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JAN 19 2006

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 W. 22nd Street, Suite 450
Oak Brook, IL 60523

Telephone: 630-574-6001
Fax: 630-574-6999

that payers regularly refine requirements for additional information necessary to pay claims. The use of standardized electronic transactions occurs within a "dynamic" environment and that "dynamic" must also be reflected in the regulatory framework.

This threshold implementation issue was cited in the December 2005 published evaluation report of the electronic claim attachments pilot by Empire Medicare Services. The report entitled "Evaluation of the Electronic Claim Attachments Pilot" reviewed a "proof of concept" pilot test for electronic claims attachments. Referencing Medicare's medical review policies in their report, the findings note that "as medical review policies are continually revised, created, and deleted, there is a probability that defined attachment types may never meet 100-percent of the payer's needs without constant and rapid revisions by the SDO and promulgation of new regulations."

See, "Evaluation of the Electronic Claim Attachments Pilot" at page 2, available electronically at: http://www.empiremedicare.com/hug/ecapfiles/Final_Draft_%20Evaluation_of_ECA_Pilot.pdf.

DDPA believes that HHS should adopt electronic claims attachment requirements in a manner that will allow flexibility for maintaining standards that are current with health care and payment practices. We recommend that proposed and future attachment standards, including the periodontal charting attachment, should not have a limited set of LOINC codes named internally in the AIS implementation guide created and balloted by HL7. A subset of LOINC known as a "class" of codes should be designated in the AIS for each attachment and that class should be referenced in the AIS.

As a result, all specific LOINCs will be maintained external to the implementation guides and can thus be updated periodically to meet the changing needs of the industry rather than to be imbedded in a formal rule that requires a lengthy agency review. As we noted in our initial comments, in many instances the industry has already updated the standards by the time the agency officially adopts an outdated version by rulemaking.

As an example, for periodontal attachments, a class would be established within LOINC called "Perio attachment." The AIS would only reference the class, and all codes related to that attachment would fall within the scope of that class. This would be a preferred approach because adding, modifying, and deleting codes would not require balloting by the HL7 to update the AIS followed by the promulgation of a new federal regulation. Users of the attachment standard would simply need to justify a change request through the LOINC code maintenance process to add or retire a code. The revision would be made effective upon the date assigned by the committee.

Our current experience with the HIPAA standards for transactions and code sets leads us to conclude that it will take up to ten years to adopt corrections and changes that meet the business needs of industry. This assumes that the current regulatory framework would continue to determine the "dynamic" of the standards. An even more cumbersome approach would rely upon the Congress constantly amending the statute to keep up with the changes occurring in the industry. Clearly, a better procedure must be employed if these standards are to remain relevant to industry.

Finally, it is our view that the potential impact and consequences of this proposed rule cannot be fully evaluated in the abstract. Only through a further "pilot" or demonstration for actual implementation of claims attachment standards can the real issues and problems be identified and addressed.

In conclusion, DDPA recommends that HHS strongly consider an approach to this rule wherein the rule incorporates by reference the "type" of standard included as a matter of federal law. However, the details and addition, modification, and deletion of such standards would be performed by the designated standards organization. That designated standards organization would be required to have a fair and open process for adding, modifying, or deleting standards. In the alternative, it is vitally important that HHS provide for expedited review and consideration of such standard setting to maintain relevance to the business world.

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On behalf of DDPA and its member companies, we very much appreciate the agency's granting of the extended comment period on this proposed rule. If you have any questions please call me at (630)574-0001.

Sincerely,

Kim E. Volk

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President and Chief Executive Officer

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Standards would be established for an attachment request transaction, the attachment response transaction, the content and format, and code sets for questions and answers. New definitions would be added for: claims attachment request transaction; claims attachment response transaction; ambulance services; attachment information; clinical reports; emergency department; laboratory results; medications; and rehabilitation services.

The purpose of this letter is to provide comments on issues raised by proposed definitions or the absence of definitions, and specific comments are provided with respect to the attachment standards themselves.

Comment on Claims Attachment Types

The 1994 report of the WEDI Attachments Workgroup identified several hundred "types" of paper-based claims attachments and formats. This proposed rule establishes uniform standards for three specific services: rehabilitation services; ambulance services; and emergency department services. The proposal also establishes standards for three types of information that may be used for any service: clinical reports; laboratory results; and medications.

DDPA requests clarification with respect to what is included in "clinical reports." The proposed rule defines "clinical reports" to mean reports, studies, or notes, including tests, procedures, and other clinical results, used to analyze and/or document an individual's medical condition. That broad definition could be read to include x-rays and other radiographic images. We request that the agency clarify the meaning of "clinical reports" to explicitly exclude x-rays and other radiographic images.

Future Periodontal Care Rule

We are particularly interested in the standards that the Standards Development Organizations are developing for a later proposed rulemaking with respect to periodontal chart information. First of all, reference must be made to a periodontal "chart information" instead of "care," because the chart information is the claims attachment. A payer may need to request full mouth radiographs and clinical narrative in addition to the periodontal chart in order to make accurate payment under the terms and conditions of the contract providing the benefit. A payer should not be restricted to requesting only the named attachments in order to determine the appropriate benefit payment.

Combined Clinical and Administrative Data

Unlike the prior "transaction" standards that are administrative data, the claims attachment standards, for the first time, includes *both* clinical and administrative data. The agency has solicited comment regarding this strategy since the two standards have not been used together before, and whether this same general structure and information can

be applied to all electronic claims attachments to allow for some level of consistency. DDPA is offering specific comments below on these new standards.

Initial Types of Claims Attachments

These six claims attachment types were selected based upon "industry consensus" with respect to their relevance to a significant percentage of covered entities, and to the claims that typically require additional documentation. This limited number is designed to gain experience and to evaluate technical and business impacts. HHS has solicited comment on whether these initial six types are still the most frequently requested and if there are others that are equally or more pressing for the industry.

Dental Benefits Attachments

The initial six attachments proposed for adoption are largely appropriate for medical benefit claims except where "clinical reports" might include information important to dental benefit claims. Most important to DDPA and its members with respect to claims attachments are periodontal charts and radiographs. These are the two most commonly requested attachments in the dental benefits industry. DDPA is working with HL7 and the American Dental Association (ADA) in the design of the standard for periodontal charting.

DDPA also notes for the record that the number of dental "claims attachments" would be reduced significantly, if the ICD diagnostic codes were included in dental "claims" information. This would greatly simplify the administration of dental benefit claims.

Timely Process for Standards Adoption

As important to DDPA as the standards, is the process by which new versions of the named claims attachments will be adopted. The current process fails to timely meet the business needs of health plans. Oftentimes new versions are released by the standards organization in order to meet evolving business needs; however, health plans must await

the agency's notice-and-comment process which imposes great delay. In many instances the industry has already updated the standards by the time the agency officially adopts an outdated version of the standards by rulemaking. The industry would prefer to use new versions of standards as they become available. We further recommend that, in addition to using newer versions of standards as they become available, health plans must be accorded adequate implementation time that is coordinated with promulgation of other new standards and procedures.

Effective Date of Final Standards

DDPA recommends that any final rule for "claims attachments" be delayed until the following conditions are satisfied: (1) CDA Release 2 is finalized and reflected in all supporting documentation such as the AIS guides; and (2) a pilot (or pilots) is accomplished which thoroughly tests the X12N Transactions and all of the HL7 guides (each attachment guide should be incorporated into the pilot and should include at least one-thousand 277 requests and at least one-thousand 275 responses for each attachment; and communications, storage requirements. Savings could be determined based on the pilot. Testing must be done with the Human Decision Variant, and the Computer Decision Variant could be phased in two or more years after the Human Decision Variant is in place.

Health plans and other covered entities must be provided sufficient time to comply with the claims attachment standards once a final rule is published. The statutory requirements of HIPAA provide for a general compliance date that is 24-months after the date on which standards are "adopted or established". DDPA recommends that the agency utilize a delayed effective date for any final rule, or an interim final rule, that provides for additional time before the HIPAA required 24-month compliance date begins. This additional "start up" time was used by the agency for the National Provider Identifier Rule (NPI). The final NPI rule was published on January 23, 2004; however, the rule became "effective" on May 23, 2005, and enforceable 24-months later on May 23, 2007. This approach allowed an additional 16 months of transition to the compliance date for the NPI Rule.

Comments on Standards for Claim Attachments

The proposed standards themselves are based upon standards that have been under development for the past several years by the Accredited Standards Committee X12, and Health Level Seven (an ANSI accredited standards development organization). The X12N transaction standards (and implementation guides) would be used for the claim attachment request and response. The HL7 specifications for the content and format would be used for communicating the actual clinical information. Finally, the Logical Observation Identifiers Names and Codes ("LOINC") are used for standardized questions that specifically identify the additional information and coded answers. **DDPA is providing comments on the standards below and in chart format attached as an Appendix to this letter.**

LOINC Code Usage

Because LOINC is adopted as a Medical Code Set, the regulation needs to clarify the use of which LOINCs are used in each of the AIS documents. There is concern that, absent this clarification, entities may attempt to argue that any LOINC code may be used for any claims attachment. DDPA recommends the following clarification: (1) those AIS documents that contain static content (e.g. ambulance, emergency, rehabilitation, medications) only the LOINCs enumerated in the AIS are allowed; and (2) those AIS documents that reference the LOINC database (such as laboratory results, clinical reports) only the LOINC class (such as laboratory results, clinical reports) as defined for that AIS are allowed. We also recommend a process to enable covered entities that believe a LOINC code was either omitted from an AIS document or that should be included in an AIS document to petition for inclusion of the LOINC code.

AIS Books Technical

DDPA recommends a technical correction to the AIS books that reference the LOINC database clarifying how to determine the appropriate subset of LOINC codes.

X12 and HL7 Standards

DDPA agrees with the approach using standards developed by X12 and HL7, and the LOINC code set as developed for these business purposes. We agree that the final rule should adopt both the Computer Decision Variant and Human Decision Variant for claims attachments. DDPA recommends that the content of the BIN segment does not have to be validated for the portion of the data that is not being used. DDPA also recommends that receivers of these transactions have the option of accepting or rejecting imperfect transactions, specifically the BIN01.

Maintenance of LOINC

DDPA is not confident that the assignment of the LOINC codes meets the needs of the dental benefit industry. We recommend the following: (1) clarify the process for access to the LOINC codes used for the specific attachment AIS; and (2) clearly establish the process for requesting new LOINC codes.

Comments on Definitions and Scope of the Proposed Rule

The proposed rule makes reference to several matters that are already defined in other federal laws and regulations. It is critically important that, where definitions exist, those definitions should be incorporated into the proposed rule. Reference is also made to new matters without definition, and the proposed rule should include such definitions. These are discussed specifically below.

Definition of Claims Attachment

Claims attachments are described as "additional documentation" or "supplemental health care information" related to billed services that are necessary for further explanation to complete the adjudication of a "claim" before payment can be made. The actual proposed regulatory language defines only "attachment information" to mean supplemental health information needed to support a specific health care claim. We propose that the term "claims attachment" be specifically defined in the regulation to mean additional electronic documentation or supplemental

health care information requested from a health care provider related to billed health care services and that are necessary to complete the adjudication of a claim before a benefit payment can be made. In addition, it must be clear that a health plan is not restricted arbitrarily in the number of health care claims attachment requests that may be solicited from a provider in connection with a claim.

Definition of a Claim

The proposed rule does not define the term "claim." We propose that the term "claim" be defined in the regulation to mean a request by a participant or beneficiary of a health plan for the payment of benefits for heath care items and services that may be covered under the terms and conditions of the plan. DDPA also recommends that the regulations incorporate the definition of the term "payment" as defined in current regulations for privacy standards at 45 C.F.R. 164.501. The activities enumerated as "payment" activities in this existing regulation are relevant and appropriate to the benefit claims adjudication process and the consequent need for claims attachments, and include: determining eligibility or coverage (including coordination of benefits or determination of cost sharing amounts); review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care; utilization review activities, including precertification of services, concurrent and retrospective review of services).

Definition of Adjudication of a Claim

The proposed rule does not define the term "adjudication of a claim." We propose that the phrase "adjudication of a claim" be defined in the regulation to mean the procedures established under the terms and conditions of the health plan to: make a claim, process a benefit claim including eligibility verification of a claimant or beneficiary, eligibility verification of a health care provider, a benefit determination, review of health care services with respect to medical necessity, the coordination of benefits, determination of cost sharing, and any other payment-related activities. The "adjudication" of a claim must be defined consistent with the "claims procedure" rules that ERISA-governed group health plans must follow. See 29 C.F.R. 2560.503-1. DDPA also recommends that the term

"payment" as defined in this rule similar to the current privacy regulations at 45 C.F.R. 164.501 and that the definition for "payment" be incorporated into the definitions for "claims attachments".

Definition of Solicited and Unsolicited Information

The agency distinguishes "solicited" (after a claim is received) from "unsolicited" (requested in advance of a specific attachment request by a health plan) claims attachment information, and limits the use of "unsolicited" attachments with an initial claim. A health plan must provide instructions for a specific type of health care claim that permits a provider to submit attachment information on an "unsolicited" basis each time the specified type of claim is submitted.

The proposed rule does not define the terms "solicited" or "unsolicited" claims attachment information. We propose that the term "solicited attachment information" be defined in the regulation to mean a claim attachment requested after a claim is received by a health plan; and that the term "unsolicited attachment information" be defined in the regulation to mean a claim attachment received in advance of a request from a health plan for additional information.

Definition of Adjudication and Post-Adjudication

In addition, HHS distinguishes "adjudication" and "post-adjudication" requests for claims information, noting that "post-adjudication" requests (quality control, fraud and abuse, and reporting) are not covered by this proposed rule. This preamble discussion is not reflected in any proposed regulatory language; and seems implicit only in the meaning of "claim" which is not defined in the proposed rule.

The proposed rule does not define the terms "adjudication" and "post-adjudication". We propose that the term "adjudication" be defined in the regulation to mean "adjudication of a claim" (discussed above) and include activities defined as "payment" under the current privacy rule's definition of "payment" at 45 C.F.R. 164.501 (determinations of eligibility, coordination of benefits, utilization review, precertification, preauthorization,

concurrent and retrospective review, etc.); we propose that the term "post-adjudication" be defined in the regulation to mean activities of a health plan that occur after the claims adjudication process has been completed and the benefit has been paid under the terms and conditions of the health plan. We also propose that the agency clarify that the rule for "claims attachments" does not foreclose health plan requests for information relevant to the conduct of quality assessments and improvement activities including outcomes evaluation and development of clinical guidelines, and other permissible "health care operations" of a health plan.

Other Definitional Issues

As noted earlier in our comments we propose that the agency clarify the meaning of "clinical reports" to explicitly exclude x-rays and other radiographic images. The preamble discussion for the proposed rule includes a more helpful discussion of the meaning of "clinical reports" (at 70 Fed. Reg. 55994) as well as the term "laboratory results". We recommend that the agency incorporate the additional discussion into the text of the regulation with respect to these definitions.

Comments on Voluntary Implementation

This proposed rule is required only when using electronic media to conduct a health care claims attachment request transaction. While providers are not required to participate, health plans must generally implement "support" for providers that do participate.

In issuing this proposed rule, HHS notes that, for many years now, health plans have been encouraging health care providers to move toward electronic transmissions of claims and inquiries, both directly and through health care clearinghouses. However, the transition has been inconsistent across the board. Like the earlier "transaction and code set" standards, the claims attachment standards apply only where providers *voluntarily* choose to utilize electronic media. These proposed rules apply specifically to electronic health care claims attachments and do not apply to paper attachments.

In the past, providers have resisted claims attachment requests because they view additional information as unnecessary and not in accord with "prompt pay" laws. On the other hand, health plans regard claim attachments as critical to their fiduciary responsibility of ensuring that payment is made in accord with the plan's terms and conditions. The agency notes that the proposed rule makes no determination about the appropriateness of requests for additional information and is required to issue the proposal under the Social Security Act.

While we recognize that CMS cannot transform the statutory provisions of HIPAA into mandatory requirements, for the record, DDPA notes that the achievement of a pervasive use of national transaction standards will continue on a very slow track so long as providers may pick and choose when to participate in the electronic transaction program. For example, studies have shown that less than 3% of dentists' offices are completely "paperless". On average, DDPA carriers receive 38% of dental benefit claims electronically from providers out of some 66 million claims submitted annually.

Voluntary compliance with electronic transaction regulations is costly for dental plans as a majority of providers do not submit claims electronically. So long as it is voluntary for providers to submit claims and claims attachments electronically, the cost per electronic claim and attachment is very expensive because the development costs are not spread over a large number of electronic claims or attachments. The overall return on investment of implementing a large scale electronic transactions system changes is poor when reviewed in terms of use by a select few providers compared to all providers.

Comments on Cost Impact

HHS notes that industry-wide cost data could not be compiled for use in assessing the actual financial impact of the claims attachment rule, because there is a lack of data available regarding any industry wide HIPAA transaction costs or savings, or the current use of claims attachments; or the cost of manual processes; or the impact of conducting any transactions electronically. The agency relied upon the 1993 WEDI report and assumptions made for the Transactions Rule to predict costs and savings for the claims attachment rule. DDPA understands that the Department of Defense (DOD) is implementing standards for "attachments" and will be reviewing the cost and

benefits of using electronic transactions in its system. We recommend that HHS work with the DOD to include an analysis of "claims attachments" for purposes of analysis of this proposed rule.

Cost Information Related to Claims Attachments

HHS has solicited information from the industry regarding: implementation costs; types and frequency of claims attachments; workload and other relevant cost information.

Frequent Claims Attachment Types

The 1993 WEDI report suggested that 25 percent of all health care claims required support by an attachment or additional documentation. The agency notes that this data is over 10 years old and does not take into account the HIPAA transaction, privacy, and security rules, as well as the new claims procedure rules for health plans issued by the U.S. Department of Labor. Based on available data, HHS indicates that over 50 percent of claims submitted annually are for hospital and physician services, and that 50 percent of all claims attachments are likely to be represented by the six attachment types in the proposed rule. The agency has solicited comments on which claims most commonly require additional information for "adjudication" and what types of electronic attachments might be required in the next 5 to 10 years.

For dental benefit claims, the most frequent type of claims attachments are periodontal charts and radiographic images. Approximately 20% of dental claims (out of 66 million annually) submitted to payers are submitted with unsolicited attachments that are not needed for claims adjudication. These unsolicited attachments impose additional costs (ranging from $0.21 to $1.25 per claim) on the claims process for the dental benefit industry. These additional costs relate to processing and returning to providers these unsolicited attachments.

Comments on Privacy and Security Rules

The agency notes that the past practice of sending an individual's entire medical record to a health plan for justifying a claim is not generally inconsistent with the "minimum necessary" standards of the HIPAA Privacy Rule. HHS notes that the Privacy Rule exempts from the minimum necessary standard any use or disclosure that is required for compliance with the HIPAA Transactions Rule. We propose that the agency clarify that the same exemptions for "payment" that apply under the Privacy Rule, would also apply with respect to activities relating to "claims" and "claims attachments" because these activities all relate to "payment". DDPA also recommends that the agency provide additional guidance, in the form of examples, with respect to the application of the Privacy Rule and the "claims attachment" process. Here are a few possible examples: (1) payer has received a claim attachment but did not receive the claim and payer might store an image and then return it, file it, or destroy it; (2) in payer-to-payer coordination of benefits an attachment may be sent on to the subsequent payer; (3) a health plan may request specific information and providers send scanned documents with more information than requested; (4) a request may not specify a timeframe using a LOINC modifier and the issue is how far back must a provider go with respect to the medical history or only the episode of care that is the subject of the claim; and (5) a claim and unsolicited attachment is submitted to a health plan, however, the patient is not a participant or beneficiary covered by the health plan.

Exercise of Discretion

The agency comments, however, that the minimum necessary rule *would* apply to data elements for which health plans or providers may exercise discretion as to whether the information should be provided or requested. DDPA believes that it is very unclear what circumstances would be interpreted as "discretionary."

Comment Period Extension

Because DDPA believes that it is critically important to issue definitions applicable to this proposed rule, the agency should reissue a proposal with suggested definitions for public notice and comment. Accordingly, an additional 60-day comment period for review of such matters must be provided in connection with a reissued proposed rule.

* * * * * * * *

On behalf of DDPA and its member companies, we very much appreciate the opportunity to comment on this proposed rule. If you have any questions please call me at (630)574-0001.

Sincerely,

Kim E. Volk

Kim Volk

President and Chief Executive Officer

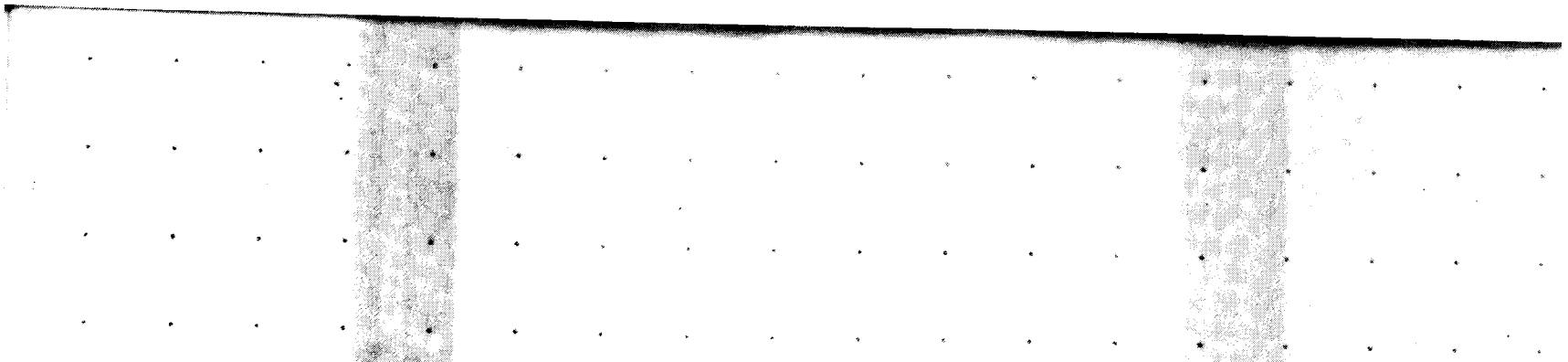
Delta Dental Plans Association

Chart Attachment

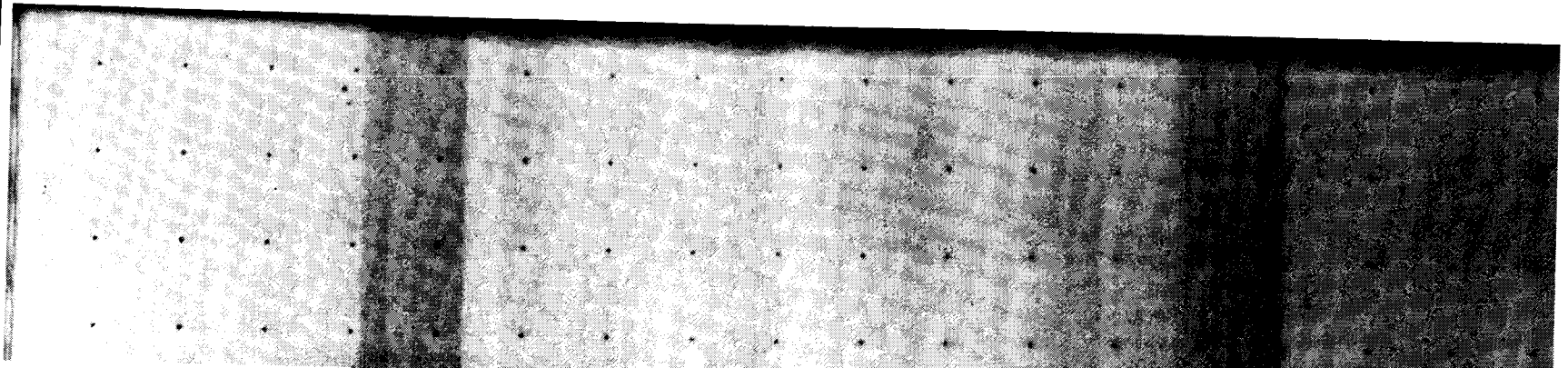
Delta Dental Plans Association (DDPA) Response to Claims Attachment NPRM
(Based on WEDI PAG Issues List)

1	56023 56024 56024	C C R	162.1002 (LOINC) 162.1915 162.1925	RT RT RT	Standards	Yes	**Is there agreement with the proposed X12 and HL7 standards, including versions and code set as the appropriate code set to identify the questions.** Comment #1 We agree with the approach using standards developed by X12 and HL7 developed for these business purposes. Comment #2: We agree that the final rule should adopt both the Computer Decision V for electronic claims attachment. Comment #3: Recommend that the content of the BIN segment does not have to be v that is not being used. Comment #4: Recommend that receivers of these transactions have the option of acc transactions, specifically the BIN01.
2	55999	R	II, C, 2 Overview of Clinical Document Architecture	P	Standards	Yes	Comment #1: Recommend to move to CDA release 2 assuming that there is a pilot th understand that HL7 will need changes to the HL7 IG and each AIS developed to be o adoption of CDA release 1 will cause extra work since HIT encourages CDA release 2 Comment #2: DDPA recommends the adoption of a mechanism for the timely migrat standards documentation as they become available.
3	55996	C	II.C.5 Electronic Claims Attachment Types Reg is 162.1910 –C	P RT	Standards	Yes	Comment #1: The six attachments adopted are largely appropriate for the medical ind the clinical reports: where dental reports are identified for use. Most important to DD Periodontal chart and radiographs as these are two of the most commonly requested at has been working with HL7 and the ADA in the design of the periodontal standard. Comment#2: Most important to DDPA is the process by which updated attachment sp recommend that no new standards be adopted under HIPAA until a process is in place updated versions to occur no less than every three years, allowing for adequate implen of other standards requirements impacting implementer workloads. In addition, notific adoption and implementation needs to be added after HL7 publication.

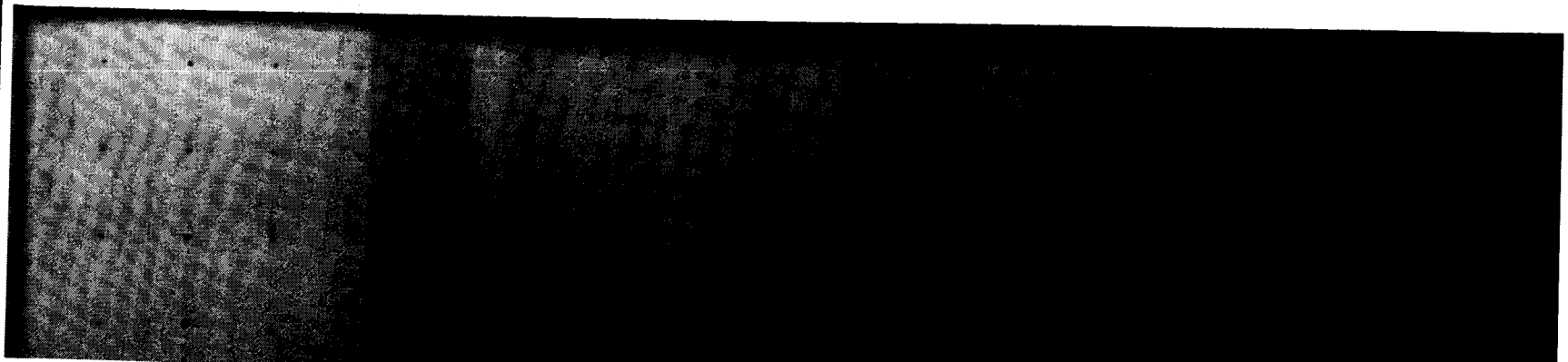
4	56001	R	II, E Attachment Content and Structure	P	Standards	No	Comment #1: Recommend that the 64 MB be left as a recommendation and not be a
5	55993 56022	R	II, A Definitions	P RT	Standards	Yes	Included in text letter
6	56024	R	162.1920 (d)	RT	Standards		No Comment
7	56014		III. Modifications to Standards ,A & B. 1st paragraph	P	Standards Maintenance		A lot of this was adopted as comment two under the attachment types question (Comr
8	56014		III. Modifications to Standards ,A & B.	P	Standards Maintenance	Yes	**Discuss maintenance of LOINC code sets in the future. Changes, additions, etc.** **Discussion: CMS requires health plans to comply with the standards. The health plar requested by a provider. If this is part of your business, then you must comply.** Comment#1: Delta Dental is not confident that the assignment of LOINC codes meet To ensure that the needs of the dental industry are met we would suggest the followin a. Clarify the process for accessing the LOINC codes used for the specific attachment b. Clearly lay out the process for requesting new LOINC codes
10	56025	C	162.1930	RT	Implementation	Yes	**Implementation timing: Is 24 months from the final rule publication date to the effecti** Comment #1: During the implementation of the first sets of HIPAA standards, it was frequently did not meet the needs of the industry. Further, it was not possible to easil identified need. In order to avoid that during implementation of the attachment standa the Final Rule not be released until all of the following conditions are met a. CDA Release 2 is finalized and reflected in all supporting documentation suc b. A pilot or pilots is (are) accomplished which thoroughly test the X12N Trans Each of the attachment guides should be incorporated into the pilot and inclu least 1000 275 responses for each attachment. Communications, storage requ determined based on such pilots. c. Fund each pilot with respective industry players e.g. dental offices, medical c payers, billing offices. d. Recommend that testing be done with the Human Variant. Phase in the Con is in place.
11	56001	C	II, D, 9 HC Clearinghouse	RT	Implementation	No	**Should the government have a national rollout plan?** Comment #1: DDPA recommends that the regulation support a national roll-out plan



			perspective				workgroup on claims attachments.
12	N/A	N/A	N/A	N/A	Implementation		
13	55999	C	II.D.2 Solicited vs. Unsolicited Attachments Reg is 162.1910 –C	P RT	Business Process	Yes	**Completeness/Single iteration process that only allows a single 277 request and a sing** Comment #1: Payers should endeavor for completeness of the request by asking all k with the understanding that further questions may be asked based on information cont and providers should not be penalized for the occasional mistake that could occur in e providing the response. This may necessitate more than one request/response set.
14	56024	C	II.D.2 Solicited vs. Unsolicited Attachments 162.1910 (a)(3)	P RT	Business Process	No	**Unsolicited 275 using payer instructions method.** Comment #1: A provider, based on prior arrangement or experience with a plan, may health plan either issues advance instructions to clarify its requirements, or, explicitly attachment is not required for the type of claim in question.
15	N/A	N/A	N/A	N/A	Business Process	No	**Should we allow for ability to send the unsolicited attachment separately from the 837 transaction file** Comment #1: The regulation should allow for the ability to send the unsolicited elect 837 claim i.e. not required to be bundled in the same interchange or transmission file (the same daily cycle.
16	55998	R	II, D Electronic Claims Attachment Types Business Use	P	Business Process	No	**Discussion of the post adjudication and the current definition of what is an attachment used attachments for purposes other than adjudication.** Comment 1: The regulation should not be interpreted to disallow health plans from c attachment process for purposes other than the purposes defined in this rule, such as p dental industry has needs for pretreatment and predeterminations as part of the approv The use of attachments would facilitate this part of the care/payment continuum. Comment #2: The process of making such arrangements should Remove the require using trading partner agreements. Comment #3: The proposed rule recommends adoption of standards, which will mand DDPA recommends that the preamble to the final rule strongly encourage entities to v in all other situations where they meet business needs for information exchange, prior public health reporting, etc.
17	55999	R	II, D, 3 Coordination of	P	Business Process	No	**Is the method proposed for use of attachments with COB appropriate?**

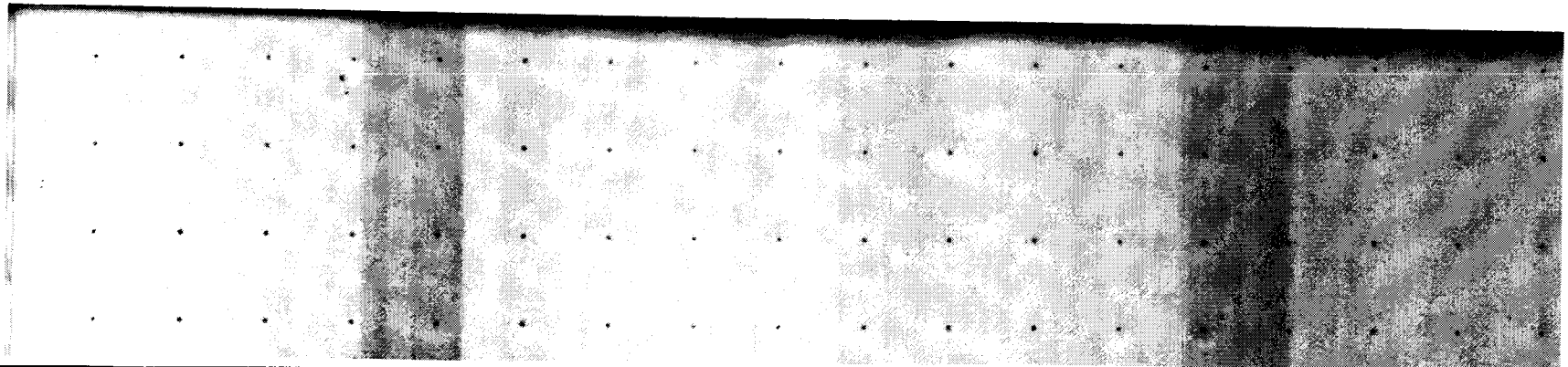


			Benefits				Comment #1: Add to the COB section language that will specifically state that if a pa they are not required to send this information to the subsequent payer.
18	56000	C	II , D.6 Connection to Sugnatures	P	Business Process		No comment
19	56012	L	II, H Requirements (HP, CH, Providers)	P	Business Process		No comment
20	N/A	N/A	N/A	N/A	Business Process		No comment.
21					Business Process		Moved to next section.
22					Clarification	No	Asking for clarification of when a covered entity must implement the announced trans Comment #1 Need clarification: If a health plan does not have a current business mo information (electronic or hardcopy), does the health plan have to use the 277 if a pro the health plan uses the unsolicited business model thus publishing the criteria in adva claim. Comment #2: Need clarification: Some health plans currently use a business process "needing additional clinical information," i.e. needing information that would be in a continue? Or does the request for that information now have to come through a 277 R how does the provider know what additional information to submit? Which electroni in the additional information? Comment #3: Need clarification: Will a provider be required to do both the solicited electronic attachments?
23	56024	L	162.1910 (a)(2) Electronic health care claims attachment request transaction	RT	Clarification	No	Comment #1 Please clarify the workflow is being described here at (2) "(a) The health care claims attachment request transaction is the transmission, from a of a request for attachment information to support the adjudication of a specific healt such a request … (2) In advance of submission of the health care claim" –



24	55999 - 56000	R L	II, D, 4 Impact of Privacy Rule	P	Privacy	Yes	**Ability to meet "minimum necessary" requirements and burden of doing so. Example documents with more than minimum information. Payers' retention of those scanned responsibilities in this area. Recommend that HHS should provide added guidance re minimum necessary** Comment #1: Recommend that HHS should provide added guidance from CMS in just minimum necessary. Examples for where we want guidance: Example #1 Payer has received a claim attachment but did not receive the claim. To and then return the paper original or shred it or file it. Example #2 Payer to payer COB if the attachment is sent on to the subsequent paye privacy rule. Example #3 Plan requests specific questions. and providers send scanned document information , since it is in a scanned document. Example #4 If a request does not specify a timeframe using a LOINC modifier, how Today, if it is not defined, then some providers only send the information related to Example #5 If a claim and attachment come in but the patient is not covered by tha return the information.
25	56014	N/A	VI Regulatory Impact Analysis	P	Impact Analysis	Yes No	**Comments on the Impact Analysis section. Are the citations related to the cost & be appropriate and realistic?** Comment #1: DDPA considers this regulation to be an unfunded mandate. We re the Department of Defense include a cost benefit analysis and be published for the i Comment #2: Recommend process to provide funding for initial implementation o relationship to the NHIN initiatives for funding since claims attachments are part o
	X12					No	**Acknowledgements and Error reporting** Comment #1: Recommend that the 275 IG be changed to remove the use of the 102. Change the the use of the X12 TR3 999 for syntax errors, and the X12 824 TR3 to acknowledg is in line with the WEDi Acknowledgement PAG recommendations. Comment#2: Recommend requirement for use of these Acknowledgement transac acknowledgements is problematic. This is in line with the WEDi Acknowledger

							Comment #3: Recommend that in the implementation of the acknowledgement stan the file level and not for each attachment within the file. Comment #4 Use of the TA1 acknowledgement. If this is a WEDi recommendatior should also be included in the recommendation for these transaction set.
	HL7					Yes	**LOINC code usage** Comment #1: Because LOINC is adopted as a Medical Code Set, the regulation nee LOINCs are used in each of the AIS documents. There is a concern that, absent this legalistic position that any LOINC code may be used for any attachment. Recommendation that the regulation be clarified as follows: 1. Those AIS documents that contain static content (e.g. Ambulance, Emergency, regulations must be clear that only the LOINCs enumerated in the AIS are all 2. Those AIS documents that reference the LOINC database (such as Laborato regulation should clarify that only the LOINC class (such as Laboratory Re that AIS is allowed. Comment #2: Recommend a technical correction to the AIS books that reference the determine the appropriate subset of LOINC codes.
	X12					No	**Other:** **The 275 and 277 books are not synchronized.** Comment #1: In implementation of previous standards, one of the ongoing issues has between request and response transactions. An example in the current set is the miss 275 2000A REF segment where the code qualifier of 'AD' for the dental codes is not present in the 277 transaction 222E SVC segment (page 98). Further, there is inconsi identification between the 275 and 277 for the same segments. It seems that the Qua between the 275 and 277, instead Code Qualifier HC is used in the 277 and CPT is us
	X12					No	Comment #2: The 277 book lacks reference to all of the 837 transactions. Dental is documentation---yet dental is included in the expectations for the claims attachment. reference include in the 277 manual are: P.22 Note---should also include reference t p.77 should also include that this segment is not needed for dental,' p. 79 Medical Re needed for dental
	HL7					Yes	Periodontal Attachment - Comment: Regarding the upcoming attachment for a perioc should be for a periodontal chart---not periodontal care. A payer may need to reques narrative in additional to the periodontal chart in order to make accurate contractual p. limited to requesting only the named attachments in order to accomplish payment.



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Health Level Seven, Inc.®

The Standard for electronic data exchange in health care

An ANSI accredited standards developer

JAN 2 3 2006

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

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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

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	**Joint HL7/X12 Comment** **HL7 Comment:** HL7 and X12 have collaborated on the following topic and submit this joint response **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: 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 Contact Number: (734) 677-7777
HL7 Contact Email: Karenvan@hl7.org

Comment Number	NPRM or Tech.Spec Page #	NPRM Column (L,C, R)	Comment Section	HL7 Comment to CMS
				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. 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. 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. 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
2	N/A	N/A	N/A	**HL7 Comment**: For the Ambulance Services AIS: <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 <u>Need to create and add a LOINC for:</u> "Patient is confined to a bed or chair.

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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
3	N/A	N/A	N/A	**HL7 Comment:** 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. 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. <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> o 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 o 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 o 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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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
4	55999		2. Solicited vs Unsolicited Electronic Health Care Claims Attachments	**Joint HL7/X12 Comment** **HL7 Comment:** HL7 and X12 have collaborated on the following topic and submit this joint response 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.
5	56001		E. Electronic Health Care Claims Attachment Content and Structure	**Joint HL7/X12 Comment** **HL7 Comment:** HL7 and X12 have collaborated on the following topic and submit this joint response 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.
6	56023 56024 56024	C C R	162.1002 (LOINC) 162.1915 162.1925	**Joint HL7/X12 Comment** **HL7 Comment:** HL7 and X12 have collaborated on the following topic and submit this joint response: 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.

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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
7	56013		III. Modifications to Standards and New Electronic Attachments	**Joint HL7/X12 Comment** **HL7 Comment:** HL7 and X12 have collaborated on the following topic and submit this joint response 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.
8	56023		162.1900 Definitions	**Joint HL7/X12 Comment** **HL7 Comment:** HL7 and X12 have collaborated on the following topic and submit this joint response 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.
9	55999	R	II, C, 2 Overview of Clinical Document Architecture	**Joint HL7/X12 Comment** **HL7 Comment:** HL7 and X12 have collaborated on the following topic and submit this joint response: 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. Comment 2: The benefits of using CDA Release 2 would be: 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.

Comment Number	NPRM or Tech.Spec Page #	NPRM Column (L,C, R)	Comment Section	HL7 Comment to CMS
				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	**Joint HL7/X12 Comment** **HL7 Comment:** HL7 and X12 have collaborated on the following topic and submit this joint response: 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.
11	55996	C	II.C.5	

Comment Number	NPRM or Tech.Spec Page #	NPRM Column (L,C, R)	Comment Section	HL7 Comment to CMS
			Electronic Claims Attachment Types Reg is 162.1910 –C	**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	II, E Attachment Content and Structure	**HL7 Comment**: HL7 believes that the recommended size limit of 64 MB is a limitation per BIN segment, 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**

Comment Number	NPRM or Tech.Spec Page #	NPRM Column (L,C, R)	Comment Section	HL7 Comment to CMS
			Standards ,A & B. 1st paragraph	**HL7 Comment:** HL7 and X12 have collaborated on the following topic and submit this joint response: Comment 1: 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. 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. Comment 2: Additionally, we recommend that five of the six initial attachment types be adopted as standards. *See separate HL7 comment regarding the Emergency Department attachment.* Comment 3: Our main goal is to move the regulatory process forward more quickly. For *new versions* 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. 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 sunsetting older versions of the standards after a transition period must be included. 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. 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.

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.	**HL7 Comment:** Comment 1: 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. Comment 2: 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. **LOINC code usage** Comment 1: because LOINC is adopted as a medical code set, the regulation needs to clarify the use of which LOINCs 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: 1. those AIS documents that contain static content (e.g. ambulance, ED, Rehab, Medication) the regulation must be clear that only the LOINCs enumerated in the AIS are allowed. 2. 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. Comment 2: 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. 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.
17	56000	C	II , D.6	**HL7 Comment:** We concur that there is no interoperable standard for electronic

Comment Number	NPRM or Tech.Spec Page #	NPRM Column (L,C, R)	Comment Section	HL7 Comment to CMS
			Connection to Signatures	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: (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. 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. 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. 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. 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,

Comment Number	NPRM or Tech.Spec Page #	NPRM Column (L,C, R)	Comment Section	HL7 Comment to CMS
				much less a strongly authenticated user. 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.
18	56024	L	162.1910 (a)(2) Electronic health care claims attachment request transaction	**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?
19	55999 - 56000	R L	II, D, 4 Impact of Privacy Rule	**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.
20				**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.

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
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:**

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
				HL7 and X12 have collaborated on the following topic and submit this joint response: 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.

HL7 Comments to Claims Attachment NPRM
Recommended Standard Document Changes
NPRM Reference: 45 CFR Part 162
[CMS-0050-P]
RIN 0938-AK62

HL7 requests the following changes to the HL7 related standards documents:

Track #	Task #	Change Request Description	Action Items - Next Steps	Doc # or Future Doc Key Word	Doc Description	Page #	Doc Section	Data Element	Origin	
1	1.1	27492-8 Change verbiage to "Date Patient Referred for Treatment" as agreed to for 8/2003 Ballot comment	Change verbiage to "Date Patient Referred For Treatment".	CDAR1AIS0003R021	0003-Rehab			LOINC	Ballot Reconciliation	
2	2.1	27493-6 Change verbiage to "Date Treatment Plan Author Signed" as agreed to for 8/2003 ballot comment	Change verbiage to "Date Treatment Plan Author Signed".	CDAR1AIS0003R021	0003-Rehab			LOINC	Ballot Reconciliation	
3	3.1	27540-4 Change verbiage to "Date Patient Referred for Treatment" as agreed to for 8/2003 ballot comment	Change verbiage to "Date Patient Referred For Treatment".	CDAR1AIS0003R021	0003-Rehab			LOINC	Ballot Reconciliation	
4	4.1	27541-2 Change verbiage to "Date Treatment Plan Author Signed" as agreed to for 8/2003 ballot comment	Change verbiage to "Date Treatment Plan Author Signed".	CDAR1AIS0003R021	0003-Rehab			LOINC	Ballot Reconciliation	
5	5.1	27766-5 Change verbiage to "Date Patient Referred for Treatment" as agreed to for 8/2003 ballot comment	Change verbiage to "Date Patient Referred For Treatment".	CDAR1AIS0003R021	0003-Rehab			LOINC	Ballot Reconciliation	
6	6.1	27767-3 Change verbiage to "Date Treatment Plan Author Signed" as agreed to for 8/2003 ballot comment	Change verbiage to "Date Treatment Plan Author Signed".	CDAR1AIS0003R021	0003-Rehab			LOINC	Ballot Reconciliation	
7	7.1	27613-9 Change verbiage to "Date Patient Referred for Treatment" as agreed to for 8/2003 ballot comment	Change verbiage to "Date Patient Referred For Treatment".	CDAR1AIS0003R021	0003-Rehab			LOINC	Ballot Reconciliation	
8	8.1	27614-7 Change verbiage to "Date Treatment Plan Author Signed" as agreed to for 8/2003 ballot comment	Change verbiage to "Date Treatment Plan Author Signed".	CDAR1AIS0003R021	0003-Rehab			LOINC	Ballot Reconciliation	
9	9.1	27676-6 Change verbiage to "Date Patient Referred for Treatment" as agreed to for 8/2003 ballot comment	Change verbiage to "Date Patient Referred For Treatment".	CDAR1AIS0003R021	0003-Rehab			LOINC	Ballot Reconciliation	
10	10.1	27677-4 Change verbiage to "Date Treatment Plan Author Signed" as agreed to for 8/2003 ballot comment	Change verbiage to "Date Treatment Plan Author Signed".	CDAR1AIS0003R021	0003-Rehab			LOINC	Ballot Reconciliation	

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HL7 requests the following changes to the HL7 related standards documents:

Track #	Task #	Change Request Description	Action Items - Next Steps	Doc # or Future Doc Key Word	Doc Description	Page #	Doc Section	Data Element	Origin	R D
11	11.1	18646-0 Change verbiage to "Date Patient Referred for Treatment" as agreed to for 8/2003 ballot comment	Change verbiage to "Date Patient Referred For Treatment".	CDAR1AIS0003R021	0003-Rehab			LOINC	Ballot Reconciliation	
12	12.1	18647-8 Change verbiage to "Date Treatment Plan Author Signed" as agreed to for 8/2003 ballot comment	Change verbiage to "Date Treatment Plan Author Signed".	CDAR1AIS0003R021	0003-Rehab			LOINC	Ballot Reconciliation	
13	13.1	27715-2 Change verbiage to "Date Patient Referred for Treatment" as agreed to for 8/2003 ballot comment	Change verbiage to "Date Patient Referred For Treatment".	CDAR1AIS0003R021	0003-Rehab			LOINC	Ballot Reconciliation	
14	14.1	27716-0 Change verbiage to "Date Treatment Plan Author Signed" as agreed to for 8/2003 ballot comment	Change verbiage to "Date Treatment Plan Author Signed".	CDAR1AIS0003R021	0003-Rehab			LOINC	Ballot Reconciliation	
15	15.1	27678-2 Answer Part is incorrect. Should be 27678-2	Change answer part to 27678-1.	CDAR1AIS0003R021	0003-Rehab			LOINC	Ballot Reconciliation	
16	16.1	27684-0 Answer Part is incorrect. Should be 27684-0. Page 30 Answer part states: 27548-7. The LOINC database shows 27548 7 as Cardiac Rehab. Answer part should be corrected to 27684-0.	Correct Answer part to 27684-0. This has been validated against the LOINC Db.	CDAR1AIS0003R021	0003-Rehab Phys Ther	30		LOINC	Ballot Reconciliation	
17	17.1	18658-5 Answer Part cardinality should be 1,1. Cardinality should be 1,1 for this answer part, since it is the only answer part for this question.	Correct Cardinality to 1,1	CDAR1AIS0003R021	0003-Rehab Psych Rehab	33		LOINC	Ballot Reconciliation	
18	18.1	27713-7 Answer Parts should be 27738-4 and 27739-2 according to LOINC database. e LOINC Answer Parts for 27713-7 are reversed. (However, the narrative is in the correct position. It should be 27738-4 (Start Date) and 27739-2 (End Date) according to LOINC	On Page 35, change 27739-2 to 27738-4 and change 27738-4 to 27739-2, leaving the narratives as is. This has been validated against the LOINC Db.	CDAR1AIS0003R021	0003-Rehab Resp Ther	35		LOINC	Ballot Reconciliation	

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HL7 requests the following changes to the HL7 related standards documents:

Track #	Task #	Change Request Description	Action Items - Next Steps	Doc # or Future Doc Key Word	Doc Description	Page #	Doc Section	Data Element	Origin	Re Da
19	19.1	27560-2 Answer Parts should be 27585-9 and 27586-9 according to LOINC database. Page 38 The LOINC Answer Parts for 27560-2 are reversed. (However, the narrative is in the correct position. It should be 27585-9 (Start Date) and 27586-9 (End Date) according to the LOINC Db.	On Page 38, change 27586-7 to 27585-9 and change 27585-9 to 27586-7, leaving the narratives as is. This has been validated against the LOINC Db.	CDAR1AIS0003R021	0003-Rehab Resp Ther	38		LOINC	Ballot Reconciliation	
20	20.1	Section 2.4.3, p.3. The description after the example does not match the example. Change either the example of the corresponding text.	Write new text for the example and replace.	CDAR1AIS0000R021	HL7 Imp Guide		2.4.3		Ballot Reconciliation	
21	21.1	2.9 Value Table diagram - cardinality of answer part for 18671-8 should be 1,1 in diagram	Change cardinality to 1,1	CDAR1AIS0000R021	HL7 Imp Guide		2.9		Ballot Reconciliation	
22	22.1	15513-5 first Answer Part should be 18814-4 instead of 15513-5 according to LOINC database. Should the cardinality for this be 1,n instead of 1,1?	Correct the Answer part from 15513-5 to 18814-4. This has been validated against the LOINC Db.	CDAR1AIS0001R021	0002-Emer Dept			LOINC	Ballot Reconciliation	
23	23.1	4.1.2 CDV coded example - rationale for choice. LOINC code 15509-3 is missing from V attribute value of <caption_cd> (times 2)	Update example	CDAR1AIS0001R021	0001-AMB				Ballot Reconciliation	
24	24.1	18693-2 answer part is missing 18702-1 Provider ED Practitioner Role (appears to have been dropped in coversion to CDA)	Add 18702-1 answer part to 18693-2 LOINC Question.	CDAR1AIS0002R021	0002-Emer Dept			LOINC	Ballot Reconciliation	
25	25.1	18605-6 answer part 18616-3 Medication Administered Strength missing.	Confirm with Dan Pollock if change is needed.	CDAR1AIS0002R021	0002-Emer Dept				Ballot Reconciliation	

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Track #	Task #	Change Request Description	Action Items - Next Steps	Doc # or Future Doc Key Word	Doc Description	Page #	Doc Section	Data Element	Origin	Re Da
26	26.1	18698-1 answer part "see note" - there is a code for this in the LOINC database of 18696-5; however,Wes believes that this should stay "see note" since there can be a variety of LOINCS used here. Check with Clem on LOINC database.	Research	CDAR1AIS0002R021	0002-Emer Dept				Ballot Reconciliation	
27	27.1	18610-6 answer part Time Administration started missing.	Confirm with Dan Pollock if change is needed.	CDAR1AIS0002R021	0002-Emer Dept				Ballot Reconciliation	
28	28.1	18617-1 answer part 18616-3 medication administered strength missing.	Confirm with Dan Pollock if change is needed.	CDAR1AIS0002R021	0002-Emer Dept				Ballot Reconciliation	
29	29.1	Suggestion to add business purpose in Section 1.	Write new business purpose sections	CDAR1AIS0001R021	0001-AMB				External Request	
29	29.2	Suggestion to add business purpose in Section 1.	Write new business purpose sections	CDAR1AIS0002R021	0002-Emer Dept				External Request	
29	29.3	Suggestion to add business purpose in Section 1.	Write new business purpose sections	CDAR1AIS0003R021	0003-Rehab				External Request	
29	29.4	Suggestion to add business purpose in Section 1.	Write new business purpose sections	CDAR1AIS0004R021	0004-Clinical Reports				External Request	
29	29.5	Suggestion to add business purpose in Section 1.	Write new business purpose sections	CDAR1AIS0005R021	0005-Lab Results				External Request	
29	29.6	Suggestion to add business purpose in Section 1.	Write new business purpose sections	CDAR1AIS0006R021	0006-Medications				External Request	
30	30.1	Clarify use and structure for <local markup> in the IG.	Write new description if continue with Release 1	CDAR1AIS0000R021	HL7 Imp Guide				WGM	

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Track #	Task #	Change Request Description	Action Items - Next Steps	Doc # or Future Doc Key Word	Doc Description	Page #	Doc Section	Data Element	Origin	Rx Dx
31	31.1	Remove references to namespaces if we continue with R1.	Namespaces will be removed	CDAR1AIS0000R021	HL7 Imp Guide				WGM	
32	32.1	Ambulance example in the AIS is not the same as the example in the IG for the XAD CDV datatype. Sync examples.	Determine which book is correct and fix the other to match	CDAR1AIS0001R021	0001-AMB				WGM	
33	33.1	The last sentence states: "The formats for specific data types are described in section 3.6." Shouldn't this not point to 3.7 instead? Correct reference to 3.7.	Correct to: The formats for specific data types are described in section 3.7.	CDAR1AIS0000R021	HL7 Imp Guide	33	3.5.2		WGM	
36	36.1	Throughout the booklets, in MEDICATION (COMPOSITE), it states that the MEDICATION NAME AND IDENTIFIER can have a value of NASK, ASKU, or OTH. When this occurs, what is the correct value for the DOSE AND UNITS, TIMING AND QUANTITY, and MEDICATION ROUTE, etc if the MEDICATION ROUTE = NASK, ASKU, or OTH?	1. Per discussion at ASIG Meeting, all of the components here can be answered with the "No Information values. Section 2.1, page 5, "In the case of the DEEDS attachment," will be expanded to point back to Section 3.7.8 in the CDAR1AIS0000R021 IG. This will apply thoughout the booklets. 2. Remove the note :"To record an attempt to collect this information use the "No Information" data type." from all places in the Booklets. 3. Add examples to the booklets for "no information"	CDAR1AIS0002R021	0002-Emer Dept	1,12,13		MEDICATION DOSE AND UNITS, MEDICATION TIMING AND QUANTITY, MEDICATION ROUTE	WGM	

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Track #	Task #	Change Request Description	Action Items - Next Steps	Doc # or Future Doc Key Word	Doc Description	Page #	Doc Section	Data Element	Origin
37	37.1	Code table, HL70161, referenced for LOINC 19012-4, needs to be added to the code sets in the Emergency Department booklet. It can be copied from the 0006-Medications Booklet.	Copy HL70161 from 0006-Medications Booklet.	CDAR1AIS0003R021	0002-Emer Dept	13		CODE TAI	WGM
38	38.1	Page iv lists Tables 5.1 through 5.7. Pages 59 through 62 show Tables 5.1 through 5.12. Page iv needs to be updated to include Tables 5.8 through 5.12.	Update to include 5.8 to 5.12.	CDAR1AIS0003R021	0003-Rehab	iv			WGM
39	39.1	Page 9 states: 27678-2 PHYSICAL THERAPY TREATMENT PLAN, DATE PHYSICAL THERAPY PROFESSIONAL SIGNED. Page 29 states: 27678-2 PHYSICAL THERAPY TREATMENT PLAN, DATE REHAB PROFESSIONAL SIGNED. The LOINC database, in the Physical Therapy section states: 27678-2 DATE REHABILITATION PROFESSIONAL SIGNED. Page 9 needs to be corrected.	Correct page 9 to DATE REHABILITATION PROFESSIONAL SIGNED. This has been validated with the LOINC Db. Make change.	CDAR1AIS0003R021	0003-Rehab	9		LOINC	WGM
40	40.1	Further explain how the No Information values can be used.	Explain use of No Information in section 3.5.1 part 2. See if other sections also need to be changed	CDAR1AIS0000R021	HL7 Imp Guide				WGM
40	40.2	Further explain how the No Information values can be used.	Explain use of No Information in appropriate section.	CDAR1AIS0001R021	0001-AMB				WGM

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Track #	Task #	Change Request Description	Action Items - Next Steps	Doc # or Future Doc Key Word	Doc Description	Page #	Doc Section	Data Element	Origin	Rationale
40	40.3	Further explain how the No Information values can be used.	Explain use of No Information in appropriate section.	CDAR1AIS0002R021	0002-Emer Dept				WGM	
40	40.4	Further explain how the No Information values can be used.	Explain use of No Information in appropriate section.	CDAR1AIS0003R021	0003-Rehab				WGM	
40	40.5	Further explain how the No Information values can be used.	Explain use of No Information in appropriate section.	CDAR1AIS0004R021	0004-Clinical Reports				WGM	
40	40.6	Further explain how the No Information values can be used.	Explain use of No Information in appropriate section.	CDAR1AIS0005R021	0005-Lab Results				WGM	
40	40.7	Further explain how the No Information values can be used.	Explain use of No Information in appropriate section.	CDAR1AIS0006R021	0006-Medications				WGM	
42	42.1	Page 17 states 27505-5. This is a typo. Need to correct to 27505-7.	Correct to 27505-7. This has been validated against the LOINC Db. Make change.	CDAR1AIS0003R021	0003-Rehab Alcho Subst Abuse	17		LOINC	WGM	

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HL7 requests the following changes to the HL7 related standards documents:

Track #	Task #	Change Request Description	Action Items - Next Steps	Doc # or Future Doc Key Word	Doc Description	Page #	Doc Section	Data Element	Origin	Re Do
43	43.1	Page 7 states: 27539-6 CARDIAC REHABILITATION TREATMENT PLAN, CONTINUATION STATUS. Page 20 states:27539-2 CARDIAC REHABILITATION TREATMENT PLAN, CONTINUATION STATUS. The correct number is 27539-6. Need to correct the 2 codes on page 20.	Correct the 2 codes on page 20 to 27539-6. This has been validated against the LOINC Db. Make change.	CDAR1AIS0003R021	0003-Rehab Card Rehab	20		LOINC	WGM	
45	45.1	Page 21 has Cardinaity of 0,1 on Answer part. Cardinality should be 1,1 for this answer part, since it is the only answer part for this question.	Correct Cardinality to 1,1	CDAR1AIS0003R021	0003-Rehab Card Rehab	21		LOINC	WGM	
46	46.1	Page 8 lists 27769-9 and 27770-7 in numerical order. Page 24 lists them out of order. Need to correct to numeric order for consistency.	Page 24. Put 27769-9 and 27770-7 in numerical order.	CDAR1AIS0003R021	0003-Rehab Med Social Serv	24		LOINC	WGM	
49	49.1	Page 29 Answer part states: 27542-0. The LOINC database shows 27542-0 as Cardiac Rehab. Answer part should be corrected to 27678-2.	Correct Answer part to 27678-2. This has been validated with the LOINC Db. Make change.	CDAR1AIS0003R021	0003-Rehab Phys Ther	29		LOINC	WGM	

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Recommended Standard Document Changes
NPRM Reference: 45 CFR Part 162
[CMS-0050-P]
RIN 0938-AK62

HL7 requests the following changes to the HL7 related standards documents:

Track #	Task #	Change Request Description	Action Items - Next Steps	Doc # or Future Doc Key Word	Doc Description	Page #	Doc Section	Data Element	Origin	R D
51	51.1	Page 9 states: 27686-5 PHYSICAL THERAPY TREATMENT PLAN, INITIAL ASSESSMENT Page 30 states: 27685-5 PHYSICAL THERAPY TREATMENT PLAN, INITIAL ASSESSMENT (NARRATIVE) The LOINC database, in the Physical Therapy section states: 27686-5 PHYSICAL THERAPY TREATMENT PLAN, INITIAL ASSESSMENT Page 30 needs to be corrected.	Correct Question part and answer part to 27686-5. This has been validated with the LOINC Db. Make change.	CDAR1AIS0003R021	0003-Rehab Phys Ther	30		LOINC	WGM	
53	53.1	Page 35 Answer part states: 27768-1. The LOINC database shows 27768-1 as Medical Social Services. Answer part should be corrected to 27717-8.	Correct Answer part to 27717-8. This has been validated with the LOINC Db. Make change.	CDAR1AIS0003R021	0003-Rehab Resp Ther	35		LOINC	WGM	
57	57.1	Page 61 states:" 5.7 HL79015: HL7 Frequency Base Period.This is a domain drawn from the HL7 iso+ system of units. It consists of codes to represent the denominator in an expression of frequency. The OID for this table is 2.16.840.1.113883.12.9015." This table is not referenced elsewhere in the document. Should it be removed or should a LOINC code show it as a reference?	This needsd to be removed as Frequency is now used with the TQ datatype.	CDAR1AIS0003R021	0003-Rehab	61	5.7		WGM	
58	58.1	This booklet states OID for "iso+" is 2.16.840.1.113883.6.2. All of the other booklets state the OID for "iso+" as "2.16.840.1.113883.5.141". .	Page 61 needs correction to show "2.16.840.1.113883.5.141".	CDAR1AIS0003R021	0003-Rehab	61	5.9	OID	WGM	

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59	59.1	This booklet states OID for "NDC" is 2.16.840.1.113883.5.141. Other booklets state the OID for "NDC" as "2.16.840.1.113883.6.69". Page 61 needs correction to show "2.16.840.1.113883.6.69".	Page 61 needs correction to show "2.16.840.1.113883.6.69".	CDAR1AIS0003R021	0003-Rehab	61	5.1	OID	WGM	
60	60.1	Has additional sentence not in other 5 booklets. Should remove sentence for consistency. Compare to 0001:AMB, Page 5, section 2.2.	Remove the sentence: Before we get into more detail...	CDAR1AIS0004R021	0004-Clinical Reports	6	2.4	Scope Mo	WGM	
61	61.1	Page 38 states: "5.1 C4: CPT-4 Procedure coding from American Medical Association, P.O. Box 10946, Chicago IL 60610. The OID for this table is 2.16.840.1.113883.6.12." However, some of the procedures are HCPCS codes. Is there an OID for HCPCS/CPT that should be listed here instead?	1. Per discussion at ASIG, will look for codes for HCPCS, ABC, HIPSS, RUGGS, etc., and add them in the NPRM process. 2. Do we have an OID Dictionary?	CDAR1AIS0004R021	0004-Clinical Reports	38			WGM	
62	62.1	In the "HL7 Additional Information Specification Implementation Guide" "CDAR1AIS0000R021" Page 42, it states: "3.7.9 Numeric (NM) Data Type. When an Additional Information Specification specifies a numeric datum, it shall be represented in PCDATA in the <content> element formatted according to the decimal data type as described in section 3.2.3 of XML Schema Part 2: Datatypes (HL7, 02 May 2001)". This document is a W3C document, not an HL7 document.	Correct the reference to point to W3C and include the URL: http://www.w3.org/TR/xmlschema-2/	CDAR1AIS0000R021	HL7 Imp Guide	42			WGM	

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63	63.1	Typo: in this sections,	Correct to singular : "in this section",	CDAR1AIS0005R021	0005-Lab Results	6	2.2		WGM	
65	65.1	1. Need to add examples of MIME wrappers. 2. Expand Section 3.8 to include: Normative MIME headers, Rules for when to MIME or not MIME the CDA, and Examples.	Take the information from PIUC draft and move it to the IG. The following clarification needs to be made to the documentation: "Images must be sent as a multipart MIME package in the BIN segment. The standard requires the first object of MIME to be HL7 encoded in XML, the images are considered a separate body. The XML encoded HL7 and the image are wrapped in one MIME package."	CDAR1AIS0000R021	HL7 Imp Guide	2 & 51	3.8		WGM	
65	65.2	MIME needs further explanation	Add reference to MIME information secton in each booklet	CDAR1AIS0001R021	0001-AMB				WGM	
65	65.3	MIME needs further explanation	Add reference to MIME information secton in each booklet	CDAR1AIS0002R021	0002-Emer Dept				WGM	
65	65.4	MIME needs further explanation	Add reference to MIME information secton in each booklet	CDAR1AIS0003R021	0003-Rehab				WGM	
65	65.5	MIME needs further explanation	Add reference to MIME information secton in each booklet	CDAR1AIS0004R021	0004-Clinical Reports				WGM	
65	65.6	MIME needs further explanation	Add reference to MIME information secton in each booklet	CDAR1AIS0005R021	0005-Lab Results				WGM	
65	65.7	MIME needs further explanation	Add reference to MIME information secton in each booklet	CDAR1AIS0006R021	0006-Medications				WGM	

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67	67.1	CDAR1AIS0000R021, Section "5.1 iso+: Extended ISO Units Codes" starting on page 53 does not have "lb" or "mi" on it. That section references HL7 Version 2.4 Figure 7-9. However, in the standard, those values are instead listed in HL7 Version 2.4 Figure 7-7. "ANSI+ unit codes for some U.S. customary units."	We should have a distinction for ANSI+ . The ASIG will need to add ANSI+ references and instructions and examples in our booklets. There should already be an OID for ANSI - need to locate it	CDAR1AIS0000R021	HL7 Imp Guid	53	5.1 iso+		WGM	
68	68.1	In the Ambulance booklet, Page 7, it states that : Weight will be reported in iso+ units of either kilograms (KG) or pounds (LB). However, LB is an ISO+, but KG is ANS+	We should have a distinction for ANS+ . The ASIG will need to add ANS+ references and instructions and examples in our booklets. There should already be an OID for ANS+ need to locate it	CDAR1AIS0001R021	0001-AMB	7		Weight	WGM	
68	68.3	Correct OID references for ans+ and iso+.	We should have a distinction for ANS+ . The ASIG will need to add ANS+ references and instructions and examples in our booklets. There should already be an OID for ANS+ and we need to locate it	CDAR1AIS0002R021	0002-Emer Dept					
68	68.4	Correct OID references for ans+ and iso+.	We should have a distinction for ANS+ . The ASIG will need to add ANS+ references and instructions and examples in our booklets. There should already be an OID for ANS+ and we need to locate it	CDAR1AIS0003R021	0003-Rehab					
68	68.5	Correct OID references for ans+ and iso+.	We should have a distinction for ANS+ . The ASIG will need to add ANS+ references and instructions and examples in our booklets. There should already be an OID for ANS+ and we need to locate it	CDAR1AIS0004R021	0004-Clinical Reports					

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68	68.6	Correct OID references for ans+ and iso+.	We should have a distinction for ANS+ . The ASIG will need to add ANS+ references and instructions and examples in our booklets. There should already be an OID for ANS+ and we need to locate it	CDAR1AIS0005R021	0005-Lab Results					
68	68.7	Correct OID references for ans+ and iso+.	We should have a distinction for ANS+ . The ASIG will need to add ANS+ references and instructions and examples in our booklets. There should already be an OID for ANS+ and we need to locate it	CDAR1AIS0006R021	0006-Medications					
69	69.1	Throughout the booklets, we show the NPI and the OID for NPI for Provider Codes. See Clinical Reports, LOINC code 11489-2 on Page 34 and Section 5.4 on the last page. We do not have any instructions for non-NPI provider codes.	Next versions add language to allow for proprietary numbers. ASIG will request one OID for generic proprietary non-NPI provider number. ASIG needs to revise the language and number of repeats to allow for an NPI and a proprietary number during the implementation phase. See the note in the Rehab booklet, code 27787-1 MEDICAL SOCIAL SERVICES TREATMENT PLAN, AUTHOR IDENTIFIER "Unique identifier for the professional who established the treatment plan. At some point use of the National Provider Identifier (NPI) will be mandated, until such time other identifiers such as UPIN or state license number are allowed." This is the kind of note that should be in all booklets and will need to be expanded. This is to be used only until the NPI is implemented (and for transition).	All AIS attachment docs	All AIS attachment docs	30	5.4		Conf Call	

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69	69.2	Add OID for non-NPI identifier. Add to examples use of both non-NPI ID and NPI.ers	Update AIS for non-NPI provider identifers use including examples.	CDAR1AIS0001R021	0001-AMB				Conf Call	
69	69.3	Add OID for non-NPI identifier. Add to examples use of both non-NPI ID and NPI.ers	Update AIS for non-NPI provider identifers use including examples.	CDAR1AIS0002R021	0002-Emer Dept				Conf Call	
69	69.4	Add OID for non-NPI identifier. Add to examples use of both non-NPI ID and NPI.ers	Update AIS for non-NPI provider identifers use including examples.	CDAR1AIS0003R021	0003-Rehab				Conf Call	
69	69.5	Add OID for non-NPI identifier. Add to examples use of both non-NPI ID and NPI.ers	Update AIS for non-NPI provider identifers use including examples.	CDAR1AIS0004R021	0004-Clinical Reports				Conf Call	
69	69.6	Add OID for non-NPI identifier. Add to examples use of both non-NPI ID and NPI.ers	Update AIS for non-NPI provider identifers use including examples.	CDAR1AIS0005R021	0005-Lab Results				Conf Call	
69	69.7	Add OID for non-NPI identifier. Add to examples use of both non-NPI ID and NPI.ers	Update AIS for non-NPI provider identifers use including examples.	CDAR1AIS0006R021	0006-Medications				Conf Call	
70	70.1	In the Clinical Reports Booklet, we have many categories of Clinical Reports. 3 of the Studies have a cardinality listed at the Question part and all of the others , including all of the Radiology Studies don't. For instance, there are 3 that do. 11522-0 CARDIAC ECHO STUDY 0,1; 11524-6 EKG STUDY 0,1; 11490-0 PHYSICIAN HOSPITAL DISCHARGE SUMMARY 0,1	ASIG will remove the cardinality from these 3 to make it consistent with the rest of the Clinical Reports Booklet.	CDAR1AIS0004R021	0004-Clinical Reports			11522-0 11524-6 11490-0		
72	72.1	CDA only allows one patient identifier now and multiple identifiers are needed, since it will be different by provider and by payer	Use of </is_known_to> and </is_known_by> for patient identifiers in the Ambulance booklet	CDAR1AIS0001R021	0001-AMB				WGM	

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72	72.2	CDA only allows one patient identifier now and multiple identifiers are needed, since it will be different by provider and by payer	Use /is_known_to> and </is_known_by> for patient identifiers in the ED booklet	CDAR1AIS0002R021	0002-Emer Dept				WGM
72	72.3	CDA only allows one patient identifier now and multiple identifiers are needed, since it will be different by provider and by payer	Use /is_known_to> and </is_known_by> for patient identifiers in the Rehab booklet	CDAR1AIS0003R021	0003-Rehab				WGM
72	72.4	CDA only allows one patient identifier now and multiple identifiers are needed, since it will be different by provider and by payer	Use /is_known_to> and </is_known_by> for patient identifiers in the Clinical Reports booklet	CDAR1AIS0004R021	0004-Clinical Reports				WGM
72	72.5	CDA only allows one patient identifier now and multiple identifiers are needed, since it will be different by provider and by payer	Use /is_known_to> and </is_known_by> for patient identifiers in the Lab Results booklet	CDAR1AIS0005R021	0005-Lab Results				WGM
72	72.6	CDA only allows one patient identifier now and multiple identifiers are needed, since it will be different by provider and by payer	Use /is_known_to> and </is_known_by> for patient identifiers in the Medications booklet	CDAR1AIS0006R021	0006-Medications				WGM
72	72.7	CDA only allows one patient identifier now and multiple identifiers are needed, since it will be different by provider and by payer	Explain use of </is_known_to> and </is_known_by> for patient identifiers in the HL7 IG	CDAR1AIS0000R021	HL7 Imp Guide				WGM
73	73.1	Is <patient encounter> a required element in the clinical header. It is shown in example of scanned lab attachment.	Since it is not required, changes the example to remove it	CDAR1AIS0000R021	HL7 Imp Guid	18		patient enc	Conf Call
73	73.2	check clinical report booklet to see if examples include <patient encounter>	Since it is not required, changes the example to remove it	CDAR1AIS0004R021	0004-Clinical Reports				Conf Call
73	73.3	check meds booklet to see if examples include <patient encounter>	Since it is not required, changes the example to remove it	CDAR1AIS0006R021	0006-Medications				Conf Call
74	74.1	Confusion on what OIDs are and what do they mean	In Section 5 in each booklet for any example that refences OID, include definition of what the OID is.	CDAR1AIS0000R021	HL7 Imp Guide			OID	WGM
74	74.2	Confusion on what OIDs are and what do they mean	In Section 5 in each booklet for any example that refences OID, include definition of what the OID is.	CDAR1AIS0001R021	0001-AMB				WGM

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74	74.3	Confusion on what OIDs are and what do they mean	In Section 5 in each booklet for any example that refences OID, include definition of what the OID is.	CDAR1AIS0002R021	0002-Emer Dept				WGM	
74	74.4	Confusion on what OIDs are and what do they mean	In Section 5 in each booklet for any example that refences OID, include definition of what the OID is.	CDAR1AIS0003R021	0003-Rehab				WGM	
74	74.5	Confusion on what OIDs are and what do they mean	In Section 5 in each booklet for any example that refences OID, include definition of what the OID is.	CDAR1AIS0004R021	0004-Clinical Reports				WGM	
74	74.6	Confusion on what OIDs are and what do they mean	In Section 5 in each booklet for any example that refences OID, include definition of what the OID is.	CDAR1AIS0005R021	0005-Lab Results				WGM	
74	74.7	Confusion on what OIDs are and what do they mean	In Section 5 in each booklet for any example that refences OID, include definition of what the OID is.	CDAR1AIS0006R021	0006-Medications				WGM	
75	75.1	HL7 OIDS are used in the context of attachments. Add statement to clarify this.	add OID requirement statement into the Implementation Guide.	CDAR1AIS0000R021	HL7 Imp Guide				WGM	
76	76.1	Add references to ICD-10 where appropriate. Include language for use of it.	Determine what sections need to be modified	CDAR1AIS0001R021	0001-AMB				WGM	
76	76.2	Add references to ICD-10 where appropriate. Include language for use of it.	Determine what sections need to be modified	CDAR1AIS0002R021	0002-Emer Dept				WGM	
76	76.3	Add references to ICD-10 where appropriate. Include language for use of it.	Determine what sections need to be modified	CDAR1AIS0003R021	0003-Rehab				WGM	
76	76.4	Add references to ICD-10 where appropriate. Include language for use of it.	Determine what sections need to be modified	CDAR1AIS0004R021	0004-Clinical Reports				WGM	
76	76.5	Add references to ICD-10 where appropriate. Include language for use of it.	Determine what sections need to be modified	CDAR1AIS0005R021	0005-Lab Results				WGM	
76	76.6	Add references to ICD-10 where appropriate. Include language for use of it.	Determine what sections need to be modified	CDAR1AIS0006R021	0006-Medications				WGM	
76	76.7	Add references to ICD-10 where appropriate. Include language for use of it.	Determine what sections need to be modified	CDAR1AIS0000R021	HL7 Imp Guide				WGM	

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77	77.1	#31 - > and < are XML tags, so we will replace with **>** and **<** for all booklets	Search and replace > and <	CDAR1AIS0000R021	HL7 Imp Guide				WGM	
77	77.2	#31 - > and < are XML tags, so we will replace with **>** and **<** for all booklets	Search and replace > and <	CDAR1AIS0001R021	0001-AMB				WGM	
77	77.3	#31 - > and < are XML tags, so we will replace with **>** and **<** for all booklets	Search and replace > and <	CDAR1AIS0002R021	0002-Emer Dept				WGM	
77	77.4	#31 - > and < are XML tags, so we will replace with **>** and **<** for all booklets	Search and replace > and <	CDAR1AIS0003R021	0003-Rehab				WGM	
77	77.5	#31 - > and < are XML tags, so we will replace with **>** and **<** for all booklets	Search and replace > and <	CDAR1AIS0004R021	0004-Clinical Reports				WGM	
77	77.6	#31 - > and < are XML tags, so we will replace with **>** and **<** for all booklets	Search and replace > and <	CDAR1AIS0005R021	0005-Lab Results				WGM	
77	77.7	#31 - > and < are XML tags, so we will replace with **>** and **<** for all booklets	Search and replace > and <	CDAR1AIS0006R021	0006-Medications				WGM	
78	78.1	WPC mailing address needs to be updated.	Update WPC mailing address	CDAR1AIS0000R021	HL7 Imp Guide				WGM	
78	78.2	WPC mailing address needs to be updated.	Update WPC mailing address	CDAR1AIS0001R021	0001-AMB				WGM	
78	78.3	WPC mailing address needs to be updated.	Update WPC mailing address	CDAR1AIS0002R021	0002-Emer Dept				WGM	

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78	78.4	WPC mailing address needs to be updated.	Update WPC mailing address	CDAR1AIS0003R021	0003-Rehab				WGM	
78	78.5	WPC mailing address needs to be updated.	Update WPC mailing address	CDAR1AIS0004R021	0004-Clinical Reports				WGM	
78	78.6	WPC mailing address needs to be updated.	Update WPC mailing address	CDAR1AIS0005R021	0005-Lab Results				WGM	
78	78.7	WPC mailing address needs to be updated.	Update WPC mailing address	CDAR1AIS0006R021	0006-Medications				WGM	
79	79.1	The date indicates ccyymmdd, but it includes the dashes. Suggest the dashes be removed from the dates, but that could have an impact back to CDA R1.	HL7 date format must be ccyymmdd and framework includes the dashes between "ccyy-mm-dd". Correct all examples to include the dashes	CDAR1AIS0000R021	HL7 Imp Guide				WGM	
79	79.2	The date indicates ccyymmdd, but it includes the dashes. Suggest the dashes be removed from the dates, but that could have an impact back to CDA R1.	HL7 date format must be ccyymmdd and framework includes the dashes between "ccyy-mm-dd". Correct all examples to include the dashes	CDAR1AIS0001R021	0001-AMB				WGM	
79	79.3	The date indicates ccyymmdd, but it includes the dashes. Suggest the dashes be removed from the dates, but that could have an impact back to CDA R1.	HL7 date format must be ccyymmdd and framework includes the dashes between "ccyy-mm-dd". Correct all examples to include the dashes	CDAR1AIS0002R021	0002-Emer Dept				WGM	
79	79.4	The date indicates ccyymmdd, but it includes the dashes. Suggest the dashes be removed from the dates, but that could have an impact back to CDA R1.	HL7 date format must be ccyymmdd and framework includes the dashes between "ccyy-mm-dd". Correct all examples to include the dashes	CDAR1AIS0003R021	0003-Rehab				WGM	
79	79.5	The date indicates ccyymmdd, but it includes the dashes. Suggest the dashes be removed from the dates, but that could have an impact back to CDA R1.	HL7 date format must be ccyymmdd and framework includes the dashes between "ccyy-mm-dd". Correct all examples to include the dashes	CDAR1AIS0004R021	0004-Clinical Reports				WGM	

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79	79.7	The date indicates ccyymmdd, but it includes the dashes. Suggest the dashes be removed from the dates, but that could have an impact back to CDA R1.	HL7 date format must be ccyymmdd and framework includes the dashes between "ccyy-mm-dd". Correct all examples to include the dashes	CDAR1AIS0006R021	0006-Medications				WGM	
81	81.1	Add to Ambulance att, physician certification for transport	new data element, need LOINC, check on OID	CDAR1AIS0001R021	0001-AMB				WGM	
82	82.1	Request for new section in Rehab Att for Pulmonary Rehab	Assign leader & do outreach	CDAR1AIS0003R021	0003-Rehab				WGM	
83	83.1	Include a reference to the location of the definition for "ambulance services" in the regulation.	Determine appropriate section and add reference to section "Subpart S—Electronic Health Care Claims Attachments, § 162.1900 Definitions"	CDAR1AIS0001R021	0001-AMB				Conf Call	1
83	83.2	Include a reference to the location of the definition for "emergency department" in the regulation.	Determine appropriate section and add reference to section "Subpart S—Electronic Health Care Claims Attachments, § 162.1900 Definitions"	CDAR1AIS0002R021	0002-Emer Dept				Conf Call	1
83	83.3	Include a reference to the location of the definition for "rehabilitation services" in the regulation.	Determine appropriate section and add reference to section "Subpart S—Electronic Health Care Claims Attachments, § 162.1900 Definitions"	CDAR1AIS0003R021	0003-Rehab				Conf Call	1
83	83.4	Include a reference to the location of the definition for "clinical reports" in the regulation.	Determine appropriate section and add reference to section "Subpart S—Electronic Health Care Claims Attachments, § 162.1900 Definitions"	CDAR1AIS0004R021	0004-Clinical Reports				Conf Call	1

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HL7 requests the following changes to the HL7 related standards documents:

Track #	Task #	Change Request Description	Action Items - Next Steps	Doc # or Future Doc Key Word	Doc Description	Page #	Doc Section	Data Element	Origin	R ID
83	83.5	Include a reference to the location of the definition for "laboratory results" in the regulation.	Determine appropriate section and add reference to section "Subpart S—Electronic Health Care Claims Attachments, § 162.1900 Definitions"	CDAR1AIS0005R021	0005-Lab Results				Conf Call	
83	83.6	Include a reference to the location of the definition for "medications" in the regulation.	Determine appropriate section and add reference to section "Subpart S—Electronic Health Care Claims Attachments, § 162.1900 Definitions"	CDAR1AIS0006R021	0006-Medications				Conf Call	
84	84.1	Add section which lists all of the CDA header element and there cardinality. This information is included in the CDA Framework for Release 1 but it would be beneficial to be included in the HL7 IG as well.	Include a list of the required CDA header data elements that are used in attachments in HL7 IG. Will include only the required ones, not optional ones	CDAR1AIS0000R021	HL7 Imp Guide				Conf Call	
85	85.1	List of permissible file types. Add clarifying information or recommendation on which file type should be used for color pictures.	We need to make sure we are okay with this list. Add clarifying information or recommendation on which file type should be used for color pictures.	CDAR1AIS0000R021	HL7 Imp Guid	34	3.5.3		Conf Call	
86	86.1	Section 3.5.3 should be revised to state that the TIFF images must be scanned at a minimum of 200 bits per inch.	Revise section	CDAR1AIS0000R021	HL7 Imp Guid	34	3.5.3		Conf Call	
87	87.1	In section 3.5.3 the paragraph under the Permissible file type table references table 5. This should be changed to reference table 4	Revise section	CDAR1AIS0000R021	HL7 Imp Guid	34	3.5.3		Conf Call	

Health Level Seven (HL7)
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HL7 requests the following changes to the HL7 related standards documents:

Track #	Task #	Change Request Description	Action Items - Next Steps	Doc # or Future Doc Key Word	Doc Description	Page #	Doc Section	Data Element	Origin
89	89.1	We recommend adding a persistent body part attribute to be used to identify that the BIN segment answer is included in a previous BIN segment. The additional BIN segments would refer to a permanent name instead of sending the same image multiple times	Reseach and write language	CDAR1AIS0000R021	HL7 Imp Guide				Conf Call
90	90.1	Add and define OID 2.16.840.1.113883.3.933 into Section 5. Also, we need to add it the current OID database. (It is shown 6 times in the examples)	Edit section.						Ballot Reconciliation
90	90.2	Add and define OID 2.16.840.1.113883.3.933 into Section 5. Also, we need to add it the current OID database. (It is shown 6 times in the examples)	Edit section.						Ballot Reconciliation
90	90.3	Add and define OID 2.16.840.1.113883.3.933 into Section 5. Also, we need to add it the current OID database. (It is shown 6 times in the examples)	Edit section.						Ballot Reconciliation
90	90.4	Add and define OID 2.16.840.1.113883.3.933 into Section 5. Also, we need to add it the current OID database. (It is shown 6 times in the examples)	Edit section.						Ballot Reconciliation

Health Level Seven (HL7)
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HL7 Comments to Claims Attachment NPRM
Recommended Standard Document Changes
NPRM Reference: 45 CFR Part 162
[CMS-0050-P]
RIN 0938-AK62

HL7 requests the following changes to the HL7 related standards documents:

Track #	Task #	Change Request Description	Action Items - Next Steps	Doc # or Future Doc Key Word	Doc Description	Page #	Doc Section	Data Element	Origin
90	90.5	Add and define OID 2.16.840.1.113883.3.933 into Section 5. Also, we need to add it the current OID database. (It is shown 6 times in the examples)	Edit section.						Ballot Reconciliation
90	90.6	Add and define OID 2.16.840.1.113883.3.933 into Section 5. Also, we need to add it the current OID database. (It is shown 6 times in the examples)	Edit section.						Ballot Reconciliation
91	91.1	Add and define OID 2.16.840.1.113883.5.200 into Section 5. Also, we need to add it the current OID database. (It is shown 4 times in the examples) There is an OID 2.16.840.1.113883.12.200 in the database, which is also an OID for Name. Should we be using this one instead?	Edit section.						Ballot Reconciliation
91	91.2	Add and define OID 2.16.840.1.113883.5.200 into Section 5. Also, we need to add it the current OID database. (It is shown 4 times in the examples) There is an OID 2.16.840.1.113883.12.200 in the database, which is also an OID for Name. Should we be using this one instead?	Edit section.						Ballot Reconciliation

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HL7 Comments to Claims Attachment NPRM
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NPRM Reference: 45 CFR Part 162
[CMS-0050-P]
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HL7 requests the following changes to the HL7 related standards documents:

Track #	Task #	Change Request Description	Action Items - Next Steps	Doc # or Future Doc Key Word	Doc Description	Page #	Doc Section	Data Element	Origin	
91	91.3	Add and define OID 2.16.840.1.113883.5.200 into Section 5. Also, we need to add it the current OID database. (It is shown 4 times in the examples) There is an OID 2.16.840.1.113883.12.200 in the database, which is also an OID for Name. Should we be using this one instead?	Edit section.						Ballot Reconciliation	
91	91.4	Add and define OID 2.16.840.1.113883.5.200 into Section 5. Also, we need to add it the current OID database. (It is shown 4 times in the examples) There is an OID 2.16.840.1.113883.12.200 in the database, which is also an OID for Name. Should we be using this one instead?	Edit section.						Ballot Reconciliation	
91	91.5	Add and define OID 2.16.840.1.113883.5.200 into Section 5. Also, we need to add it the current OID database. (It is shown 4 times in the examples) There is an OID 2.16.840.1.113883.12.200 in the database, which is also an OID for Name. Should we be using this one instead?	Edit section.						Ballot Reconciliation	

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HL7 requests the following changes to the HL7 related standards documents:

Track #	Task #	Change Request Description	Action Items - Next Steps	Doc # or Future Doc Key Word	Doc Description	Page #	Doc Section	Data Element	Origin
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92	92.1	Expand the examples of CDA header in the document: CDAR1AIS0000R021 (HL7 Additional Information Specification Implementation Guide) to include instructions on the Patient ID. That is the document that the AIS will use to create the CDA Header in the BIN.	Edit IG						Ballot Reconciliation
93	93.1	Make change to intro: The format of this document and the methods used to arrive at its contents are prescribed in the HL7 Additional Information Specification Implementation Guide, CDAR1AIS0000R010.	Edit						Ballot Reconciliation
93	93.1	The DHHS Administrative Simplification web site is http://aspe.hhs.gov/admnsimp .	Edit						Ballot Reconciliation
94	94.1	The OID for this identifier is...	Edit						Ballot Reconciliation
95	95.1	Do we need to explain more thoroughly what to do if they're not using an NPI? Two cases: a) between now and the mandatory date, and b) if they're not a CE	Write language						Ballot Reconciliation
96	96.1	Add language to AIS to point them back to the database descriptions in the IG.	Write language						Ballot Reconciliation

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HL7 requests the following changes to the HL7 related standards documents:

Track #	Task #	Change Request Description	Action Items - Next Steps	Doc # or Future Doc Key Word	Doc Description	Page #	Doc Section	Data Element	Origin	Ballot
96	96.2	Add language to AIS to point them back to the datatype descriptions in the IG.	Write language						Ballot Reconciliation	
96	96.3	Add language to AIS to point them back to the datatype descriptions in the IG.	Write language						Ballot Reconciliation	
96	96.4	Add language to AIS to point them back to the datatype descriptions in the IG.	Write language						Ballot Reconciliation	
96	96.5	Add language to AIS to point them back to the datatype descriptions in the IG.	Write language						Ballot Reconciliation	
96	96.6	Add language to AIS to point them back to the datatype descriptions in the IG.	Write language						Ballot Reconciliation	
97	97.1	Change non-normative stylesheet to accommodate both NPI and Proprietary IDs with the appropriate labels for each.	Make change to stylesheet						Ballot Reconciliation	
98	98.1	Add reference area in section 5 for each OID used in the examples with an explanation of what they are.	Evaluate OIDS used in examples and add to section 5.						Ballot Reconciliation	
98	98.2	Add reference area in section 5 for each OID used in the examples with an explanation of what they are.	Evaluate OIDS used in examples and add to section 5.						Ballot Reconciliation	
98	98.3	Add reference area in section 5 for each OID used in the examples with an explanation of what they are.	Evaluate OIDS used in examples and add to section 5.						Ballot Reconciliation	
98	98.4	Add reference area in section 5 for each OID used in the examples with an explanation of what they are.	Evaluate OIDS used in examples and add to section 5.						Ballot Reconciliation	
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HL7 Comments to Claims Attachment NPRM
Recommended Standard Document Changes
NPRM Reference: 45 CFR Part 162
[CMS-0050-P]
RIN 0938-AK62

HL7 requests the following changes to the HL7 related standards documents:

Track #	Task #	Change Request Description	Action Items - Next Steps	Doc # or Future Doc Key Word	Doc Description	Page #	Doc Section	Data Element	Origin	Re
99	99.1	Section 2.1 should include language that requires the Emergency Department Attachment, LOINC codes 18679-1, 26436-6, and 27899-4 be sent when sending the emergency department supporting documentation in the unsolicited 275 transaction. Another option would be to add a "parent" LOINC for all three.	Research and discuss with ASIG						Conf Call	1
100	100.1	Need to clarify what elements need to be sent when doing the unsolicited model or when sending the entire attachment.	Research and discuss with ASIG						Conf Call	1
101	101.1	We recommend including clear, strong language that states the LOINC components included in Section 3 are the only questions or data that can be requested when exchanging data electronically.	Discuss with ASIG						Conf Call	1
102	102.1	Section 2.1 should include language that requires the Ambulance Service Attachment, LOINC code 18682-5 be sent when sending the ambulance supporting documentation in the unsolicited 275 transaction. Proposed wording – The LOINC code that defines the complete attachment data set must be sent when using the unsolicited 275.	Discuss with ASIG						Conf Call	1

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comment to be numbered 31

AFEHCT

Association For Electronic Health Care Transactions

CLAIMS ATTACHMENTS
AFEHCT Comment on NPRM

AFEHCT Comment to CMS on the Proposed Standards of September 23, 2005, for Electronic Health Care Claims Attachments CMS–0050–P NPRM (45 CFR Part 162)

January 6, 2006

DISCLAIMER

The recommendations to CMS contained in this paper were prepared by an AFEHCT Policy Workgroup and approved by the AFEHCT Board of Directors. The recommendations address the CMS Notice of Proposed Rulemaking (NPRM) for Standard Electronic Health Care Claims Attachments published September 23, 2005, in the Federal Register.

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AFEHCT

Association For Electronic Health Care Transactions

AFEHCT Chair

Sheila H. Schweitzer
Chairperson & CEO
CareMedic Systems, Inc.

AFEHCT Comment to CMS on the Proposed Standards of September 23, 2005, for Electronic Health Care Claims Attachments CMS–0050–P NPRM (45 CFR Part 162)

January 6, 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

AFEHCT is pleased to offer comment and recommendations on the Centers for Medicare and Medicaid Notice of Proposed Rule Making (NPRM) of September 23, 2005, that proposes standards for electronically requesting and supplying additional health care information in the form of an electronic attachment to support submitted health care claims data.

We would especially like to emphasize the following recommendations:

Ref	Name of Issue
4	Adopt CDA Release 1.0. Adopt a Process for CDA Release 2.0 and Later Releases
8	Health Plans Should be Required to Accept both HDV and CDV Attachments
10	Permit Experience-Based Unsolicited Attachments without Instruction from Plan
12	Permit Multiple Requests for Additional Information When Needed
15	Should Clearinghouses Comply First? No. Certification and Testing is First.
20	Streamline Standards Revision Process. Adopt an IG "and Its Successors".
22	Implementation Compliance Date. Publish final rule rapidly. Allow 3½ Years Total.
30.1	Attachments Need High Bandwidth. They Need the Internet

Please feel to contact Peter Barry (414-732-5000 peterbarry@aol.com) or Don Bechtel (610-219-1695 donald.bechtel@siemens.com) for clarification of any comment or recommendation in this document.

Cordially,

Sheila H. Schweitzer
AFEHCT Chairperson

Table of Contents

AFEHCT Policy Workgroup
October 27, 2005
Standards for Electronic Health Care Claims Attachments

Electronic Claims Attachments NPRM

The Centers for Medicare and Medicaid published a Notice of Proposed Rule Making (NPRM) that proposes standards for electronically requesting and supplying particular types of additional health care information in the form of an electronic attachment to support submitted health care claims data. A PDF copy of the NPRM may be obtained at:

http://a257.g.akamaitech.net/7/257/2422/01jan20051800/edocket.access.gpo.gov/2005/pdf/05-18927.pdf.

Other documents referred to in the NPRM may be obtained at **www.wpc-edi.com**.

Purpose of AFEHCT Policy Working Group

The purpose of this AFEHCT Policy Workgroup is to assist AFEHCT in preparing recommendations to CMS on the NPRM in fulfillment of AFEHCT's advisory role.

Issues and Concerns

The AFEHCT Policy Workgroup for Claims Attachments addresses the following issues and concerns:

1. X12 Implementation Guide Approval Process

Reference: NPRM Section I.D.1 – page 55993, first column

Citation:

> This work is then reviewed and approved by the membership of ASC X12 as a whole. In sum, Implementation Guides developed by ASC X12N must be ratified by a majority of voting members of the ASC X12N subcommittee and the executive committee of X12 itself.

Issue: This is not an accurate reflection of the approval process followed by X12N for Implementation Guides. Approvals are required by developing Work Group, the Healthcare Task Group, the Full Insurance Subcommittee X12N, and X12J (Technical Assessment) to insure that technical design requirements are fully observed. The Process Review Board of X12 (PRB) is responsible for insuring that full due process was followed before publication is permitted.

Recommendation: AFEHCT recommends the following changes to section 1.D.1, third paragraph:

The Accredited Standards Committee (ASC) X12 is responsible for obtaining consensus before seeking ANSI approval for a standard EDI transaction. The Subcommittee, ASC X12N, develops standards and conducts maintenance

activities in the field of health insurance and submits them to ASC X12.

The approval process for Implementation Guides is as follows:

- The draft documents Technical Reports Type 3 (TR3, a.k.a., Implementation Guides) are made available for public review and comment.
- After the comments are addressed and approved by the authoring Work Group, a public open Information Forum is held to review the comments and responses and to take last minute corrections if approved by authoring WG and attendees.
- The revised TR3 is presented to the entire Healthcare Task Group (TG2) for review and approval, approval requires a major vote of TG2 member organizations.
- The TR3 is then reviewed and approved by the ASC X12N Subcommittee membership for approval, which requires a majority vote by the member organizations.
- The approved work is then reviewed and approved by the ASC X12 Technical Assessment Subcommittee (TAS), which requires a majority vote of its members. TAS is reviews such documents to ensure the technical specifications do not violate any X12 design rules or guidelines.
- Once approved by TAS, the Process Review Board of X12 ensures that all due process and procedures were properly followed, and assuming all was proper, they advise the publisher that a TR3 is ready for publication.

In sum, Implementation Guides developed by ASC X12N must be reviewed and commented on by the public, ratified by a majority of the voting members of the ASC X12N Subcommittee; and related Task Group(s), authoring Work Group(s), and the governing committees of X12 itself before they can be published.

Sometimes certain TR3's require cross development with other X12 Subcommittees where there is a shared interest or more that one TG within the X12N Subcommittee and/or more than one WG. In these cases, all affected WGs, TGs, and Subcommittees must approve the work in the manner described above before it goes to TAS for final approval and PRB for a final process review.

2. Current HIPAA transactions are misnamed

Reference: NPRM, Section I.D.2 – page 55993, second column

Citation:

> The 4050 versions of the X12 Implementation Guides are compatible with the current X12 4010 guides adopted for HIPAA transactions – version 4010-1a so that the two transactions can be used together as necessary. In other words, a claims transaction (837 version 4010-1a)...

Issue: Incorrect version is named.

Recommendation: Change both references to 4010-1a to be 4010A1.

3. XML Enables Manual or Automated Processing

Reference: NPRM Section II.C., p55995, column 1

Citation:

> The HL7 standard being proposed here would allow the same records and data to be "read" and used by either people or computers. In other words, regardless of how the data are sent with the proposed transaction, they can be processed either manually or through automation.

Issue: This statement seems to overly simplify how transactions might be used manually, and it assumes that the users of the transactions actually have technology that will allow this. We don't believe this is a given that it can be processed manually without some enabling technology, and the X12 enveloping transactions will need to be dealt with.

Recommendation: This statement may overly simplify how transactions would be processed manually. An assumption is that a web-browser can process a human decision variant (HDV) file, and that potential users of the transactions currently have technology for this. The word "manual" may not adequately recognize that significant technology is needed to read the 277 request, create a 275 attachment, and read the attachment.

Rural Providers may have bandwidth and technical issues when sending a claim attachment. For these providers electronic claim attachments are not always feasible.

AFEHCT is concerned about ongoing industry changes that may compromise the ability to read and display attachments. Examples are parsing engines and security updates. Without a clear description of the baseline enabling technology, providers may be unable to conduct electronic attachments in compliance with the rule.

AFEHCT recommends identifying a minimal configuration necessary for the processing the human decision variant (HDV) claim attachment transactions. AFEHCT offers to assist HHS in drafting this document.

4. Use of CDA Release 1.0 vs CDA Release 2.0

Reference: NPRM Section II.C.2., page 55995

Citation:

> We invite comment on the pros and cons of each CDA release, the issues related to the use of a style-sheet to permit use of either CDA release, and the

costs and timing associated with implementing one release version over the other.

Issue: What process should be followed for adoption of a CDA?

Recommendation: AFEHCT recommends moving to CDA Release 2, but this recommendation depends on resolution of two items:

- That the HL7 ASIG completes revision of the implementation guides (c.f. #4 below).
- That the Pilot test for R2 is successful (c.f. #3 below).

1. **Vendors Do Not Want to Implement Twice**. CDA Release 1 (R1) and Release 2 (R2) are sufficiently different that a single XSLT style-sheet for both is probably not realistic. In addition, because the images are external to the R1 but are internal XML in R2, the processing of the CDA would be different enough between R1 and R2 to require separate implementations. On the other hand, except for the demonstration projects, vendors are waiting until a final rule is published before starting their operational implementation of this standard, so no functional implementations will have to go through a transition from R1 to R2 if R2 is adopted now.

2. **R2 supports human readability** just like R1 and is likewise technically very easy to implement at that level. The changes incorporated into R2 are concentrated on the "computer-decision variant" to make it technically consistent with the expected adoption of CDA R2 by the health care industry for other purposes and enable implementers to use commercial off-the-shelf software solutions and tools in producing and interpreting the attachments.

3. **Need Results of R2 Pilot**. Before the industry will feel comfortable adopting R2, the industry must conduct at least a positive proof-of-concept pilot implementation with several trading partners to confirm the feasibility of implementing R2 for the six proposed standard attachments. Fortunately, R2 for attachments is currently being piloted and there are other pilots being discussed.

4. **R2 Implementation Guides Expected by fall 2006**. The adoption of R2 would require new Implementation Guides for all the standard attachments. The HL7 Attachment Special Interest Group (ASIG) is already working on these revised guides and although decisions must be made on a number of very technical questions, the ASIG has promised the revisions to HHS by fall 2006. Since historically a final rule would not be expected before early 2007 anyway, the potential few months of delay introduced by this additional work would be minor compared with the years of expected delay in getting another final rule allowing the R1 standard to be updated to R2. Adopting an obsolete standard at this point in the process is unsound.

5. **CMS Should Let Industry Know Immediately that Choice is R2.** CMS should give a unambiguous, immediate indication of its adoption of the CDA R2 Implementation Guides so that the industry will be motivated to work on the revisions and then can get on with the work of implementing the attachments without uncertainty over which version will be adopted.

5. Electronic Claims Attachment Types

Reference: **"ELECTRONIC CLAIMS ATTACHMENT TYPES"**
NPRM II.C.5. – page 55997, column 1; Also at
NPRM II.D.1. – page 55999

Citation:

> Page 55997 – "Comments are invited as to whether the six proposed attachment types are still the most frequently requested by health plans, and if there are others that are equally or more pressing for the industry."
>
> Page 55999 – "Therefore, it is critical that members of the health plan industry and the healthcare provider community actively engage themselves in the final development of this proposed rule so that the proposed attachments are indeed those which will yield significant benefits to health care providers and health plans alike."

Recommendation: AFEHCT yields comment on the selection of attachment types to representatives of providers and plans.

6. Which Data Elements Should be Required, Situational, Optional?

Reference: **"ELECTRONIC CLAIMS ATTACHMENT TYPES"** NPRM II.C.5. p55997

Citation:

> ...we strongly encourage the health care provider and health plan segments of the industry to review them [attachments] and then provide substantial input on the "questions" or LOINC codes, and on the cardinality (priority values) of the data elements—in other words, which elements should be required and which should be situational or optional for each electronic attachment type.

Issue: It's important to understand that the concept of data usage is different for the X12 HIPAA IG's and HL7 AIS'. In the X12 HIPAA IG's, data usage is defined as either REQUIRED, NOT USED or SITUATIONAL. Required and Not Used are self explanatory. In the case of SITUATIONAL usage, the condition that mandates the inclusion of that data element is clearly documented within the IG. If that condition is not met, then the data element should be considered NOT USED. There is no concept of OPTIONAL within the HIPAA X12 IG's.

However, within the HL7 AIS' the definition of usage is different. First of all, the term "usage" is replaced with the term "cardinality". "Cardinality" determines whether or not an element must be present. Cardinality is also

expressed differently than Usage:

- The provider shall return all data components for which data is available.
- The minimum attachment data set equates to the required components; those identified in the value table, below, with cardinality (Card) of
  {1,1} (component is required and has one and only one occurrence), or
  {1,n} (component is required and has one or more occurrences).
- Those data components with a cardinality of
  {0,1} (if available has one and only one occurrence) or
  {0,n} (if available may have one or more occurrences) shall be sent if available.

The notion of "if available" is used frequently throughout the AIS'. This concept might be considered to be in alignment with the X12 IG's usage of "if known" (such as the note found frequently at NM105 - **Name, Middle** "*Required if NM102=1 and the middle name/initial of the person is known.*"

"If available" and "if known" are specific conditions that stipulate the inclusion of a specific data element, however they should not be considered conditions of optionality.

Recommendation: The X12 IG's and HL7 AIS' should include front matter detailing the definitions of USAGE and CARDINALITY and a X12/HL7 co-published document on this topic should be made available to implementers of the Claim Attachment transaction.

7. What is Impact on Servers and Storage?

Reference: **"ELECTRONIC CLAIMS ATTACHMENT TYPES"** NPRM II.C.5. p55997

Citation:

> "We also solicit industry input on the impact to servers and other data storage systems for processing and storing electronic files of clinical information, both coded and text or image based."

Issue: This seems like a significant question for vendors of provider and health plan systems to respond to, but equally important, what about clearinghouses? Must clearinghouses keep this data or should clearinghouses specifically not keep this data? Would there be situations when we should and when we shouldn't. Seems this could be a critical question to get resolved. Should only the provider and health plan keep the data?

Recommendation: AFEHCT recommends that Clearinghouses not be required to retain attachment data beyond business requirements. Clearinghouses should not be required to be archival repositories.

8. Health Plans Should be Required to Accept both HDV and CDV Attachments

Reference: **"FORMAT OPTIONS"** NPRM II.C.6 – pp 55997-55998

Citation: The whole section 6.

Issue: Will health plans be required to handle both HDV and CDV transactions? Such that, a provider who wants to send images or text documents can, even though the health plan may want to be fully automated and not support attachments such as these? We believe this is the thought, but it is not specifically spelled out.

Recommendation: Yes, health plans should be required to be able to accept both HDV and CDV, and they may not compel submitter to use one or the other.

9. Combined Use of Different Standards

Reference: **"COMBINED USE OF DIFFERENT STANDARDS"** NPRM II.C.7. p55998

Citation:

> [Standard claims attachment transactions combine X12 & HL7 transactions.] "However, because these two standards have not been used together before, we solicit industry feedback regarding this strategy."

Issue: Is combining standards from X12 and HL7 a concern?

Recommendation: AFEHCT does not believe this is a significant problem, but one that needs to be addressed by vendors and software products that will be reading and creating these transactions to handle them correctly. Many EDI Translator applications have already been modified to accommodate this implementation.

10. Modify Prohibition Against Sending Attachments without Instruction from Plan

Reference: "**SOLICITED vs. UNSOLICITED ATTACHMENTS**" NPRM II.D.2. pp 55999, 56024

Citation:

> If health care providers were permitted to submit unsolicited electronic attachments with any claim without prior arrangement with the health plan, there would be a number of issues, including compliance with the Privacy Rule's minimum necessary standards, and identifying the new business and technical procedures health plan would need to develop to review, evaluate, store, return, or destroy the unsolicited documents. Similarly, health care providers would need systems and processes to track submissions and returns.
>
> § 162.1920 (e). A health care provider may submit an unsolicited response transaction only upon advance instructions by a health plan.

Issue: This rule as written invites plans to delay claims adjudication. A plan in practice may always ask for an attachment for a given type of claim, but the plan may elect not to give advance instruction but rather to wait until the claim is received, possibly delay even to the maximum allowed under prompt pay constraints, then ask for an attachment that the provider already knows from experience will be required. In addition, a plan should not be permitted to ignore an unsolicited attachment only later to request what it already received.

Recommendation: AFEHCT supports advance instructions and recommends that §162.1920(e) be replaced with the following concepts:

1. A provider, based on experience with a plan, may send unsolicited attachments until a health plan either issues advance instruction to clarify its requirement 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.
2. If a plan receives an unsolicited attachment, it may not later request the same attachment.

11. Method to Convey Advance Instructions

Reference: "**SOLICITED vs. UNSOLICITED ATTACHMENTS**" NPRM p55999, p56012, p56024

Citation:

> We are proposing that health care providers may submit an unsolicited electronic attachment with a claim only when a health plan has given them specific **advance instructions** pertaining to that type of claim or service.
>
> No other electronic transaction format or content would be permitted for the identified transactions.
>
> § 162.1910 (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**—
> (1) Upon receipt of the health care claim;
> (2) In advance of submission of the health care claim;
> **(3) Through instructions for a specific type of health care claim which permit a health care provider to submit attachment information on an unsolicited basis each time such type of claim is submitted.**
> ["(b)" states the request should be a standard transaction.]
>
> § 162.1920 (e) A health care provider may submit an unsolicited response transaction only upon advance instructions by a health plan. [emphasis added]

Issue:

1. **Language error**. We believe this to be an error in the wording of the

proposed rule. §162.1910(c)(3) and §162.1910(b) together specify use of the 277 transaction to communicate advance instructions; however, the 277 is not capable of supporting advance instructions. In fact, there is presently no standard for advance instructions.

2. **Should not mandate design.** Moreover, specifying any transaction for advance instructions is mandating a transactional system design when the eventual implementation of electronic advance instructions will most likely be access to a database maintained by a plan or its agent.

Recommendation: Correct the wording so that the rule does not specify any standard transaction for advance instructions. Final rule should permit advance instructions to be conveyed electronically but not necessarily as a standard transaction, and conveyance should include the Internet.

12. Permit Multiple Requests for Additional Information

Reference: "**SOLICITED vs. UNSOLICITED ATTACHMENTS**" NPRM p55999

Citation:

> We also propose that for each specific claim, health plans may solicit only one electronic attachment request transaction which would have to include all their required or desired "questions" and/or documentation needs relevant to that specific claim.
>
> § 162.1910 (c) A health plan that conducts a health care claims attachment request transaction electronic media, must submit complete requests and identify in the transaction, all of the attachment information needed to adjudicate the claim, which can be requested by means of the transaction.

Issue:

1. **Premise for the prohibition.** The prohibition against multiple requests contains an inaccurate premise that the entire need for additional information can be determined by examining the claim. But it is possible that for some cases, the need for a second request is not knowable until a first request has been satisfied. If a second request is not permitted, the result would be for a plan to load up the first request to obtain, at the provider's expense, contingent information that is generally not needed.

2. **Probable Impact.**

   - A health plan will ask for more information than it needs on average in order to obtain what it needs for low frequency cases.
   - Request for unneeded information increases the burden on providers

3. **What happens if a plan finds it did not request sufficient information?** Does the plan deny the claim and require resubmission?

That detracts significantly from efficiency for both the plan and provider. Or must the plan pay the claim with insufficient information? Perhaps that raises health care costs.

Recommendation: Permit multiple requests provided that a later request is based on information obtained in an earlier attachment and is not duplicative of earlier attachments.

13. How to Apply 'Minimum Necessary' Standard to Attachments

Reference: "**SOLICITED vs. UNSOLICITED ATTACHMENTS**" NPRM II.D.4. p 56000

Citation:

> "We solicit comments on the extent to which the use of the proposed electronic attachment standards will facilitate the application of the "minimum necessary" standard by covered entities when conducting electronic health care claims attachment transactions."

Issue: Is not the Privacy Rule already applicable and sufficient?

Recommendation: The Privacy Rule already restrains a plan from asking for more information than it needs. It also restrains a provider from sending more information than requested. But there is a reasonableness issue here as well; a provider should make an assessment of what is being requested if it seems to exceed what is necessary for the purpose required, as required by Privacy rule section 164.514. We think the Privacy Rule is fully applicable and this rule should not contain more privacy language.

14. Method for Signatures on Claims Attachments

Reference: "**SOLICITED vs. UNSOLICITED ATTACHMENTS**" NPRM II.D.6. p56000

Citation:

> "We solicit input from the industry on how signatures should be handled when an attachment is requested and submitted electronically."

Issue: Most health plans, including Medicare and Medicaid programs require signatures certifying certain types of services, such as sterilization, certain rehabilitation plans, and authorization for certain types of equipment. Health plans may request a paper copy of the signature page, or they may accept the response code indicating that the signature is on file. Would it be practical to use the CDA to send such signatures? Does AFEHCT want to comment on this request for information?

Recommendation: None of the attachments in the proposed rule have provision for a signature. Any attachment that requires a signature may not be requested through these standards. The use of signatures will require modification to the implementation guides.

15. Should Clearinghouses Comply First? No.

Reference: **"PROVIDER VS. PLAN PERSPECTIVE"** NPRM II.D.9. p56001, column 2.

Citation:

> "It would be helpful if healthcare clearinghouses were among the first of all entity types to come into compliance with these standards so that testing between trading partners—health care providers and health plans—could be executed in a timely fashion."

Issue:

This statement is a reference to a national roll-out plan. AFEHCT supports a rational roll-out plan; in the past AFEHCT has suggested that Health Plans need to come into compliance first; does this suggestion make more sense or should both health plans and clearinghouses come into compliance together? A real chicken and the egg type of question.

Recommendation:

Clearinghouses are unable to fulfill the type of 'early testing' role that is indicated by the language here, since they, like providers and health plans, need their trading partners up-and-running before they can test.

AFEHCT supports the idea of certification for the purpose described; so we suggest the important entities to be ready first are 3rd party testing and certification vendors. These vendors would enable providers, health plans and clearinghouses with an early test facility so that, as the NPRM language says, "testing between trading partners could be executed in a timely fashion." Entities are able to schedule testing independently of other entities.

Once health plans, clearinghouses, and providers have completed their testing with a testing and certification vendor, they would receive certification.

- Certification, when recognized by their trading partners, would eliminate a significant portion of the testing necessary between trading partners, as well as keep less-prepared entities from burdening others with low quality transactions.
- Certification also helps those who are dependent on vendors for their implementation of the standards.

We recommend both (a) certification of vendors and software and (b). transaction-based certification for all implementers. In transaction-based certification, the transaction capabilities of health plans, clearinghouses, and providers are each certified. AFEHCT therefore recommends a three-phased approach to implementation:

Phase 1: A period of time for software vendors to prepare their systems and conduct a process to certify their capabilities.

Phase 2: Covered entities (providers, clearinghouses, and health plans) implement the new software from their vendors or internal development organizations and conduct a transaction-based

certification of their implementation

Phase 3: Transaction implementation between trading partners - health plans, clearinghouses, and providers

We recommend EHNAC as an organization that can both write certification requirements and certify testing and certification vendors. There are three elements of certification that will lend significant assistance in implementation: (i) vendor certification that their software is able to produce compliant transaction when properly implemented, (ii) standard performance, error tolerances, etc., and (ii) transaction standard requirements.

AFEHCT agrees that rational roll-out is the correct approach to the implementation phase of these standards (Phase 3 above). In our view, once health plans are certified in Phase 2, they need to be the first ones ready in the implementation phase, since their implementation of the attachments standards will determine many of the specific implementation details needed by providers and clearinghouses for their implementations. This approach was very effective in the Medicare attachments pilot initiated by Empire BCBS, the participating Medicare contractor. Immediately following health plans, clearinghouses can and should be ready, which will largely enable their provider customers to test and implement with health plans.

16. Maximum Size of a Claim Attachment Transaction

Reference: **"ATTACHMENT CONTENT AND STRUCTURE"** NPRM II.E. p56001

Citation:

> "The size of the file in the response transaction will be impacted by the option the health care provider chooses for the submission – either text and imaged documents or coded data. With imaged documents, the size of the file within a single response transaction could become large. The implementation Guide for the X12 275 response transaction permits up to 64 MB of data in a single transaction. Industry comment on file size is also welcome.

Issue: Is 64 MBs adequate for all expected file types? Should this be enlarged or should it remain as is?

Recommendation: Up to 64 MB recommended maximum for the BIN segment is adequate for the attachments named in the rule. AFEHCT supports limits on transaction size and number of transactions in a batch or file should be specified in implementation guides not the rule.

17. Are Content, Format, and Function of the Attachment Standard Correct?

Reference: **"ATTACHMENT CONTENT AND STRUCTURE"** NPRM II.E. p56001

Citation:

> In sum, the proposed standards are those that have been under development for over eight years by the HL7 ASIG. Meanwhile, the health care industry

> itself has undergone significant change. It is, therefore, critical that appropriate industry representation reviews and then weighs in on these standards: The attachment content, and format, and the transaction's function. As discussed throughout this preamble, we are soliciting comments from all affected covered entity types and their business associates (practice management vendors, software vendors, document storage contractors, and others) about these proposed standards.

Recommendation: AFEHCT supports the attachment types and current content described in the NPRM.

18. Should There Be Other Attachment Types?

Reference: NPRM II.G.3 p56006, column 2

Citation:

> We solicit comments regarding which other attachments most impact the health care industry with respect to the exchange of clinical and administrative information, specifically for the purpose of claims adjudication.

Issue: Should there be additions or changes to the list of claim attachment response transaction standards?

Recommendation: AFEHCT does not wish to add to or change the list of attachments response transactions in the proposed rule.

19. Maximum Data Set

Reference: NPRM II.H.3. – page 56013

Citation:

> Each AIS is considered to include the maximum data set for each of the named electronic attachment types. We propose to prohibit health plans from asking for additional data beyond those that are specified in the AIS for that service.
>
> ...
>
> Thus, we ask that during the comment period, health plans and health care providers engage fully in the process of evaluating this maximum data set and the required, situational, and optional elements, and provide us with comments on these issues."

Issue: Have members reviewed these Implementation Guides and Additional Information Specifications to comment on this request for information? Based on our experiences from HIPAA 1, do we anticipate problems for the clearinghouse industry specifically that may be assisting the providers to complete this information; do the clearinghouses foresee problems we should report?

Recommendation: We are not at this stage aware of concerns that may be experienced by clearinghouses or other vendors with the transactions.

20. Standards Revision Process

Reference: **"MODIFICATION TO STANDARDS AND NEW ATTACHMENTS"** NPRM III.A. p56013

Citation: This whole section.

Issue: Will this allow vendors and clearinghouses to realize needed changes quickly enough to be responsive to industry needs?

Recommendation: The final rule should allow change to new versions of implementation guides without the full Federal rulemaking process. AFEHCT recommends the approach where the rule adopts a specific implementation guide **"and its successors"**; so SDOs, which have completely open and effective industry approval processes, are able to respond to industry needs by adopting new versions of Implementation Guides without new Federal rulemaking. There is precedent for this approach; for example, CPT code is adopted as standard but new code values are introduced without new Federal rulemaking.

21. Cost Benefit Analysis

Reference: **"COSTS AND BENEFITS"** NPRM VI.B. pp56016 - 56021

Citation: The whole section

Issue: AFEHCT is named several times in this section as an organization that might want to provide industry input. It would be very helpful to HHS if we could provide input with regard to our expected costs and benefits. How would AFEHCT like to respond to these issues?

Recommendation We are not aware of available definitive quantifiable data on probable costs and benefits. This response presents a framework on what should be considered for a cost benefit analysis.

1. **Two Salient Issues**
   a. There is significant likelihood that costs and benefits from claims attachments will not accrue equally to all participants. There is the perception of a question as to who pays and who benefits.
   b. There will be need for enhancement in infrastructure such as:
      - There is need for high bandwidth communication (c.f. 30.1). Smaller and rural participants may not currently have access to high band width, although that is changing rapidly. The Human Decision Variant using images especially requires high band width because of the size of files.
      - There will be need for storage of greater capacity. However, countering this is the significant trend of more storage for less cost.

2. Framework for Analysis

a. The principal one-time costs include:

- Infrastructure enhancement, including EDI servers and translators to handle either images, text, or computer-coded data required for claims attachments.
- Development of a means for defining and conveying advance instructions.
- Development or acquisition costs for either HDV or CDV variants. We are assuming here that a provider will have choice between installing HDV or CDV such that it may begin with HDV and later move to CDV, and that a payer must be able to receive either HDV only or both HDV and CDV.
- Remediation of application systems and processes to be able to process a request for additional information and send or receive a claims attachment.
- Remediation to records management processes.

b. Operating Costs

There will be increases in operating costs, including the following:

- System maintenance cost, both to pay for an entity's own personnel and for recurring vendor fees for maintaining the new systems or new functionality for existing systems.
- Increased complexity of interfaces, systems, and processes in the entity. Each time significant new functionality is added to existing systems, the life of the existing system may be shortened. There may be increased pressure to replace existing systems, and that is usually highly expensive.
- Training costs.

c. Operating Offsets and Other Benefits

- Possible financial efficiency in amounts sought and paid on claims.
- Efficiency in FTE's and mail preparation.
- Reduction in FedEx, UPS, and other delivery costs.
- Speed
- More definitive payer requirements (c.f. Issues 10 & 11)
- Greater benefit accrues to both provider and plan from CDV, but easier to install HDV; this adds incentive for eHR in the future.

3. Magnitude of Costs for AFEHCT Members

Although quantifiable data is not available, a number of the large AFEHCT members believe development costs will be on the order of $1 million or more per company. AFEHCT members are vendors who may experience increased operating costs and will in general not experience operating benefits other than increasing customer service. Some AFEHCT members may be able to pass the costs on to their customers; some may not be able to do so. On the other hand, some AFEHCT members, especially those which are smaller, may experience considerably lower development costs and less impact on operations.

22. Implementation Compliance Date

Reference: **"EFFECTIVE DATES"** NPRM pp55994, 56025

Citation:

§ 162.1930
(a) Health care providers – 24 months after the effective date
(b) Health plans – 24 months after the effective date
(c) Small health plans – 36 months after the effective date
(d) Health care Clearinghouses – 24 months after effective date

Issue: Is two years going to be enough time to develop software, roll out to customers and go into production? Most vendors only begin to develop after publication of a final rule.

Recommendation: AFEHCT agrees with the lengths of time after the effective date should be as described in the proposed rule; however, it recommends that (i) the final rule be published as soon as possible because it is when a final is published that vendors can have confidence that their investment is prudent, but (ii) that the effective date of the final rule be 1½ years after its publication in that way allowing a total of 3½ years. We propose the additional time in acknowledgment of the significant development work required.

23. "Code 30 & Code 40" (Ambulance Service Attachment)

Reference: Ambulance Service Attachment – CDAR1AIS0001R021

Citation:

15513-5 EMS Transport, Reason For Scheduled Trip
18815-1 EMS Transport, Reason for Scheduled Trip Additional Service Information
Required for Code 30 and Code 40 to define specific services

Issue: In ambulance attachment the response for reason for scheduled trip an associated note references "Code 30 and Code 40"...not sure where these codes are defined

Recommendation: Please specify what Code 30 and Code 40 are in reference to. I believe this is referring to two codes in table 5.2 "HL7 Reason for Scheduled EMS Trip" 30 = Other Lab Testing (Specify Type of Lab Test) & 40 = EKG/ECG/EEG. But if that is the case then why isn't code 43 (Other Psych Services – Specify Type of Service) also listed?

24. "See note at left" (Ambulance Service Attachment)

Reference: Ambulance Service Attachment – CDAR1AIS0001R021

Citation: 11514-3 EMS Transport, Ordering Practitioner. There is a note in the column "Response Code/Numeric Units" that states "see note at left"

Issue: Not sure what "note at left" is referring to

Recommendation: Please clarify the note

25. "See section 5 for list of codes" (Ambulance Service Attachment)

Reference: Ambulance Service Attachment – CDAR1AIS0001R021

Citation: Table 3

Issue: Throughout Table 3 the note "see section 5 for list of codes" is included. The note doesn't specify which of the 5 different code lists found in section five is the correct one to use for that specific response.

Recommendation: It would be better to specify "see section 5, Table 5.x for list of codes"

26. OID (Ambulance Service Attachment)

Reference: Ambulance Service Attachment – CDAR1AIS0001R021

Citation: "The OID for this table is 2.16.840.1.113883.12.136"

Issue: In each of the tables listed in section 5 an OID reference number and in other sections of the document and OID number is given. There is no previous explanation regarding what an OID is. This is an issue in all of the AIS'

Recommendation: Explain what an OID is in the front matter

27. See note at left (Emergency Dept Attachment)

Reference: Emergency Department Attachment – CDAR1AIS0002R021

Citation: At 18710-4 Provider, Primary Practitioner there is a reference in the "Response Code/Numeric Units" column that says "see note at left"

Issue: See "note at left" – not sure where exactly that note is. This is an issue in all of the AIS'

Recommendation: Change to "see note below"

28. Data Types in All AIS

Reference: All of the AIS'

Issue: Various data types are listed: PN, CX, CE, TQ, DT, NM but they aren't defined within the AIS documentation

Recommendation: Need to define the various data types in the front matter of the AIS booklets

29. See note (Emergency Dept Attachment)

Reference: Emergency Department Attachment – CDAR1AIS0002R021

Issue: At 18698-1 ED Clinical Finding (Composite) there are 3 references to "see note". Not sure what "note" this is referring to...3 different notes, the same note, where is the note?

Recommendation: For each "see note" reference, please indicate which note one is to "see"

30. Additional Comments

30.1 Attachments need high bandwidth, need Internet. AFEHCT believes that attempt to implement attachments over low-speed communications such as dial-up will not succeed. During the pilot multiple lines were tied up for hours. The most reasonable solution is to employ broadband access to the Internet. The Internet solution must be a secure, open standard for multi-trading partner environment, not a proprietary technology. AFEHCT strongly supports use of the Internet for all transaction types, including attachments.

30.2 Acknowledgment transactions. We recommend use of the X12 standard acknowledgment transactions: 999 for syntax reporting; 824 for implementation guide rules and the HL7 reporting. We recommend not using the X12 102 recommended in the 275 implementation guide.

30.3 Coordination of Benefit Issues:

a. The first plan should not be required to know the rules of the second plan.

b. If an attachment has become part of a claim, it should be passed on to the second plan. There may be some concern about minimum necessary information constraints; however, we believe the need to send the attachment with the claim overrides this concern.

30.4 Disallow Posting an Attachment on a Web Site. AFEHCT recommends the final rule prohibit the potential practice of posting an attachment on a web site and sending to the plan only a URL reference. This practice is part of the CDA standard but not included in the listed attachment types. The reference in the IG does not apply to the booklets for these transactions.

30.5 Interfaces Between Clinical and Financial Systems Not Addressed. AFEHCT recommends that crosswalks be developed between CPT, ICD, and LOINC codes. There will be many APIs built to request information between financial, medical, and billing systems. There is no standardized way to do this.

30.6 Non-Participating Providers: Currently, a majority of health plans require physician enrollment for the transaction types involved in an initial claim, attachments, and COB. Without enrollment, a physician will neither receive a request for additional information nor be able to send an unsolicited attachment. Consequently, many physicians, who by law must treat an out of network patient, will be unable to submit claims and attachments electronically.

This problem also adversely affects teaching hospitals, teaching practices, and locum tenans physicians where it is not cost effective to pursue credentialing and enrollment.

AFEHCT recommends that the rule states non-par physicians will not be excluded from the rule, and that health plans should address issues of non-par enrollment to gain maximum ROI benefit from claims attachments.

AFEHCT Policy Workgroup for Claims Attachments

Shelia Schweitzer	CareMedic Systems, Chair of AFEHCT
Miriam Paramore	Miriam Paramore Physician Financial Services, Vice Chair of AFEHCT
Tom Gilligan	AFEHCT, Executive Director of AFEHCT
Peter Barry	Peter T Barry Company, Assistant to AFEHCT Chair & Exec Director
Dyan Anderson	QuadraMed
Lee Barrett	Claredi
Don Bechtel	Siemens Medical Solutions, Health Services
David Cheli	Gateway EDI
John Hawkins	QuadraMed
Mary Highland	SSI Group
Tom Hughes	NEA
Deborah Meisner	Emdeon Corporation
Bonnie Nelson	ZirMed, Inc
Conny Nichols	Claredi
Bill Osuch	GHN-Online
Frank Romanosk	Eclipsys Corporation
Mark Sandvigen	athenahealth, Inc
Catherine Schulten	Sybase
Sunny Singh	Edifecs, Inc
Ashwin Srinivas	GHN-Online
Larry Watkins	Claredi
Kepa Zubeldia	Claredi

Attachment A
Proposed Claims Attachment Code

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PART 162--ADMINISTRATIVE REQUIREMENTS

1. The authority citation for part 162 is revised to read as follows:

Authority: 42 U.S.C. 1320d-1320d-8, as amended, and sec. 264 of Pub. L. 104-191, 110 Stat. 2033-2034 (42 U.S.C. 132

2. In Sec. 162.103, the introductory text to the section is republished, and a definition for ``LOINC[supreg]'' is added in al read as follows:

Sec. 162.103 Definitions.

For purposes of this part, the following definitions apply:
* * * * *
LOINC[supreg] stands for Logical Observation Identifiers Names and Codes.
* * * * *

3. In Sec. 162.920, the following changes are made:
A. The section heading is revised.
B. The introductory text is revised.
C. New paragraph (a)(10) is added.
D. New paragraph (a)(11) is added.
E. New paragraph (c) is added.
The changes read as follows:

Sec. 162.920 Availability of implementation specifications and guides.

A person or an organization may directly request copies of the implementation standards described in subparts I through the publishers listed in this section. The Director of the Office of the Federal

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Register approves the implementation specifications and guides described in this section for incorporation by reference in S of this part in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The implementation specifications and guides describe paragraph are also available for inspection by the public at the Centers for Medicare & Medicaid Services, 7500 S Baltimore, Maryland 21244 or at the National Archives and Records Administration (NARA). For information on the availabil material at NARA, call 202-741-6030, or go to: http://frwebgate.a bin/leaving.cgi?from=leavingFR.html&log=linklog&to=http://www.archives.gov/federal_register/code_of_federal_regulations

Copy requests must be accompanied by the name of the standard, number, if applicable, and version number. Implement and guides are available for the following transactions:
(a) ASC X12N specifications. * * *
(10) The ASC X12N 277--Health Care Claim Request for Additional Information, Version 4050 (004050X150), May Publishing Company as referenced in Sec. 162.1915.
(11) The ASC X12N 275--Additional Information to Support a Health Care Claim or Encounter, Version 4050 (00405(Washington Publishing Company as referenced in Sec. 162.1925.
* * * * *
(c) HL7 specifications. (1) The HL7 CDAR1AIS0000R021 Additional Information Specification Implementation Guide, F on HL7 CDA Release 1.0), May 2004, Health Level Seven, Inc. The AIS Implementation Guide for the HL7 standard ma Health Level Seven, Inc., 3300 Washtenaw Avenue, Suite 227, Ann Arbor, MI 48104-4250, or via http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log=linklog&to=http://www.hl7.org; or from the

Washington Publishing Company, PMB 161, 5284 Randolph Road, Rockville, MD 20852, or via

http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log=linklog&to=http://www.wpc-edi.com/.

(2) The HL7 Additional Information Specifications for each of the six attachments listed in Sec. 162.1915 and Sec. obtained from Health Level Seven, Inc., 3300 Washtenaw Avenue, Suite 227, Ann Arbor, MI 48104-4250, or v http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log=linklog&to=http://www.hl7.org ; or from Washington Publishing Company, PMB 161, 5284

Randolph Road, Rockville, MD 20852, or via the Internet at http://frwebgate.a bin/leaving.cgi?from=leavingFR.html&log=linklog&to=http://www.wpc-edi.com/.

The six HL7 AIS documents are:

(i) Ambulance services information: The CDAR1AIS0001R021 Additional Information Specification 0001, Ambulance S Release 2.1, based on HL7 CDA Release 1.0, May 2004, as referenced in Sec. 162.1915(b)(1) and Sec. 162.1925(c)(1).
(ii) Emergency department information: The CDAR1AIS0002R021 Additional Information Specification 0002: Emer Attachment, Release 2.1, based on HL7 CDA Release 1.0, May 2004, as referenced in Sec. 162.1915(b)(2) and Sec. 162.1
(iii) Rehabilitation services information: The CDAR1AIS0003R021. Additional Information Specification 0003: Reha Attachment, Release 2.1, based on HL7 CDA Release 1.0, May 2004, as referenced in Sec. 162.1915(b)(3) and Sec. 162.1
(iv) Clinical reports information: The CDAR1AIS0004R021 Additional Information Specification 0004: Clinical Reports At 2.1, based on HL7 CDA Release 1.0, May 2004, as referenced in Sec. 162.1915(b)(4) and Sec. 162.1925(c)(4).
(v) Laboratory results information: The CDAR1AIS0005R021 Additional Information Specification 0005: Laboratory R Release 2.1, based on HL7 CDA Release 1.0, May 2004, as referenced in Sec. 162.1915(b)(5) and Sec. 162.1925(c)(5).
(vi) Medications information: The CDAR1AIS0006R021 Additional Information Specification 0006: Medications Attachr based on HL7 CDA Release 1.0, May 2004, as referenced in Sec. 162.1915(b)(6) and Sec. 162.1925(c)(6).
(3) The LOINC[supreg] Modifier Codes booklet ``for use with ASC X12N 277 Implementation Guides when req Information," is available from Washington Publishing Company, PMB 161, 5284 Randolph Road, Rockville, MD 20852, or http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log=linklog&to=http://www.wpc-edi.com/.

4. In Sec. 162.1002, paragraph (c) is added to read as follows:

Sec. 162.1002 Medical data code sets.

* * * * *

(c) For the period beginning [24 months after the effective date of the final rule published in the Federal Register]: L Identifiers Names and Codes[supreg] (LOINC[supreg]), as maintained and distributed by the Regenstrief Institute and t Committee. The LOINC[supreg] database may be obtained from the Regenstrief Institute Web site at the following Internet http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log=linklog&to=http://www.regenstrief.org/loinc/lo without access to the Internet may obtain the LOINC[supreg] database from the Regenstrief Institute, c/o LOINC[supreg], 1 Blvd., Indianapolis, IN 46202.

5. A new subpart S is added to part 162 to read as follows:

Subpart S--Electronic Health Care Claims Attachments
Sec.
162.1900 Definitions.
162.1905 Requirements for covered entities.
162.1910 Electronic health care claims attachment request transaction.
162.1915 Standards and implementation specifications for the electronic health care claims attachment request transaction
162.1920 Electronic health care claims attachment response transaction.
162.1925 Standards and implementation specifications for the electronic health care claims attachment response transactic
162.1930 Initial compliance dates for the electronic health care claims attachment response and electronic health care request transaction standards.

Subpart S--Electronic Health Care Claims Attachments

Sec. 162.1900 Definitions.

Ambulance services means health care services provided by land, water, or air transport and the procedures and su the trip by the transport personnel to assess, treat or monitor the individual until arrival at the hospital, emergency departm destination. Ambulance documentation may also include non-clinical information such as the destination justification and or

Attachment information means the supplemental health information needed to support a specific health care claim.

Clinical reports means reports, studies, or notes, including tests, procedures, and other clinical results, used to analyz an individual's medical condition.

Emergency department means a health care facility or department of a hospital that provides acute medical and services on an ambulatory basis to individuals who require immediate care primarily in critical or life-threatening situations.

Laboratory results means the clinical information resulting from tests conducted by entities furnishing biologic serological, chemical, immunohematological, hematological, biophysical, cytological, pathology, or other examinations of human body.

Medications means those drugs and biologics that the individual is already

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taking, that are ordered for the individual during the course of treatment, or that are ordered for an individual after tr furnished.

Rehabilitation services means those therapy services provided for the primary purpose of assisting in an individ program of evaluation and services. These services are: Cardiac rehabilitation, medical social services, occupational therapy, respiratory therapy, skilled nursing, speech therapy, psychiatric rehabilitation, and alcohol and substance abuse rehabilitation.

Sec. 162.1905 Requirements for covered entities.

When using electronic media to conduct a health care claims attachment request transaction or a health care claims att transaction, a covered entity must comply with the applicable standards of this subpart if:

(a) Information not contained in a health care claim is needed for the adjudication of that health care claim; and

(b) The health care claim is for one or more of the following types of services:

(1) Ambulance services;

(2) Emergency department services;

(3) Rehabilitation services; or

(c) The additional information requested is for one or more of the following types of information:

(1) Clinical reports;

(2) Laboratory results; or

(3) Medications.

Sec. 162.1910 Electronic health care claims attachment request transaction.

(a) The health care claims attachment request transaction is the transmission, from a health plan to a health care provid attachment information to support the adjudication of a specific health care claim. A health plan may make such a request--

(1) Upon receipt of the health care claim;

(2) In advance of submission of the health care claim; or

(3) Through instructions for a specific type of health care claim which permit a health care provider to submit attachmen unsolicited basis each time such type of claim is submitted.

(b) If a health plan conducts a health care claims attachment request transaction using electronic media and the attac requested is of a type described at Sec. 162.1905 , the plan must conduct the transaction in accordance with the appro Sec. 162.1915.

(c) A health plan that conducts a health care claims attachment request transaction using electronic media, must submit and identify in the transaction, all of the attachment information needed to adjudicate the claim, which can be requeste transaction.

(d) The health care claims attachment request transaction sent using electronic media, is comprised of two component p

(1) The general request structure that identifies the related claim; and

(2) The LOINC[supreg] codes and LOINC[supreg] modifiers identifying the attachment information being requested.

Sec. 162.1915 Standards and implementation specifications for the electronic health care claims attachment request trans

The Secretary adopts the following standards and implementation specifications for the electronic health care claims a transaction:

(a) The ASC X12N 277--Health Care Claim Request for Additional Information, Version 4050, May 2004, Washington Pu 004050X150 (incorporated by reference in Sec. 162.920).

(b) The following HL7 AIS documents to convey the LOINC[supreg] codes that identify the attachment type and specific requested--

(1) Ambulance services information: The CDAR1AIS0001R021 Additional Information Specification 0001, Ambulance S Release 2.1, based on HL7 CDA Release 1.0 (incorporated by reference in Sec. 162.920);

(2) Emergency department information: The CDAR1AIS0002R021 Additional Information Specification 0002: Emer Attachment, Release 2.1, based on HL7 CDA Release 1.0 (incorporated by reference in Sec. 162.920);

(3) Rehabilitation services information: The CDAR1AIS0003R021. Additional Information Specification 0003: Reha Attachment, Release 2.1, based on HL7 CDA Release 1.0 (incorporated by reference in Sec. 162.920);

(4) Clinical reports information: The CDAR1AIS0004R021 Additional Information Specification 0004: Clinical Reports At 2.1, based on HL7 CDA Release 1.0 (incorporated by reference in Sec. 162.920);

(5) Laboratory results information: The CDAR1AIS0005R021 Additional Information Specification 0005: Laboratory R Release 2.1, based on HL7 CDA Release 1.0 (incorporated by reference in Sec. 162.920).

(6) Medications information: The CDAR1AIS0006R021 Additional Information Specification 0006: Medications Attachr based on HL7 CDA Release 1.0 (incorporated by reference in Sec. 162.920).

Sec. 162.1920 Electronic health care claims attachment response transaction.

(a) The health care claims attachment response transaction is the transmission of attachment information, from a health health plan, in response to a request from the health plan for the information.

(b) If a health care provider conducts a health care claims attachment transaction using electronic media, and the attachi of the type described at Sec. 162.1905, the health care provider must conduct the transaction in accordance with the app of Sec. 162.1925.

(c) A health care provider that conducts a health care claims attachment response transaction using electronic me complete response by providing, to the extent available, all of the requested attachment information or other appropria transaction.

(d) A health care provider that sends scanned images and text documents in the attachment transaction, for the humar is not required to use the LOINC[supreg] codes as the response, other than to repeat the LOINC[supreg] codes used in the request. Response information may be free text, scan an embedded document within the BIN segment of the response transaction.

(e) A health care provider may submit an unsolicited response transaction only upon advance instructions by a health pla

Sec. 162.1925 Standards and implementation specifications for the electronic health care claims attachment response trai

The Secretary adopts the following standards and implementation specifications for the electronic health care claims att trans action:

(a) The ASC X12N 275--Additional Information to Support a Health Care Claim or Encounter, Version 4050, May Publishing Company, 004050X151 (incorporated by reference in Sec. 162.920).

(b) The HL7 Additional Information Specification Implementation Guide Release 2.1 (incorporated by reference in implementing the HL7 Additional Information Specifications to convey attachment information within the Binary Data se X12N 275 (004050x151).

(c) The following HL7 AIS documents to convey the LOINC[supreg] codes that identify the attachment type and

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specific attachment information being sent--

(1) Ambulance Services information: The CDAR1AIS0001R021 Additional Information Specification 0001: Ambulance S Release 2.1, based on HL7 CDA Release 1.0 (incorporated by reference in Sec. 162.920);

(2) Emergency Department information: The CDAR1AIS0002R021 Additional Information Specification 0002: Emer Attachment, Release 2.1, based on HL7 CDA Release 1.0 (incorporated by reference in Sec. 162.920);

(3) Rehabilitation services information: The CDAR1AIS0003R021 Additional Information Specification 0003: Reha

Attachment, Release 2.1, based on HL7 CDA Release 1.0 (incorporated by reference in Sec. 162.920);
(4) Clinical reports information: The CDAR1AIS0004R021 Additional Information Specification 0004: Clinical Reports At
2.1, based on HL7 CDA Release 1.0 (incorporated by reference in Sec. 162.920);
(5) Laboratory results information: The CDAR1AIS0005R021 Additional Information Specification 0005: Laboratory R
Release 2.1, based on HL7 CDA Release 1.0 (incorporated by reference in Sec. 162.920); and
(6) Medications information: The CDAR1AIS0006R021 Additional Information Specification 0006: Medications Attachr
based on HL7 CDA Release 1.0 (incorporated by reference in Sec. 162.920).

Sec. 162.1930 Initial compliance dates for the electronic health care claims attachment response and electronic
attachment request transaction standards.

(a) Health care providers. A covered health care provider must comply with the applicable requirements of this subpart
months after the effective date of the final rule published in the Federal Register].
(b) Health plans. A health plan must comply with the applicable requirements of this subpart S no later than one of the fol
(1) Health plans other than small health plans--[24 months after the effective date of the final rule published in the Federa
(2) Small health plans--[36 months after the effective date of the final rule published in the Federal Register].
(c) Health care clearinghouses. A health care clearinghouse must comply with the applicable requirements of this subp
[24 months after the effective date of the final rule published in the Federal Register].

