>
18.	56001 - 2	E. ATTACHMENT CONTENT AND STRUCTURE	<p>The DeCC finds the 64 megabyte file size to be acceptable, but the final rule should not prohibit trading partners to agree on a higher limit when necessary to adjudicate a claim. In addition, the DeCC recommends that there be a process in place to periodically review the rule's file size limit to accommodate technology change.</p>
19.	56004	G. Proposed Standards	<p>The DeCC supports adoption of the HL7 and X12 standards, as named in the preamble and Section 162.1915 of the regulatory text, to fulfill the business need addressed by the proposed claims attachment transaction standard. The X12 standards request and response transactions coupled with the HL7 messaging structures appear to represent the best electronic solution for exchanging additional information for the purposes of claims adjudication.</p>
20.	56004	1. Code Set	<p>The DeCC supports LOINC as the code set for representing the specific elements of attachment information. We, in part, are basing our support on the understanding that the "Proof of Concept" study in 1996 demonstrated that another code set, Health Care Claim Status Reason, did not adequately support the electronic claims attachment needs.</p> <p>Further, we believe that many sectors of the health care community are not familiar</p>

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			with the frequency or process by which the LOINC code set is changed. Therefore, the DeCC recommends that a process and timetable be established and published for updates to the LOINC code set as it applies to the proposed claims attachment standard. The data content committees (DeCC, NUBC and NUCC) named by the Secretary of HHS should review the business case for proposed changes to the LOINC code set for the claims attachment standards.
21.	56005	3. Electronic Health Care Claims Attachment Response Transaction	The DeCC recommends that HHS develop a survey and ongoing process to track the utilization of the named and any unnamed attachment types to determine which attachment types are most needed by the health care industry.
22.	56006	4. a. Use of the Proposed Transaction, Specifications, and Codes for Electronic Health Care Claims Attachments	The DeCC interprets this section as meaning one transaction may contain multiple attachments and attachment types to satisfy the need of the payer to adjudicate a claim."
23.	56012	H. Requirements (Health Plans, Covered Health Care Providers and Health Care Clearinghouses)	<p>The preamble of the NPRM states that "No other electronic transaction format or content would be permitted for the identified transactions." In addition, the regulatory text in Section 162.1905 states that when using "electronic media" a covered entity must comply with the applicable standards. The DeCC would like further clarification of what constitutes "other electronic transactions" and "electronic media."</p> <p>Currently, some health plans and health care providers have systems in place in which the health plan can access patient information from the provider through a web portal. In this situation, there is no exchange of information between the health plan and provider. The health plan is able to obtain the information they need through the viewing capability. In addition, some providers respond to requests for additional information by emailing the scanned document to the health plan.</p> <p>The DeCC recommends that the final rule recognize that these types of exchanges are allowed via web portals. In addition, the rule should state that a payer may not force a provider to use a web portal in lieu of the standard transaction (i.e., the payer must still be able to accept the standard transaction).</p>
24.	56012	H. Requirements (Health Plans, Covered Health Care Providers and Health Care Clearinghouses)	<p>The DeCC request clarification of the second paragraph in this section, which states that "...use of the standard electronic health care claims attachment would not preclude the health plan from using other processes or procedures to verify the information reported in the attachment documentation." Clarification is needed when considering possible scenarios, including the following two examples:</p> <ol style="list-style-type: none"> 1) If the intent of this language is to address a post-payment review, then this should be more clearly stated. 2) If the intent is to allow for non-electronic verification of claims attachment information without any specific limitations to when the verification can be requested, then there would be an undue burden to the health care provider to

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			respond to the claims attachment request and later verify the attachment information either via the phone or paper submission.
25.	56012	[H.] Covered Health Care Providers	The DeCC supports the provisions which enable providers to convey information via paper or in other non-standard electronic formats when such matter is not part of the claims attachment transaction standard. This flexibility enables uninterrupted continuation of existing business processes, and may well facilitate transition to the proposed standard for its enumerated attachment types.
26.	56013	3. Maximum Data Set	The DeCC agrees that each AIS should be considered to contain the "...maximum data set for each of the named electronic attachment types." The ability to predict the maximum facilitates implementation planning and execution.
27.	56013	III. MODIFICATIONS TO STANDARDS AND NEW ELECTRONIC ATTACHMENTS	<p>The DeCC agrees that the 1993 WEDI estimate of attachments should be reviewed for currency and accuracy. We believe, and have submitted comments on earlier portions of this NPRM, that the nature and number of attachment types should be determined by the named Data Content Committees, with information provided through surveys/information collection supported by HHS.</p> <p>Further, the DeCC agrees that modifications to the claims attachment standard, once adopted by the Secretary, HHS, should be submitted, evaluated and acted upon through the DSMO process. Such modifications include transaction content and format, and attachment types, including new attachments. Modifications to external code sets would be not be subject to the DSMO process as such maintenance would be according to the protocols established by the entities responsible for such code sets.</p> <p>Practically speaking, the current process for adoption of new versions of named standards under HIPAA requires a minimum of eight years. This hampers the evolution of our industry and adds additional costs to doing business. The DeCC strongly opposes the adoption of any additional standards, including those proposed herein, until a mechanism has been developed for the industry to adopt regular periodic (e.g., biennial) updates as required.</p>
28.	56016	COSTS AND BENEFITS 1. General Assumptions, Limitations, and Scope	<p>The DeCC does not support the assumption that attachments are "...usually...sent in response to a specific request after a claim has been submitted..." especially if this assumption is being used in the cost and/or savings estimates. We find that this assumption is false as what is actually occurring is submission of attachments without waiting for a specific request.</p> <p>Providers regularly comment, and health plans confirm, that currently attachments are frequently submitted in conjunction with the original claim submission whether or not they are necessary for a specific health plan's adjudication process. Myriad attachments are routinely sent by providers due to the lack of accepted standards concerning when an attachment is necessary for a particular type of claim.</p>
29.	56017	COSTS AND BENEFITS 1. General Assumptions, Limitations, and	The DeCC strongly disagrees with one of the "...assumptions ...based on anecdotal comments by industry professionals..." The assumption "The volume of unsolicited attachments accompanying original health care claims today is relatively small." is not applicable to the dental community. As noted in the DeCC comment for page 56016, myriad attachments are routinely sent by providers due to the lack of accepted standards concerning when an attachment is necessary for a particular type of claim.

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		Scope	The perception that the overall volume is small may be correct for the entire health care community, but it is important to recognize that difference sectors work in different business environments.
30.	56018	COSTS AND BENEFITS 3. Cost and Benefit Analysis for Covered Health Care Providers	<p>The DeCC takes exception to the presumption that "...many of these items should not represent unusual expenditures..." or the cost "... to implement this proposal...are not to be considered to be significant..." Within dentistry and other medical arts the predominant organizational size results in annual revenue far under the \$8.5 million for physicians or \$6.0 million for other practitioners cited in the preamble's discussion of Small Business Association table of size standards (page 56015).</p> <p>Solo or two-person professional practices with annual revenues are more prevalent than the preamble suggests. The American Dental Association's "2003 Survey of Dental Practice" determined that 64.3% of all dentists were in solo practice and the annual gross billings per owner dentist were \$550,920 for general practitioners and \$778,630 for specialists. The combined weighted annual billings were \$592,310, with 95.3% of billings collected (\$564,471) and considered annual revenue.</p>
31.	56024	162.1910 Electronic health care claims attachment request transaction	The DeCC would like clarification of the language in Section 162.1910 (a) (2) that indicates an attachment can be sent in advance of the health care claim submission. The process being allowed by this language would begin to make sense if the attachment was in support of a request for predetermination.
32.	56024	162.1920 Electronic health care claims attachment response transaction	The DeCC find the language in Section 162.1920 (e) to be unclear. As the proposed standard provides for an unsolicited attachments transaction from provider to health plan, what is meant by limiting such submissions "...only upon advance instructions by a health plan."

Submitter : Mr. Philip Heinrich
Organization : California Department of Health Services
Category : State Government

Date: 01/19/2006

Issue Areas/Comments

GENERAL

GENERAL

I am submitting additional comments on behalf of the California Department of Health services. These comments are in addition to the comments I submitted in the original comment period.

CMS-0050-P-80-Attach-1.DOC

Commenting organization
Date Comment Submitted

Philip Heinrich on behalf of California Department of Health Services Workgroup

Jan. 19, 2006

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Document Number	Page #	Par/Sec or Fed Reg Column	LOINC (if appropriate)	Comment or Suggested Change	Business Justification
Comments to 275					
275 Additional Information to Support a Health Care Claim or Encounter	9	1.3.2	N/A	<p>Currently the proposed 275 standard for claims attachments requires that for unsolicited attachments, the 275 and the 837 should be sent in the same interchange. Medi-Cal would prefer if this decision be left to agreements between trading partners. Trading Partners should have the option to allow the 275 and the 837 to come in different interchanges as long as their business flow can handle it. The current 5010 version of the 275 allows for this.</p>	<p>Some translators have difficulty with two different transactions within the same interchange.</p>

275 Additional Information to Support a Health Care Claim or Encounter	F.1	F.1	N/A	Medi-Cal recommends that the 824 be used to acknowledge data in the BIN segment versus the stated 102 in the 275 IG.	During the EMS Claims Attachment Pilot, it was proven that the 824 is a better solution for acknowledging the contents of the BIN segment. Medi-Cal agrees with this assessment and would like to see the 824 as the recommended acknowledgement for the 275.
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Submitter : Mrs. Karen Van Hentenryck

Date: 01/19/2006

Organization : Health Level Seven

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment. Attached are HL7's comments on the Attachments NPRM.

CMS-0050-P-81-Attach-1.DOC

CMS-0050-P-81-Attach-2.DOC

HL7 comments submitted to HHS regarding NPRM for Electronic Claims Attachments standards

Formatted: French (Canada)

Re: 45 CFR Part 162
[CMS-0050-P]
RIN 0938-AK62

HIPAA Administrative Simplification Standards for Electronic Health Care Claims Attachments

Comment Number	NPRM or Tech.Spec Page #	NPRM Column (L,C, R)	Comment Section	HL7 Comment to CMS
1	N/A	N/A	N/A	<p style="text-align: center;">Joint HL7/X12 Comment</p> <p>HL7 Comment: HL7 and X12 have collaborated on the following topic and submit this joint response</p> <p>HL7 Comment: HL7 and X12 have always been aware that additional work was needed to address the issue of data that "belongs in the claim" versus data that "belongs in the claims attachment." This is particularly apparent when we consider ambulance services, some rehabilitative services (currently proposed attachments) as well as home health services, DME services and others. Being aware of the importance of this issue, X12 created a special workgroup led in their data modeling task group (TG3) in 1998 and 1999 to address this issue. HL7 was represented and active in these deliberations. This work went on for over a year, and there were several conclusions, among them:</p> <ol style="list-style-type: none"> 1. A "data migration strategy" needed to be developed, and when an NPRM for claims attachments was published X12 and HL7 would address this issue. It could not be done sooner as we had no idea of dates and versions until we knew the expected implementation date for attachments. 2. Draft criteria were developed to help determine where data should reside 3. Certain data should come out of the claim - for example home health segments - and be represented in the attachment. This X12 decision was the impetus for HL7 developing the home health attachment. We also agreed that we needed to deliberate more on other data and where it should reside. Home Health is just an example of where there was clear direction established.

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HL7 comments submitted to HHS regarding NPRM for Electronic Claims Attachments standards

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				<p>Understanding the importance of this issue, HL7 took the measure to collect all meeting minutes as well as formal recommendations from that work effort and record it on a "CD" which was later distributed to X12 and HL7 members (CMS included) so that everyone understood our go-forward strategy as well as why and how we developed it. Should CMS desire another copy of this CD, we would be happy to provide it.</p> <p>Now that the NPRM for claims attachments has been published, X12 and HL7 have reinitiated this work effort, as we had always planned to do. We will be holding a "kickoff" meeting on this topic in spring 2006 - planning for this meeting is already underway. Our expectation is that subsequent work will take place via tele-conference. Once a final set of recommendations are prepared, they will be vetted through other industry organizations. Our kickoff meeting as well as working tele-conference meetings will be open to anyone wishing to participate.</p> <p>Most importantly, HL7 and X12 strongly recommend that the Final Rule, particularly the regulation text, <u>does not</u> dictate what data is appropriate for a claim or an attachment. Our primary reasons for this recommendation is because the issue needs to be studied further by industry and the decisions aren't tied to a regulation, and therefore not able to change when business needs dictate. Furthermore, we recommend that the Final Rule acknowledge the significant amount of good work already done in this regard between X12 and HL7 and recognize that these two SDO's are addressing the data needs and data migration strategies as described above.</p> <p>We are aware of other comments that will be submitted that will ask CMS to take a position that states that data already in the claim should not be included in an attachment. For all of the reasons stated above, we urge CMS not to make a statement one way or the other in the final rule, rather support the SDOs in their effort to work with industry to address this issue</p>
2	N/A	N/A	N/A	<p>HL7 Comment: For the Ambulance Services AIS:</p> <p><u>Need to remove 2 LOINC's:</u> 18591-8 EMS TRANSPORT, CONFINED TO BED BEFORE TRANSPORT 18592-6 EMS TRANSPORT, CONFINED TO BED AFTER TRANSPORT</p> <p><u>Need to create and add a LOINC for:</u> "Patient is confined to a bed or chair.</p>

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3	N/A	N/A	N/A	<p>HL7 Comment:</p> <p>After much consideration and coordination with the HL7 Emergency Care (EC) SIG, HL7 recommends that the Emergency Department Attachment (AIS) not be included in the Final Rule for claims attachments.</p> <p>Furthermore, HL7 recommends that the ASIG and EC SIG undertake a project to evaluate the necessity for the ED attachment, and propose a solution that may result in an updated ED attachment or inclusion of some of the ED data elements in other attachments, such as clinical reports and labs. An ED report is considered a type of clinical report, and as such may be appropriate to be incorporated in that attachment.</p> <p><u>Preliminary rationale for this decision includes the following. The ASIG and EC SIG will further explore these observations as they determine the best course of action related to attachments for ED services.</u></p> <ul style="list-style-type: none"> ○ Current ED AIS specification has a dependency on DEEDS 1.0 – DEEDS –in need of updating to current time, so its inclusion in ED attachment to be used now is an issue ○ The ED attachment does not contain much more than what's contained in clinical reports / labs. Payers could get the information they needed related to an ED visit using the clinical reports and lab attachments. Do not want to have duplication ○ Many of the LOINC codes specified in the Clinical Reports are specific to the narrative data type. Since it is not the intent of the ASIG to preclude/prohibit the use of nominal (coded) data, this requires addition discussion. At this point we believe that the next step is to discuss with LOINC the possibility of providing appropriate codes which do not specify or exclude any specific data type for the reply. There are changes underway with LOINC that would make this a non-issue, once they are published.

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4	55999		2. Solicited vs Unsolicited Electronic Health Care Claims Attachments	<p align="center">Joint HL7/X12 Comment</p> <p>HL7 Comment: HL7 and X12 have collaborated on the following topic and submit this joint response</p> <p>This section states that the ASIG refers to the scenario of sending an attachment with the initial claim as an unsolicited attachment. The unsolicited attachment was defined by the X12 work groups. X12 and HL7 recommend that the sentence be revised to read as follows: ASC X12N WG9 refers to this scenario, of sending attachment information with the initial claim, as an unsolicited attachment because a request was not made after the fact, using the standard request transaction.</p>
5	56001		E. Electronic Health Care Claims Attachment Content and Structure	<p align="center">Joint HL7/X12 Comment</p> <p>HL7 Comment: HL7 and X12 have collaborated on the following topic and submit this joint response</p> <p>This section states that the standards have been under development for over 8 years by the HL7 ASIG. Since the standards were also developed by X12, HL7 and X12 recommend revising the sentence to read as follows: In sum, the proposed standards are those that have been under development for over eight (8) years by the SDO's.</p>
6	56023 56024 56024	C C R	162.1002 (LOINC) 162.1915 162.1925	<p align="center">Joint HL7/X12 Comment</p> <p>HL7 Comment: HL7 and X12 have collaborated on the following topic and submit this joint response:</p> <p>HL7 and X12 are in agreement with the proposed X12 and HL7 standards, including HDV and CDV, and furthermore, HL7 approves the LOINC code set to be used to identify the questions.</p>

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7	56013		III. Modifications to Standards and New Electronic Attachments	<p align="center">Joint HL7/X12 Comment</p> <p>HL7 Comment: HL7 and X12 have collaborated on the following topic and submit this joint response</p> <p>This section states that the industry should identify the relevant attachment types and collaborate to assign priority to each one. Since the industry collaboration will be to work with the SDO's through their accredited process, X12 and HL7 recommend revising the sentence to read as follows: The industry should identify the relevant attachment types and work with the Standard Development Organizations to assign priority to each one, so that new electronic attachment specifications that are appropriate to the business needs of the health care industry can be developed.</p>
8	56023		162.1900 Definitions	<p align="center">Joint HL7/X12 Comment</p> <p>HL7 Comment: HL7 and X12 have collaborated on the following topic and submit this joint response</p> <p>The definitions in the regulation text do not match the definitions in the preamble. X12 and HL7 recommend that section 162.1900 be revised to be consistent with the definitions in the preamble. In addition, X12 and HL7 recommend adding definitions for LOINC codes, the LOINC database and LOINC modifiers to the definitions in the regulation text.</p>
9	55999	R	II, C, 2 Overview of Clinical Document Architecture	<p align="center">Joint HL7/X12 Comment</p> <p>HL7 Comment: HL7 and X12 have collaborated on the following topic and submit this joint response:</p> <p>Comment 1: HL7 and X12 recommend moving to CDA release 2, assuming that there is a pilot that uses CDA release 2. Additionally we note that HL7 will need changes to the HL7 IG and each AIS developed to be based on CDA release 2. HL7 has every intention of making all necessary specification changes in as timely a manner as is possible.</p> <p>Comment 2: The benefits of using CDA Release 2 would be:</p> <ol style="list-style-type: none"> 1. More technical consistency with all new standards coming from HL7 including, but not limited to genomic reporting, adverse event reporting, and CDA implementation guides, including the Care Record Summary.

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				<ol style="list-style-type: none"> 2. More consistency with code being developed by EHR developers (vendors and users) for standard and other applications based on the CDA 3. More ability to use off-shelf software being developed by health care vendors 4. Improved technology for validating computer-decision variant instances of attachments (when this is required) 5. Compliance with the U.S. Federal Consolidated Healthcare Informatics initiative 6. Providers who implement EHRs would benefit from CDA release 2 because they could take advantage of commercial off-the-shelf software (COTS) solutions in their EHRs to create the electronic attachments. Most EHR vendors are developing CDA R2 implementations and not CDA R1 implementations. 7. Military Health System Enterprise Wide Referrals and Authorizations will use X12 278/275 and CDA Release 2. 8. R2 HDV no more complex than R1 HDV.
10	55997	C	6. Format Options	<p align="center">Joint HL7/X12 Comment</p> <p>HL7 Comment: HL7 and X12 have collaborated on the following topic and submit this joint response:</p> <p>The HDV allows economic benefits given the limitations of current provider/payer systems. The CDV allows extended benefits to be obtained (for attachment types ambulance, emergency department, rehabilitation services, lab results, medications, and clinical reports) as provider and payer systems evolve to have and use more structured data. Allowing both, and giving the industry the option to implement them in parallel, allows the extended benefits to be obtained gradually through incremental business decisions, which is far sooner than the benefits could be obtained through a "one size fits all" regulatory mandate.</p>
11	55996	C	II.C.5	

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			Electronic Claims Attachment Types	HL7 Comment: HL7 supports five of the six initial attachment types being proposed as standards. See separate HL7 comment regarding the Emergency Department attachment.
12	56001	R	Reg is 162.1910 –C II, E Attachment Content and Structure	HL7 Comment: HL7 believes that the recommended size limit of 64 MB is a limitation <u>per BIN segment</u> , not a limitation per 275 (entire transaction). HL7 does not have a comment related to the specific size recommendation for the BIN segment.
13	55993 56022	R	II, A Definitions	HL7 Comment: HL7 recommends the definitions provided in the preamble also be the definitions that are given in the regulatory text. We note that some of the definitions do not seem complete in the regulatory text.
14	56024	R	162.1920 (d)	Joint HL7/X12 Comment HL7 Comment: HL7 and X12 have collaborated on the following topic and submit this joint response: Regarding paragraph (d) A health care provider that sends scanned images and text documents in the attachment transaction, for the human decision variants, is not required to use the LOINC codes as the response, other than to repeat the LOINC codes in the HL7 CDA that are used in the 277 request. We recommend that paragraph (d) be modified to read as noted above in bold font. Also, we recommend changing the following sentence to reflect the verbiage noted in "bold" below: Response information may be free text, scanned documents, or an embedded document within the BIN segment as expressed in accordance with the HL7 CDA, which must be included in the BIN segment of the response transaction.
15	56014		III. Modifications to	Joint HL7/X12 Comment

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HL7 comments submitted to HHS regarding NPRM for Electronic Claims Attachments standards

Comment Number	NPRM or Tech.Spec Page #	NPRM Column (L,C, R)	Comment Section	HL7 Comment to CMS
			Standards ,A & B. 1 st paragraph	<p>HL7 Comment:</p> <p>HL7 and X12 have collaborated on the following topic and submit this joint response:</p> <p><u>Comment 1:</u> Our main goal is to move the regulatory process forward more quickly. For new attachment types* (AIS), we recommend that the DSMO be authorized to adopt those that are developed, balloted and published by HL7 through the DSMO process. Stop the process here and do not go through the full regulatory process.</p> <p>This overall process will include provisions for outreach and comments in the HL7 SDO processes. In addition, notification and rollout time between adoption and implementation date needs to be added after the HL7 publication. More time is needed to implement new types than for changes to existing ones.</p> <p><u>Comment 2:</u> Additionally, we recommend that five of the six initial attachment types be adopted as standards. <i>See separate HL7 comment regarding the Emergency Department attachment.</i></p> <p><u>Comment 3:</u> Our main goal is to move the regulatory process forward more quickly. For <i>new versions</i> of standards by HL7 or X12, we recommend that the DSMO be authorized to adopt those that are developed, balloted and published by HL7 or X12 through the DSMO process. Stop the process here and do not go through the full regulatory process.</p> <p>This overall process will include provisions for outreach and comments in the SDO processes. In addition, notification and rollout time between adoption and implementation date needs to be added after publication. Provisions for sunseting older versions of the standards after a transition period must be included.</p> <p>Additionally HL7 and X12 recommend that the Implementation timeframes of new HL7 AIS booklets should allow six months, minimum, for new attachment types, and 12 months for new versions of existing attachment types. The timeframe begins once the DSMO has completed its review/approval process.</p> <p>Attachment types currently in varying stages of development, but not named in the Final Rule include EAP, DME, CPHS, Periodontal, Home Health, and Consent Forms.</p>

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Comment Number	NPRM or Tech.Spec Page #	NPRM Column (L,C, R)	Comment Section	HL7 Comment to CMS
16	56014		III. Modifications to Standards ,A & B.	<p>HL7 Comment:</p> <p><u>Comment 1:</u> We need a clear process on how to access the LOINC codes used for the HIPAA specific code set. Information: LOINC codes used for laboratory services and clinical reports AIS. This is treated like an external code set, maintained by Regenstrief Institute.</p> <p><u>Comment 2:</u> We need clear understanding of the maintenance and update schedule of the LOINC code set. Information: LOINC used in the static AIS – Emergency department, ambulance, medications and rehab AIS. Changes are only done when there are new versions of the existing standards and these are maintained by HL7.</p> <p>LOINC code usage <u>Comment 1:</u> because LOINC is adopted as a medical code set, the regulation needs to clarify the use of which LOINC codes are used in each of the AIS documents. There is a concern that absent this clarification entities may attempt a legalistic position that any LOINC code may be used for any attachment. Recommendation that the regulation be clarified as follows:</p> <ol style="list-style-type: none"> those AIS documents that contain static content (e.g. ambulance, ED, Rehab, Medication) the regulation must be clear that only the LOINC codes enumerated in the AIS are allowed. those AIS documents that reference the LOINC database (Lab results, clinical reports) the regulation should clarify that only the LOINC class as described in the LOINC DB (such as Lab results or clinical reports) defined for the AIS is allowed. <p><u>Comment 2:</u> Recommend a technical correction to the HL7 AIS booklets that reference the LOINC database to clarify how to determine the appropriate subset of the LOINC codes.</p> <p>Additionally, we need a clear process on how to access the LOINC codes for the HIPAA specific code sets, and an understanding of how maintenance (of the LOINC codes) occurs.</p>
17	56000	C	II , D.6	HL7 Comment: We concur that there is no interoperable standard for electronic

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Comment Number	NPRM or Tech.Spec Page #	NPRM Column (L,C, R)	Comment Section	HL7 Comment to CMS
			Connection to Signatures	<p>signatures. The term electronic signature is broadly understood to include a variety of technical approaches that vary in technological complexity and forensic accountability. Some representative technological approaches include:</p> <ul style="list-style-type: none"> (a) simply transmitting a data field that indicates that the sender has a "wet" signature on file (b) simply transmitting a data field that indicates that an authenticated user of an electronic document has performed an overt act that would serve as a "signing ceremony" (c) transmitting an image of a document, or a portion thereof, that includes a wet signature (d) strongly authenticating a computer user and using digital signature technologies to record the electronic act of signing a document and associate it with the electronic document itself in a manner that allows subsequent verification that only the authorized signer could have performed the act of signing and the electronic document has not been subsequently altered. <p>The choice of approach depends on the specific business use, applicable legislation and governmental regulations and the policies of the parties exchanging electronically signed documents.</p> <p>We further concur that there is an important business requirement to share signatures electronically as information in support of a healthcare claim. The signature that must be shared is often not the signature of the author of the electronic attachment document. For example, a consent signature is generally that of the patient or the patient's agent and a rehabilitation plan may include the signatures of multiple providers not all of whom are the authors of the plan.</p> <p>The <signature_cd> element of CDA Release 1 is only defined for case (b), above, and only describes the signature of the author of the CDA document.</p> <p>It is important that the standard for additional information in support of a claim support multiple approaches to signature so that the correct approach may be chosen that is practical, cost-effective and consistent with the federal, state and local legislation, regulations and policy. For example, there are regulatory and practical concerns that rule out approaches (a), (b) and (d) for consent forms, since policy makers have indicated that a "wet signature on file" is not adequate and it is unlikely that the person providing the signature will usually be an authenticated user of a healthcare provider's electronic system,</p>

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				<p>much less a strongly authenticated user.</p> <p>We would propose, therefore, that the final rule and commentary either be silent on electronic signature or indicate that individual attachments should specify the approach to electronic signature appropriate to the business needs for that attachment.</p>
18	56024	L	162.1910 (a)(2) Electronic health care claims attachment request transaction	<p>HL7 Comment: HL7 requests clarification on section 2 "(a) The health care claims attachment request transaction is the transmission, from a health plan to a health care provider, of a request for attachment information to support the adjudication of a specific health care claim. A health plan may make such a request (2) In advance of submission of the health care claim" –what workflow is being described here?</p>
19	55999 - 56000	R L	II, D, 4 Impact of Privacy Rule	<p>HL7 Comment: A requirement for providers to black out sections of a document that includes more than the minimum necessary information will be so costly, as to inhibit adoption of electronic claims attachments.</p>
20				<p>HL7 Comment: The HL7 ASIG has been maintaining a document identifying all changes that need to be made to the HL7 AIS documents and Implementation Guide for claims attachments. Changes identified in this document are the result of previous ballots, the Empire Medicare Services claims attachment pilot and other things brought to the committee by ASIG participants. Please see separate comment submitted by HL7 with this document change listing as an attachment. It is our expectation that by submitting this spreadsheet with specification changes identified, we will be able to make those changes as part of the NPRM "comment response" process.</p>

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Comment Number	NPRM or Tech.Spec Page #	NPRM Column (L,C, R)	Comment Section	HL7 Comment to CMS
21				Joint HL7/X12 Comment HL7 Comment: HL7 and X12 have collaborated on the following topic and submit this joint response: HL7 recommends that the 275 Implementation Guide be changed to remove the use of the X12 102 transaction. Change the reference in the 275 Implementation Guide to recommend the use of the X12 999 for syntax errors, and the use of the X12 824 TR3 to acknowledge both the X12 and HL7 content. This is in line with WEDI Acknowledgements PAG recommendations.
22				HL7 Comment: 'LOINC modifier' must be specifically cited in Sections 162.1915 and 162.1925. DISCUSSION items included: a. one reference to LOINC modifier in the preamble b. the modifier does go back in the STC of the 275
23				HL7 Comment: HL7 recommends that LOINC and LOINC modifiers should be included in the definition section of the preamble of the Final Rule.
24	56005	C3	Last paragraph	HL7 Comment: The examples cited in the preamble are not modifiers used in the six proposed attachments. LOINC modifiers used in claims attachments are the time-window modifiers and item-selection modifiers. HL7 recommends the examples in the Final Rule reflect the appropriate use of modifiers for the claims attachments business use.
25	55995	C2	Overview of Extensible Markup Language (XML)	HL7 Comment: The preamble of the NPRM references style sheets incorrectly and HL7 recommends clarifying this in the Final Rule. The individual attachment AIS's (booklets) do not include a stylesheet; the stylesheet is provided separately by HL7. It should also be noted that at this time, one style sheet works for all 6 attachment types.
26	56024	R	162.1920 Electronic healthcare claims attachment response transaction	Joint HL7/X12 Comment HL7 Comment:

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Comment Number	NPRM or Tech.Spec Page #	NPRM Column (L,C, R)	Comment Section	HL7 Comment to CMS
				<p>HL7 and X12 have collaborated on the following topic and submit this joint response:</p> <p>HL7 and X12 recommend that this section be named "Electronic healthcare claims attachment transaction." We recommend removing "response" from the section title as well as any of the paragraphs in that section. Since the 275 attachment transaction is not always sent in response to a request, it is more appropriate to refer to it as the "attachment transaction." Additionally, we point out that in paragraph (e) the regulation refers to an unsolicited response transaction. If the 275 is being sent in an unsolicited mode, it is not a response. We recommend referring to the "unsolicited attachment transaction" in this paragraph.</p>

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**THIS IS A DUPLICATE OF ELECTRONIC COMMENTS SUBMITTED VIA CMS
WEBSITE ON Thursday, January 19, 2006**

January 19, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0050-P, Mail Stop C4-26-05
Baltimore, MD 21244-1850

Re: CMS 0050-P NPRM (45-CFR Part 162) – Comments

Dear Centers for Medicare & Medicaid Services:

Health Level Seven (HL7) is pleased to submit the following comments regarding the HIPAA Administrative Simplification: Standards for Electronic Health Care Claims Attachments Notice of Proposed Rule Making (NPRM).

Founded in 1987, Health Level Seven, Inc. (<http://www.HL7.org/>) is a not-for-profit, ANSI-accredited standards developing organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services. HL7's more than 2,000 members represent approximately 500 corporate members, including 90 percent of the largest information systems vendors serving healthcare.

Since 1997 HL7 has been dedicated to the development of standards to support the electronic exchange of attachments for both claims and other healthcare industry processes (e.g. prior authorization, pre-certification). Throughout this time we have worked collaboratively with ASCX12N in not only developing the standards proposed in this NPRM, but also in educating the industry, promoting the use of standards and raising awareness about the benefits of the standards among healthcare industry stakeholders. Most recently we have worked in partnership with X12N on formulating a number of "joint SDO comments" to this proposed rule. Joint comments are identified as such in the attached document.

The comments that follow are the result of much thoughtful consideration on the part of the HL7 membership. Our comments preparation initiative, like our approach to standards development, was an open, consensus – based process. HL7 welcomes the

opportunity to continue working closely with CMS on this important standards process and we look forward to the publication of the Final Rule.

Should you have any questions regarding HL7's comments to this NPRM, please contact Karen Van Hentenryk at (734-677-7777) or Karenvan@hl7.org.

Sincerely,

Mark D. McDougall
Executive Director

cc: Lorraine Doo, CMS/ OESS

Submitter : JODI FEKETE
Organization : HORIZON BLUE CROSS BLUE SHIELD OF NJ
Category : Health Plan or Association

Date: 01/19/2006

Issue Areas/Comments

GENERAL

GENERAL

See attachments

CMS-0050-P-82-Attach-1.DOC

Horizon-BCBSNJ Comments on Claims Attachments Proposed Rule

Effective Dates p. 55994

Proposed Rule: It states that covered entities must comply within 24 months from the effective date of the final rule unless they are small health plans.

Comments: Due to the scope of work involved, this may not be reasonable.

Electronic Claims Attachment Types p. 55997

Proposed Rule: The six attachments are ambulance services; emergency dept; rehab services; clinical reports; lab results; medications.

Comment: Horizon-BCBSNJ is fine with these 6 attachment types.

Industry Standards, Implementation Guides and Additional Information Specifications p. 55992

Proposed Rule: It states the 4050 version of the X12 Implementation Guides are compatible with the current X12 4010 guides

Comment: I know that X12 is considering the 5010 guides as the next set of mandated transaction guides - is there any possibility that this may change to 5010 and if so, would there be a new review done to determine compatibility and would it also include a new public comment period?

Solicited vs. Unsolicited Attachments p. 55999

Proposed Rule: It states only one electronic attachment request including all questions per specific claim is allowed, and that providers should respond to all requests in one response.

Comment: What would the process be if a provider **does not** supply the answers or documentation for all the items listed in the request, or supplies data that is invalid. Is there a checks and balances between the two transactions to indicate that all requests have been answered? If not, what is out recourse - deny the claim?

Comment: If the submitter sends an Unsolicited 275 with the 837 claim, and we still require additional information to process the claim, can we send out a 277 and ask the provider to send another 275?

Proposed Rule: A health care provider would not be able to send bits & pieces of the requested information at different times or dates.

Comment: How would that be regulated?

Impact of Privacy Rule p. 56000

Proposed Rule: Comments are solicited regarding the 'minimum necessary'

Comment: Sending an unsolicited 275 seems to conflict with the minimum necessary rulings.

Attachment Content and Structure p. 56001

Proposed Rule: Transaction permits up to 64 mb of data in a single transaction.

Comment: This may not be enough to allow for the type of data being sent.

Proposed Standards

Proposed Rule: Comments are invited as to whether the 6 proposed attachment types are still the most frequently requested by health plans.

Comment: Horizon-BCBSNJ is fine with the current list of codes.

277 Guide

Response Due Date – Loop 2200D: Requesting that information be sent back within a 'reasonable amount of time'.

Comment: 'Reasonable' is an ambiguous term. What may be reasonable for a large payer may not be reasonable for a small provider.

Section 1.3.1 (page 9) of the guide - "Unsolicited Request for Additional Information" - states that when the need for additional information is generated by the payer system, it is deemed to be "Unsolicited".

Comment: I think that may be a typo, because all previous documentation has stated that an "Unsolicited" Request comes in with an 837, and a "Solicited Request" comes from the payer.

275 Guide

Binary Data Segment: Loop 2110B, BIN01 Length of Binary Data

Comment: Dependent upon the method of communication, sometimes transactions need to be wrapped and/or unwrapped before processing. There is potential of the count then being off due to extraneous characters from this process.

Acknowledgement Transactions: The 275 notes 997 scenarios, but also mentions the 102 Transaction-this is used for Syntactical Checking for the HL7 data which will be sent via the 275. The 102 Transaction is like the 997 in the sense that it can be used for accepts and rejects.

Comment: This would be a third new transaction for this one implementation. Through other discussions in the X12 Conference there was recommendation to using the 824 Transaction opposed to the 102 Transaction. This just doesn't seem very clear.

General Comments

- What is the level of validation that should be done for each type of transaction? What happens if a response for Ambulance contains a LOINC that is specific to, say Laboratory Results? Is it the assumption that each type of attachment will only be able to submit related LOINC codes?
- Along the lines of discussing the HL7 acknowledgement transactions we questioned a couple of scenarios, such as what if the HL7 piece in the BIN Segment is syntactically incorrect and the X12 pieces of the 275 are also syntactically incorrect do we send out 2 acknowledgements a 102 or 824 and a 997 ?

Submitter : Mrs. Karen Van Hentenryck
Organization : Health Level Seven
Category : Association

Date: 01/19/2006

Issue Areas/Comments

GENERAL

GENERAL

HL7 has an excel spreadsheet that contains a number of comments addressing changes to our specifications. The CMS website will not allow Excel attachments; therefore, we expect that CMS will consider our hardcopy of this attachment as well as an e-mail of the attachment sent to Lorraine Doo today, Thursday, January 19, 2006.

Submitter : Megan Ward
Organization : United Concordia Companies, Inc.
Category : Health Care Industry

Date: 01/19/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-0050-P-84-Attach-1.PDF

GUIDE	Page(s)	LOOP	SEGMENT	COMMENT
275	Entire Guide			The dates in the examples should be updated. They are currently 2003 dates.
	Entire Guide			We support the Dental Comment Committee (DeCC) comment #3 regarding adoption of attachment standards.
	74	2000A	REF	AD American Dental Association codes should be included in SVC01-1.
	C.1		C-External Code Sources	AD American Dental Association codes should be included.
277	Entire Guide			The dates in the examples should be updated. They are currently 2003 dates.
	96	2210D	N4	DSMO approved Change Request# 739 to make Postal Code Situational in all Guides. This Guide indicates it is still Required.

Submitter : Mrs. Alissa Fox
Organization : Blue Cross and Blue Shield Association
Category : Health Care Provider/Association

Date: 01/19/2006

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-0050-P-85-Attach-1.DOC

CMS-0050-P-85-Attach-2.DOC



**BlueCross BlueShield
Association**

An Association of Independent
Blue Cross and Blue Shield Plans

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January 19, 2006

The Honorable Mark B. McClellan, MD, Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Room 445-G
Washington, D.C. 20201

Via Electronic Mail

Attention: **CMS-0050-P**

Re: Comments on Proposed Rule: HIPAA Administrative Simplification: Standards for Electronic Health Care Claims Attachments NPRM CMS-0050-P (45 C.F.R. Part 162) (70 Fed. Reg. 55990, September 23, 2005)

Dear Dr. McClellan:

On behalf of the Blue Cross and Blue Shield Association (BCBSA) – made up of 39 independent, locally operated Blue Cross and Blue Shield companies that collectively provide health care coverage for more than 93 million Americans – I would like to offer comments on the Proposed Rule to adopt standards for an electronic claims attachments under Title XI of the Social Security Act, subpart C, Administrative Simplification.

Before commenting specifically on the Proposed Rule, we would like to commend CMS for sponsoring a pilot project with Empire Medicare Services to business-test electronic attachments. The pilot generated invaluable insights into documenting workflow requirements and uncovering problems so they can be fixed before the nation's health care industry is required to implement the rule. Building on this success, we would urge CMS to consider pilot testing the "computer variant" of the electronic attachment to identify unique issues arising when attachments are in that format rather than scanned or imaged formats.

Although detailed comments are attached – arrayed to follow the issues as presented in the Proposed Rule – we would like to highlight two particular issues.

First, we support CMS's decision to limit unsolicited electronic attachments. We share CMS' concern about the added burdens on payers of reviewing, evaluating, storing, returning, or destroying unsolicited attachments. Allowing unsolicited attachments would make the inventory control process for transactions extremely difficult, unnecessarily raising costs and reducing productivity.

Second, we urge CMS to develop a strategy for ensuring that providers use claims attachments. Today, comparatively few providers use electronic transactions for anything other than claims and remittances – if this history is repeated, claims attachments will become another costly mandate that yields little benefit. Before a final rule is adopted we urge CMS to

undertake a critical examination of whether providers will use the new transaction. If not, CMS should identify the barriers and address them to assure widespread adoption. This analysis should also explore potential incentives, possibly even requiring these transactions for Medicare.

A strategy for ensuring that providers use claims attachments should also overcome two potential implementation barriers by:

- Applying the minimum necessary requirement in a manner that will encourage, not discourage, use of electronic attachments. If CMS takes a strict view of the minimum necessary requirement – for example, deeming data in a scanned document that have not been specifically requested as outside the minimum necessary requirement – then providers may decide that it would be easier and more efficient not to send electronic attachments; and
- Developing a certification process for vendor software. Some vendors have not incorporated the full complement of HIPAA standards into their practice management systems, making it impossible for providers who depend on those vendors to use all the HIPAA transactions. A certification process would create an incentive for vendors to offer the needed functionalities, as well as help providers who want to use the new transaction.

Finally, we understand that some in the industry have suggested that ICD-10 has the ability to reduce or eliminate reliance on claims attachments. ICD-10 codes may offer greater clinical specificity than ICD-9 codes, but ICD-10 codes still will not answer the electronic attachments' predefined questions that relate to specific lab results, or current medications, or distance traveled in an ambulance, etc. We believe ICD-10 will have little to no effect on the need for claims attachments.

BCBSA appreciates the opportunity to offer these comments, and looks forward to continuing to work with you and your staff on this and all other issues relating to HIPAA Administrative Simplification.

Sincerely,



Alissa Fox
Vice President, Legislative and Regulatory Policy
Blue Cross and Blue Shield Association



**BlueCross BlueShield
Association**

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January 19, 2006

**BLUE CROSS BLUE SHIELD ASSOCIATION COMMENTS ON
“HIPAA ADMINISTRATIVE SIMPLIFICATION:
STANDARDS FOR ELECTRONIC HEALTH CARE CLAIMS ATTACHMENTS”
PROPOSED RULE
NPRM CMS-0050-P (45 C.F.R. Part 162) (70 Fed. Reg. 55990, September 23, 2005)
CMS-0050-P**

The Center for Medicare and Medicaid Services (CMS) requested that comments be organized by the section of the proposed rule to which they apply, using the specific “issue identifier” that precedes the section: **Background**; and **Provisions**. The order of these comments follows the issues as presented in the NPRM. Page number references are to the NPRM as published in the Federal Register on September 23, 2005.

PROVISIONS OF THE PROPOSED REGULATIONS

Industry Standards CDA releases 1 and 2 (Page 55995)

***Proposed Rule:** CMS invites comments on the pros and cons of each CDA release.*

Issues: We understand that there are pros and cons to using CDA version 1 or CDA version 2. It is our understanding that some of the benefits of CDA version 2 are that it is more technically consistent with new HL7 standards, is more consistent with code being adopted by EHR developers, and has improved technology for validating the computer decision variant. However at this time it is unclear as to what the implication to payers’ systems will be of using one version or another.

BCBSA Recommendation: CMS should seek additional recommendations from stakeholders on how to assess CDA version 1 versus version 2 to determine which has the greatest chance of success during the initial implementation. If not used at initial implementation, CDA version 2 should receive consideration as part of the eventual 5010 upgrade.

Industry Standards LOINC Codes (Page 55997)

***Proposed Rule:** Under the current rule the finite list of LOINC Codes documented within four of the six H17 AIS workbooks would require rulemaking that either add or delete codes from the lists.*

Issue: BCBSA believes the potential for code changes for the workbooks is relatively high and the need for code changes will occur frequently. If such additions and deletions are subject to

rulemaking it will generally take three years to get changes implemented. We believe that the combination of LOINC maintenance by the Regenstrief Institute and the HL7 ballot and approval process for the workbook content is sufficient for LOINC code list maintenance.

BCBSA Recommendation: BCBSA requests that CMS change the rule to designate LOINC code workbook lists as external code sets that are not subject to the rule making process.

Proposed Rule: *Within the Clinical workbook LOINC code 11503-0 "Medical Records" is listed as a sub-set of the Chart Sections (SET).*

Issue: When health plan medical reviewers order medical records they expect to receive the full record including all clinical notes. The LOINC use of the term Medical Record in the above context is unclear.

BCBSA Recommendation: CMS should clarify the definition of the term Medical Record for LOINC code 11503-0.

Industry Standards X12N 277 and 275 version 4050 (Page 55996).

Proposed Rule: *Version 4050 of the X12N 275 and 277 is proposed to carry the attachment related questions and the related answers or responses.*

Issue: The 4050 version has been finalized by the SDO and its content and requirements are fully understood by our member Plans. The 5010 version is still being developed and certain provisions need to be more fully understood and agreed to before being adopted as the standard. The SDO process for the 5010, including health plan input, needs to be completed before being mandated.

BCBSA Recommendation: BCBSA agrees with the decision to use version 4050. Any decision to use a later version should trigger an additional notice and comment period on the content and associated Implementation guides for the 5010 versions of the transactions.

Industry Standards Acknowledgements (Page 55996)

Proposed Rule: *The proposed rule makes no mention of standard electronic acknowledgements.*

Issue: There are no requirements for the use of standard acknowledgements such as the ANSI X12N 997, 998, TA1 and 824. While none of the other HIPAA transactions requires the use of standard acknowledgements, acknowledgements are critical to controlling and managing electronic transactions. Because of a lack of required standards, health plans have incorporated instructions concerning acknowledgements in their companion guides. Also, we have noted a lack of standard reports being used by the clearinghouse community. We also note reference to a 102 transaction in the 275 transactions implementation guide that would not be useful to this endeavor.

By adding requirements for using standard acknowledgements, we believe industry process flow will be improved by eliminating many duplicate claim submissions, which will reduce claim inquiries and, subsequently, administrative costs. We believe improvements such as this are consistent with Blue Plan commitments to make health plan business processes work more efficiently.

BCBSA Recommendation: CMS should work with X12N to establish requirements for the use of standard electronic acknowledgements and to eliminate the reference to the 102 transaction. **Format Options scanned images (Page 55997)**

Proposed Rule: *After an image has been rendered, the information should be clear enough and contain sufficient data for a person to make a decision about the claim.*

Issue: The term "clear enough" does not provide a measurable standard with respect to acceptability.

BCBSA Recommendation: CMS should define a measurable standard for clarity. One suggestion would be to require that images be as clear to read as the original.

Combined Use of Different Standards (Page 55998)

Proposed Rule: *CMS invites input with respect to the strategy of using different standards.*

Issue: Using both the HL7 and X12N standards works well for our member Plans. It would be more difficult and costly to implement the electronic claims attachments if they were sent only using HL7 standards.

BCBSA Recommendation: BCBSA fully supports the dual maintenance strategy adopted by CMS.

Electronic Health Care Claims Attachments VS Health Care Claims Data (Page 55999)

Proposed Rule: *Electronic health care claims attachments must not be used to convey information that is already required on every claim.*

Issue: In certain cases there appears to be a duplication of information between the 837 claim and the claims attachment. An example is ambulance transport code (initial trip, return trip).

BCBSA Recommendation: CMS should provide policy guidance on the appropriate place in which to send the data. We also recommend that CMS work with X12 and HL7 for technical consultation on situations where duplicate data requirements are identified. We believe that the first priority should be to keep the data with the claim if the result would be the elimination of the need for an attachment.

Impact of Privacy Rule (Page 56000)

Proposed rule: *For health care providers who choose to submit attachment information in the form of scanned documents, efforts will need to be made to ensure that those documents do not contain more than the minimum necessary information.*

Issue: In an effort to strictly comply with minimum necessary provisions, providers may determine that it would be easier and more efficient **not** to send electronic attachments. If this occurs it will greatly diminish the potential return on investment for health plans that are being required to implement an electronic claims attachments rule.

BCBSA Recommendation: CMS should apply a reasonable approach to minimum necessary. If the data in a document are related to a request but not specifically requested, those data should be allowed. Both parties are covered entities, both parties are obligated to protect the information, and there should be minimal risk to the person whose protected health information is being exchanged.

Solicited and Unsolicited Attachments (Page 55999)

Proposed Rule: *For each specific claim health plans may solicit only one electronic attachment request transaction, which, would have to include all of their required or desired questions.*

Issue: Certain business situations require more than one request: for example, a provider may submit a claim with a miscellaneous code that requires additional information for pricing. Once the additional information has been requested and received, the plan may determine that additional information is now required for medical necessity reasons. However, if limited to one request, a prudent plan may have no option but to deny the claim, which in turn would drive subsequent manual processes and appeals processing. That result would be costly and burdensome to both parties.

BCBSA Recommendation: While the majority of attachment requests can probably be held to one, multiple requests should be permitted when the information provided in the first request triggers the need for additional information, or when the initial response does not provide all of the requested information. Subsequent requests could be supported by the use of Claim Status Codes that begin with R: specifically, R5 or a similar code could be used under situations where supplemental information would be permitted.

Proposed Rule: *For each specific claim, health plans may solicit only one electronic attachment request transaction, which would have to include all of their required or desired questions.*

Issue: A contractual provision between the BCBS Federal Employee Plan (FEP) and the Federal Employees Health Benefits Program (FEHBP), as well as similar provisions in other programs administered by Plans, requires under certain situations that the FEP obtain historical information from primary physicians after receiving a claim from a specialist. It is unclear if requesting electronic attachment information from a provider not associated with a specific claim is or will be permitted under this rule. In addition, it is not clear if a request could be made to both the specialist and the primary care physician for any given claim.

BCBSA Recommendation: CMS should clarify what would be permitted under the rule for these situations. Consistent with the government's current requirements for the FEHBP, we believe that such requests should be permitted.

Proposed Rule: *The rule is silent on requirements for handling unsolicited attachments and provides no specific requirements for use of data received on compliant 275 response transactions.*

Issue: The implications for health plans that receive but do not use unsolicited data are not clear. For example, what liability (if any) will plans incur from not using the unsolicited data to adjudicate the claim. And what effect might the unsolicited data have on the health plan's ability to request additional information?

BCBSA Recommendation: CMS should specify appropriate handling procedures for unsolicited attachments submitted without prior agreement. We believe payers should be able to return those unsolicited attachments as non-compliant or destroy the records, without affecting payers' ability to make a subsequent request for an attachment.

Health Care Provider vs. Health Plan Perspective (Page 56001)

Proposed Rule: *The rule mentions business associates and instructions for payers to have transactions sent to the providers' business associate.*

Issue: Many providers are completely dependent on business associates (e.g., vendors) to conduct standard electronic transactions. Yet business associates are not required to demonstrate that they are able to conduct all required HIPAA transactions using the standard formats. If too high a percentage of providers lack access to the functionalities required to do business, the electronic attachment rule will not generate a positive return on investment (ROI).

BCBSA Recommendation: Business associates that offer HIPAA solutions to providers should be subject to a certification process that providers could rely on to know they will have the full range of transactions available when they chose to use them.

Proposed Standards Code Set (Page 56004)

Proposed Rule: *We noted that a number of code sets are referenced in the AIS workbooks. Some are very small, but others are large: for example, DEEDs, in the Emergency Department AIS.*

Issue: It is unclear why CMS names LOINC as a standard while not naming some of the other code sets such as "DEEDS". While this may not create any problems for scanned or imaged attachments, it may pose some issues for the computer variant if and when that variant is used to auto adjudicate claims.

BCBSA Recommendation: CMS should clarify why certain code lists are not part of the standard.

Proposed Standard Electronic Attachment Types (Page 56005)

Proposed Rule: *CDAR1AIS0001R021 provides the instructions and LOINC code tables for requesting ambulance supplemental information.*

Issue: Medical review activities sometimes require a description of the medical treatment that was provided to the patient during transport (resuscitation, intubation, trach, etc.) There are no LOINC codes in the Ambulance AIS to request that type of information.

BCBSA Recommendation: CMS should request additional LOINC codes be added to the AIS for ambulance services that would enable health plans to ask those questions.

Proposed Rule: *CMS solicits comments regarding which other attachments most impact the health care industry.*

BCBSA Recommendation: CMS should include DME and Home Health with the next set of required attachment types. We also concur with the approach of using additional types on a trading partner agreement basis prior being mandated.

Costs and Benefits (Page 56016)

Proposed Rule: *Using HIPAA estimates for the original transactions, an old WEDI report, and several assumptions, CMS has projected the cost for two years to be \$120 million, and savings over 5 years to be \$414 million to \$ 1.1 billion.*

Issue: CMS's estimates assume that providers use the electronic attachment transaction, an assumption not supported by experience with the initial set of HIPAA transactions. Many providers have been slow to use electronic transactions for other than claims and remittances. Savings and other benefits based on utilization of electronic claims attachments can occur only if they are widely used by a high percentage of providers.

BCBSA Recommendation: CMS needs to take actions to increase providers' use of the electronic claims attachments. Accordingly, in addition to previous recommendations that should boost providers' use – applying the minimum necessary provision in a reasonable manner, and developing a certification process for vendor software – BCBSA recommends that CMS consider requiring that institutional providers submit standardized electronic attachments instead of paper attachments for Medicare claims.

Subpart S-Electronic Health Care Claims Attachments Section 162.1910 (Page 56023)

Proposed Rule: *The proposed rule states that a health plan may make a request for attachment information in advance of submission of the health care claim.*

Issue: It is unclear as to what business process this supports. Is this intended to support a prior-authorization? If so, it was not clear that the support of claims adjudication included prior-authorizations and this process is not supported by the 277 implementation guide.

BCBSA Recommendation: CMS should clarify what business process are to be supported by an attachment request in advance of submission of the health care claim.

Submitter : Ms. Kimberly Volk
Organization : Delta Dental Plans Association
Category : Health Plan or Association

Date: 01/19/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-0050-P-86-Attach-1.DOC

January 20, 2006

Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-0050-P
Mail Stop C4-26-05
Baltimore, Maryland 21244-1850

Re: Additional Comments on Proposed Standards for Electronic Health Care Claims Attachments Pursuant to Extended Comment Period Invitation

To Whom It May Concern:

I am writing on behalf of the Delta Dental Plans Association (“DDPA”) to provide additional comments on the proposed standards for electronic health care claims attachments. See, 70 Fed. Reg. 55989 (September 23, 2005). These comments are intended to supplement our initial comments dated November 21, 2005, and are submitted pursuant to the notice extending the comment period. See, 70 Fed. Reg. 70574 (November 22, 2005).

DDPA represents the nation’s largest, most experienced dental benefits carriers. A nationwide system of 39 independent dental health service plans offers employers in all 50 states, the District of Columbia, and Puerto Rico, custom programs and reporting systems that provide employees with quality, cost-effective dental benefit programs and services. DDPA carriers provide dental coverage to over 46 million people in over 80,000 groups across the nation.

In further analyzing the proposed rule and the intent of HIPAA’s goal to standardize electronic health care transactions in order to reduce administrative costs, it is critically important to recognize

Delta Dental Plans Association
1515 West 22nd Street, Suite 450
Oak Brook, Illinois 60523

Telephone 630-574-6001
Facsimile 630-574-6999

Submitter : Mrs. Tamara Unger-Peterson

Organization : WPS Insurance Corporation

Category : Health Plan or Association

Date: 01/19/2006

Issue Areas/Comments

GENERAL

GENERAL

Attachment of Comments for WPS Commercial Insurance - document name Comments_WPS_submitted.doc
Inquiries should be directed to:

Tamara Unger-Peterson
WPS Electronic Data Services
608-223-5856
Tamara.Unger-Peterson@wpsic.com

CMS-0050-P-87-Attach-1.DOC

WPS NPRM Claims Attachment - NPRM Comments

	File Code - CMS- 0050-P	Page	Issue Identifier (Section Heading)	Comment
1	CMS-0050-P	55999	Solicited vs. Unsolicited Electronic Health Care Claims Attachments	SOLICITED vs. UNSOLICITED ELECTRONIC HEALTH CARE CLAIMS ATTACHMENTS: Paragraph 4, Solicited: In regards to the verbiage, " <i>We also propose that for each specific claim, health plans may solicit only one electronic attachment request transaction which would have to include all of their required or desired 'questions' and/or documentation needs relevant to that specific claim.</i> " We question the number of times plans are restricted to request. The concept of requesting information under the minimum necessary standard will not reasonably answer all decision information once that information on the original request is returned. The information returned may require additional requests for information dependent on service. For example, if a claim is received with an unlisted surgical procedure 17999, a request is done for a valid procedure code or description of service rendered. If the response to that request identifies the procedure as cosmetic, additional information regarding medical necessity, history & physical, pathology report or office notes would then be needed. With the review of the claim, there may be multiple departments that view the claim for different levels of information. It is not always apparent, upon the initial review of the claim, what additional information is needed to complete processing.
2	CMS-0050-P	55999	Coordination of Benefits	For COB in general, if we have <i>solicited</i> attachment information, is the primary health care plan required or permitted to forward this information?
3	CMS-0050-P	55999	Coordination of Benefits	For COB in general, if we have <i>unsolicited</i> attachment information, is the primary health care plan required or permitted to forward this information?
4	CMS-0050-P	55999	Coordination of Benefits	If a payer receives an attachment as a scanned image (jpg), and internally must store the document in a different format (tif), can the payer forward the additional information for COB in the stored format if all data from the original format is present? Must the attachment be forwarded in the same format as it was received?
5	CMS-0050-P	55997	Electronic Claims Attachment Types	ELECTRONIC CLAIMS ATTACHMENT TYPES: We agree with the 6 proposed attachment types for this rule. Additional attachment types such as DME and Home Health would like to be seen in the future
6	CMS-0050-P	55998	Electronic Health Care Claims Attachment Business Use	Post Adjudication: Reads Anything that involves the actual payment or processing of the claim should be included in this rule. Does post adjudication include adjustments to previously processed claims.
7	CMS-0050-P	56001	II, E Attachment Content and Structure	File size in X12 275 recommends 64mb for the BIN segment. NPRM indicates maximum size of 275 should not be greater than 64mb. Rule should reflect the X12 275 verbiage as a recommendation size of the BIN, not a maximum of the entire transaction.

WPS NPRM Claims Attachment - NPRM Comments

8	CMS-0500-P	56024	Subpart S – 162.1920 Electronic health care claims attachment response transaction	Item D does not require the use of HL7 CDA for the human decision variant. This is in disagreement with the pre-amble and the HL7 specifications. It is recommended that this section is revised to include the HL7 CDA requirement for the human decision variant. This section should be revised to state that in the HDV, repeat the LOINC codes in CDA and that the free text, scanned images or embedded documents must be in HL7 CDA within the BIN segment.
9	CMS-0050-P	56024	Subpart S – 162.1925 Standards and implementation specification for the electronic health care claims attachment response transaction	<p>The X12 275 version 4050 Implementation Guide is named in this section. Since this version is a final published guide and no changes can be made to this version, it is recommended to adopt the X12 275 version 5010 for various reasons: 1) In Unsolicited attachments using version 4050 275, the sender is limited to sending the X12 837 and 275 within the same interchange. This could impose limitations on the providers ability to transmit data separately which may be due to file size restrictions or an applications inability to combine the two transactions, thus decreasing the number of implementers.</p> <p>The draft version 5010 275 Implementation Guide does not include the limitation that an unsolicited 275 must be sent within the same interchange as the 837 transaction. This allows receivers to define specific timing rules to their business by allowing the corresponding unsolicited attachment to be sent within the same business cycle or within 3 days of the xX12 837 claim submission. This leniency allows cushion in the event , 1) The business process and software applications of the 837(claim) and X12 275 (attachment) are not housed in the same business area, therefore not linked.</p>
10	CMS-0050-P	56012	Covered Healthcare Providers	Paragraph 2: Reads 'These 'unsolicited' electronic attachments should not be sent without prior agreement or understanding between trading partner's. Need clarification of the word 'agreement'. Is this a physically signed agreement between provider/payer? It would not be cost effective for plans to obtain an additional signed trading partner agreement from providers wishing to utilize the attachment process, due to the additional steps necessary to secure signed agreements
11	CMS	55996	II.C.5 Electronic Claims Attachment Types Reg is 162.1910 –C	Need guidance in the area of reconciling overlapping data. Do we process based on what was sent on the claim or do we process based on the attachment? In the event of conflicting information, we assume that the claim data takes precedence. Please confirm our understanding.
12	CMS-0050-P	55996	2. Overview of Clinical Document Architecture	We strongly agree that the option to include imaged or text information is important to healthcare providers that do not have computer-based patient record systems, as we believe this to be the case for physician offices and small facilities such as ambulance

WPS NPRM Claims Attachment - NPRM Comments

				providers.
13	CMS-0050-P	55996	5. Electronic Claims Attachment Types	We believe the federal rulemaking process needs to be timelier. With claims attachments, new booklets and updates to current booklets will need a faster process to keep up with changes in policy and industry standard. The current process is not efficient enough to keep up with the needs of the industry.
14	CMS-0050-P	55996	5. Electronic Claims Attachment Types	Flexibility to continue the exchange of paper processes is necessary in the event the attachment types or the AIS do not cover a plan's business needs. For example, when provider bills a span of dates for any therapy, we would need to develop for a breakdown of services (specific service dates). We don't feel that the AIS booklets accommodate this.
15	CMS-0050-P	55999	2. Solicited vs. Unsolicited Attachments	When doing Unsolicited claims attachments, and the attachment does not answer all questions, is the payer allowed to send a 277 request for the additional information?
16			HL7 CDA	Due to the fact that CDA version 1 is an older version, it is probable that this version will be obsolete before full implementation occurs. We feel that version 2 will become the industry standard and therefore recommend moving to CDA release 2 for claims attachments.
17		56012	II, H Requirements (HP, CH, Providers) 1 st column	Paragraph 2: "The use of the standard electronic health care claims attachments would not preclude the health plan from using other processes or procedures to verify the information reported in the attachment documentation." Recommend changing the word 'verify' to 'clarify'. Verify infers a confirmation of the information rather than clarification of the information
18			AIS Laboratory Results	Page 11, section 3.1.1 should be 3.1.4 since there is already a 3.1.1 on page 9.
19			HL7 Rehabilitation booklet	Here are some suggestions for new ECA codes. Please note that the suggestion of "past treatment attempts" was made knowing that HL7 indicates there are already codes for Alcohol-Substance abuse and Psychiatric Rehab codes for Medical History +Level of Function. I see my suggestions as an addition to this as being more specific on how many past attempts were made at treating this disorder/disease. 1) Psychiatric Rehabilitation Service Value Table (Suggestion: Add New Code: Psychiatric Rehabilitation Treatment; Global Area of Functioning 1= 1-10 2= 11-20 3= 21-30 4= 31-40 5= 41-50

WPS NPRM Claims Attachment - NPRM Comments

				<p>6= 51-60 7= 61-70 8= 71-80 9= 81-90 0= 91-100</p> <p><i>Psychiatric Rehabilitation Service Value Table</i></p> <p><u>Suggestion</u>; add new code: Psychiatric Rehabilitation Treatment; Past Treatment Attempts (Narrative)</p> <p>2) Alcohol-Substance Abuse Rehabilitation Service Value Table</p> <p><u>Suggestion</u>; add new code: Alcohol-Substance Abuse Rehabilitation Treatment Plan; Past Treatment Attempts (Narrative)</p>
20			X12 277	<p>The X12 277 version 4050 Request for Additional Information has been named in the NPRM. Because changes have occurred in the X12 275 and 277 that improve the functional flow of the attachment process, it is recommended that the X12 277 5010 be named in place of the X12 277 4050 version. A recommendation to move the X12 275 4050 to 5010 has been submitted in a separate comment.</p>

Submitter : Mrs. Tamara Unger-Peterson
Organization : WPS - TRICARE
Category : Health Plan or Association

Date: 01/19/2006

Issue Areas/Comments

GENERAL

GENERAL

Attachment of Comments for WPS TRICARE - document name Comments_Tricare_submitted.doc

Inquiries should be directed to:

Tamara Unger-Peterson

WPS Electronic Data Services

608-223-5856

Tamara.Unger-Peterson@wpsic.com

CMS-0050-P-88-Attach-1.DOC

WPS TRICARE - NPRM Claims Attachment - NPRM Comments

	File Code - CMS- 0050-P	Page	Issue Identifier (Section Heading)	Comment
1	CMS-0050-P	55999	Solicited vs. Unsolicited Electronic Health Care Claims Attachments	SOLICITED vs. UNSOLICITED ELECTRONIC HEALTH CARE CLAIMS ATTACHMENTS: Paragraph 4, Solicited: In regards to the verbiage, " <i>We also propose that for each specific claim, health plans may solicit only one electronic attachment request transaction which would have to include all of their required or desired 'questions' and/or documentation needs relevant to that specific claim.</i> " We question the number of times plans are restricted to request. The concept of requesting information under the minimum necessary standard will not reasonably answer all decision information once that information on the original request is returned. The information returned may require additional requests for information dependent on service. For example, if a claim is received with an unlisted surgical procedure 17999, a request is done for a valid procedure code or description of service rendered. If the response to that request identifies the procedure as cosmetic, additional information regarding medical necessity, history & physical, pathology report or office notes would then be needed. With the review of the claim, there may be multiple departments that view the claim for different levels of information. It is not always apparent, upon the initial review of the claim, what additional information is needed to complete processing.
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6	CMS-0050-P	55998	Electronic Health Care Claims Attachment Business Use	Post Adjudication: Reads Anything that involves the actual payment or processing of the claim should be included in this rule. Does post adjudication include adjustments to previously processed claims.
7	CMS-0050-P	56001	II, E Attachment Content and Structure	File size in X12 275 recommends 64mb for the BIN segment. NPRM indicates maximum size of 275 should not be greater than 64mb. Rule should reflect the X12 275 verbiage as a recommendation size of the BIN, not a maximum of the entire transaction.

WPS TRICARE - NPRM Claims Attachment - NPRM Comments

8	CMS-0500-P	56024	Subpart S – 162.1920 Electronic health care claims attachment response transaction	Item D does not require the use of HL7 CDA for the human decision variant. This is in disagreement with the pre-amble and the HL7 specifications. It is recommended that this section is revised to include the HL7 CDA requirement for the human decision variant. This section should be revised to state that in the HDV, repeat the LOINC codes in CDA and that the free text, scanned images or embedded documents must be in HL7 CDA within the BIN segment.
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11	CMS	55996	II.C.5 Electronic Claims Attachment Types Reg is 162.1910 –C	Need guidance in the area of reconciling overlapping data. Do we process based on what was sent on the claim or do we process based on the attachment? In the event of conflicting information, we assume that the claim data takes precedence. Please confirm our understanding.
12			AIS Rehabilitation; Ambulance; and Emergency	The Rehabilitation; Ambulance; and Emergency Department booklets reference a practitioner or treatment plan author identifier using UPIN, NPI, or state license numbers. US territories utilize 3-digit country codes, therefore the reference to 'XX' 2-digit

WPS TRICARE - NPRM Claims Attachment - NPRM Comments

			Department booklets	US Postal abbreviations is not correct for identifying licensed practitioners in US territories.
13		AIS booklet	Psychiatric Rehabilitation Services	<p>Comment: TRICARE Policy Manual Chapter 11, Section 3.9 requires that for each claim for their services a pastoral counselor must certify that a written communication has been (or will be) made to the referring physician of the treatment results. There is no provision for documentation of this written communication in the Psychiatric Rehabilitation Services Attachment.</p> <p>Suggested wording for requesting/providing documentation:</p> <p>Written communication with the referring physician Response: Yes No</p>
14	CMS-0050-P	55996	2. Overview of Clinical Document Architecture	We strongly agree that the option to include imaged or text information is important to healthcare providers that do not have computer-based patient record systems, as we believe this to be the case for physician offices and small facilities such as ambulance providers.
15	CMS-0050-P	55996	5. Electronic Claims Attachment Types	We believe the federal rulemaking process needs to be timelier. With claims attachments, new booklets and updates to current booklets will need a faster process to keep up with changes in policy and industry standard. The current process is not efficient enough to keep up with the needs of the industry.
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WPS TRICARE - NPRM Claims Attachment - NPRM Comments

20			AIS Laboratory Results	Page 11, section 3.1.1 should be 3.1.4 since there is already a 3.1.1 on page 9.
21		AIS booklet	Speech Therapy Rehabilitation Services	Comment: TRICARE Policy Manual Chapter 7, Section 7.1 requires review of the Individual Education Plan (for beneficiaries aged 3 to 21), to ascertain that the intensity or timeliness of outpatient speech services as proposed by the educational agency are not appropriate medical care, and thus cost shared under TRICARE. The IEP will need to be furnished with the claim so that the claims processor may perform the above review.
22			X12 277	The X12 277 version 4050 Request for Additional Information has been named in the NPRM. Because changes have occurred in the X12 275 and 277 that improve the functional flow of the attachment process, it is recommended that the X12 277 5010 be named in place of the X12 277 4050 version. A recommendation to move the X12 275 4050 to 5010 has been submitted in a separate comment.

Submitter : Ms. Alexandra Goss
Organization : Accredited Standards Committee (ASC) X12
Category : Association

Date: 01/20/2006

Issue Areas/Comments

GENERAL

GENERAL

Note: Cover letter is below and comments are attached.

January 19, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0050-P
P.O. Box 8014
Baltimore, MD 21244-8014

Re: HIPAA Administrative Simplification ? Standards for Electronic Health Care Claims Attachments [CMS-0050-P]

Dear Centers for Medicare and Medicaid Services:

The ANSI Accredited Standards Committee (ASC) X12 would like to take this opportunity to thank you for allowing our standards body to comment on this very important proposed ruling regarding electronic health care claims attachment. ASC X12 brings together business and technical e-business professionals in an open, cross-industry setting to develop and maintain electronic data exchange standards, based on X12 EDI, XML, and UN/EDIFACT formats as well as collaborate with industry organizations to build best of breed standards for the global market. These key ASC X12 initiatives create new and improved forms of data sharing, enhance business processes, reduce costs and expand organizations' reach.

I'd like to highlight a few items:

- 1) We recommend moving to CDA release 2 and have addressed specific benefits as to why this should take place.
- 2) We also recommend giving the industry the option to implement human decision variant and computer decision variant in parallel, allowing the extended benefits to be obtained gradually through incremental business decisions.
- 3) Regarding modification to the standard, multiple comments reflect the goal of moving the regulatory process forward more quickly.
- 4) ASC X12 and Health Level 7 (HL7) collaborated on our proposed rule assessments with certain areas resulting in the submission of a joint comment. Joint comments are found at the end of the attached document.

ASC X12 looks forward to the adoption of a set of standards that will facilitate the electronic exchange of clinical and administrative data to further improve the claims adjudication process when additional documentation is required. If you require further explanation regarding the attached comments, please contact me at anytime (see contact information below).

Sincerely,

Alexandra Goss
Chair, ASC X12 Insurance Subcommittee
717-763-1643 (extension 204) / alix@wpc-edi.com

CMS-0050-P-89-Attach-1.DOC

Comments on the Claims Attachment NPRM from X12

Comment Number	Page Number	Section	Comment
1	55992 - 55993	D. Industry standards, Implementation Guides, and Additional Information Specifications	<p>The ASC X12 hierarchical approval process should be replaced with the following: "The ASC X12 committee is the decision-making body responsible for the development and maintenance of their standards in an open consensus based documented process, which is necessary before seeking ANSI approval of a standard. The ASC X12N Subcommittee develops standards and conducts maintenance activities for healthcare related standards and implementation guides. The draft documents are made freely available for public review and comment. The comments are posted and then replied to by use of an online conference. Additionally, X12N holds a public forum to report on public comments and associated outcomes. The revised document is presented to the entire ASC X12N subcommittee membership group for approval. This work is then reviewed and approved by the ASC X12 Technical Assessment Subcommittee. In sum, Implementation Guides developed by ASC X12N must go through an entirely visible open process and be ratified by a majority of voting members of the ASC X12N subcommittee."</p>
2	55993	D. Industry standards, Implementation Guides, and Additional Information Specifications - Implementation Guides	<p>The HIPAA adopted versions are 4010A1 not 4010 -1A.</p>
3	55999	2. Solicited vs. Unsolicited Electronic Health Care Claims Attachment	<p>X12 agrees with the proposal that health care providers may submit an unsolicited electronic attachment with a claim only when a health plan has given the specific advance instructions pertaining to that type of claim or service.</p>

4	55999	3 Coordination of Benefits	This section states that the primary health plan may not know the secondary health plan's business rules and therefore would not be expected or required to request an attachment on behalf of the secondary health plan. This section does not however state that the primary health plan would not be expected to forward an attachment that they received on to the secondary health plan. X12 recommends that this section be revised to include this statement.
5	56001	E. Electronic Health Care Claims Attachment Content and Structure	This section states that the X12N 275 response transaction permits up to 64 megabytes of data in a single transaction. The version 4050 275 Implementation Guide includes a BIN segment note that recommends the size of the BIN segment does not exceed 64 MB. A single transaction (275) supports multiple BIN segments therefore the recommended size limitation is not on the transaction but rather the BIN segment within the transaction. X12 recommends revising this sentence to read as follows " The X12N 275 response transaction recommends that the size of the BIN segment does not exceed 64 megabytes. "
6	56024	Subpart S – 162.1915 Standards and implementation specification for the electronic health care claims attachment request transaction	This section names the X12 277 version 4050 Implementation Guide. Since this version is a final published guide and no changes can be made to this version, X12 recommends adopting the X12 277 version 5010. This will allow X12 to include any changes to the Implementation Guide based on the NPRM comment period. Justification for moving to version 5010 includes the following changes that have been incorporated into the 277 5010 draft: <ul style="list-style-type: none"> ○ The HL structure of the 277 Request for Additional Information to Support a Health Care Claim or Encounter has been changed to only support the patient HL rather than the subscriber and Patient HL structure. This change is consistent with the 275 patient structure. ○ The Empire Medicare Services pilot identified several notes that were inconsistent or incorrect. The 5010 version includes all of these revisions.
7	56024	Subpart S – 162.1925 Standards and implementation specification for the electronic	This section names the X12 275 version 4050 Implementation Guide. Since this version is a final published guide and no changes can be made to this version, X12 recommends adopting the X12 275 version 5010. This will allow X12 to include any changes to the Implementation Guide based on the NPRM comment period.

		<p>health care claims attachment response transaction</p>	<p>Justification for moving to version 5010 includes the following changes that have been incorporated into the 275 5010 draft:</p> <ul style="list-style-type: none"> ○ Version 4050 limits the sender of the 275 to submit the unsolicited 275 and the 837 transaction within the same interchange. X12N TG2 Work Group 9 has heard overwhelming requests to eliminate this limitation. The justification includes; due to the size of the 275 files it may be necessary for the receiver's to use different communication protocol methods for the 837 and the 275. The receivers are concerned that a combined 275/837 file may create a bottle neck in their 837 processing. Several sender's as well as receiver's have voiced concerns with creating and/or processing a combined file. Some systems do not currently have this capability today. The draft version 5010 275 Implementation Guide does not include the limitation that an unsolicited 275 must be sent within the same interchange as the 837 transaction. The X12N TG2 work group 9 consensus was the 5010 guide should be written to allow the receiver of the file to define the unsolicited process which may include timing factors of the submission of the 275 and the 837. For example, a receiver may require the sender to submit the 275 within the same business day as the corresponding 837 or the receiver may require the sender to submit the 275 within the same business week as the corresponding 837. ○ The Empire Medicare Services pilot identified several notes that were inconsistent or incorrect. The 5010 version includes all of these revisions. ○ X12 and HL7 have collaborated on the following topic and submit this joint response: The 4050 version currently recommends the 102 Transaction to acknowledge the 275/HL7 CDA. The 5010 version includes the use of the 824 transaction to acknowledge the 275 as well as all components of the HL7 CDA. The 824 has the ability to support the need to provide the acknowledgement information for X12, XML, MIME, and Base64 encoding. The 102 Transaction does not have this capability. ○ The 5010 version includes guidance regarding the 275 acknowledgment such as 'The developers of this Implementation Guide recommend accepting or rejecting the 275 at the transaction level and not at the BIN segment level.' ○ The BIN segment examples have been revised to show the BIN02 accurately with the HL7 CDA. ○ The 5010 version includes revised qualifier for the CAT02 element. Several qualifiers were added to the CAT02 element. These qualifiers should allow the receiver of the 275 transaction to determine if the BIN02 content is in the Human Decision Variant or the Computer Decision Variant. The following were added Qualifier TX – Text with the
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			<p>note: Required for claim attachment types under HIPAA when the BIN02 contents are HL7 CDA with XML markup in the Human Decision Variant. The CDA must be in ASCII format. Added qualifier MB – Binary Image with the note: Required for claim attachment types under HIPAA when the BIN02 content are the HL7 CDA with Non-ASCII text objects in the Human Decision Variant. The CDA must be in ASCII format. Revised HL qualifier note to read, 'Required for Claim Attachment types named under HIPAA when the BIN02 contents are the HL7 CDA with the Computer Decision Variant. The CDA must be in ASCII format. Revised the IA qualifier note to include the TX and MB qualifiers.</p> <ul style="list-style-type: none"> ○ The 5010 version includes the standard definition of Binary data to Appendix A in the 275 Implementation Guide. This was necessary since the BIN02 is defined as a binary element.
8	56024	Subpart S – 162.1915 Standards and implementation specification for the electronic health care claims attachment request transaction	Section D. Electronic Health Care Claims Attachment Business Use on page 55998 of the pre-amble include language that excludes attachment data requested on a post payment basis from compliance with the electronic standards named in this rule. However, the regulation text does not include any reference to this process. X12 recommends that the preamble and the regulation text are consistent. In addition, X12 requests clarification of the Claim Attachment definition in the regulation text as it currently states "Attachment information means the supplemental health information needed to support a specific health care claim." The definition does not address post payment.
9	84	ASC X12N 275 Implementation Guide	The segment note for the BIN segment recommends that the size of the BIN02 does not exceed 64 MB. X12 strongly supports this language since it does not limit the trading partners and allows for some flexibility. If this data element would be limited to a specific size trading partners would not be able to exchange data electronically if the attachment data for a specific question exceeds the size limitation. Willing trading partners should be able to mutually agree on size limitations based on their business needs.

			JOINT X12/HL7 COMMENTS
1		Subpart S – Electronic Health Care Claims Attachments	<p>X12 and HL7 have collaborated on the following topic and submit this comment:</p> <p>HL7 and X12 have always been aware that additional work was needed to address the issue of data that "belongs in the claim" versus data that "belongs in the claims attachment." This is particularly apparent when we consider ambulance services, some rehabilitative services (currently proposed attachments) as well as home health services, DME services and others. Being aware of the importance of this issue, X12 created a special workgroup led in their data modeling task group (TG3) in 1998 and 1999 to address this issue. HL7 was represented and active in these deliberations. This work went on for over a year, and there were several conclusions, among them:</p> <ol style="list-style-type: none"> 1. A "data migration strategy" needed to be developed, and when an NPRM for claims attachments was published X12 and HL7 would address this issue. It could not be done sooner as we had no idea of dates and versions until we knew the expected implementation date for attachments. 2. Draft criteria were developed to help determine where data should reside 3. Certain data should come out of the claim - for example home health segments - and be represented in the attachment. This X12 decision was the impetus for HL7 developing the home health attachment. We also agreed that we needed to deliberate more on other data and where it should reside. Home Health is just an example of where there was clear direction established. <p>Understanding the importance of this issue, HL7 took the measure to collect all meeting minutes as well as formal recommendations from that work effort and record it on a "CD" which was later distributed to X12 and HL7 members (CMS included) so that everyone understood our go-forward strategy as well as why and how we developed it. Should CMS desire another copy of this CD, we would be happy to provide it.</p> <p>Now that the NPRM for claims attachments has been published, X12 and HL7 have reinitiated this work effort, as we had always planned to do. We will be holding a "kickoff" meeting on this topic in March 2006 - planning for this meeting is already underway. Our expectation is that subsequent work will take</p>

			<p>place via tele-conference. Once a final set of recommendations are prepared, they will be vetted through other industry organizations. Our kickoff meeting as well as working tele-conference meetings will be open to anyone wishing to participate.</p> <p>Most importantly, HL7 and X12 strongly recommend that the Final Rule, particularly the regulation text, <u>does not</u> dictate what data is appropriate for a claim or an attachment. Our primary reasons for this because the issue need to be studied further by industry and so that the decisions aren't tied to a regulation, and therefore not able to change when business needs dictate. Furthermore, we recommend that the Final Rule acknowledge the significant amount of good work already done in this regard between X12 and HL7 and recognize that these two SDO's are addressing the data needs and data migration strategies as described above.</p>
2	55997	6. Format Options	<p>X12 and HL7 have collaborated on the following topic and submit this comment:</p> <p>The HDV allows economic benefits given the limitations of current provider/payer systems. The CDV allows extended benefits to be obtained (for attachment types ambulance, emergency department, rehabilitation services, lab results, medications, and clinical reports) as provider and payer systems evolve to have and use more structured data.</p> <p>Allowing both, and giving the industry the option to implement them in parallel, allows the extended benefits to be obtained gradually through incremental business decisions, which is far sooner than the benefits could be obtained through a "one size fits all" regulatory mandate.</p>
3	55999	II, C, 2 Overview of Clinical Document Architecture	<p>X12 and HL7 have collaborated on the following topic and submit this joint response:</p> <p>Comment 1: X12 and HL7 recommend moving to CDA release 2, assuming that there is a pilot that uses CDA release 2. Additionally we note that HL7 will need changes to the HL7 IG and each AIS developed to be based on CDA release 2. HL7 has every intention of making all necessary specification changes in as timely a manner as is possible.</p> <p>Comment 2: The benefits of using CDA Release 2 would be:</p> <ol style="list-style-type: none"> 1. More technical consistency with all new standards coming from HL7

			<p>including, but not limited to genomic reporting, adverse event reporting, and the care record summary used.</p> <ol style="list-style-type: none"> 2. More consistency with code being developed by EHR developers (vendors and users) for standard and other applications based on the CDA. 3. More ability to use off-shelf software being developed by health care vendors. 4. Improved technology for validating computer-decision variant instances of attachments (when this is required). 5. Compliance with the U.S. Federal Consolidated Healthcare Informatics initiative. 6. Providers who implement EHRs would benefit from CDA release 2 because they could take advantage of commercial off-the-shelf software (COTS) solutions in their EHRs to create the electronic attachments. Most EHR vendors are developing CDA r.2 implementations and not CDA R.1 implementations.
4	55999	2. Solicited vs. Unsolicited Electronic Health Care Claims Attachments	<p>X12 and HL7 have collaborated on the following topic and submit this comment:</p> <p>This section states that the ASIG refers to the scenario of sending an attachment with the initial claim as an unsolicited attachment. The unsolicited attachment was defined by the X12 work groups. X12 and HL7 recommend that the sentence be revised to read as follows: ASC X12N WG9 refers to this scenario, of sending attachment information with the initial claim, as an unsolicited attachment because a request was not made after the fact, using the standard request transaction.</p>
5	56001	E. Electronic Health Care Claims Attachment Content and Structure	<p>X12 and HL7 have collaborated on the following topic and submit this comment:</p> <p>This section states that the standards have been under development for over 8 years by the HL7 ASIG. Since the standards were also developed by X12, HL7 and X12 recommend revising the sentence to read as follows: In sum, the proposed standards are those that have been under development for over eight (8) years by the SDO's.</p>
6	56013	III. Modifications to Standards and New Electronic	<p>X12 and HL7 have collaborated on the following topic and submit this comment:</p> <p>This section states that the industry should identify the relevant attachment types and collaborate to assign priority to each one. Since the industry</p>

		Attachments	collaboration will be to work with the SDO's through their accredited process, X12 and HL7 recommend revising the sentence to read as follows: The industry should identify the relevant attachment types and work with the Standard Development Organizations to assign priority to each one, so that new electronic attachment specifications that are appropriate to the business needs of the health care industry can be developed.
7	56014	III. Modifications to Standards ,A & B. 1 st paragraph	<p>X12 and HL7 have collaborated on the following topic and submit this comment:</p> <p><u>Comment 1:</u> Our main goal is to move the regulatory process forward more quickly. For new attachment types* (AIS), we recommend that the DSMO be authorized to adopt those that are developed, balloted and published by HL7 through the DSMO process. Stop the process here and do not go through the full regulatory process.</p> <p>This overall process will include provisions for outreach and comments in the HL7 SDO processes. In addition, notification and rollout time between adoption and implementation date needs to be added after the HL7 publication. More time is needed to implement new types than for changes to existing ones.</p> <p><u>Comment 2:</u> Additionally, we recommend that the initial six AIS be adopted as standards.</p> <p><u>Comment 3:</u> Our main goal is to move the regulatory process forward more quickly. For <i>new versions</i> of standards by HL7 or X12, we recommend that the DSMO be authorized to adopt those that are developed, balloted and published by HL7 or X12 through the DSMO process. Stop the process here and do not go through the full regulatory process.</p> <p>This overall process will include provisions for outreach and comments in the SDO processes. In addition, notification and rollout time between adoption and implementation date needs to be added after publication. Provisions for sunseting older versions of the standards after a transition period must be included.</p> <p>Additionally X12 and HL7 recommend that the Implementation timeframes of new HL7 AIS booklets should allow six months, minimum, for new attachment types, and 12 months for new versions of existing attachment types. The timeframe begins once the DSMO has completed its review/approval process.</p> <p>Attachment types currently in varying stages of development, but not named in</p>

			the Final Rule include EAP, DME, CPHS, Periodontal, Home Health, and Consent Forms.
8	56023	162.1900 Definitions	<p>X12 and HL7 have collaborated on the following topic and submit this comment:</p> <p>The definitions in the regulation text do not match the definitions in the preamble. X12 and HL7 recommend that section 162.1900 be revised to be consistent with the definitions in the preamble. In addition, X12 and HL7 recommend adding definitions for LOINC codes, the LOINC database and LOINC modifiers to the definitions in the regulation text.</p>
9	56023 56024	162.1002 162.1915 162.1925	<p>X12 and HL7 have collaborated on the following topic and submit this comment:</p> <p>X12 and HL7 is in agreement with the proposed X12 standard transactions, 277 and 275, as well as the HL7 CDA standard, including HDV and CDV. Furthermore, X12 and HL7 approve the LOINC code set to be used to identify the questions.</p>
10	56024	162.1920 Electronic healthcare claims attachment response transaction	<p>X12 and HL7 have collaborated on the following topic and submit this comment:</p> <p>X12 and HL7 recommend that this section be named "Electronic healthcare claims attachment transaction." We recommend removing "response" from the section title as well as any of the paragraphs in that section. Since the 275 attachment transaction is not always sent in response to a request, it is more appropriate to refer to it as the "attachment transaction." Additionally, we point out that in paragraph (e) the regulation refers to an unsolicited response transaction. If the 275 is being sent in an unsolicited mode, it is not a response. We recommend referring to the "unsolicited attachment transaction" in this paragraph.</p>
11	56024	162.1920 Electronic healthcare claims attachment response transaction	<p>X12 and HL7 have collaborated on the following topic and submit this comment:</p> <p>Regarding paragraph (d) A health care provider that sends scanned images and text documents in the attachment transaction, for the human decision variants, is not required to use the LOINC codes as the response, other than to repeat the LOINC codes in the HL7 CDA that are used in the 277 request. We recommend that paragraph (d) be modified to read as noted above in bold font.</p>

			<p>Also, we recommend changing the following sentence to reflect the verbiage noted in "bold" below:</p> <p>Response information may be free text, scanned documents, or an embedded document within the BIN segment as expressed in accordance with the HL7 CDA, which must be included in the BIN segment of the response transaction.</p>
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Submitter : Mr. David Feinberg
Organization : Rensis Corporation - A Consulting Company
Category : Health Care Industry

Date: 01/20/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-0050-P-90-Attach-1.DOC

From: "David A. Feinberg, C.D.P." <dafeinberg@computer.org>
To: "Doo, Lorraine T. (CMS/OESS)" <Lorraine.Doo@cms.hhs.gov>
Sent: Tuesday, January 10, 2006 7:18 AM
Subject: Re: eComments for Attachment NPRM

Lorraine,

What will be the federal government's response to a stymied Claims Attachments NPRM commenter who, on Monday morning, 23 January 2006, as specified in the thus far un-amended Federal Register {Volume 70, Number 184, 23 September 2005, page 55990, column 1} links to <http://www.cms.hhs.gov/regulations/ecomments> and

(a) is unable to timely "find their way" to the e-comment Dockets Open for Comment page due to the present absence of specific navigation instructions [such as I've provided below],

and/or

(b) can not find the docket entry for CMS-0050-P because the present Comment Period Ends date of 1/21/2006 has caused it to disappear too early

???

DAF

----- Original Message -----

From: "Doo, Lorraine T. (CMS/OESS)" <Lorraine.Doo@cms.hhs.gov>

To: "David A. Feinberg, C.D.P." <DAFeinberg@computer.org>

Sent: Monday, January 09, 2006 6:45 PM

Subject: RE: eComments for Attachment NPRM

hi david - thanks for sharing. i'm glad you have been able to provide the new link to some folks - everyone will have to change their "favourites" to the new webpage. I don't think that there will be any publicity per se, on the new site - but when folks visit www.cms.hhs.gov, they will find their way to the new erulemaking location.... To the best of my knowledge, the public comments are not yet visible, and we are continuing to work with that branch to resolve.

Lorraine Tunis Doo Senior Policy Advisor Office of e-Health Standards
and Services CMS 410-786-6597

From: David A. Feinberg, C.D.P. [mailto:dafeinberg@computer.org]
Sent: Mon 09/01/2006 4:00 PM
To: jajoseph@columbus.rr.com
Cc: Doo, Lorraine T. (CMS/OESS)
Subject: Re: eComments for Attachment NPRM

Jack,

No, you're not doing anything stupid at all. CMS has been working on their web site for the past several weeks and the link landing spot for e-commenting on all of their materials has fluctuated -- including not working at all for a while last month.

As of today, 1/09/2006, here's how to make e-commenting work.

Link to <http://www.cms.hhs.gov/regulations/ecomments>
[as stated in the Claims Attachments NPRM]

Click on "e-Rulemaking"
[located under the Policies heading in the lower portion of the second column in the main box on the screen]

Click on "Submit electronic comments on CMS regulations with an open comment period"
[located near the bottom of the screen]

Click on "Go" for the row identified as CMS-0050-P:
"Standards for Electronic Health Care Claim Attachments".

Fill in some minimal demographics on a screen, and then click "Continue"

Type up to 4,000 characters into the displayed comment box ... and/or include a file, which may be longer, as an attachment.

Feel free to pass these steps -- as they exist today -- along to anybody else you think can take advantage of them.

Dave Feinberg
Rensis Corporation [A Consulting Company]
206-617-1717
DAFeinberg@computer.org

Claims Attachments NPRM
e-Commenting Process Issues
as of 10 January 2006

Page 4

----- Original Message -----

From: Jack A. Joseph <<mailto:jajoseph@columbus.rr.com>>

To: dafeinberg@computer.org

Sent: Monday, January 09, 2006 10:49 AM

Subject: eComments for Attachment NPRM

Dave,

I hope you don't mind that I am emailing you directly, If I am doing something really stupid, I didn't wan the entire listserv to know. I am trying to access the CMS site to post comments to the Attachment NPRM. When I enter in <http://www.cms.hhs.gov/regulations/ecomments> I get redirected to the general regulation page. Any insight?

Thanks,

Jack A. Joseph

PricewaterhouseCoopers LLP

----- Original Message -----

From: "Doo, Lorraine T. (CMS/OESS)" <Lorraine.Doo@cms.hhs.gov>
To: "David A. Feinberg, C.D.P." <DAFeinberg@computer.org>
Sent: Wednesday, December 21, 2005 3:42 AM
Subject: RE: ecomments web site not working

Good morning, and thanks for finding that issue - we will work to resolve it quickly, needless to say! We do indeed need to get the word out, for all of the regs, but I don't know yet how they will handle it. Finding the new ecomments site is not intuitive, since you would need to know to click on "policies" to get to that page..... Stay tuned.

And of course I would love to see your marketing campaign. It is going to be very difficult to reach the right people from the business side of the house, because if covered entities have not figured out already that this is an IT and business issue, there is not much time.....nonetheless, the effort is worth it if we reach more people than we have, and they find some time to review and comment on a few of the booklets or the two IG's.

----- Original Message -----

From: "David A. Feinberg, C.D.P." <dafeinberg@computer.org>
To: "Doo, Lorraine T. (CMS/OESS)" <Lorraine.Doo@cms.hhs.gov>
Sent: Tuesday, December 20, 2005 4:15 PM
Subject: Re: ecomments web site not working

Lorraine,

Appreciate your confirmation that it's not just my computers. Small
whew.

What's going to be done for all the folks who follow the e-commenting
instructions in the Claims Attachments NPRM? Will they automatically be
re-directed to the new url? Will a Notice modifying the commenting
instructions be issued? How soon will the new url be stable and usable
for CMS-0050-P? et cetera, et cetera, et cetera

You get the immediate interim and longer term pictures, I'm sure :-)

DAF

P.S. I'm working on a small Claims Attachments NPRM Commenting
'marketing campaign'. If you're interested, I'll share my first draft
of the first missive with you and you can provide feedback should you
wish. Tentative timing for sending the first of at least 2-3 messages
is middle of the first week in January. Hoping to 'hit' around 5,000 or
more addressees each time.

DAF again

----- Original Message -----

From: "Doo, Lorraine T. (CMS/OESS)" <Lorraine.Doo@cms.hhs.gov>

To: "David A. Feinberg, C.D.P." <DAFeinberg@computer.org>

Sent: Tuesday, December 20, 2005 1:57 PM

Subject: RE: ecomments web site not working

David, we've had a web re-design at CMS, so there are a number of issues that are surfacing - I've shared your find with the right folks, and it is being investigated. In the meantime, here's a link, but our reg is not up yet, and we're looking for that too! Thanks, as usual. loraine

<http://www.cms.hhs.gov/home/regsguidance.asp>

-----Original Message-----

From: David A. Feinberg, C.D.P. [mailto:dafeinberg@computer.org]

Sent: Tuesday, December 20, 2005 2:39 PM

To: Doo, Lorraine T. (CMS/OESS)

Subject: ecomments web site not working

Importance: High

Just thought I'd let you know that

www.cms.hhs.gov/regulations/ecomments

is not available as I write this.

Everybody and all open NPRM's, etc. are affected.

DAF

Submitter :

Date: 01/20/2006

Organization : Aetna

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-0050-P-91-Attach-1.PDF



James D. Cross, M.D.
National Medical Director
Head of Medical Policy Administration

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8201 Peters Road
Suite 2001
Plantation, FL 33324

January 20, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0050-P
Mail Stop C4-26-05
Baltimore, MD 21244-1850

Dear Sir/Madam,

Aetna appreciates the efforts made by HHS to develop regulations that will result in administrative simplification, and also commends the efforts of the volunteers who have worked under the auspices of ASC X12 and HL7 to create suitable standards.

We are providing the following comments on the HIPAA Administrative Simplification Standards for Electronic Health Care Claims Attachments (File code CMS-0050-P) as published in the Federal Register on September 23, 2005. Our intent is to help HHS ensure that the final regulation will provide a net benefit to the public as well as to healthcare providers, payers and other covered entities.

Our comments on the proposed NPRM fall into three main areas which are covered in more detail in the following pages.

1. We believe the requirement for a single request for attachments per claim will add considerable administrative expense, and inconvenience providers as well as payers, while providing limited benefits. We recommend this requirement be removed.
2. We support the WEDI recommendation that urges HHS to provide funding for a cost-benefit study. We encourage careful consideration of the results of such a study before issuing a final rule.
3. We believe some aspects of the requirements need clarification.

In addition, we want to note that we support limiting the scope of the regulation to the initial processing of claims only, and not applying it to post-adjudication reviews.

For further information contact: Peter Walker, 55 Lane Road, Fairfield, NJ 07004 Tel: (973) 244 3355
email: walkerpt@aetna.com

Sincerely,

A handwritten signature in black ink, appearing to read "James D. Cross", written in a cursive style.

We believe the requirement in the proposed § 162.1910 (c) for a single request for attachments per claim will add considerable administrative expense, and inconvenience providers as well as payers, while providing limited benefits. We recommend this requirement be removed.

(This requirement is discussed in the NPRM under the caption SOLICITED VS. UNSOLICITED ATTACHMENTS)

- In addition to recommending the payer requirement be removed, we do not believe that there is a need for a regulatory requirement for a single response to a request, and would not object to allowing providers to send multiple responses.
- We do not believe that removing these requirements would result in a “continuous loop of query and response in order to have a claim processed”
- We do believe that removing the requirements would allow providers and payers appropriate flexibility to handle issues in the most efficient way, and would minimize the amount of protected health information requested.
- We do not believe that this requirement contributes to the goal of administrative simplification. In fact, as we point out below, we believe it will complicate administration.
- We believe that this requirement will create significant costs for payers without commensurate benefits for the industry.
- We believe including these requirements goes beyond the legislative requirement to establish standards for the electronic transmission of health care information.
- Both payers and providers recognize that minimizing the number of interactions required to process claims is essential to controlling costs. Commercial health plans have significant competitive pressure to control costs, and thus have no incentive to extend the process of settling claims unnecessarily.
- In addition, many states and plan sponsors already require commercial payers to process claims on a timely basis.
- We recognize that payers processing claims for government funded plans may not be covered by state or plan sponsor requirements, or may not be subject to competitive pressures to reduce costs. However, if there is a concern that without those factors, those plans could create “a continuous loop”, we suggest that CMS take administrative action separate from HIPAA to control the actions of those payers.
- If (§ 162.1910 (c)) or similar wording remains in the final regulation, we request that CMS prepare to provide clarification on the many questions that can be expected to be raised by this requirement, which include the following:

- If the response to initial request is lacking in needed specificity or fails to fully respond to request – can the request be resent?
 - If the response to a request leads to follow up questions – can a subsequent request be sent?
 - If there is a change in the member's status that requires us to ask for additional information – can a subsequent request be sent? For example, we may need accident data, and while we are waiting for that we get a claim that indicates COB (when there is none indicated on the file). Then we get back the accident data, and now we have to ask about COB.
 - A claim for multiple services may be “split” for timely processing. Can separate requests be sent for each part? This could delay release of payment on the parts of the claims.
- A small proportion of claims require additional information at different stages in the process of handling the claim (for example, stage 1 - establishing eligibility for benefits and appropriate plan when patient has multiple coverages, stage 2 – establishing whether claim meets provisions of a particular plan – for example medical necessity, coverage under preventive health provisions, etc. (The current AIS standards appear to mainly cover stage 2 issues, but the regulation should be a structure that meets future needs.) To send a single request, we would need to send every potentially affected claim through non-clinical and clinical areas prior to requesting any type of information, even though the possibility exists that, based on responses to claim-related inquiries - like eligibility, Co-ordination of Benefits (COB), Full-Time Student verification etc. - we may or may not end up needing clinical information.
 - Currently, processors experienced in handling non-clinical information handle most non-automated aspects of processing, while issues requiring clinical knowledge are handled by clinically experienced staff. A single request creates a concern with involving processors in requesting information for things that are beyond the scope of their job/training.
 - Privacy concerns may be raised by attempts to make one request up front for every piece of information that could ever be required for any level of review for a claim. This creates a risk that members' personal and confidential records are going to be circulating with greater frequency than is currently required. There is also the impact of processing information we subsequently determine we did not need, and an impact on the providers in submitting such information. Overall this could be more burdensome to providers than handling more limited initial requests, of which a proportion might require follow-up requests.
1. **We support the WEDI recommendation that urges HHS to provide funding for a cost-benefit study. We encourage careful consideration of the results of such a study before issuing a final rule.**

(The following comments relate to issues discussed in the NPRM under the caption COSTS & BENEFITS)

- We believe such a study would require as part of its input results from a broader set of pilot implementations. As the proposed standards have only been partially tested in low volume pilots by government program payers, without further and most extensive pilots there is not enough experience to use for estimating costs and benefits.
- Studies of information sent with paper claims indicate that most common situation is that information not needed to process a claim or duplicating information already on the claim is sent attached to a standard claim form – for example, provider bills attached to a CMS 1500 or UB92.
- In the majority of those situations where information not duplicative of a paper form is sent, all the relevant information could have been sent in the current 837 claim format (e.g. primary payer EOB information, ambulance information, chiropractic notes, dental information)
- The remaining situations are those that are addressed by this regulation, or could be addressed by additional AIS. These situations arise in under 3% of medical claims and under 4% of dental claims.
- However, if providers fully implemented current 837 standard capabilities, the scope for additional benefits from attachments regulations would be even less than current paper attachment volumes would indicate.
- The cost of implementing the proposed requirements (especially those for issuing requests) will be high, and the benefits obtained are dependent on the level of adoption by providers. Without widespread provider adoption, the regulation will result in a net increase in costs of administering health care plans – thus decreasing their affordability and leading to more un-insured.
- Without presentation of a compelling cost-benefit equation for providers, the level of adoption by providers will be low. Low adoption for providers means payers will not see cost savings adequate to offset costs of creating compliant processes, which will be duplicative of current processes for providers who do not adopt the standard.
- Clear cost benefit justification for a significant number of providers is therefore essential for regulations to provide overall industry cost savings.
- Study should consider impact of competing priorities for available financial capital and human resources to invest in provider IT initiatives - HIT initiatives, ICD10 implementation, transaction standard version upgrades, National Provider ID and National Plan ID are examples of areas where providers will have to prioritize investment.
- Payers will need to be able to identify which providers request this process, and which do not. The expenses are not limited to initial implementation. There are

ongoing administrative expenses involved in supporting two separate request processes (electronic and non-electronic), and for maintaining and updating records of which providers have adopted the electronic standards. These costs should be studied.

2. We believe some aspects of the requirements need clarification.

(The following comments relate to issues discussed in the NPRM under the caption DEFINITIONS)

- Definition of “clinical reports” could be interpreted to cover items not intended by the authors of the HL7 AIS spec (e.g. x-ray images).
- Dental reports content in clinical AIS specifications believed to be intended to collect information from hospitals when an inpatient stay involved dental consultation or treatment, but could be interpreted as for use in collecting dental narrative notes from dental office visits.
- The definition of attachment information refers to information needed to support a health care claim. Is it therefore correct that attachments to encounter transactions are not covered by the regulation? For example, lab results information sent with reports of services to payers who have pre-paid for lab services under a capitation agreement.

(The following comments relate to issues discussed in the NPRM under the caption MODIFICATION TO STANDARDS & NEW ATTACHMENTS).

- While the HL7 standards are intended to align with initiative to implement HIT standards, the details of the processes that emerge for HIT interoperability may not exactly align with the standards named in the NPRM. Payers and providers who can interact using interoperability “interoperability” capabilities created in line with HIT initiatives should be encouraged to do so, rather than required to set up separate, additional processes to conform to the detailed standards named in the rules.
- We would also like to note that voluntary adoption of new standards presents particular issues for the proposed request process. Payers would need to set up processes to track which providers had voluntarily adopted which standards, in order to know when to create requests in the standard format.
- In addition, we would suggest that any process for implementation of additional AIS needs to consider whether
 - an additional AIS provides additional specifications for already use by entities and with processes already covered by existing AIS (in which case a simplified process would be appropriate); or
 - will bring into scope a new category of providers, or additional health plans, or processes not covered by AIS already in effect, in which case

comment periods and advance notice equivalent to that provided by the current NPRM process would be appropriate.

(The following comments relate to issues discussed in the NPRM under the caption SOLICITED VS. UNSOLICITED ATTACHMENTS)

- If a provider indicates they will receive requests via the standard, must that provider then accept requests for all AISs, or are they allowed to specify that they can electronically handle only certain AISs?
- When we need additional information from the member, we indicate that we are requesting information from the member. For example, is a cc to a provider of a request to the member considered in scope of regulations?
- If a provider indicates they wish to receive requests electronically, does that prevent a payer from initially requesting information by telephone?
- If a provider indicates they wish to receive requests electronically, but the payer has published requirements for information to be sent with the claim, can the payer deny the claim for lack of required information or must a request be sent first?
- If a provider indicates they wish to receive requests electronically, and the payer has not published requirements for information to be sent with the claim, can the payer issue a remittance advice denying the claim for lack of required information?
- The standards for electronic remittance advice have been widely interpreted as not requiring a payer to discontinue sending paper remittance advices to providers receiving ERAs. By analogy, can a payer continue to send a request for attachment information by other means (e.g. letter, telephone, email) in addition to sending a standard attachment request?

(The following comments relate to issues that are not discussed in the NPRM)

- Applicability of standards to situations where additional information needed can only be requested in part by the standards. Does this create a situation where two separate requests must now be sent when previously one request could have been sent?
- Where information can be supplied in either the 837 claim or the attachment standard, clarification is needed as whether either approach or only one will be considered compliant, and whether payers can influence or specify the approach to be used. We prefer that only one approach be considered compliant. We prefer that approach be use of the 837. We also believe that providers would prefer to use investments already made in supporting full use of 837, rather than implementing additional requirements to support production. For dental, the implementation of full 837 capabilities by providers has had an extended timeframe – we expect that dental provider adoption of attachment standards will be further behind.