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Issue Areas/Comments

GENERAL

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See Attachment

CMS-0050-P-100-Attach-1.PDF

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1	Tech Spec - 277 v4050 IG	Pg 8		1.2	We recommend the Final Rule adopts the 277 version 4050 unless there is an open comment period before adopting the version 5010. This applies to the v5010 of 275 transaction as well.	Unable to locate and review the version 5010 at this time on WPC website
2	Tech Spec - 277 v4050 IG	Pg 8		1.3	We recommend this section does include any reference to the other 277 uses other than the unsolicited health care claim request for additional information (in support of the Claims Attachment rule).	Does not serve any purpose in this guide unless clearly distinguished at each of the use and definition verbiage for this section that it does not include these other known uses in effort to eliminate confusion.
3	Tech Spec - 277 v4050 IG	Pg 9		1.3.1	This section appears to be labeled incorrectly as "Unsolicited Request for Additional Information". Instead, this should be labeled, "Solicited Request for Additional Information". Also, shouldn't the sentence word "unsolicited" be changed to "solicited" in the following sentence: "When this activity is initiated by the payer's adjudication system it is deemed to be "unsolicited"? Is this a typo? All of the documents (i.e., HIPAA and Claims Attachments, Preparing for Regulation, NPRM, WEDI/HL7 presentation workflow slides indicate the 277 as solicited model.) It appears that the industry documents name two separate models: one as solicited and one for unsolicited which appear to be labeled as such from the payer's perspective. However, this section of the IG appears to be labeled from the provider's perspective. This causes confusion especially when there are different X12 277 transaction usages (i.e., 277 solicited response to 276 request; unsolicited 277 acknowledgement to 837 claim; and claims attachment 277 usage in "solicited model".	
4	Tech Spec - 277 v4050 IG	Pg 12		2.2.1	Implementation Table 2 - Information Receiver Detail - used to identify the receiver does not contain a PER segment to identify the specific contact for the claim the 277 should be routed to based on the PER info sent in the 837 2010AA PER segment of the claim.	To know who the 277 should be routed to for the specific claim as specified in the 837 claim if known.

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5	Tech Spec - 277 v4050 IG	Pg 13		2.2.2	We support the notion in this section that the Information Source is always the payer. We do not support the Information Source being a third party entity that is adjudicating or repricing the claim on the payer's behalf.	The 837 claim is sent to a specific payer and the provider would not know or be expected to know who the third party in this situation would be. The provider's system would maintain an insurance dictionary of the payers the claims are sent to not the outsourced entity, TPA, silent PPO, or other entity.
6	Tech Spec - 277 v4050 IG	Pg 19		2.2.3	Under "The Claim" section, we recommend that the provider's patient control number always be sent back because this is the key data element used to immediately link the 277 to a specific patient account and claim in a provider's system (with minimum of 20 characters as specified in the 837).	
7	Tech Spec - 277 v4050 IG	Pg 21		2.2.3.1.3	We recommend this section explicitly state that the provider's patient control number as originally reported in the CLM01 data element of the 837 claim "must" be returned in one of the 277 REF segments.	Our patient's control number has evolved through experience with the other transaction sets to include a patient account number, identification of a claim type (i.e., Institutional or Professional), and a unique internal record ID of the claim history record so that the claim can be easily found and linked to with the incoming 835. The more information the payer can send to

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						identify the specific 837 claim to facilitate easy identification of the applicable claim for which the 277 information is for, the better.
8	Tech Spec - 277 v4050 IG	Pg 23		2.2.3.2.1	We do not understand the need or purpose of the PWK segment.	
9	Tech Spec - 277 v4050 IG	Pg 24		2.2.3.2.2.	We do not understand the need or purpose of the PWK segment.	
10	Tech Spec - 277 v4050 IG	Pg 26		2.2 3.3.2	1. We support the use of the LOINC codes in the STC segment. 2. We also strongly recommend that the STC04 Monetary Amount (used in the 276/277 transaction to convey the Total Claim Charge Amount at the claim level and Line Item Charge Amount at the service level be changed from "NOT USED" to "REQUIRED".	Serves as key data piece for validation and reconciliation on the provider's side and for easy information reporting. Having this information in the 277 transaction would also allow for immediate identification of the dollar amounts associated with the claim attachment request, or in other words, the amount of the claim pending for additional information.

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11	Tech Spec - 277 v4050 IG	Pg 72		STC segment - STC04 data element	We recommend the STC04 data element is changed from NOT USED to REQUIRED.	
12	Tech Spec - 277 v4050 IG	Pg 25		2.2.3.3	Loop ID-2220 Figure 2.6. Service Line displays the table information from the standard and not the implementation tables. It should be replaced with the 2220 Loop from page 37.	See # 10.
13	Tech Spec - 277 v4050 IG	Pg 27		2.2.3.3.3	REF Segment at the 2220 Loop. We recommend that language be added in this section or on page 105 that the value of the line item control number and/or LX01 not be changed and must be the value as originally reported in the applicable 837 claim.	We have already experienced some payers padding the REF*6R value with zeros and/or spaces, changing the length and data of the value originally submitted in the 837I and 837P claim. This causes linking issues and when not being returned, requires internal search engines to match to the applicable service line in question (based on past experience with the 837 and 835 transaction sets.)

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14	Tech Spec - 277 v4050 IG	Pg 28		2.3.2	We recommend the 997 be adopted as the functional acknowledgment transaction for the 277 and 275.	We recommend this adoption to standardize acknowledgement reporting and we will not be motivated to invest in supporting the 997 or 824 until a standard is mandated or there is industry consensus on the acknowledgement transactions to be used. Since the 277/275 is the most immediate opportunity to do this, we are including this recommendation in this comment.
15	Tech Spec - 277 v4050 IG	Pg 28		2.3.3	Should this section be titled, "The Health Care Patient Information (275) Transaction Set"? Or should it really be titled, "Additional Information to Support a Health Care Claim or Encounter."	
16	Tech Spec - 277 v4050 IG	Pg 43		ST02 data element	We recommend, a note be added after "This unique number also aids in error resolution research." that includes, "(to be reported in the acknowledgement transaction sets for example, AK202 of the 997 or OTI09 of the 824, etc.)"	
17	Tech Spec - 277 v4050 IG	Pg 50		NM109 of 2100A Payer Name	We recommend a comment be added for this data element that states the value of Payer Identifier should be the value reported in the 2010BC of the 837I NM109 and 2010BB of the 837P NM109 until the NationalPlan ID is mandated to allow for linking to specific payer in a provider's system.	
18	Tech Spec - 277 v4050 IG	Pg 62		NM108 of 2100C Service Provider Name	If the expectation is that the NPI will be implemented and should be required to always be echoed back as the provider identifier for this segment (without changing any of the data), then we would not suggest any changes to the note usage. We would need this information to identify the hospital and/or physician delivering the care as reported in the respective 837 claim.	

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19	Tech Spec - 277 v4050 IG	Pg 68		NM108 of 2100D Subscriber Name	We question why the qualifiers for the NM108 allow "24" and "ZZ", specifically, "24" when the 837 qualifier's allowed for this data element are "MI" and "ZZ", where "MI" is the standard.	
20	Tech Spec - 277 v4050 IG	Pg 72		STC01-1 and STC01-4	1. Question why the R type claim status category codes are not reported in STC01-4 instead of STC01-1? Same with STC10-1 and STC10-4, so qualifier for the code is reported prior to the code in all other transaction sets. This would not be a problem for us but just questioning why it is defined differently for this transaction. Was this simply done this way because of the 276/277 implementation? Are R type claim status codes in the final IG for 277? 2. Also, we support the elimination of claim status reason codes in this segment (as used in the 276/277 implementation.)	
21	Tech Spec - 277 v4050 IG	Pg 75		2200D Patient Account Number Notes #1	We strongly recommend that the following sentences be removed from Note #1 for the Patient Account Number, "When this data is not available in the payer's system, use the value "0" to indicate a payer generated value is present at this location. Therefore, no Patient Account Number was supplied on the claim." The CLM01 is required for a compliant 837 so why would this ever be allowed?	The patient account number (i.e., patient control number) is the absolute key to identifying the appropriate patient account and claim in the provider's system. If this number sent on the 837 claim is not returned in the 277 request for additional information, the request is useless.
22	Tech Spec - 277 v4050 IG	Pg 75		2200D Patient Account Number Notes #3	We strongly recommend that "... however, the patient control number (CLM01 from the respective 837 claim) always be sent." be added to the end of the first sentence of Note #3.	
23	Tech Spec - 277 v4050 IG	Pg 80		REF02 2200D Medical Record Identification	We suggest the note for REF02 include reference to REF*EA.	

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24	Tech Spec - 277 v4050 IG	Pg 97		SVC 2220D Service Line Information Note #3	We recommend correction of "HCPC's" to "HCPCS's" codes and the additional clarifying note be added that states the revenue code and HCPCS are reported in SVC01-2 and SVC04 as currently implemented in the 835 and as reported in the 837I SV201 and SV202-1).	
25	Tech Spec - 277 v4050 IG	Pg 98		SVC01-1	We recommend qualifier "ZZ" be added to the valid codes as ZZ is used in the 837P SV101-1.	
26	Tech Spec - 277 v4050 IG	Pg 99		SVC01-2	We suggest correction of "HCPC's" to "HCPCS's" for this data element.	
27	Tech Spec - 277 v4050 IG				Same comments for Subscriber Level segments for the Dependent Level segments	
28	Tech Spec - 275 v4050 IG	Pg 7		1.1	We do not understand the reference to the "275 Patient Information (275) Transaction Set" in this section or IG.	
29	Tech Spec - 275 v4050 IG	Pg 8		1.2	We recommend the Final Rule adopts the 275 version 4050 unless there is an open comment period before adopting the version 5010.	
30	Tech Spec - 275 v4050 IG	Pg 8		1.2	There is no reference to the version of the CDA in this section.	
31	Tech Spec - 275 v4050 IG	Pg. 9		1.3.1	In response to this section of the IG, ""However the 275 transaction structure only allows the submitted to send additional information for one claim in each 275. A separate ST/SE must be sent for each claim response..." We do not support multiple ST/SEs within one GS/GE ISA/ISE 275 transaction. We do support the notion that each claim requires a separate 275, thus one ST/SE per 275 claim response. For myriad reasons, we recommend one ST/SE per 275 transaction to mitigate size, storage, and transmission issues.	
32	Tech Spec - 275 v4050 IG	Pg 12		2.2	Under "Data Use by Business Use" section, since parameters use to locate a claim are included in this section, we recommend that the provider's patient control number always be sent back because this is the key data element used to immediately link the 277 to a specific patient account and claim in a provider's system (with minimum of 20 characters as specified in the 837).	
33	Tech Spec - 275 v4050	Pg 24		2.3.4	We strongly recommend the Associated Data (102) be removed from this IG and that the 997 and 824 acknowledgement transaction sets be adopted	

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	IG				and mandated for use.	
34	Tech Spec - 275 v4050 IG	Pg. 37		ST02 data element	We recommend, a note be added after "This unique number also aids in error resolution research." that includes, "(to be reported in the acknowledgement transaction sets for example, AK202 of the 997 or OTI09 of the 824, etc.)"	
35a	Tech Spec - 275 v4050 IG	Pg 39		BGN01	If sending a 275 with an 837 in separate interchanges is allowed, there needs to be another code to indicate this type of 275 other than 02 and 11.	
35b		Pg 9		1.3.2 Unsolicited Additional Information to Support an 837 Health Care Claim sent within the same transmission	We strongly recommend the unsolicited 275s be sent in the same interchange with the respective 837 claims as is specified in the v4010 275 IG or the following reasons: 1. To ameliorate the timing issues that would arise with matching, linking, or validating receipt of the 275 should the 837 be received without it 2. To reduce the possibility for significant rework or retransmission of 275 data already sent if received in separate interchanges (i.e., transmissions) 3. Requiring the 275 be sent with the 837 is a much more logical and simple approach. In supporting this approach, we would suggest the claim limit submission of up to 5,000 claims in one batch be revisited due to increased size of the files with the embedded 275 data. We do not support sending the 837s and 275 in separate transmissions as may be the future requirement in the v5010 X12 275 transaction IG.	
36	Tech Spec - 277 v4050 IG	Pg. 61		NM108 Service Provider Name	We want to identify a discrepancy between the qualifiers allowed in NM108 data element of the Service Provider Name segment in the 277 versus what is allowed in the 275 NM108 data element. The 275 allows 24,34,FI, SV, XX where 24 and 34 would be used for 275 combined with 837. However, 277 only allows FI, SV, XX. Doesn't 24 and 34 need to be allowed in the 277 as well should additional info 277 be sent for additional information on 275 already received? This, of course, is only concern and discrepancy during NPI transition period. With NPI fully implemented, it is expected only XX would be used in both transactions.	
37	Tech Spec - 275 v4050 IG	Pg 52		REF Provider Secondary Identification	Why is this REF segment included in this transaction if not included in the 277 for which the 275 is one in which the BGN01 = 11? Also, with NPI, why would we need an additional segment?	

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38	Tech Spec - 275 v4050 IG	Pp 57-58		REF*EJ Patient Account Number	We want to again convey that the patient account number as reported in the CLM01 of the 837 claim is the key link in this process for identifying the appropriate patient account and claim in a provider's system. It should be clear that it must be used and the value can not be changed.	
39	Tech Spec - 275 v4050 IG	Pg 59		REF*BLT Institutional Type of Bill	Under the Notes, it is not clear if the 275 is being sent with the 837 claim that the provider has the discretion to send this segment or not. Should this segment always be sent in the unsolicited model to match the value reported in the 837 claim? We understand that the payer may send this information in the 277 in the solicited model, however, we recommend an additional note be specified whether or not the payer can change the type of bill reported in their 277 request from what was submitted on the 837 claim.	
40	Tech Spec - 275 v4050 IG	Pg 64		DTP*434 Institutional Claim Service Date	We recommend additional note be added for clarification that the DTP*434 should always be the statement from and thru dates reported in the DTP*434 segment of the applicable 837 claim. Also, there should be a note that this segment is not used nor sent for professional claims.	
41	Tech Spec - 275 v4050 IG	Pg 66		TRN - Payer's Control Number/ Provider's Control Number and REF*EJ Patient Account Number	We strongly recommend a standard schema be adopted for provider's (patient) control numbers versus payer's control numbers that could be transmitted between payers and providers to uniquely identify a specific claim in each entity's system. For example, if the provider's control number is always unique and can readily identify a specific 837 claim for an individual patient account, then the provider can always find the claim for which an incoming transaction request is for. Likewise, if the payer's control number is always unique and can readily identify a specific claim for a specific patient, then the additional REF segments for Type of Bill, Dates of Service, Medical Record Number would not be needed. The payer already has an ICN/DCN number assigned and used in the 835 transaction. We recommend this number be used from payer perspective. If we could come to a unique number on both sides, we could truly standardize the identification of a specific claim by both entities and only that number would need to be returned to the receiver.	
42	Tech Spec - 275 and 277 v4050 IG	Pg 68 275 IG and Pg 71 277 IG		STC segment - Claim Level Status Information	We suspect the claim level STC segment in the 277 is "required" as a standard for the STC segment claim level in other 277 transactions. However, we question whether this segment should remain required when the data is being request at the service level. Can't the usage be changed to "situational" instead and only required when request information is being sent at the claim level? If this is only being used to identify which loop level it resides, we would already easily ascertain a service STC versus claim STC by SVC segment preceding the STC. If claim level, there is no SVC preceding the STC.	

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43	Tech Spec - 275 v4050 IG	Pg. 74		REF 2000A Procedure or Revenue Code	We recommend the same qualifiers in the 837 for Product/Service ID Qualifier be the same ones allowed in this REF for consistency in reporting and easy mapping.	
44	Tech Spec - 275 v4050 IG	Pg. 81		CAT Category of Patient Information Service	We request additional clarification to the IA qualifier usage comments that exist. Additionally, we request some usage guidance on CAT03 - Version Identifier. What does the version in CAT03 refer to and what are examples?	
45	Tech Spec - 275 v4050 IG	Pg. 83		EFI Electronic Format Identification	What is the purpose of this segment? There is mention of this segment in HL7 presentation materials to watch this segment for changes for possible future reporting of CDV versus HDV. Is this true?	
46	Tech Spec - 275 v4050 IG	Pg 84		Binary Data Elements	What are the standards or protocols for calculating the length of the binary data? What are the recommendations and rules on calculating the length?	
47a	Ambulance Service Attachment				We do not support the removal of the ambulance data in the 837P transaction set so that it is only supported in the 275 or 277 Ambulance Service Attachment transaction for these reasons: 1. By removing this data from the 837P, you potentially force all providers to send an ambulance attachment and the use of unsolicited 275s is still an industry question as to how it will be supported. 2. Payers would be forced to accept unsolicited ambulance attachments in order to adjudicate the claim.	We have already invested time, money, and resources in developing and supporting the ambulance data elements in an 837P claim.
47b	Ambulance Service Attachment			cont'd	3. Depending on when the ambulance data were to be stripped out of the 837 transaction set, there would be backward compatibility issues for the payer and could potentially increase the need for the provider to resend data already submitted to adjudicate the claim. Since the thought of migrating the data from the 837P to the 277/275 Ambulance Attachment in the future, in itself, causes implementation problems due to versioning (ie., the thought of changing the 837P data elements to NOT USED is not already in the v5010 for which the public comment period has already occurred. Thus, this would mean a release version several years out.) We recommend the 837P continue to maintain the necessary ambulance data elements and be billed using the 837P claim and/or enhanced as such in future version of 837P to include the small number of data elements excluded from 837P today.	

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48	HL7 Additional Information Specification IG	Pg 12		Multimedia Elements	From vendor perspective, allowing the use of an URL to point to where a specific attachment can be found is technically much more straightforward and easier to build and support. However, from a provider and payer perspective, it becomes difficult due to having the need for a central repository and various security and privacy issues.	
49	HL7 Additional Information Specification IG				We support use of the MIME packaging for the BIN segment and recognize it's value in terms of security, transmission speed and potentially reduced storage space.	
50	Tech Spec - 275 v4050 IG	Pg. 68		STC segment - Claim Level Status Information and BIN segment	Although discussed in various X12 and HL7 forums, the IG does not specify how to report or point to one image which contains the answers to multiple questions. This will become a very problematic implementation issue if the IG is not clear on how to handle this, as we would not want to send the image over and over again to answer each question individually (i.e., there should be a pointer or qualifier to respond to subsequent questions that the answer is in the image provided in the first or previous BIN segment.)	Specific guidance on this situation should be clearly specified in the IG to avoid interpretation and implementation issues.
51	Tech Spec - 275 v4050 IG			278	It has been stated in X12 and HL7 forums that there is currently work underway to use the same approach as the claims attachment to support the 278 request and response for preauthorization/precertification. If this is the case, how will this be rolled-out? What about the current 278 v4010 and proposed v5010 transactions sets? What kind of outreach is being done?	Concern expressed because of the time and money already invested in developing the v4010A1 of the 278 transaction and plans to continue further development using the corrections in the v5010.
52	Technical Comment			LOINC Codes	What is the maintenance process for new LOINC releases?	

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53	Technical Comment			Future Claims Attachment Development Efforts	What is the outreach and education plan for communicating ongoing work underway for additional attachments? HL7 has indicated that the following attachments are currently under development: 1. Home Health, 2. Periodontal Charts, 3. Medicaid Consent Forms, 4. Medicaid Children's Preventative Health Service (EPSTD Program), 5. DME, 6. EAP, 7. Pharmacy Prior Authorization. Up until now, there has been little communication and education about this work which certainly impacts our development plans and clients. We agree that building the initial infrastructure to support claims attachments in general will be a significant effort, commitment, and investment on our part; however, little communication and outreach has been done in the past. HL7 involvement in the past has been almost exclusively focused on interfaces and standard messaging; however, claims attachments is now a whole new area and does not typically utilize the same resources that have years of experience in the interface side of the business. Based on the nature of claims attachments, this moves from the "interface" knowledge base to those resources working with an understanding of the EDI transactions and patient accounting and clinical operations. So, whatever standard communication methods used by HL7 to date, have not reached the "right" stakeholders for this transaction.	
54	Technical Comment			Non XML Body Types	We support all of the non-XML body types detailed in the HL7 IG section 3.5.3.	
55	Technical Comment			CDV vs. HDV	We support HDV and CDV but strongly recommend HDV implementation comes first.	
56	NPRM Section 162.1910, A(2)	Pg 56024		Electronic health care claims attachment request transaction	In this section, "(2)" In advance of submission of the health care claim; or..." does not make sense. How can a 277 request for additional information be requested without an 837 claim already being sent from the provider? This certainly needs additional clarification and/or removed or noted that this is not even allowed based on the implementation of the claims attachment transaction sets.	
57	Technical Comment				We strongly recommend any implementation rules and guidance for MIME packaging, BIN segment issues, implementing XML namespaces without overlap, etc. be specified in the IG or Final Rule and not left for future SDO guidance papers or some other forum (including companion guides.)	

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58	NPRM II.C.5. – page 55997, column 1		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.”		We recommend that the HL7 PICU attachment, currently under development to provide a mechanism to send claims attachment information not in the six types proposed in this rule, also be included in the HIPAA attachments adopted or we suggest that some reference in the rule be made that this attachment is the defunct generic attachment standard used by trading partners for data not already included in the 6 attachment types under adoption. As a vendor, we would be hardpressed to support another attachment that is not part of the Final Rule.	
59	NPRM II, C, 1.	Pg 55995			We recommend that the XSL stylesheets supplied by HL7 be used as the standard stylesheets and that this not be optional as implied by the following text in the rule, “If covered entities choose not to use the HL7 supplied stylesheet, they will be able to create their own without significant problems, assuming the expertise exists on staff or is available through a vendor.”	
60	NPRM Section 162.1920, (E)	Pg 56024		Electronic health care claims attachment response transaction	In this section, “(E) A health care provider may submit an unsolicited response transaction only upon advance instructions by a health plan.”	AFEHCT

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61	NPRM, Section I.D.2 – page 55993, second column		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)...		Incorrect version is named. We agree with AFEHCT's recommendation to change both references to 4010-1a to be 4010A1.	

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62	NPRM Section II.C.2., page 55995		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.		We endorse and support AFEHCT's comments: 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 CDA R1 but are internal XML in CDA R2, the processing of the CDA would be different enough between R1 and R2 to require separate implementations. It is not a simple matter of upwards migration, such as when the HIPAA X12 standards were migrated with the Addenda; rather they are a completely different implementation. 1. Before CMS considers making a decision on whether to adopt CDA R1 or CDA R2, it is necessary that the industry conducts at least a proof of concept pilot implementation with several trading partners to determine the feasibility of implementing R2 for the six proposed standard attachments. Without a proof-of-concept pilot with positive outcome, CMS should not consider for adoption the CDA R2 as a standard. We also acknowledge HL7's recommendation to adopt the CDA R2.0 in the Final Rule. We would support this position if there is a proof of concept has been completed.	
63	NPRM Section II.C.2., page 55995			cont'd	Further, we do not want to expend resources to develop the 275 on release 1.0 and migration to release 2.0 occur mid-stream or immediately after initial implementation of release 1.0. This would prove very costly and problematic for us as a vendor and rollout to our clients. 2. Over the last few years all the Attachment work has been done under CDA R1. The adoption of CDA R2 could have some advantages over R1, but it would require new Implementation Guides for all the standard attachments, possibly delaying the adoption process by two or more years. Most importantly, uncertainty about which standard would cause all progress on Attachments to cease until this uncertainty is resolved. 3. CMS should adopt CDA R1 immediately and indicate it may consider CDA R2 for new attachments and future versions of the initial six attachments.	

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67	<p><u>"SOLICITED vs. UNSOLICITED ATTACHMENTS"</u> NPRM II.D.2. pp 55999, 56024</p>		<p>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,</p>		<p>We support AFEHCT's comments that section §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.</p>	

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			<p>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.</p>			

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68	<p><u>"SOLICITED vs. UNSOLICITED ATTACHMENTS"</u> NPRM p55999</p>		<p>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</p>		<p>We support AFEHCT's recommendation to "Permit multiple requests provided that a later request is based on information obtained in an earlier attachment and is not duplicative of earlier attachments." 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.</p>	

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			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.			
69	<u>"SOLICITED vs. UNSOLICITED ATTACHMENTS"</u> NPRM II.D.4. p 56000		"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		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.	

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			transaction s."			
70	<u>"PROVIDER VS. PLAN PERSPECTIVE"</u> NPRM II.D.9. p56001, column 2.		"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."		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 3 rd 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.	

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					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 are recommending a transaction-based certification model for all implementers in addition to a model where vendors or software are certified. 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 transaction-based certification of their solution(s)	
					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 two elements of certification that will lend significant assistance in implementation: (i) 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.	

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71	<p><u>“ATTACHMENT CONTENT AND STRUCTURE”</u> NPRM II.E. p56001</p>		<p>“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.</p>		<p>Up to 64 MB recommended maximum for the BIN segment is adequate for the attachments named in the rule. We support limits on transaction size and number of transactions in a batch or file should be specified in implementation guides not the rule.</p>	

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			Industry comment on file size is also welcome."			
72	"MODIFICATION TO STANDARD S AND NEW ATTACHMENTS" NPRM III.A. p56013			This whole section.	We support AFEHCT's full comment: "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."	
73	"COSTS AND BENEFITS" NPRM VI.B. pp56016 - 56021			The whole section	Based on initial projections, we expect the cost to develop and support the claims attachments standards will take several million dollars. This initial cost would be required to support the HDV approach to solicited and unsolicited claims attachments due to the significant variability and level of detail that would be necessary to build the infrastructure for identifying and mapping payer attachment needs for specific claims. Naturally, the payers medical review rules vary differently among payers. As a hospital information system vendor, it will require significant development on our part to build the systems necessary to map an attachment and/or LOINC code to a specific attachment (i.e., scanned image, etc.) Implementation of the CDV approach will be easier to develop in concert with the industry mandate, adoption, development, and reality of an Electronic Health Record.	
74	"EFFECTIVE DATES" NPRM pp55994, 56025		§ 162.1930 (a) Health care providers – 24 months after the effective		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 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.	

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			date (b) Health plans – 24 months after the effective date (c) Small health plans – 36 months after the effective date (d) Health care Clearinghouse uses – 24 months after effective date			
75	Technical Comment				The proposed rule does not address interoperability issues for interfaces between Clinical and Financial Systems of potentially different vendors. There are no guidelines or standardized way to suggest how to address this critical communication issue between vendor systems to successfully and timely produce a 275. We recommend some initiative be undertaken to come to industry consensus for intersystem interoperability. The industry should try to avoid silo approaches and/or implementation strategies and a shared approach needs to be identified to limit proprietary solutions and further complexities or complications for sharing the data needed for the 275 claims attachment.	
76	NPRM, 56000, II D-6				We echo the comment from HL7 that "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."	
77	NPRM, 56000, II D, 4				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.	

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78	NPRM, 55993, II, A				<p>We support HL7's recommendation that "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."</p> <p>We understand that HL7 and X12 have completed some work in the past to address the issue of data that "belongs in the claim" versus data that "belongs in the claims attachment." We also understand that they have developed some draft criteria to be used in determining where data should reside. As a vendor and active participant in the educational sessions and industry forums held this past year in soliciting feedback for the proposed rule comments, we have not had the opportunity to see the draft criteria that may exist. We recommend that the criteria be published and disseminated through various outreach efforts to ensure that all parties are aware of the proposed criteria and have an opportunity to participate in discussions or input on these changes since any migration work for this effort will certainly impact our current implementation of the 837 claim transaction and future development of the claims attachment transaction.</p>	
79	Technical Comment					

CMS-0050-P-100

Submitter : Ms. Dyan Anderson

Date: 01/20/2006

Organization : QuadraMed

Category : Other

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-0050-P-100-Attach-1.PDF

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1	Tech Spec - 277 v4050 IG	Pg 8		1.2	We recommend the Final Rule adopts the 277 version 4050 unless there is an open comment period before adopting the version 5010. This applies to the v5010 of 275 transaction as well.	Unable to locate and review the version 5010 at this time on WPC website
2	Tech Spec - 277 v4050 IG	Pg 8		1.3	We recommend this section does include any reference to the other 277 uses other than the unsolicited health care claim request for additional information (in support of the Claims Attachment rule).	Does not serve any purpose in this guide unless clearly distinguished at each of the use and definition verbiage for this section that it does not include these other known uses in effort to eliminate confusion.
3	Tech Spec - 277 v4050 IG	Pg 9		1.3.1	This section appears to be labeled incorrectly as "Unsolicited Request for Additional Information". Instead, this should be labeled, "Solicited Request for Additional Information". Also, shouldn't the sentence word "unsolicited" be changed to "solicited" in the following sentence: "When this activity is initiated by the payer's adjudication system it is deemed to be "unsolicited"? Is this a typo? All of the documents (i.e., HIPAA and Claims Attachments, Preparing for Regulation, NPRM, WEDI/HL7 presentation workflow slides indicate the 277 as solicited model.) It appears that the industry documents name two separate models: one as solicited and one for unsolicited which appear to be labeled as such from the payer's perspective. However, this section of the IG appears to be labeled from the provider's perspective. This causes confusion especially when there are different X12 277 transaction usages (i.e., 277 solicited response to 276 request; unsolicited 277 acknowledgement to 837 claim; and claims attachment 277 usage in "solicited model".	
4	Tech Spec - 277 v4050 IG	Pg 12		2.2.1	Implementation Table 2 - Information Receiver Detail - used to identify the receiver does not contain a PER segment to identify the specific contact for the claim the 277 should be routed to based on the PER info sent in the 837 2010AA PER segment of the claim.	To know who the 277 should be routed to for the specific claim as specified in the 837 claim if known.

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5	Tech Spec - 277 v4050 IG	Pg 13		2.2.2	We support the notion in this section that the Information Source is always the payer. We do not support the Information Source being a third party entity that is adjudicating or repricing the claim on the payer's behalf.	The 837 claim is sent to a specific payer and the provider would not know or be expected to know who the third party in this situation would be. The provider's system would maintain an insurance dictionary of the payers the claims are sent to not the outsourced entity, TPA, silent PPO, or other entity.
6	Tech Spec - 277 v4050 IG	Pg 19		2.2.3	Under "The Claim" section, we recommend that the provider's patient control number always be sent back because this is the key data element used to immediately link the 277 to a specific patient account and claim in a provider's system (with minimum of 20 characters as specified in the 837).	
7	Tech Spec - 277 v4050 IG	Pg 21		2.2.3.1.3	We recommend this section explicitly state that the provider's patient control number as originally reported in the CLM01 data element of the 837 claim "must" be returned in one of the 277 REF segments.	Our patient's control number has evolved through experience with the other transaction sets to include a patient account number, identification of a claim type (i.e., Institutional or Professional), and a unique internal record ID of the claim history record so that the claim can be easily found and linked to with the incoming 835. The more information the payer can send to

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						identify the specific 837 claim to facilitate easy identification of the applicable claim for which the 277 information is for, the better.
8	Tech Spec - 277 v4050 IG	Pg 23		2.2.3.2.1	We do not understand the need or purpose of the PWK segment.	
9	Tech Spec - 277 v4050 IG	Pg 24		2.2.3.2.2	We do not understand the need or purpose of the PWK segment.	
10	Tech Spec - 277 v4050 IG	Pg 26		2.2.3.3.2	1. We support the use of the LOINC codes in the STC segment. 2. We also strongly recommend that the STC04 Monetary Amount (used in the 276/277 transaction to convey the Total Claim Charge Amount at the claim level and Line Item Charge Amount at the service level be changed from "NOT USED" to "REQUIRED".	Serves as key data piece for validation and reconciliation on the provider's side and for easy information reporting. Having this information in the 277 transaction would also allow for immediate identification of the dollar amounts associated with the claim attachment request, or in other words, the amount of the claim pending for additional information.

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11	Tech Spec - 277 v4050 IG	Pg 72		STC segment - STC04 data element	We recommend the STC04 data element is changed from NOT USED to REQUIRED.	See # 10.
12	Tech Spec - 277 v4050 IG	Pg 25		2.2.3.3	Loop ID-2220 Figure 2.6. Service Line displays the table information from the standard and not the implementation tables. It should be replaced with the 2220 Loop from page 37.	
13	Tech Spec - 277 v4050 IG	Pg 27		2.2.3.3.3	REF Segment at the 2220 Loop. We recommend that language be added in this section or on page 105 that the value of the line item control number and/or LX01 not be changed and must be the value as originally reported in the applicable 837 claim.	We have already experienced some payers padding the REF*6R value with zeros and/or spaces, changing the length and data of the value originally submitted in the 837I and 837P claim. This causes linking issues and when not being returned, requires internal search engines to match to the applicable service line in question (based on past experience with the 837 and 835 transaction sets.)

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14	Tech Spec - 277 v4050 IG	Pg 28		2.3.2	We recommend the 997 be adopted as the functional acknowledgment transaction for the 277 and 275.	We recommend this adoption to standardize acknowledgement reporting and we will not be motivated to invest in supporting the 997 or 824 until a standard is mandated or there is industry consensus on the acknowledgement transactions to be used. Since the 277/275 is the most immediate opportunity to do this, we are including this recommendation in this comment.
15	Tech Spec - 277 v4050 IG	Pg 28		2.3.3	Should this section be titled, "The Health Care Patient Information (275) Transaction Set"? Or should it really be titled, "Additional Information to Support a Health Care Claim or Encounter."	
16	Tech Spec - 277 v4050 IG	Pg 43		ST02 data element	We recommend, a note be added after "This unique number also aids in error resolution research." that includes, "(to be reported in the acknowledgement transaction sets for example, AK202 of the 997 or OTI09 of the 824, etc.)"	
17	Tech Spec - 277 v4050 IG	Pg 50		NM109 of 2100A Payer Name	We recommend a comment be added for this data element that states the value of Payer Identifier should be the value reported in the 2010BC of the 837I NM109 and 2010BB of the 837P NM109 until the NationalPlan ID is mandated to allow for linking to specific payer in a provider's system.	
18	Tech Spec - 277 v4050 IG	Pg 62		NM108 of 2100C Service Provider Name	If the expectation is that the NPI will be implemented and should be required to always be echoed back as the provider identifier for this segment (without changing any of the data), then we would not suggest any changes to the note usage. We would need this information to identify the hospital and/or physician delivering the care as reported in the respective 837 claim.	

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19	Tech Spec - 277 v4050 IG	Pg 68		NM108 of 2100D Subscriber Name	We question why the qualifiers for the NM108 allow "24" and "ZZ", specifically, "24" when the 837 qualifier's allowed for this data element are "MI" and "ZZ", where "MI" is the standard.	
20	Tech Spec - 277 v4050 IG	Pg 72		STC01-1 and STC01-4	1. Question why the R type claim status category codes are not reported in STC01-4 instead of STC01-1? Same with STC10-1 and STC10-4, so qualifier for the code is reported prior to the code in all other transaction sets. This would not be a problem for us but just questioning why it is defined differently for this transaction. Was this simply done this way because of the 276/277 implementation? Are R type claim status codes in the final IG for 277? 2. Also, we support the elimination of claim status reason codes in this segment (as used in the 276/277 implementation.)	
21	Tech Spec - 277 v4050 IG	Pg 75		2200D Patient Account Number Notes #1	We strongly recommend that the following sentences be removed from Note #1 for the Patient Account Number, "When this data is not available in the payer's system, use the value "0" to indicate a payer generated value is present at this location. Therefore, no Patient Account Number was supplied on the claim." The CLM01 is required for a compliant 837 so why would this ever be allowed?	The patient account number (i.e., patient control number) is the absolute key to identifying the appropriate patient account and claim in the provider's system. If this number sent on the 837 claim is not returned in the 277 request for additional information, the request is useless.
22	Tech Spec - 277 v4050 IG	Pg 75		2200D Patient Account Number Notes #3	We strongly recommend that "... however, the patient control number (CLM01 from the respective 837 claim) always be sent." be added to the end of the first sentence of Note #3.	
23	Tech Spec - 277 v4050 IG	Pg 80		REF02 2200D Medical Record Identification	We suggest the note for REF02 include reference to REF*EA.	

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24	Tech Spec - 277 v4050 IG	Pg 97		SVC 2220D Service Line Information Note #3	We recommend correction of "HCPC's" to "HCPCS's" codes and the additional clarifying note be added that states the revenue code and HCPCS are reported in SVC01-2 and SVC04 as currently implemented in the 835 and as reported in the 837I SV201 and SV202-1).	
25	Tech Spec - 277 v4050 IG	Pg 98		SVC01-1	We recommend qualifier "ZZ" be added to the valid codes as ZZ is used in the 837P SV101-1.	
26	Tech Spec - 277 v4050 IG	Pg 99		SVC01-2	We suggest correction of "HCPC's" to "HCPCS's" for this data element.	
27	Tech Spec - 277 v4050 IG				Same comments for Subscriber Level segments for the Dependent Level segments	
28	Tech Spec - 275 v4050 IG	Pg 7		1.1	We do not understand the reference to the "275 Patient Information (275) Transaction Set" in this section or IG.	
29	Tech Spec - 275 v4050 IG	Pg 8		1.2	We recommend the Final Rule adopts the 275 version 4050 unless there is an open comment period before adopting the version 5010.	
30	Tech Spec - 275 v4050 IG	Pg 8		1.2	There is no reference to the version of the CDA in this section.	
31	Tech Spec - 275 v4050 IG	Pg. 9		1.3.1	In response to this section of the IG, ""However the 275 transaction structure only allows the submitted to send additional information for one claim in each 275. A separate ST/SE must be sent for each claim response..." We do not support multiple ST/SEs within one GS/GE ISA/ISE 275 transaction. We do support the notion that each claim requires a separate 275, thus one ST/SE per 275 claim response. For myriad reasons, we recommend one ST/SE per 275 transaction to mitigate size, storage, and transmission issues.	
32	Tech Spec - 275 v4050 IG	Pg 12		2.2	Under "Data Use by Business Use" section, since parameters use to locate a claim are included in this section, we recommend that the provider's patient control number always be sent back because this is the key data element used to immediately link the 277 to a specific patient account and claim in a provider's system (with minimum of 20 characters as specified in the 837).	
33	Tech Spec - 275 v4050	Pg 24		2.3.4	We strongly recommend the Associated Data (102) be removed from this IG and that the 997 and 824 acknowledgement transaction sets be adopted	

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	IG				and mandated for use.	
34	Tech Spec - 275 v4050 IG	Pg. 37		ST02 data element	We recommend, a note be added after "This unique number also aids in error resolution research." that includes, "(to be reported in the acknowledgement transaction sets for example, AK202 of the 997 or OTI09 of the 824, etc.)"	
35a	Tech Spec - 275 v4050 IG	Pg 39		BGN01	If sending a 275 with an 837 in separate interchanges is allowed, there needs to be another code to indicate this type of 275 other than 02 and 11.	
35b		Pg 9		1.3.2 Unsolicited Additional Information to Support an 837 Health Care Claim sent within the same transmission	We strongly recommend the unsolicited 275s be sent in the same interchange with the respective 837 claims as is specified in the v4010 275 IG or the following reasons: 1. To ameliorate the timing issues that would arise with matching, linking, or validating receipt of the 275 should the 837 be received without it 2. To reduce the possibility for significant rework or retransmission of 275 data already sent if received in separate interchanges (i.e., transmissions) 3. Requiring the 275 be sent with the 837 is a much more logical and simple approach. In supporting this approach, we would suggest the claim limit submission of up to 5,000 claims in one batch be revisited due to increased size of the files with the embedded 275 data. We do not support sending the 837s and 275 in separate transmissions as may be the future requirement in the v5010 X12 275 transaction IG.	
36	Tech Spec - 277 v4050 IG	Pg. 61		NM108 Service Provider Name	We want to identify a discrepancy between the qualifiers allowed in NM108 data element of the Service Provider Name segment in the 277 versus what is allowed in the 275 NM108 data element. The 275 allows 24,34,FI, SV, XX where 24 and 34 would be used for 275 combined with 837. However, 277 only allows FI, SV, XX. Doesn't 24 and 34 need to be allowed in the 277 as well should additional info 277 be sent for additional information on 275 already received? This, of course, is only concern and discrepancy during NPI transition period. With NPI fully implemented, it is expected only XX would be used in both transactions.	
37	Tech Spec - 275 v4050 IG	Pg 52		REF Provider Secondary Identification	Why is this REF segment included in this transaction if not included in the 277 for which the 275 is one in which the BGN01 = 11? Also, with NPI, why would we need an additional segment?	

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38	Tech Spec - 275 v4050 IG	Pp 57-58		REF*EJ Patient Account Number	We want to again convey that the patient account number as reported in the CLM01 of the 837 claim is the key link in this process for identifying the appropriate patient account and claim in a provider's system. It should be clear that it must be used and the value can not be changed.	
39	Tech Spec - 275 v4050 IG	Pg 59		REF*BLT Institutional Type of Bill	Under the Notes, it is not clear if the 275 is being sent with the 837 claim that the provider has the discretion to send this segment or not. Should this segment always be sent in the unsolicited model to match the value reported in the 837 claim? We understand that the payer may send this information in the 277 in the solicited model, however, we recommend an additional note be specified whether or not the payer can change the type of bill reported in their 277 request from what was submitted on the 837 claim.	
40	Tech Spec - 275 v4050 IG	Pg 64		DTP*434 Institutional Claim Service Date	We recommend additional note be added for clarification that the DTP*434 should always be the statement from and thru dates reported in the DTP*434 segment of the applicable 837 claim. Also, there should be a note that this segment is not used nor sent for professional claims.	
41	Tech Spec - 275 v4050 IG	Pg 66		TRN - Payer's Control Number/ Provider's Control Number and REF*EJ Patient Account Number	We strongly recommend a standard schema be adopted for provider's (patient) control numbers versus payer's control numbers that could be transmitted between payers and providers to uniquely identify a specific claim in each entity's system. For example, if the provider's control number is always unique and can readily identify a specific 837 claim for an individual patient account, then the provider can always find the claim for which an incoming transaction request is for. Likewise, if the payer's control number is always unique and can readily identify a specific claim for a specific patient, then the additional REF segments for Type of Bill, Dates of Service, Medical Record Number would not be needed. The payer already has an ICN/DCN number assigned and used in the 835 transaction. We recommend this number be used from payer perspective. If we could come to a unique number on both sides, we could truly standardize the identification of a specific claim by both entities and only that number would need to be returned to the receiver.	
42	Tech Spec - 275 and 277 v4050 IG	Pg 68 275 IG and Pg 71 277 IG		STC segment - Claim Level Status Information	We suspect the claim level STC segment in the 277 is "required" as a standard for the STC segment claim level in other 277 transactions. However, we question whether this segment should remain required when the data is being request at the service level. Can't the usage be changed to "situational" instead and only required when request information is being sent at the claim level? If this is only being used to identify which loop level it resides, we would already easily ascertain a service STC versus claim STC by SVC segment preceding the STC. If claim level, there is no SVC preceding the STC.	

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43	Tech Spec - 275 v4050 IG	Pg. 74		REF 2000A Procedure or Revenue Code	We recommend the same qualifiers in the 837 for Product/Service ID Qualifier be the same ones allowed in this REF for consistency in reporting and easy mapping.	
44	Tech Spec - 275 v4050 IG	Pg. 81		CAT Category of Patient Information Service	We request additional clarification to the IA qualifier usage comments that exist. Additionally, we request some usage guidance on CAT03 - Version Identifier. What does the version in CAT03 refer to and what are examples?	
45	Tech Spec - 275 v4050 IG	Pg. 83		EFI Electronic Format Identification	What is the purpose of this segment? There is mention of this segment in HL7 presentation materials to watch this segment for changes for possible future reporting of CDV versus HDV. Is this true?	
46	Tech Spec - 275 v4050 IG	Pg 84		Binary Data Elements	What are the standards or protocols for calculating the length of the binary data? What are the recommendations and rules on calculating the length?	
47a	Ambulance Service Attachment				We do not support the removal of the ambulance data in the 837P transaction set so that it is only supported in the 275 or 277 Ambulance Service Attachment transaction for these reasons: 1. By removing this data from the 837P, you potentially force all providers to send an ambulance attachment and the use of unsolicited 275s is still an industry question as to how it will be supported. 2. Payers would be forced to accept unsolicited ambulance attachments in order to adjudicate the claim.	We have already invested time, money, and resources in developing and supporting the ambulance data elements in an 837P claim.
47b	Ambulance Service Attachment			cont'd	3. Depending on when the ambulance data were to be stripped out of the 837 transaction set, there would be backward compatibility issues for the payer and could potentially increase the need for the provider to resend data already submitted to adjudicate the claim. Since the thought of migrating the data from the 837P to the 277/275 Ambulance Attachment in the future, in itself, causes implementation problems due to versioning (ie., the thought of changing the 837P data elements to NOT USED is not already in the v5010 for which the public comment period has already occurred. Thus, this would mean a release version several years out.) We recommend the 837P continue to maintain the necessary ambulance data elements and be billed using the 837P claim and/or enhanced as such in future version of 837P to include the small number of data elements excluded from 837P today.	

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48	HL7 Additional Information Specification IG	Pg 12		Multimedia Elements	From vendor perspective, allowing the use of an URL to point to where a specific attachment can be found is technically much more straightforward and easier to build and support. However, from a provider and payer perspective, it becomes difficult due to having the need for a central repository and various security and privacy issues.	
49	HL7 Additional Information Specification IG				We support use of the MIME packaging for the BIN segment and recognize it's value in terms of security, transmission speed and potentially reduced storage space.	
50	Tech Spec - 275 v4050 IG	Pg. 68		STC segment - Claim Level Status Information and BIN segment	Although discussed in various X12 and HL7 forums, the IG does not specify how to report or point to one image which contains the answers to multiple questions. This will become a very problematic implementation issue if the IG is not clear on how to handle this, as we would not want to send the image over and over again to answer each question individually (i.e., there should be a pointer or qualifier to respond to subsequent questions that the answer is in the image provided in the first or previous BIN segment.)	Specific guidance on this situation should be clearly specified in the IG to avoid interpretation and implementation issues.
51	Tech Spec - 275 v4050 IG			278	It has been stated in X12 and HL7 forums that there is currently work underway to use the same approach as the claims attachment to support the 278 request and response for preauthorization/precertification. If this is the case, how will this be rolled-out? What about the current 278 v4010 and proposed v5010 transactions sets? What kind of outreach is being done?	Concern expressed because of the time and money already invested in developing the v4010A1 of the 278 transaction and plans to continue further development using the corrections in the v5010.
52	Technical Comment			LOINC Codes	What is the maintenance process for new LOINC releases?	

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53	Technical Comment			Future Claims Attachment Development Efforts	What is the outreach and education plan for communicating ongoing work underway for additional attachments? HL7 has indicated that the following attachments are currently under development: 1. Home Health, 2. Periodontal Charts, 3. Medicaid Consent Forms, 4. Medicaid Children's Preventative Health Service (EPSTD Program), 5. DME, 6. EAP, 7. Pharmacy Prior Authorization. Up until now, there has been little communication and education about this work which certainly impacts our development plans and clients. We agree that building the initial infrastructure to support claims attachments in general will be a significant effort, commitment, and investment on our part; however, little communication and outreach has been done in the past. HL7 involvement in the past has been almost exclusively focused on interfaces and standard messaging; however, claims attachments is now a whole new area and does not typically utilize the same resources that have years of experience in the interface side of the business. Based on the nature of claims attachments, this moves from the "interface" knowledge base to those resources working with an understanding of the EDI transactions and patient accounting and clinical operations. So, whatever standard communication methods used by HL7 to date, have not reached the "right" stakeholders for this transaction.	
54	Technical Comment			Non XML Body Types	We support all of the non-XML body types detailed in the HL7 IG section 3.5.3.	
55	Technical Comment			CDV vs. HDV	We support HDV and CDV but strongly recommend HDV implementation comes first.	
56	NPRM Section 162.1910, A(2)	Pg 56024		Electronic health care claims attachment request transaction	In this section, "(2)" In advance of submission of the health care claim; or..." does not make sense. How can a 277 request for additional information be requested without an 837 claim already being sent from the provider? This certainly needs additional clarification and/or removed or noted that this is not even allowed based on the implementation of the claims attachment transaction sets.	
57	Technical Comment				We strongly recommend any implementation rules and guidance for MIME packaging, BIN segment issues, implementing XML namespaces without overlap, etc. be specified in the IG or Final Rule and not left for future SDO guidance papers or some other forum (including companion guides.)	

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58	NPRM II.C.5. – page 55997, column 1		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.”		We recommend that the HL7 PICU attachment, currently under development to provide a mechanism to send claims attachment information not in the six types proposed in this rule, also be included in the HIPAA attachments adopted or we suggest that some reference in the rule be made that this attachment is the defunct generic attachment standard used by trading partners for data not already included in the 6 attachment types under adoption. As a vendor, we would be hardpressed to support another attachment that is not part of the Final Rule.	
59	NPRM II, C, 1.	Pg 55995			We recommend that the XSL stylesheets supplied by HL7 be used as the standard stylesheets and that this not be optional as implied by the following text in the rule, "If covered entities choose not to use the HL7 supplied stylesheet, they will be able to create their own without significant problems, assuming the expertise exists on staff or is available through a vendor."	
60	NPRM Section 162.1920, (E)	Pg 56024		Electronic health care claims attachment response transaction	In this section, "(E) A health care provider may submit an unsolicited response transaction only upon advance instructions by a health plan."	AFEHCT

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61	NPRM, Section I.D.2 – page 55993, second column		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)...		Incorrect version is named. We agree with AFEHCT's recommendation to change both references to 4010-1a to be 4010A1.	

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62	NPRM Section II.C.2., page 55995		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.		We endorse and support AFEHCT's comments: 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 CDA R1 but are internal XML in CDA R2, the processing of the CDA would be different enough between R1 and R2 to require separate implementations. It is not a simple matter of upwards migration, such as when the HIPAA X12 standards were migrated with the Addenda; rather they are a completely different implementation. 1. Before CMS considers making a decision on whether to adopt CDA R1 or CDA R2, it is necessary that the industry conducts at least a proof of concept pilot implementation with several trading partners to determine the feasibility of implementing R2 for the six proposed standard attachments. Without a proof-of-concept pilot with positive outcome, CMS should not consider for adoption the CDA R2 as a standard. We also acknowledge HL7's recommendation to adopt the CDA R2.0 in the Final Rule. We would support this position if there is a proof of concept has been completed.	
63	NPRM Section II.C.2., page 55995			cont'd	Further, we do not want to expend resources to develop the 275 on release 1.0 and migration to release 2.0 occur mid-stream or immediately after initial implementation of release 1.0. This would prove very costly and problematic for us as a vendor and rollout to our clients. 2. Over the last few years all the Attachment work has been done under CDA R1. The adoption of CDA R2 could have some advantages over R1, but it would require new Implementation Guides for all the standard attachments, possibly delaying the adoption process by two or more years. Most importantly, uncertainty about which standard would cause all progress on Attachments to cease until this uncertainty is resolved. 3. CMS should adopt CDA R1 immediately and indicate it may consider CDA R2 for new attachments and future versions of the initial six attachments.	

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64	NPRM Section II.C.2., page 55995			cont'd	4. Any proof of concept pilot and development of new Implementation Guides under CDA R2 must be conducted using the HL7 and X12 standards setting processes so that the entire industry can participate in these developments. Only after the standard setting bodies recommend CDA R2 should CMS consider its adoption. CMS should not consider adoption of a standard that has not been recommended by the SDO when the standard recommended by the SDO, CDA R1, is available for use. 5. CMS should give a unambiguous, immediate indication of its adoption of the CDA R1 Implementation Guides as currently published so that the industry can get on with the work of implementing the attachments without uncertainty over which version will be adopted.	
65	"FORMAT OPTIONS" NPRM II.C.6 - pp 55997-55998		The whole section 6.		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. Additionally, we strongly recommend HDV for the initial implementation.	
66	"COMBINED USE OF DIFFERENT STANDARDS" NPRM II.C.7. p55998		[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."		Realizing that the X12 and HL7 standards are what is proposed for adoption, we see no problem with this approach and will build the infrastructure to support this approach as expected to be adopted in the Final Rule.	

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67	<p>"SOLICITED vs. UNSOLICITED ATTACHMENTS" NPRM II.D.2. pp 55999, 56024</p>		<p>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,</p>		<p>We support AFEHCT's comments that section §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.</p>	

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			<p>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.</p>			

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68	<p><u>"SOLICITED vs. UNSOLICITED ATTACHMENTS"</u> NPRM p55999</p>		<p>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</p>		<p>We support AFEHCT's recommendation to "Permit multiple requests provided that a later request is based on information obtained in an earlier attachment and is not duplicative of earlier attachments." 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.</p>	

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			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.			
69	"SOLICITED vs. UNSOLICITED ATTACHMENTS" NPRM II.D.4. p 56000		"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		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.	

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			transaction s."			
70	<p><u>"PROVIDER VS. PLAN PERSPECTIVE"</u> NPRM II.D.9. p56001, column 2.</p>		<p>"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."</p>		<p>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.</p>	
					<p>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.</p>	

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					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 are recommending a transaction-based certification model for all implementers in addition to a model where vendors or software are certified. 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 transaction-based certification of their solution(s)	
					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 two elements of certification that will lend significant assistance in implementation: (i) 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.	

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71	<p><u>“ATTACHMENT CONTENT AND STRUCTURE”</u> NPRM II.E. p56001</p>		<p>“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.</p>		<p>Up to 64 MB recommended maximum for the BIN segment is adequate for the attachments named in the rule. We support limits on transaction size and number of transactions in a batch or file should be specified in implementation guides not the rule.</p>	

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			Industry comment on file size is also welcome."			
72	"MODIFICATION TO STANDARDS AND NEW ATTACHMENTS" NPRM III.A. p56013			This whole section.	We support AFEHCT's full comment: "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."	
73	"COSTS AND BENEFITS" NPRM VI.B. pp56016 - 56021			The whole section	Based on initial projections, we expect the cost to develop and support the claims attachments standards will take several million dollars. This initial cost would be required to support the HDV approach to solicited and unsolicited claims attachments due to the significant variability and level of detail that would be necessary to build the infrastructure for identifying and mapping payer attachment needs for specific claims. Naturally, the payers medical review rules vary differently among payers. As a hospital information system vendor, it will require significant development on our part to build the systems necessary to map an attachment and/or LOINC code to a specific attachment (i.e., scanned image, etc.) Implementation of the CDV approach will be easier to develop in concert with the industry mandate, adoption, development, and reality of an Electronic Health Record.	
74	"EFFECTIVE DATES" NPRM pp55994, 56025		§ 162.1930 (a) Health care providers – 24 months after the effective		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 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.	

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			date (b) Health plans – 24 months after the effective date (c) Small health plans – 36 months after the effective date (d) Health care Clearinghouse uses – 24 months after effective date			
75	Technical Comment				The proposed rule does not address interoperability issues for interfaces between Clinical and Financial Systems of potentially different vendors. There are no guidelines or standardized way to suggest how to address this critical communication issue between vendor systems to successfully and timely produce a 275. We recommend some initiative be undertaken to come to industry consensus for intersystem interoperability. The industry should try to avoid silo approaches and/or implementation strategies and a shared approach needs to be identified to limit proprietary solutions and further complexities or complications for sharing the data needed for the 275 claims attachment.	
76	NPRM, 56000, II D-6				We echo the comment from HL7 that "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."	
77	NPRM, 56000, II D, 4				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.	

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78	NPRM, 55993, II, A				<p>We support HL7's recommendation that "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."</p> <p>We understand that HL7 and X12 have completed some work in the past to address the issue of data that "belongs in the claim" versus data that "belongs in the claims attachment." We also understand that they have developed some draft criteria to be used in determining where data should reside. As a vendor and active participant in the educational sessions and industry forums held this past year in soliciting feedback for the proposed rule comments, we have not had the opportunity to see the draft criteria that may exist. We recommend that the criteria be published and disseminated through various outreach efforts to ensure that all parties are aware of the proposed criteria and have an opportunity to participate in discussions or input on these changes since any migration work for this effort will certainly impact our current implementation of the 837 claim transaction and future development of the claims attachment transaction.</p>	
79	Technical Comment					

CMS-0050-P-101

Submitter : Ms. Carmen Hooker Odom

Date: 01/20/2006

Organization : North Carolina Dept. of Health and Human Services

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

See attachments

CMS-0050-P-101-Attach-1.PDF

CMS-0050-P-101-Attach-2.DOC



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Michael F. Easley, Governor

Carmen Hooker Odom, Secretary

January 20, 2006

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

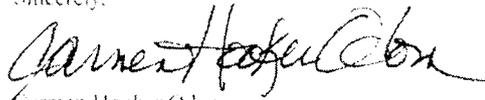
Re: 45 CFR Part 162, HIPAA Administrative Simplification: Standards for Electronic Health
Care Claims Attachments: Proposed Rule

To Whom It May Concern:

In response to the request for public comments on the proposed Standards for Electronic
Health Care Claims Attachments Rule, the North Carolina Department of Health and Human Services
(NC DHHS) would like to submit the enclosed comments for CMS-0050-P.

Thank you for your consideration in this matter.

Sincerely,



Carmen Hooker Odom

Enclosure *NC DHHS Comments on Claims Attachments NPRM*

cc: Dr. Allen Dobson, NC DHHS Assistant Secretary for Health Policy and Medical Assistance
Allyn Gaffey, NC DHHS Acting Assistant Secretary for Finance and Business Operations
Dan Stewart, NC DHHS Acting Assistant Secretary for Policy, Planning and Compliance
Floyd Jones, NC DHHS Division of Budget and Analysis
Karen Tomczak, NC DHHS Division of Information Resource Management



Comments for Claims Attachment NPRM: 45 CFR 162
NPRM Release Date: 09/23/2005
Comment Due Date: 01/23/2006

Commenting Organization: North Carolina Department of Health and Human Services (NC DHHS)
Date Comments Submitted: January 19, 2006
Contact Person Name: Mike Mason
Contact Person Telephone: 919.855.3138
Contact Person e-mail: Mike.Mason@ncmail.net

#	Document Number and ISSUE IDENTIFIER	Page #	Par/Fed Reg Column	LOINC (if appropriate)	Comment or Suggested Change	Business Justification
1	Federal Register	N/A	N/A		The final rule should make it clear that the Prior Authorization attachment is not included as part of this regulation, but that this claim attachment could be performed using a similar approach not governed by HIPAA.	
2	X12 275 (004050X151)	9	1.3.2		<p>NC DHHS recommends that the final rule adopt the 5010 versions of the X12 275 and 277 Implementation Guides for the following reasons:</p> <ol style="list-style-type: none"> 1) 5010 is the most recent version being developed at X12; 2) the 5010 275 supports the ability to send the 275 and 837 in separate interchanges for unsolicited attachments; 3) the 5010 275 supports the ability to identify the type of information being sent in the BIN via the CAT02 segment (CDV, HDV-image, HDV-text or non-CDA image); 4) the 5010 takes advantage of changes made as a result of the EMS pilot; and 5) 277 5010 corrects numerous errors from the 4050 version. <p>We support the movement to 5010 as long as it goes through the appropriate X12 public comment period, giving all parties the opportunity for input into the final product.</p>	Willing trading partners should be able to send the 275 separate from the 837 transaction for unsolicited attachments.

#	Document Number and ISSUE IDENTIFIER	Page #	Par/Fed Reg Column	LOINC (if appropriate)	Comment or Suggested Change	Business Justification
3	Federal Register CDA R1 vs. R2	55995	sii C2: col3		NC DHHS supports the adoption of Health Level Seven (HL7) Clinical Document Architecture (CDA) Release 2.	
4	Federal Register FORMAT OPTIONS	55997	sii C6: col 3		NC DHHS supports the concept of using both the human decision variant (HDV) and computer decision variant (CDV), thereby providing each entity with the option to choose which variant the entity will implement for each attachment type.	
5	Federal Register COMBINED USE OF DIFFERENT STANDARDS	55998	sii C7: col1		Combining two different standards into one transaction and how it can be done depends in part on how or whether vendors choose to develop software that will allow it. Our ability to meet this requirement relies on vendors supporting these standards.	
6	Federal Register	59999	sii D1: col 1		NC DHHS recommends that the regulation text include instruction on how the industry should implement standard attachments that have data content that overlaps claims transactions elements. The final rule should also provide information about a migration or roll-out plan for handling these data overlaps.	
7	Federal Register SOLICITED VS UNSOLICITED	55999	sii D2: col2		NC DHHS recommends that the rule be clarified to state that even though only one request for additional information can be made, that a health plan can request more than one piece of information on any given attachment.	

#	Document Number and ISSUE IDENTIFIER	Page #	Par/Fed Reg Column	LOINC (if appropriate)	Comment or Suggested Change	Business Justification
8	Federal Register SOLICITED VS UNSOLICITED	55999	sii D2: col2		If a claim is denied because the additional information sent (solicited or unsolicited) was not adequate to justify payment of the claim, can the health plan request more information? NC DHHS recommends that a health plan be able to set their own policy regarding the number of requests it will make for additional information needed to adjudicate a claim after the initial set of attachment data is received.	We understand the purpose for only allowing a single iteration for the request and response is to stop providers and health plans from piecemealing the attachment information; however, if the data sent with the original response is not adequate to adjudicate the claim or prompts additional questions, this should not prohibit the health plan from asking for more information.
9	Federal Register SOLICITED VS UNSOLICITED ATTACHMENTS	55999	sii D2: col1		NC DHHS supports the need for both unsolicited and solicited claims attachment models; both models should be allowed.	
10	Federal Register COB	55999	sii D3: col3		NC DHHS recommends that the primary payer should not be allowed to forward attachment information to a secondary payer when the payer -to-payer coordination of benefits (COB) model is used.	The needs of the secondary payer may be different than that of the primary payer.
11	Federal Register BUSINESS USE	56000	sii D4: col1		Can a health care payer request that the provider submit any named attachment supporting the provision of and payment for another medical service? Can the payer request multiple attachments? If so, please clarify this in the final rule.	Examples: the physical therapy and occupational therapy rehabilitation attachments could be necessary for processing a power wheelchair claim; the laboratory results attachment might be needed for an enteral nutrition claim.

#	Document Number and ISSUE IDENTIFIER	Page #	Par/Fed Reg Column	LOINC (if appropriate)	Comment or Suggested Change	Business Justification
12	Federal Register SIGNATURES	56000	sii D6: col3		There are currently attachments in development at HL7 that require signatures; therefore, an appropriate way to capture these signatures must be accommodated within the standard. In addition, NC DHHS requests clarification from the Centers of Medicare and Medicaid Services (CMS) whether allowance of an image of the "wet" signature within an electronic claims attachment would satisfy the federal regulatory requirement that Medicaid agencies obtain certain signatures for consent forms. Currently, Medicaid agencies must require these attachments via paper to obtain the federally mandated signature.	
13	Federal Register PROVIDER VS PLAN PERSPECTIVE	56001	sii D8: col1		<p>NC DHHS requests clarification on the following statement in the preamble: "a health care provider may direct a health plan to send any request for additional documentation in standard form and the health plan must do so."</p> <p>If the health plan does not currently request additional information but instead requires that the additional information needed to adjudicate the claim be submitted at the same time as the initial claim (i.e., unsolicited), does this rule require that a health plan implement a process to request additional information if the provider requests that the health plan do so?</p>	If yes, this would require that a health plan enter into a business process they have not performed.
14	Federal Register ATTACHMENT CONTENT AND STRUCTURE	56001	sii E: col3, par3		The existing file size should be fine in most cases, but there must be a way to either send a larger file for exceptions or to link multiple attachments together if there is a need for more than 64 megabytes of data. There also needs to be a way within the transaction to alert the receiver when a file larger than 64 megabytes will be sent prior to the transmission of the file.	There must be a way to send more than 64 megabytes if necessary. What do you do if you find that the transaction is larger than 64 megabytes? The health plan should have a way to handle from the beginning the initial claims filing rather than try to figure out when the situation occurs.
15	Federal Register PROPOSED STANDARDS	56004	sii G1: col2		NC DHHS requests clarification concerning the process and frequency for updating the LOINC codes.	

#	Document Number and ISSUE IDENTIFIER	Page #	Par/Fed Reg Column	LOINC (if appropriate)	Comment or Suggested Change	Business Justification
16	Federal Register PROPOSED STANDARDS	56006	sii G3: col2		<p>NC DHHS encourages the completion and adoption of the following attachment types as quickly as possible:</p> <p>Children's Preventive Health Services, Durable Medical Equipment, Consent Forms (Abortion, Hysterectomy and Sterilization), and Non-Ambulance Transportation.</p> <p>NC DHHS also recommends that the Patient Information Unspecified Content attachment be named for optional use.</p>	
17	Federal Register COSTS AND BENEFITS	56018	svi B3: col1 and col3		<p>At this time, NC DHHS does not have the resources and time to conduct the cost benefit analysis necessary to quantify projected savings from the conversion to electronic claims attachments under this model. In addition, NC DHHS has not done a comprehensive assessment to determine both technical and operational implementation impacts/costs.</p>	
18	Federal Register REG TEXT - DEFINITIONS	56023	162.1900		<p>The final rule should clarify the differences between the form-based and the non-form based Additional Information Specification (AIS). The Clinical Reports AIS only references a subset of the available LOINC's for Clinical Reports. The entire list of available LOINC's for Clinical Reports can be obtained from the LOINC database. In addition, the LOINC's available for the Laboratory Results AIS can be found on the LOINC database. For all other AIS documents, the LOINC values in the document are the only ones available for use. These are the form-based documents and this should be fully explained in the final rule.</p>	
19	Federal Register REG TEXT	56024	162.1915 and 1925		<p>NC DHHS supports the proposed combined solution to use both the X12 and HL7 standards for electronic claims attachments. In addition, NC DHHS supports the use of LOINC's to identify the questions and answers on the attachment.</p>	

#	Document Number and ISSUE IDENTIFIER	Page #	Par/Fed Reg Column	LOINC (if appropriate)	Comment or Suggested Change	Business Justification
20	Federal Register REG TEXT	56024	162.1905		NC DHHS is requesting a clarification in the final rule stating that covered entities must only support these standard transactions for electronic claims attachments if they currently conduct the business function of using claims attachments.	
21	Federal Register EFFECTIVE DATES	55994	sii B: col2, par1		<p>"Covered entities must comply with the standards for electronic health care claims attachments 24 months from the effective date of the final rule unless they are small health plans. Small health plans will have 36 months from the effective date of the final rule to come into compliance."</p> <p>24 months is not enough time to bring on line a new version of transactions. NC DHHS may require the implementation of a new translator in addition to system modifications. NC DHHS is requesting that the implementation effective date be extended to 36 and 48 months, respectively, after the effective date of the final rule. However, willing trading partners should be allowed to implement at a mutually agreed upon time if both parties are ready in advance of the implementation effective date.</p>	NC DHHS is currently working on the implementation of a new multi-payer system (MMIS) to support Medicaid and other departmental programs. To reduce risk to the current implementation effort and to implement the claims attachments effectively, NC would require an additional 12 months, thereby resulting in an implementation date of 36 months following the effective date of the final rule.

End of Document

CMS-0050-P-102

Submitter : Mr. Donald Bechtel
Organization : Siemens Medical Solutions, USA
Category : Health Care Industry

Date: 01/20/2006

Issue Areas/Comments

GENERAL

GENERAL

See attached.

CMS-0050-P-102-Attach-1.PDF

SIEMENS Medical Solutions, USA

January 16, 2006

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Department of Health and Human Services
CMS-0050-P NPRM (45 CFR Part 162)

Siemens Comments to HHS on the Proposed Standards for Electronic Health Care Claims Attachments Issued on September 23, 2005

Siemens Medical Solutions Health Services (Siemens) is please to offer the following comments to Centers of Medicare and Medicaid Services of the Department of Health and Human Services concerning the above named NPRM (Notice of Proposed Rule Making). Siemens is a vendor of a wide variety of provider-sided products and services, and also operates a healthcare EDI clearinghouse, namely Healthcare Data Exchange, LLC (HDX).

As the person coordinating Siemens comments for this response, I (Don Bechtel) would also like to disclose that I participate in several industry organizations that have contributed to the development, testing, and evaluation of these proposed standards. Some of our responses reflect my knowledge or understanding of Claims Attachments as learned from these organizations. Specifically, my involvement includes:

- Co-chair X12 N TG2 Healthcare Task Group
- Co-chair WEDI SNIP Transactions Work Group
- Member of WEDI Claims Attachment Pilot Advisory Group
- Past Chair AFEHCT and Facilitator for their Claims Attachment NPRM Response
- AFEHCT Facilitator for Claims Attachment Vendor Forums, a joint effort between HL7, X12, WEDI, AFEHCT, and HIMSS.

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 description 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: Siemens 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.
- Changes are made to the Final Draft, which is then reviewed and approved by Implementation Guide Task Group (X12N TG4).
- The revised TR3 is presented to the entire Healthcare Task Group (X12N 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 J Technical Assessment Subcommittee (TAS), which requires a majority vote of its members. TAS reviews TR3 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 than 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.

We recommend identifying that more than a web-browser will be required for a minimal configuration necessary to process the human decision variant (HDV) claim attachment transactions. Such things as, depending on the facility, an EDI tool to assemble and disassemble EDI transactions, a document scanner or a document imaging system, software to integrate the document with the EDI transaction, etc.. Granted many of these items will already be present for an entity that is already processing other HIPAA transactions, but these are still needed components to process claims attachments.

4. Use of CDA Release 1.0 versus 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: CDA Release 1 is ready now, to move to release 2 may require additional time to develop and test (validate) the needed implementation guide(s). However, release 2 will bring significant improvements to those who want to implement the computer decision variant. And, version 2 will support all the current functions found in release 1.

Recommendation: Siemens would support moving to CDA Release 2, but this decision requires 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. On the other hand, except for the demonstration projects, many stakeholders 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. However, these tests are not using the R2 Implementation Guide from HL7, as this is not yet written, so the test implementation may vary from what is defined by HL7.

4. **R2 Implementation Guides are needed 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 is working toward completing 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.

CMS Should Let Industry Know Immediately their Choice is R2, if that is the decision. 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. What is the impact on servers and storage

Reference:

"ELECTRONIC CLAIMS ATTACHMENT TYPES" NPRM I.I.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 could be a significant issue for clearinghouses. Must a clearinghouse keep claim attachment data or should clearinghouses specifically not keep this kind of information? Would there be situations when a clearinghouse should and when it shouldn't keep this data? This is a critical question to resolve as it would have a significant impact on servers and data storage requirements.

Recommendation:

We recommend that Clearinghouses not be required to retain attachment data beyond their business requirements as defined by their Trading Partner and Business Agreements. Clearinghouses should not be required to be archival repositories.

6. Health plans should be required to accept both HDV and CDV Attachments

Reference:

"FORMAT OPTIONS" NPRM I.I.C.6 - pp 55997-55998

Citation:

All of 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

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automated and not support attachments such as scanned documents?
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.

7. 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: We support this approach of using X12 and HL7, and feel it is the right solution.

8. Modify prohibition against sending claim attachments without health plan instruction

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: Siemens 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.

9. 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.

10. How to apply "minimum necessary" standard to claim 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.

11. Method for signatures on claim 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?

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. For the use of signatures to be required, the implementation guides would need to be modified.

Although the attachments don't require an electronic signature, if one were included with an attachment, it should not be reason for denying

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the claim. For example, when a "wet signature" is included in a PDF file. In another case where a provider has a robust implementation of CDA documents for non-HIPAA purposes, these CDA document instances may already be stored in the provider's archive with some kind of digital signature, as the CDA standard allows. While none of the existing attachments explicitly require a signature, the fulfillment of an attachment request might be to send one of these previously archived document instances containing the signature – and in this case, the payer should accept the attachment if other content in the attachment fulfills the request.

12. Should clearinghouses comply first?

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: We do not believe this would be the best recommendation as proposed and offer the following alternative recommendation.

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.

Siemens 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-

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based certification, the transaction capabilities of health plans, clearinghouses, and providers are each certified. Therefore, we recommend 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 suggest EHNAC is an organization that can write certification requirements, certify testing, and conduct vendor certification. 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 (iii) transaction standard requirements.

Lastly, Siemens agrees that a 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 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 used 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.

13. Maximum size of a claim attachment standard

Reference:

“ATTACHMENT CONTENT AND STRUCTURE” NPRM I.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:

First, the information about the BIN as stated in this citation implies

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that the 64MB size is per transaction, not per BIN segment, however multiple BIN segments can be sent inside an X12 275-transaction. Second, is the size adequate for a single BIN segment?

Recommendation: First, the above citation should be corrected to state: "The Implementation Guide for the X12 275 response transaction permits up to 64 MB of data in a single BIN segment."

Second, the up to 64 MB recommended maximum for the BIN segment is adequate for the attachments named in the rule. Siemens believes the current limit on transaction size and number of transactions in a batch or file should be specified in implementation guides not the rule. That said, the current size is only a recommendation not a limit. Therefore, willing trading partners could send larger sizes without violating the standard. We believe that in most situations, the 64 MB size will be adequate. As new attachment types are added, this recommendation can be revisited at those times.

14. 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. Siemens recommends an 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 and new attachment types without additional 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.

With respect to LOINC Codes, the addition process should be once per year, perhaps on a different cycle from other code sets.

15. Cost benefit analysis

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

Citation: The whole section

Issue: Can we anticipate the cost and benefit to develop the software to support this requirement and determine the benefit to our customers to know

whether they will chose to use our solution or something else? Will there be sufficient benefit to the provider to use this? We believe their will be benefits that our provider customers will want to utilize, but at this time we're unclear about ROI expectations.

Our comment:

Siemens expects that the development costs for this solution will be extensive. Some products may use only the Human Decision Variant, while others will support the Computer Decision Variant. Interfaces between the financial systems and the clinical systems that store and maintain the data needed for claims attachments will require the most effort. Interfaces between the Financial and Clinical systems will not always be between systems from the same vendors, in fact, most customers have multiple vendors. Hence, interfacing requirements will vary as there is no standard defined for how these interfaces will be implemented. This will cause delays in implementation until the interfaces are defined by each of the vendors. There are countless "work-flow" issues that will need to be analyzed and developed. When considering our cost, we must also include the cost of rolling out new software, installation support, testing support, education requirements, and documentation. We believe our cost to develop support for claims attachments will be far more significant and complicated than what we experienced for HIPAA claims transactions. We can not put a number on development costs, but our HIPAA development costs were in the millions. Nor can we at this time predict what the cost will be to our customers. Based on what a customer may currently have installed, some functions or features may fall into stream-of-enhancements, while others may result in new functions or products that our customers may need to acquire.

16. 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:

Siemens 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 development investment is prudent, but (ii) that the effective date of the final rule be 1½ years after its publication of the final rule, in that way allowing a total of 3½ years. We propose the additional time in acknowledgment

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January 16, 2006

of the significant development work required.

This completes our comments, thank you for considering them.

Donald Bechtel
Siemens Medical Solutions Health Services
Foundation Enterprise Systems
Standards and Regulations Manager

CMS-0050-P-103

Submitter : Mr. David Moertel

Organization : Mayo Clinic

Category : Physician

Date: 01/20/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-0050-P-103-Attach-1.DOC

Mayo Clinic
200 1st Street SW
Rochester, MN 55905

January 4, 2006

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

We appreciate the opportunity to comment on the Proposed Rule of September 23, 2005, regarding the Standards for Electronic Health Care Claims Attachments.

We strongly support the use of electronic claims attachments as another step towards the goal of reducing health care administrative costs.

The detailed comments enclosed with this letter are largely based on our experience with a pilot project we have participated in with one of our Medicare carriers. While the pilot is not yet complete, we would like to highlight the preliminary results and general comments here.

The pilot has given us some practical experience with implementation, which will be very complex for providers. Providers face a significant technological challenge in electronically collecting the information that is needed for each transaction type. In some cases, the necessary information will reside in multiple source systems and pathways to collect it will need to be developed. Due to this complexity, we agree that a staged implementation is necessary and we would support a national roll-out strategy developed by the Work Group for Electronic Data Interchange (WEDI).

The pilot is using CDA R2 and we recommend that the transaction standard include CDA R2. Our detailed comments include a technical discussion of this subject.

The pilot has confirmed our initial thoughts and reaffirmed our experience with the implementation of other transactions. The implementation of an effective electronic transaction must be done collaboratively, with extensive negotiation and communication between trading partners. Through our collaboration with the carrier, we have determined that the unsolicited claims attachment is most efficient for both parties, as it avoids unnecessary rework. Our detailed comments express our view that providers be allowed to submit unsolicited attachments following mutual agreement between the payer and the provider.

We thank you for the opportunity to provide comment on this proposed rule. If there are any subjects you wish to discuss further, you may contact Laura Darst at 507-266-3054, Calvin Beebe at 507-284-3827, or Lynette Beck at 507-284-1935.

Very truly yours,

Dr. Nina M. Schwenk
Chair, Mayo Clinic Information Technology Committee
Mayo Clinic

Abdul Bengali
Chair, Department of Information Technology
Secretary, Mayo Clinic Information Technology Committee
Mayo Clinic

Enclosure: Electronic Claims Attachments – Detailed Comments on Proposed Rule

Mayo Clinic

Standards for Electronic Health Care Claims Attachments Detailed Comments on the Proposed Rule

C. OVERVIEW OF KEY INFORMATION FOR ELECTRONIC HEALTH CARE CLAIMS ATTACHMENTS

2. OVERVIEW OF CLINICAL DOCUMENT ARCHITECTURE

Mayo Clinic recommends moving to CDA Release 2 (CDA R2), assuming that a number of technical issues related to such a migration can be resolved in a timely manner. Mayo has participated extensively in Health Level Seven (HL7), an ANSI Standards Development Organization (SDO), and sees great potential benefits in adoption of CDA Release 2.0.

The benefits of using CDA R2 are:

1. CDA Release 2.0, like CDA Release 1.0 (CDA R1) identifies markup which can be used to simply specify a clinical document for human readability. Specification of CDA R2, coupled with the "human-decision variant" called for in the proposed rule, will allow for early adoption at Mayo and likely across a wide spectrum of Electronic Medical Records Systems (EMR Systems) used within the United States.
2. Movement to CDA R2 will enable the limited resources available within the industry to be focused on one set of education programs and training for implementers and software vendors. Currently, HL7, a mostly volunteer organization working only on health care standards, has limited time and resources (tutorial slots) at its disposal to allocate to training and promoting health care standards. Specifying an essentially obsolete standard, CDA R1, as the basis of the claims attachment transaction standard will stretch HL7's ability to match its resources to the needs of the industry.
3. One of the challenges of adopting the "computer-decision variant" called for in the proposed rule, is the extensive use of non-standard tags (local markup) required when using CDA R1 as the basis of the attachments markup. CDA R2 has been extended to alleviate the need for this local markup, which is used extensively in modeling discrete clinical data within the attachments.

Note: Some of the encoding rules specified in CDA R1, specifically Data Types, were published prior to formal adoption within HL7. As an example,

the specification of Date & Time (DT) within the ruling is inconsistent with all other standards at HL7. Adoption of CDA R2 would remove this inconsistency.

4. CDA R2, just like CDA R1, supports human readability. The significant improvements incorporated into CDA R2 are actually focused on the modeling of discrete clinical information called entries, which can be optionally included in CDA R2 documents. Migrating to CDA R2 would ensure that the "computer-decision variant," as discussed in the proposed rule, is consistent with expected adoption of CDA R2 by the rest of the health care industry. As clinical systems serve as the head waters to these downstream business activities, one standard across all activities within a health care business is an essential requirement.

Technical issues that need to be resolved in a timely manner:

In general, movement to CDA R2 will require that decisions be made on a number of very technical questions. As best possible, we have attempted to outline some of the issues here. Where possible, we will recommend one or more options that may need to be considered in resolving the issue. We fully expect that these issues will be discussed and resolved in upcoming joint meetings between Structured Documents Technical Committee and Attachments Special Interest Group.

1. Proper encoding of the Attachment Control Number within CDA R2

This is a detail that needs to be agreed upon, rather than a significant issue. The Attachment Control Number (ACN) is currently specified in CDA R1 using local header and local attributes. The current CDA R2, being based on W3C Schema and not DTD as was CDA R1, calls for the use of a locally defined namespace for all locally defined tags and attributes. We need to define the local namespace and specify the markup to be used. This should pose no difficulty and is simply a detail.

(Ref: HL7 Additional Information Specification Implementation Guide, Page: 30, Section: 3.4.2)

2. Management of Provider references within CDA R2.

Current guidance within the specification makes it difficult to know how to model for the "computer-decision variant" references for provider entries commonly found in Attachment Components within various attachment specifications. The problem is one of modeling this within CDA R2. Proper modeling is central to ensuring that the intended meaning is conveyed accurately between parties. CDA R2 allows essentially any textual content desired to be placed within

section text elements. Technically, for the “human-decision variant,” there is nothing at issue with allowing provider and provider identifiers to be presented as text within given sections of an attachment document.

The issue is in the specification of the “computer-decision variant” modeling of these references. CDA R2 prescribes parse-able provider references within a fixed set of elements. In general, a provider reference is supported within a root element of the context that it spans. In general, this means that a number of provider identifiers and names called for within given Attachment Component Answer Parts should actually be encoded within the header of the CDA R2 documents. While we are not advocating that all provider identifiers and names be placed in the header, we recognize that most will need to be placed there to be CDA R2 compliant.

With this issue, comes the question of how will we ensure that the “computer-decision variant” provider references stored within the CDA R2 header be presented. Given our current experience with CDA R1 and CDA R2, we believe that this issue can potentially be resolved via a sample XSLT stylesheet being provided which styles all provider references stored in the header and presents them in a standardized and consistent manner. We have every confidence that this can be easily provided.

We would recommend that the specification be revised to indicate that these provider references must be present with the CDA R2 header as appropriate for the “computer decision variant” and remove the requirement that they be specified within the sections of the document.

We would also suggest that all provider references available and shared, be modeled in the header for both “computer-decision variant” and for “human-decision variant.” This will ensure that there will be a single stylesheet can be used for rendering all CDA R2 structured documents.

(Ref: HL7 Additional Information Specification Implementation Guide, Page: 30, Section: 3.4.1 Item: 3)

3. Proper modeling of Attachment Components and Attachment Component Answer Parts within the CDA R2 document

Here we are talking about attachment documents which are in the form of the “computer-decision variant.” This is where the greatest challenge will exist in moving from CDA R1 to CDA R2 modeling.

Some of the issues that need to be resolved are:

3.1. Usage of LOINC codes to define Attachment Components

The HL7 Structured Documents Technical Committee is currently struggling with the question of which LOINC codes should be used within a CDA document to identify sections. Given that CDA R2 now separates the machine processable entries away from the narrative text, we are inclined to use only LOINC – Narrative (NAR) codes for section codes and other codes like, Nominal (NOM) for entries.

Unfortunately, the attachment guide predated this understanding and used a mixture of both types of codes. In general, we would like to revise the codes called for to be consistent with the intent to CDA R2 to manage narrative content and machine processable entries separately.

We would recommend that all LOINC NOM codes specified for narrative text be revised to LOINC NAR codes.

3.2. Mapping Attachment Answer Parts into CDA R2 entry classes

Inherent in migration from CDA R1 to CDA R2 will be the mapping from the extensively used local markup elements in the current attachment specifications to the new CDA R2 entries. The new entries defined in CDA R2 support a number of sub-elements that should map to at least one and possibly more than one Answer Part currently called for in a given attachment specification. Some of the new entries defined are:

- Observation
- Procedure
- Encounter
- Substance Administration
- Supply
- Act and some others...

We will need to review each attachment to determine what entry classes will be required and revise the attachment specifications to reference those entry classes and identified required sub-elements that must be included.

3.3. Encoding strategies for Attachment Answer Parts into CDA R2

One of the potentially challenging issues likely to be faced in moving from CDA R1 to CDA R2 will be the question of switching coding systems for CDA R2 entries. The modeling defined within CDA R2 is rather flexible in that it supports complex constructions where entries can express relationships with other entries and form parse-able or machine processable statements.

However, to take full advantage of this capability, conventions need to be established and best practices followed in the construction of these statements so receivers can parse and understand the intended meaning. Current thinking in this area is inclined towards the avoidance of highly pre-coordinated encodings so that elegant parsing algorithms can process and correlate clinical findings from multiple sources and determine their clinical significance via access to poly-hierarchical coding systems (like SNOMED).

There is another pragmatic approach, which calls for assigning an arbitrary code for each question that appears in an attachment and associating those codes with values or entries contained. This approach utilizes highly pre-coordinated LOINC codes to identify questions and answers, but not define them.

Recommendation:

Mayo encourages HHS to continue to specify LOINC codes for questions defined within attachment specifications. This is a pragmatic approach made in the context of this use case and in no way discourages or criticizes the efforts made to establish semantic interoperability of clinical content in other implementations. It really is about supporting the requirements expressed within the NPRM to provide essentially specific answers to rather specific questions. In order to accelerate the adoption for billing review processing, we would suggest that it is best to keep it simple.

C.5. ELECTRONIC CLAIMS ATTACHMENT TYPES

We support the staged implementation of electronic claims attachments and the specific attachment types identified in the Proposed Rule. In addition to the six identified, there are three additional attachment types that we believe should be developed and included in the final rule to further administrative simplification efforts. The three additional types are described below and represent the three we feel are most important.

Durable Medical Equipment (DME): Medicare requires the submission of a certificate of medical necessity (CMN) for most DME items billed. This high-volume area of billing would receive significant benefit from the DME claim attachment type as an unsolicited request.

Miscellaneous procedure code descriptions: Most payers require a narrative description of the items or services billed with miscellaneous ("99") CPT/HCPCS codes. With the rapid pace of change in medical care, we believe that use of miscellaneous codes will increase. The addition of a reference file claim attachment type would improve the payment cycle for new items or services that have not yet been assigned a unique CPT/HCPCS code.

Invoices: Some payers, especially government payers, require providers to submit vendor invoices to support the billing for certain services or items. These are currently submitted on paper, with the subsequent effort by the payer to match the electronic claim with the paper.

We concur with the intent of HHS to limit the use of the claims attachment transaction for supplemental information only and not for information that could be provided in the claim transaction itself.

We note that there is currently overlap between certain data in some of the AIS and the 4010-837. Data that can currently be provided in the claim should remain in the claim and not be required as an attachment. If such data were to be removed from the claim and assigned to a claim attachment type, providers unable to implement electronic claim attachments would not have a way to electronically communicate the data in question.

In addition, we recommend that the final rule include wording that would prohibit payers from requiring information in an attachment that could be provided in the claim transaction.

C. 6 FORMAT OPTIONS

We agree that the final rule should adopt both the Computer Decision Variant (CDV) and Human Decision Variant (HDV) for electronic claims attachments.

C. 7 COMBINED USE OF DIFFERENT STANDARDS

We agree with the proposal to use the X12 and HL7 standards for claims attachments, including the use of LOINC codes as the code set to identify the questions.

D. ELECTRONIC HEALTH CARE CLAIMS ATTACHMENT BUSINESS USE

We request that a definition of “post-adjudication” be added to the Final Rule. Our interpretation of this section is that a payer and provider, through mutual agreement, could use the electronic claims attachment for purposes other than claims adjudication. We support this use of the transaction. Our request for a definition of “post adjudication” is to receive HHS affirmation that trading partners could agree to use the claim attachment for these other purposes. Without the definition, it is possible that some payers could interpret this section to be an endorsement of the claims processing model referred to as Model 2 in our comments to the section, **EXAMPLES OF HOW ELECTRONIC HEALTH CARE CLAIMS ATTACHMENTS COULD BE IMPLEMENTED.**

D. 2 SOLICITED vs. UNSOLICITED ATTACHMENTS

We strongly agree with the proposal that providers be allowed to submit unsolicited attachments, when there is a mutual agreement between the payer and provider about the circumstances under which a claim attachment is needed. The unsolicited attachment model is the most efficient model in that it allows the provider to submit all necessary information at the time of initial claim submission (although it may be in multiple transactions). This eliminates the re-work and unnecessary delays inherent in the solicited attachment model.

The language in the proposed rule, “when a health plan has given them specific advance instructions,” is of concern because it suggests unilateral decision-making by the health plan regarding what claim attachments may be used and under what circumstances. We believe that a far more effective approach would include negotiation and agreement between the payer and the provider regarding claims attachments. In addition, we note that the unilateral approach differs from previous administrative simplification rules that begin the exchange of electronic transactions at the request of the provider.

Lastly, we want to comment on the proposed limitation to the “request-response” cycle. While we appreciate the concept of the payer requesting all necessary information in one transaction and the provider responding to the entire request in one transaction, this concept does not fit with the current business practices of either party. There are occasions where a response will generate a subsequent question. There will also be occasions where a provider is unable to provide all responses in one transaction. For example, it may not be technologically feasible

for a provider to combine (into one transaction) responses that require the manual scanning of a document and an extraction from an electronic medical record.

D. ELECTRONIC HEALTH CARE CLAIMS ATTACHMENT BUSINESS USE

3. COORDINATION OF BENEFITS

We concur that the secondary health plan should request its own attachments in a separate transaction sent directly to the provider.

D. ELECTRONIC HEALTH CARE CLAIMS ATTACHMENT BUSINESS USE

6. CONNECTION TO SIGNATURES

We propose 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. Our rationale is as follows:

We concur that there is no interoperable standard for electronic signatures. The term electronic signature is broadly understood to include a variety of technical approaches that vary in technological complexity and forensic accountability. Some representative technological approaches include:

- (a) simply transmitting a data field that indicates that the sender has a "wet" signature on file
- (b) simply transmitting a data field that indicates that an authenticated user of an electronic has performed an overt act that would serve as a "signing ceremony"
- (c) transmitting an image of a document, or a portion thereof, that includes a wet signature
- (d) strongly authenticating a computer user and using digital signature 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 health care 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 and 2 are only defined for case (b) above, and only describes the signature of the author of the CDA document.

It is important that the standard 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. For consent forms, it is unlikely that the person providing the signature will usually be an authenticated user of a health care provider's electronic system, much less a strongly authenticated user.

As noted in the Proposed Rule, there is no current standard for electronic signatures, we, therefore, propose 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

E. **ATTACHMENT CONTENT AND STRUCTURE**

We believe that the final regulation should allow the ability to send solicited and unsolicited attachments separately from the 837 claim transactions.

From a technical perspective, it should not be required that the attachment be bundled in the same interchange or transmission file (ISA/IEA). This will allow flexibility on the part of the provider who may be retrieving information from multiple sources.

G. **PROPOSED STANDARDS**

4. EXAMPLES OF HOW ELECTRONIC HEALTH CARE CLAIMS ATTACHMENTS COULD BE IMPLEMENTED

From the provider's perspective, there are essentially two claims adjudication models used by health plans. In one model, the electronic claims attachment transaction has the potential to significantly improve the billing cycle and support provider initiatives to improve consumer satisfaction and reduce administrative costs. In the other model, the benefits resulting from the transaction will be less significant and will take longer to realize.

Model 1 uses claims attachments to collect information needed to accurately adjudicate the claim. In this model, the payer analyzes the claim, requests the

necessary, additional (non-claim) information, and, upon receipt, adjudicates the claim.

Model 2 uses the remittance process to notify the patient and provider that the information on the claim was insufficient to adjudicate the claim. In this model, the payer analyzes the claim and denies it when additional information is needed. At the point of denial, the provider may begin taking action, or, the patient may need to request that the provider take action. Typical actions include contacting the payer to determine what additional information is needed, preparing a new claim with the necessary attachment(s), and re-submission to the payer for analysis and adjudication.

Model 2 is laden with inefficiency and rework for the providers. It also causes a great deal of patient dissatisfaction. The prevalence of this model is one of the reasons we believe it is critical for cooperatively developed, unsolicited claims attachments to be allowed by the final rule. The unsolicited claim attachment will provide the opportunity to minimize the effects of Model 2. In those cases where an unsolicited attachment is not feasible, the use of the solicited attachment in Model 1 is still more efficient than Model 2.

Model 2 also has a direct impact on the patient whose claim is being adjudicated. Any claim denial, including denials due to insufficient information, typically results in communication from the payer to the patient that he/she is now financially responsible for the entire amount of the claim. The unintended effect of Model 2 is creation of unnecessary stress and hardship for vulnerable individuals, solely for the purpose of accommodating payer administrative processes.

H. REQUIREMENTS (HEALTH PLANS, COVERED HEALTH CARE PROVIDERS AND HEALTH CARE CLEARINGHOUSES)

We suggest a wording change to the second paragraph in this section:

“The use of the standard electronic health care claims attachments would not preclude the health plan from using other processes or procedures to clarify attachment documentation.”

We believe that the intent of this section is to note that implementation of the claims attachment standard should not prohibit a health plan from requesting additional information through other non-electronic processes. The wording in the proposed rule, “...verify attachment documentation,” is of concern because it suggests that a health plan could request paper documentation to verify the accuracy of information submitted electronically, i.e. request a paper version of what was provided electronically. We think “clarify” is more in keeping with the

health plan need that arises when additional questions are generated by the first request-response cycle.

III. MODIFICATIONS TO STANDARDS AND NEW ELECTRONIC ATTACHMENTS

We request that HHS identify alternatives to the current rulemaking process that will be used for establishing new claims attachment types. Rather than establishing a new process for this purpose, we recommend the Data Standards Maintenance Organizations (DSMOs) or other organizations such as the Healthcare Informatics Technology Standards Panel (HITSP) be authorized to adopt those attachment types that are developed, balloted and published by HL7 through the DSMO process.

The current regulatory process involving a proposed rule, comment period, and final rule takes too long to complete. We believe that after the standards development organizations (SDOs), payers and providers reach a certain level of proficiency with electronic claims attachments, implementation of new types should be relatively simple. Thus, the industry should work towards a state where new claims attachment types are implemented closer to the time that the need is identified, without the delays inherent in the current process.

This concludes Mayo Clinic's comments on the Notice of Proposed Rulemaking regarding the Standards for Electronic Health Care Claims Attachments published in the Federal Register on September 23, 2005.

CMS-0050-P-104

Submitter : Pamela Greenberg
Organization : American Managed Behavioral Healthcare Association
Category : Health Care Professional or Association

Date: 01/20/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-0050-P-104-Attach-1.DOC

A M B H A
A M E R I C A N M A N A G E D B E H A V I O R A L
H E A L T H C A R E A S S O C I A T I O N

January 20, 2006

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

To Whom It May Concern:

The American Managed Behavioral Healthcare Association (AMBHA) is pleased to submit this letter commenting on the proposed rule for electronic health care claims attachments. AMBHA represents the nation's leading specialty behavioral health companies that provide coverage for mental health, substance use and behavioral management services to over 110 million people.

The greatest need that AMBHA members have regarding claims attachments is the need for an Employee Assistance Program (EAP) claims attachment. We have initiated dialogue with the HL7 about this need and hope to successfully work with the HL7 in 2006 to obtain an EAP claims attachment. The current attachments do not have provisions for information needed to adjudicate reimbursement requests for Employee Assistance Program services.

AMBHA supports HL7 and X12's comment that the DSMO be authorized to adopt new attachment types (included EAP) that are developed, balloted and published by the HL7 through the DSMO process. The process should be stopped here and not have to go through the full regulatory process. The HL7 has an extensive outreach and comment period and this will help move the regulatory process forward more quickly.

In addition, AMBHA would like to make some general statements about the impact of the proposed rule.

1) Implementing the construct

Since this is not the de facto standard that is implemented for nearly all trading partners, allowing different transaction types in the same interchange will present a construct that is not actively working in the production systems of AMBHA member trading partners. Therefore, this construct will require testing for all trading partners. If the testing fails, process and code changes will be required. These changes will require testing, and will, in at least some cases, introduce other issues (industry average: 10% of all system changes introduce other issues). This is considerable overhead for the industry.

2) Coordination with trading partners

Different trading partners will implement approaches to this situation that are not compatible across the industry. AMBHA members have many trading partners now who do not use compliant ISA or GS envelope headers. This will cause AMBHA members or their trading partners rework to be compatible.

3) EDI and business workflow

If a good claim is sent with an associated unsolicited attachment, and the attachment fails, AMBHA members should be able to provide a standard process that is reasonably stable. If the claim fails and the attachment passes, the attachment will be in "limbo" until the claim is resubmitted. The resubmitted claim will have to retain the reference ID linking it

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H E A L T H C A R E A S S O C I A T I O N

to the attachment. AMBHA members cannot ask again for information successfully received, and will have to connect the two documents if and when a successful claim is received. If a good claim is never resent, AMBHA members will have to retain the attachment for some extended period of time to allow the reconnection. Our industry regularly has questions about claims that are resent 4 to 14 months after the original. Our members have had consistent issues with trading partner's exception/resubmission processes, and this construct is more complicated than current concepts.

Thank you for the opportunity to provide comments on the proposed rule. If you have any questions or would like to discuss our comments please feel free to call me at (202) 756-7726.

Sincerely,

Pamela Greenberg, MPP
Executive Director

CMS-0050-P-105

Submitter : Mr. Benjamin Loy
Organization : National Health Systems, Inc.
Category : Health Care Industry

Date: 01/20/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-0050-P-105-Attach-1.PDF



NHS
National
Health
Systems

**NHS Comments on the Proposed Standards for
Electronic Health Care Claims Attachments
(CMS-0050-P)**

Written Comments Submitted by:

**Benjamin E. (Ben) Loy, R.Ph.
Sr. Vice President, Industry Relations
National Health Systems, Inc.**

To:

**U. S. Department of
Health and Human Services
Centers for Medicare and Medicaid**

Extended Public Comment Period:

Through January 23, 2006

The National Health Systems, Inc. (NHS) companies appreciate the opportunity to submit comments to the U. S. Department of Health and Human Services Centers for Medicare and Medicaid on the proposed regulation to provide standards for health care claims attachments.

NHS is composed of a several software development companies including the wholly own subsidiary PDX, Inc., a retail pharmacy software provider, that was established by Ken Hill in 1985 in Granbury, Texas and which was preceded by the still viable pc1, Inc. a software application provider primarily to independent pharmacies. The PDX pharmacy system is the most widely distributed single-source retail pharmacy application in North America and is used for prescription processing by independents, small to moderate sized chains and large national pharmacy chains. PDX and its affiliated companies provide pharmacy technology to a customer base of approximately 1,000 independent pharmacies and some 60 chains for a total of more than 10,000 pharmacies. These pharmacies serve more than 60,000,000 customers each year and fill approximately 720,000,000 prescriptions annually. PDX has installations in all 50 states, the District of Columbia, Puerto Rico, Guam and the U.S. Virgin Islands. PDX has earned a position as a leader in pharmacy technology innovation including currently available central-fill and centralized database technology. PDX is working to provide our customers and their clients with secure broadband access to both an electronic medical record and to a personal electronic medical record. PDX has participated in the standards development process for over two decades and promotes such standards as a value to our company, our customers, the retail pharmacy industry and to the country itself.

NHS written comments to the U. S. Department of Health and Human Services (HHS) on the proposed Standards for Electronic Health Care Claims Attachments.

The Standards Development Organizations (SDO) that participated in developing the proposed claims attachment standard and code sets were X12N and HL7. These are both highly recognized and well respected organizations that represent dozens if not hundreds of different businesses and provide standards that are widely used by many members of the health care industry. These organizations provide health care claims processing standards that primarily utilize Electronic Data Interchange (EDI) that is processed in batch mode and which is not generally considered to be time critical. The HIPAA named SDO that was not a direct contributor to the proposed claims attachment standard was the National Council for Prescription Drug Programs (NCPDP) an organization that develops standards used primarily by the 60,000 retail pharmacies and pharmacy benefits managers. The membership of NCPDP has moved over the past three decades from paper based claims, to electronic batch billing processes and finally to a true on-line real-time claims processing environment that is the envy of the world. The claims process developed by the NCPDP membership has greatly contributed to the efficiency and cost effectiveness of the U.S. retail pharmacy industry.

As a technology developer NHS understands that retail pharmacy represents a unique entity within the health care arena with regard to the techniques used in claims processing. As such, we know that methodologies that work for other segments of the industry do not necessarily work for retail pharmacy. Although not specifically mentioned as being covered by the proposed standard, retail pharmacy is also not specifically exempted. The inclusion of information concerning medications in section 162.1905(c)(3) as qualifying a covered entity as having to comply with this subpart may be interpreted to include retail pharmacy, which we do not believe was intended. Such a requirement would impose an excessive and truly unfair requirement on retail pharmacy as EDI batch processes are not easily integrated with on-line real-time claims billing. If attachments do become needed for retail pharmacy claims then the SDO that supports this industry, NCPDP, should be given the opportunity to determine the requirements and the most appropriate means of addressing such needs.

However, if the intent was to include retail pharmacy under this rule, then HHS must conduct a thorough analysis, studying how these attachments would impact the pharmacy claims billing processes and the impediments that such use could raise. Implementing this rule on retail pharmacy without such analysis could seriously impact the retail pharmacy claims billing process and possibly result in the inability to provide pharmaceutical care (prescriptions) to healthcare beneficiaries. Pharmacies have been significantly impacted by the HIPAA Privacy Rule, HIPAA Transactions and Code Sets Rule, HIPAA Security Rule and Medicare Part D in recent years and are looking at the implementation of the HIPAA National Provider Identifier (NPI) within the next 18 months. All of these programs have imposed significant costs on the retail pharmacy providers.

Conclusion

We strongly recommend that retail pharmacy be exempted from the proposed Standards for Electronic Health Care Claims Attachments. Retail pharmacy's use of an on-line real-time claims adjudication process would be negatively impacted by the required use of the recommended EDI batch electronic health care claims attachment standards. We do not believe HHS intended this and request it be clearly stated that retail pharmacy is exempted from this rule.

CMS-0050-P-106

Submitter : Mr. Brent Barnhart
Organization : Kaiser Permanente
Category : Health Plan or Association

Date: 01/20/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.