Submitter :

Date: 11/18/2005

Organization : **Illinois Healthcare & Family Services**

Category : **State Government**

Issue Areas/Comments

GENERAL

GENERAL

Page 55994 "Effective Dates"
Because of the complexity of this transaction, the use of two different standards, and the other major HIPAA implementations that are underway, Illinois Medicaid would like to see the effective date extended by 1 year to allow a 36 month implementation period. We understand that there will always be competing projects, but Illinois will be starting from the ground up with this transaction and really feel the extra time is needed for successful implementation.

Submitter : Mr. David Feinberg **Date:** 11/18/2005

Organization : Rensis Corporation - A Consulting Company

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment that consists of a one page cover letter plus thirteen pages of comments. Should the attachment need format clean-up, the following page setup values should be used: top_margin=0.5", bottom_margin=0.5", left_margin=1.0", right_margin=1.0", gutter=0.0", header_from_edge=0.5", footer_from_edge=0.5", and gutter_position=left.

CMS-0050-P-34-Attach-1.DOC

David A. Feinberg, C.D.P.
3662 SW Othello Street • Seattle, Washington 98126-3246
206 617-1717 • DAFeinberg@computer.org

18 November 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0050-P

via: Electronic Comments @ http://www.cms.hhs.gov/regulations/ecomments

References: (a) 70 FR 184, 9/23/2005, pages 55989-56025
(b) CMS-0050-P
(c) RIN 0938-AK62

Following are additional written comments on the proposed rule for HIPAA Administrative Simplification Standards for Electronic Health Care Claims Attachments. These comments are in addition to those dated 14 November 2005 and already submitted via Priority Mail. Unlike those comments that are organized based on the NPRM Table of Contents, these comments are only regarding the **Electronic Health Care Claims Attachment Response Transaction** and are ordered based on key criteria expected of any rule and regulations for HIPAA Administrative Simplification Transactions and Code Sets (TCS).

Please use any of the methods shown above should you wish to contact me about any of these written comments.

Yours truly,

David A. Feinberg

David A. Feinberg, C.D.P.
President, Rensis Corporation

Rensis Corporation

Intelligently Linking Information Systems

Comment Number: Rensis-90.01

Criterion: PROVIDERS WANT CERTAINTY OF FORMAT AND CONTENTS FOR WHAT THEY MUST TRANSMIT

A. This NPRM provides anything but certainty. It's list of Variants, Options, and unbounded Non-XML file types / implementation specifications is the antithesis of the major reason for HIPAA Administrative Simplification Transactions and Code Sets (TCS) and National Identifiers. As repeatedly reinforced over the past few years by implementations of the first round of HIPAA transactions and plans for the second ... .

- Health care providers want single straight-forward precise implementation specifications that direct them on what to send, under what situations, and using a precise format.
- Health care providers want these single implementation specifications to be independent of any and all actual or potential recipients.
- Health care providers do not want to have to contact or be contacted by each potential recipient to determine or negotiate anything at all regarding what they are to send.
- Health care providers certainly don't want to have to send different contents or different formats to different receivers based on any trading partner agreements or other multiple sender-receiver pair "companion guides".
  Health plans probably have the same position should a newer version of this NPRM require them to accept whatever a provider independently elects to send.

Unfortunately, this NPRM provides no policy on how a provider can achieve this within the blizzard of variabilities proposed.

B. Providers should not be required to comply with the HL7 CDAR1AIS0000R021 Additional Information Specification Implementation Guide, Release 2.1, May 2004, §3.5.3, statement that additional Human Decision Variant file types / implementation specifications may be established at any time by trading partner agreement – voluntarily by both parties or imposed by a payer as a condition of doing business; as is allowed by this NPRM, operational precedent, and CMS guidance for the earlier HIPAA transactions.

(Comment continued on next page.)

C. There is no authority in the legislation that allows the Secretary to permit adoption and use of additional Implementation Specifications by trading partner agreement; *e.g.*, as is stated in the HL7 CDAR1AIS0000R021 Additional Information Specification Implementation Guide, Release 2.1, May 2004, §3.5.3, for the many file types – which are implementation specifications – or DICOM and its many [unmentioned] optional, mix-and-match Supplements. Such a situation would be particularly onerous when imposed by a payer as a condition of doing business; as is allowed by this NPRM, operational precedent, and CMS guidance for the earlier HIPAA transactions.

D. For the implementation specifications needed to <u>create</u> the Human Decision Variant file types – *e.g.*, .PDF, .PNG, .JPG, .RTF – explicitly and potentially – *i.e.*, by trading partner agreement – required in HL7 CDAR1AIS0000R021 Additional Information Specification Implementation Guide, Release 2.1, May 2004, §3.5.3, the following information needs to be provided should Human Decision Variants continue to be allowed:

- source of the specification for creating the file type,
- version of the specification to be used for creating the file type,
- versions of the specification to be used for viewing documents of a particular file type,
- process for requesting upgrades to newer versions of the file type, and
- process for requesting changes to version(s) of the file type.

Though not named explicitly at this time, based on results thus far of the EMS Pilot, the information above should also be provided for MIME.

Discussions of the following topics regarding these file type standards are also needed for NPRM completeness:

- Relationships to the HIPAA Legislation, and
- Sources as Standards Setting Organizations.

The above applies only if Human Decision Variants are actually adopted – which should not be done for these and other reasons noted elsewhere in this document.

Comment Number: Rensis-90.02

Criterion: HEALTH PLANS WANT A TRANSACTION THAT ALLOWS THEM TO MOVE TO AUTOMATED ADJUDICATION AS READILY AS POSSIBLE WHENEVER THEY ARE READY – PREFERABLY WITHOUT ADDITIONAL COORDINATION WITH SENDING PROVIDERS

Only the Computer Decision Variant allows automated adjudication. If a health plan is not yet ready to perform automated adjudication, then they can parse a Computer Decision Variant message into a human readable form. On the other hand, any Human Decision Format message can't, for all practical and economic purposes, be parsed into a machine processable form. Once providers become established sending Human Decision Variants, a health plan will have to force subsequent conversions to Computer Decision Variant when they wish to commence automated adjudication. Providers will obviously resist such a conversion once they've invested in sending what are adopted Human Decision Variant messages or if they're unable to send Computer Decision Variant. It would be even worse if such conversions were piecemeal-required by attachment type, subtype, or data variants. At the very least, providers forced to convert would expect to be compensated for their efforts. Unfortunately, this NPRM provides no policy of how such conversions should be managed or estimates of the costs that would be incurred.

The above applies only if Human Decision Variants are actually adopted – which should not be done for these and other reasons noted elsewhere in this document.

Comment Number: Rensis-90.03

Criterion: PROVIDERS WHO HAVE ALREADY INVESTED IN CLINICAL INTERFACES DON'T WANT TO EXPEND RESOURCES TO DEVELOP AND OPERATE ANOTHER METHODOLOGY ... OR TWO

A. In spite of several years of marketing and entreaties, United States health care providers who are already using HL7 version 2 series messages have almost universally declined to convert to HL7 CDA. This decision is economic: CDA provides essentially no additional functionality over what is already being achieved using HL7 version 2. Even the new e-Prescribing final rule {42 CFR 423.160 (a) (3) (ii) as described in 70 FR 214, 11/07/2005, pages 67581 & 67594} recognizes this in relation to using NCPDP SCRIPT. Moreover, HL7 version 2 isn't broken – just not as new as CDA and XML. Unfortunately, this NPRM would force these health care providers to expend resources to add use of CDA only for claims attachments – without converting their other HL7 interfaces. As a consequence, use of CDA for claims attachments adds an additional interfacing methodology for these providers – with its attendant ongoing costs of operation in addition to the start-up costs noted in this NPRM.

   The same discussion applies equally to the creation of Human Decision Variant transactions instead of just continuing to use HL7 version 2 standard data element messages.

B. The costs of acquiring, installing, and updating software to <u>create</u> Human Decision Variant Non-XML files are not listed. As but one example, for PDF, Acrobat Reader is indeed free, but the software to create PDF (e.g., full Acrobat, Photoshop, InDesign) is not. Additionally, there could be recurring costs for software upgrades. Again, for PDF, Adobe can and sometimes does change the standard annually.

   The above applies only if Human Decision Variants are actually adopted – which should not be done for these and other reasons noted elsewhere in this document.

(Comment continued on next page.)

C. The costs of acquiring, installing, and operating hardware (*e.g.*, scanners, additional memory, cables, high speed communications lines, *etc.*) to use Human Decision Variant scanned images, and in some cases very large XML Computer Decision Variant files, are not listed. This is a particular concern for smaller providers.

The above applies only if Human Decision Variants are actually adopted – which should not be done for these and other reasons noted elsewhere in this document.

Comment Number: Rensis-90.04

Criterion: HUMAN DECISION VARIANTS NEED EXPLICIT POLICIES REGARDING THEIR COMPLIANCE WITH HIPAA LEGISLATION

The Human Decision Variants, despite their X12 and HL7 envelopes and wrappers of discrete control items, are not standard data elements as intended and everywhere else defined and interpreted for current HIPAA standard transactions. The law clearly states that health plans would be in violation if they accepted other than standard data elements – which is what Human Decision Variants are. No explanations or rationale regarding the relationship of Human Decision Variants to this requirement is offered in the NPRM, so readers are left to wonder what's going on.

Assuming for a moment that Human Decision Variants are adopted in a final rule for Claims Attachment Response Transactions, the obvious counter position will almost certainly be raised as to why scanned images (*e.g.*, facsimiles – which are communicated using the TIF format explicitly listed in CDAR1AIS0000R021 Additional Information Specification Implementation Guide, Release 2.1, May 2004) or free text can't also now be used for already adopted HIPAA transactions.

The above applies only if Human Decision Variants are actually adopted – which should not be done for these and other reasons noted elsewhere in this document.

Comment Number: Rensis-90.05

Criterion: HUMAN DECISION VARIANTS NEED EXPLICIT SPECIFICATIONS THAT OVERCOME THE UNSTATED ASSUMPTIONS ON WHICH THEY ARE BASED

A. There seems to be an unwritten presumption that scanned images will arrive with good quality as well as being decipherable. No such presumption should exist as scanned images could be just as garbled and unintelligible as their paper (or other) originals.

Moreover, it also seems to be presumed that scanned images are of only machine-created documents – also fallacious as hand written [scrawled?] documents and sketches could just as easily be imaged and then transmitted.

B. There seems to be an unwritten presumption that Human Decision Variant messages will arrive with only the appropriate data and that this data will always be readily identifiable and readable.

As but a simple example of what this NPRM and its incorporated materials presently allow, consider the following highly simplified scanned or free text:

"1.4 mg/dl 4.3 g/dl K 4.2 meq/l".

Any Human Decision Variant could contain gobbledygook such as this with no hope of it being deciphered.

Without any automated mechanisms to control free text and scanned image contents, it's impossible in general to determine whether:

- all specific attachment data requested to adjudicate a claim is actually present or clearly indicated as not available, and
- too much or superfluous data is communicated.

Not only could this be detrimental to the objectives of adjudicating claims based on a one-time-only attachment request–response paradigm, but the implications for providers and payers repeatedly, economically, and reliably verifying "minimum necessary" based on HIPAA Privacy rules are highly negative.

(Comment continued on next page.)

C. There are no specifications for how some Human Decision Variant files are themselves to be formatted. As but one example, are PDF files to be sent as text or with embedded scanned images? Both of these techniques are commonly in use.

D. Use of Human Decision Variants blocks health plans from use of auto-adjudication – one of the primary mechanisms by which Administrative Simplification cost reductions may be achieved.

- No "stylesheets" that will put Human Decision Variants into Computer Decision Variant are described or even mentioned.
- No tools for identifying standard data elements contained within Humans Decision Variants are noted or referenced.
- No methodology or algorithms for putting standard data elements contained within Humans Decision Variants into Computer Decision Variant are provided.
- No policy regarding who controls when to change from Human Decision Variants to Computer Decision Variant is given.
- Once a Human Decision Variant standard transaction is established between a provider and a health plan, the health plan loses any opportunity to incent a provider to later convert to Computer Decision Variant, since
  - the health plan may no longer refuse to conduct such (Human Decision Variant) transaction as a standard transaction, and
  - the insurance plan may no longer adversely affect or attempt to adversely affect – *e.g.*, provide a bonus for a Computer Decision Variant – a now standard Human Decision Variant transaction.

All of the above applies only if Human Decision Variants are actually adopted – which should not be done for these and other reasons noted elsewhere in this document.

Comment Number: Rensis-90.06

Criterion: SPECIFICATIONS AND/OR POLICIES ARE NEEDED TO PREVENT HEALTH PLANS FROM OVERWHELMING PROVIDERS WITH ATTACHMENT REQUESTS

The claims attachments operational paradigm is new in the HIPAA Transactions and Code Sets environment. It's the first HIPAA transaction that allows health plans to initiate HIPAA electronic communications with other entities – in this case providers.

There are no ceiling or other limiting mechanisms specified that control or prevent health plans from overloading providers with attachment requests when health plans condition doing business with providers on their use of electronic Claims Attachments transactions; as is allowed by this NPRM, operational precedent, and CMS guidance for the earlier HIPAA transactions.

Comment Number: Rensis-90.07

Criterion: MORE EXPLANATION IS NEEDED REGARDING THE RESTRICTIONS BEING PLACED ON PROVIDERS SUBMITTING UNSOLICITED ATTACHMENTS

No such restrictions or requirements for advance instructions presently exist for paper attachments that providers routinely send along with paper claims because they know from experience that they are needed to obtain timely payment. Notwithstanding the discussion on page 55999 of this NPRM, wouldn't the same rationale apply to electronic attachments?

Alternatively, if such advance coordination *is* really needed, suggest that this NPRM be modified to allow providers to send at any time descriptions of certain types of claims, procedures, or services for which they might send unsolicited attachments, and, unless or until each health plan specifically case-by-case objects in writing, such unsolicited attachments must be received and appropriately processed.

Comment Number: Rensis-90.08

Criterion: POLICIES ARE NEEDED TO ENSURE THAT HEALTH PLANS DON'T UNFAIRLY SHIFT THE COSTS OF CREATING ELECTRONICALLY MANIPULATABLE SCANNED IMAGES TO PROVIDERS WHO DON'T ALREADY HAVE IMAGE MANAGEMENT CAPABILITIES

The process of scanning a paper document into a computer system for later computer-to-computer transmission is the same as scanning a paper document into a facsimile machine for immediate transmission. In both cases, a human must do the scanning and a human must do the reading. If health plans wish to receive facsimiles as electronically manipulatable images, they are free to do so using their own information technology resources. Forcing providers to add the overhead and ongoing costs – equipment, communications lines, and software for of computer-to-computer transmission – plus all the extra X12 and HL7 "envelopes" – to send such images only for the use of health plans' humans is an added and unfair burden; and subtracts from any provider efficiencies in the end-to-end process of obtaining payment for services provided.

The above applies only if Human Decision Variants are actually adopted – which should not be done for these and other reasons noted elsewhere in this document.

Comment Number: Rensis-90.09

Criterion: THE GENERAL PUBLIC NEEDS MORE TIME TO REVIEW AND COMMENT ON THE HL7 IMPLEMENTATION SPECIFICATIONS AND THEIR CONSEQUENCES

A. A review of HL7 ballot procedures in effect at the time the Additional Information Specifications (AIS) were balloted shows that only voting members of HL7 were invited and authorized to vote. This is borne out by the small number and list of voting pool members. Thus the HL7 materials are officially brand new to the industry at large with the publication of this NPRM.

B. The structure, vocabulary, content, and numerous and novel interactions of the AIS documents – both internally and with X12 Implementation Guides and this NPRM – are very different from those used by all previous HIPAA transactions and code sets documents for the environments in which the proposed rule would apply; *i.e.*, professional claims, institutional claims, and dental claims. More than the usual sixty days is needed for the general public to just become familiar and comfortable with these materials so that rational comments may be synthesized and submitted.

C. This NPRM is characterized by the policies it *does not* specifically state. This is very different from previous HIPAA NPRM's. Thus, complex interactions between this NPRM, previously promulgated HIPAA rules and regulations, X12 Implementation Guides, and the AIS must laboriously be determined. As a consequence, it takes much longer to ferret-out what is missing so that applicable comments can be written and submitted.

D. Until the results of at least the first claims attachment pilot project are finalized and disseminated as broadly as this NPRM, and sufficient time to read and evaluate the results of this pilot is allowed, the general public is not provided all available relevant information on which to base and sufficient opportunity to submit all potential comments.

Comment Number: Rensis-90.10

Criterion: HAS ANYBODY RECENTLY PAUSED TO CONSIDER THAT THE PROPOSED APPROACH HAS BECOME JUST WAY TOO COMPLEX?

The presently proposed approach requires:

> Variable length, delimited X12 transactions, that must include an exact byte count [for the binary (BIN) segment] – that may be difficult to reliably achieve for differing carriage return line feed or scanned image combinations – while enveloping ...
>
> > Un-similar structured and tagged XML, that could envelope ...
> >
> > > Un-similar un-structured free text and scanned images, that might need ...
> > >
> > > > An unbounded list of scanned image format implementation specifications / formats writers and viewers and decoders,
> > > >
> > > > and/or
> > > >
> > > > MIME wrapping in order for the free text or scanned images to be accurately communicated and decoded.
>
> All of which may generate extremely large message sizes that might require all sorts of special, trading-partner-pair by trading-partner-pair specific, handling – both for the message as a whole as well as potentially just the binary (BIN) segment(s) within each message.
>
> And the entirety of this likely, based on the present absence of specific NPRM policies, to be mixed and matched on a trading-partner-pair by trading-partner-pair specific basis!

Maybe the largest providers can afford to negotiate, implement, and daily operate this methodology. Maybe? But what about all of the other providers in the country?

Maybe the largest health plans can afford to negotiate, implement, and daily operate this methodology. Maybe? But what about all of the other health plans in the country?

(Comment continued on next page.)

Have we created "frog soup" [*i.e.*, place a frog in cold water and slowly heat and the frog will cook - versus a frog that is dropped into hot water will jump out]?

Based on the preliminary information available thus far from the pilot – really only a comparatively tiny and non-comprehensive motivated *Hawthorne Effect* proof of concept – project, the outcome remains quite uncertain.

A much much simpler approach was proposed via e-mail to the HL7 ASIG in a late 2002 white paper!

END OF WRITTEN COMMENTS

Submitter : **Ms. Kim Volk** **Date: 11/18/2005**

Organization : **Delta Dental Plans Association**

Category : **Health Plan or Association**

Issue Areas/Comments

GENERAL

GENERAL

Attached please find the Delta Dental Plan Association?s final comments to the Claims Attachments NPRM. DDPA represents the nation?s largest, most experienced dental benefits carriers. A nationwide system of 39 independent dental health service plans offers employers in all 50 states, the District of Columbia, and Puerto Rico, custom programs and reporting systems that provide employees with quality, cost-effective dental benefit programs and services. DDPA carriers provide dental coverage to over 46 million people in over 80,000 groups across the nation. You will receive these comments in hard copy form as well.

CMS-0050-P-35-Attach-1.DOC

DELTA DENTAL

November 21, 2005

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

Re: Comments on Proposed Standards for Electronic Health Care Claims Attachments

To Whom It May Concern:

I am writing on behalf of the Delta Dental Plans Association ("DDPA") to provide comments on various issues raised in connection with proposed standards for electronic health care claims attachments.

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

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

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

Comment on Claims Attachment Types

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

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

Future Periodontal Care Rule

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

Combined Clinical and Administrative Data

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

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

Initial Types of Claims Attachments

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

Dental Benefits Attachments

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

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

Timely Process for Standards Adoption

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

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

Effective Date of Final Standards

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

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

Comments on Standards for Claim Attachments

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

LOINC Code Usage

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

AIS Books Technical

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

X12 and HL7 Standards

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

Maintenance of LOINC

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

Comments on Definitions and Scope of the Proposed Rule

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

Definition of Claims Attachment

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

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

Definition of a Claim

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

Definition of Adjudication of a Claim

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

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

Definition of Solicited and Unsolicited Information

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

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

Definition of Adjudication and Post-Adjudication

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

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

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

Other Definitional Issues

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

Comments on Voluntary Implementation

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

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

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

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

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

Comments on Cost Impact

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

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

Cost Information Related to Claims Attachments

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

Frequent Claims Attachment Types

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

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

Comments on Privacy and Security Rules

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

Exercise of Discretion

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

Comment Period Extension

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

* * * * * * * *

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

Sincerely,

Kim Volk

President and Chief Executive Officer

Delta Dental Plans Association

Chart Attachment

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

	162.1002 (LOINC) 162.1915 162.1925	RT RT RT	Standards	Yes	**Is there agreement with the proposed X12 and HL7 standards, including versions and with LOINC codes – using LOINC code set as the appropriate code set to identify the questions.** Comment #1: We agree with the approach using standards developed by X12 and HL7 and the LOINC code set as developed for these business purposes. Comment #2: We agree that the final rule should adopt both the Computer Decision Variant and Human Decision Variat for electronic claims attachment. Comment #3: Recommend that the content of the BIN segment does not have to be validated for the *portion of the* data that is not being used. Comment #4: Recommend that receivers of these transactions have the option of accepting or rejecting imperfect transactions, specifically the BIN01.
	II, C, 2 Overview of Clinical Document Architecture	P	Standards	Yes	Comment #1: Recommend to move to CDA release 2 assuming that there is a pilot that uses CDA release 2. We understand that HL7 will need changes to the HL7 IG and each AIS developed to be on CDA release 2, but believe that adoption of CDA release 1 will cause extra work since HIT encourages CDA release 2. Comment #2: DDPA recommends the adoption of a mechanism for the timely migration to new releases and versions of standards documentation as they become available.
	II.C.5 Electronic Claims Attachment Types Reg is 162.1910 –C	P RT	Standards	Yes	Comment #1: The six attachments adopted are largely appropriate for the medical industry with a few exceptions within the clinical reports where dental reports are identified for use. Most important to DDPA is the adoption of the Periodontal chart and radiographs as these are two of the most commonly requested attachments in our industry. DDPA has been working with HL7 and the ADA in the design of the periodontal standard. Comment#2: Most important to DDPA is the process by which updated attachment specifications will be adopted. We recommend that no new standards be adopted under HIPAA until a process is in place that will allow for adoption of updated versions to occur no less than every three years, allowing for adequate implementation time, and in consideration of other standards requirements impacting implementer workloads. In addition, notification and rollout time between adoption and implementation needs to be added after HL7 publication.

	II, E Attachment Content and Structure	P	Standards	No	Comment #1: Recommend that the 64 MB be left as a recommendation and not be a standard or maximum.
	II, A Definitions	P RT	Standards	Yes	Included in text letter
	162.1920 (d)	RT	Standards		No Comment
	III. Modifications to Standards ,A & B. 1st paragraph	P	Standards Maintenance		A lot of this was adopted as comment two under the attachment types question (Comment #3)
	III. Modifications to Standards ,A & B.	P	Standards Maintenance	Yes	**Discuss maintenance of LOINC code sets in the future. Changes, additions, etc.** **Discussion: CMS requires health plans to comply with the standards. The health plans need to be ready if this is requested by a provider. If this is part of your business, then you must comply.** Comment#1: Delta Dental is not confident that the assignment of LOINC codes meets the needs of the dental industry. To ensure that the needs of the dental industry are met we would suggest the following: a. Clarify the process for accessing the LOINC codes used for the specific attachment AIS b. Clearly lay out the process for requesting new LOINC codes
	162.1930	RT	Implementation	Yes	**Implementation timing: Is 24 months from the final rule publication date to the effective date feasible?** Comment #1: During the implementation of the first sets of HIPAA standards, it was discovered that the standard frequently did not meet the needs of the industry. Further, it was not possible to easily change the standard to meet an identified need. In order to avoid that during implementation of the attachment standard, DDPA would recommend that the Final Rule not be released until all of the following conditions are met a. CDA Release 2 is finalized and reflected in all supporting documentation such as the AIS guides b. A pilot or pilots is (are) accomplished which thoroughly test the X12N Transactions and all of the HL7 guides. Each of the attachment guides should be incorporated into the pilot and include at least 1000 277 requests and at least 1000 275 responses for each attachment. Communications, storage requirements, savings could be determined based on such pilots. c. Fund each pilot with respective industry players e.g. dental offices, medical offices, health system, clearinghous payers, billing offices. d. Recommend that testing be done with the Human Variant. Phase in the Computer variant 2 years after the HDS is in place.
	II, D, 9 HC Clearinghouse	RT	Implementation	No	**Should the government have a national rollout plan?** Comment #1: DDPA recommends that the regulation support a national roll-out plan to be developed by the WEDI sub-

	perspective				workgroup on claims attachments.
	N/A	N/A	Implementation		
	II.D.2 Solicited vs. Unsolicited Attachments Reg is 162.1910 –C	P RT	Business Process	Yes	**Completeness/Single iteration process that only allows a single 277 request and a single 275 reponse.** Comment #1: Payers should endeavor for completeness of the request by asking all known questions at the initial reques with the understanding that further questions may be asked based on information contained in the initial response. Payor and providers should not be penalized for the occasional mistake that could occur in either asking the question or providing the response. This may necessitate more than one request/response set.
	II.D.2 Solicited vs. Unsolicited Attachments 162.1910 (a)(3)	P RT	Business Process	No	**Unsolicited 275 using payer instructions method.** Comment #1: A provider, based on prior arrangement or experience with a plan, may send unsolicited attachments until health plan either issues advance instructions to clarify its requirements, or, explicitly instructs the provider that the attachment is not required for the type of claim in question.
	N/A	N/A	Business Process	No	**Should we allow for ability to send the unsolicited attachment separately from the 837 claim? Not bundled in the same transaction file** Comment #1: The regulation should allow for the ability to send the unsolicited electronic attachment separately from tl 837 claim i.e. not required to be bundled in the same interchange or transmission file (ISA/ISE), as long as they are sent i the same daily cycle.
	II, D Electronic Claims Attachment Types Business Use	P	Business Process	No	**Discussion of the post adjudication and the current definition of what is an attachment. Is it permissible but not required used attachments for purposes other than adjudication.** Comment 1: The regulation should not be interpreted to disallow health plans from collecting information via the claim attachment process for purposes other than the purposes defined in this rule, such as post adjudication purposes. The dental industry has needs for pretreatment and predeterminations as part of the approval process prior to any payment. The use of attachments would facilitate this part of the care/payment continuum. Comment #2: The process of making such arrangements should Remove the requirement that this can only be done using trading partner agreements. Comment #3: The proposed rule recommends adoption of standards, which will mandate their use for claims purposes. DDPA recommends that the preamble to the final rule strongly encourage entities to voluntarily adopt the named standar in all other situations where they meet business needs for information exchange, prior authorization, post adjudication, public health reporting, etc.
	II, D, 3 Coordination of	P	Business Process	No	**Is the method proposed for use of attachments with COB appropriate?**

	Benefits				Comment #1: Add to the COB section language that will specifically state that if a payer receives attachment informatio they are not required to send this information to the subsequent payer.
	II , D.6 Connection to Sugnatures	P	Business Process		No comment
	II, H Requirements (HP, CH, Providers)	P	Business Process		No comment
	N/A	N/A	Business Process		No comment.
			Business Process		Moved to next section.
			Clarification	No	**Asking for clarification of when a covered entity must implement the announced transactions:** Comment #1 Need clarification: If a health plan does not have a current business model that send requests for additiona information (electronic or hardcopy), does the health plan have to use the 277 if a provider requests it to be used. Exampl the health plan uses the unsolicited business model thus publishing the criteria in advance and expecting the 275 with the claim. Comment #2: Need clarification: Some health plans currently use a business process that will deny a claim for a reason "needing additional clinical information," i.e. needing information that would be in a claim attachment. Can that proces continue? Or does the request for that information now have to come through a 277 RFI? If this process can continue, how does the provider know what additional information to submit? Which electronic transaction would be used to send in the additional information? Comment #3: Need clarification: Will a provider be required to do both the solicited and unsolicited models if they do electronic attachments?
	162.1910 (a)(2) Electronic health care claims attachment request transaction	RT	Clarification	No	Comment #1 Please clarify the workflow is being described here at (2) "(a) The health care claims attachment request transaction is the transmission, from a health plan to a health care provide of a request for attachment information to support the adjudication of a specific health care claim. A health plan may mak such a request . . . (2) In advance of submission of the health care claim"

II, D, 4 Impact of Privacy Rule	P	Privacy	Yes	Ability to meet "minimum necessary" requirements and burden of doing so. Examples, providers sending scanned documents with more than minimum information. Payers' retention of those scanned documents. Clearinghouse responsibilities in this area. Recommend that HHS should provide added guidance related to privacy and security, not jus minimum necessary Comment #1: Recommend that HHS should provide added guidance from CMS in relation to privacy and security, not just minimum necessary. Examples for where we want guidance: Example #1 Payer has received a claim attachment but did not receive the claim. Today, payers may be storing an image and then return the paper original or shred it or file it. Example #2 Payer to payer COB if the attachment is sent on to the subsequent payer, what are the implications of the privacy rule. Example #3 Plan requests specific questions, and providers send scanned documents with more than minimum information , since it is in a scanned document. Example #4 If a request does not specify a timeframe using a LOINC modifier, how far back does the provider go? Today, if it is not defined, then some providers only send the information related to that episode of care. Example #5 If a claim and attachment come in but the patient is not covered by that health plan. Today we print and return the information.
VI Regulatory Impact Analysis	P	Impact Analysis	Yes No	Comments on the Impact Analysis section. Are the citations related to the cost & benefits findings appropriate and realistic? Comment #1: DDPA considers this regulation to be an unfunded mandate. We recommend that the work being done by the Department of Defense include a cost benefit analysis and be published for the industry. Comment #2: Recommend process to provide funding for initial implementation of these transactions. There is a relationship to the NHIN initiatives for funding since claims attachments are part of clinical information.
			No	Acknowledgements and Error reporting Comment #1: Recommend that the 275 IG be changed to remove the use of the 102. Change the reference in the 275IG to recommend the use of the X12 TR3 999 for syntax errors, and the X12 824 TR3 to acknowledge both the X12 and HL7 content. Thi is in line with the WEDI Acknowledgement PAG recommendations. Comment#2: Recommend requirement for use of these Acknowledgement transactions. Implementing without acknowledgements is problematic. This is in line with the WEDI Acknowledgement PAG recommendations.

					Comment #3: Recommend that in the implementation of the acknowledgement standards that the acknowledgment be at the file level and not for each attachment within the file. Comment #4 Use of the TA1 acknowledgement. If this is a WEDi recommendation along with the 999 and 824, then it should also be included in the recommendation for these transaction set.
				Yes	**LOINC code usage** Comment #1: Because LOINC is adopted as a Medical Code Set, the regulation needs to clarify the use of which LOINCs are used in each of the AIS documents. There is a concern that, absent this clarification, entities may attempt a legalistic position that any LOINC code may be used for any attachment. Recommendation that the regulation be clarified as follows: 1. Those AIS documents that contain static content (e.g. Ambulance, Emergency, Rehabilitation, Medications) the regulations must be clear that only the LOINCs enumerated in the AIS are allowed. 2. Those AIS documents that reference the LOINC database (such as Laboratory Results, Clinical Reports), the regulation should clarify that only the LOINC class (such as Laboratory Results, Clinical Reports) defined for that AIS is allowed. Comment #2: Recommend a technical correction to the AIS books that reference the LOINC database to clarify how to determine the appropriate subset of LOINC codes.
				No	**Other:** **The 275 and 277 books are not synchronized.** Comment #1: In implementation of previous standards, one of the ongoing issues has been lack of synchronization between request and response transactions. An example in the current set is the missing Procedure Code Qualifier in the 275 2000A REF segment where the code qualifier of "AD" for the dental codes is not present (page 74). It is, however, present in the 277 transaction 222E SVC segment (page 98). Further, there is inconsistency in the code qualifier identification between the 275 and 277 for the same segments. It seems that the Qualifier HC should be used consistent between the 275 and 277, instead Code Qualifier HC is used in the 277 and CPT is used in the 275.
				No	Comment #2: The 277 book lacks reference to all of the 837 transactions. Dental is completely missing from the documentation---yet dental is included in the expectations for the claims attachment. Examples of areas of missing reference include in the 277 manual are: P.22 Note---should also include reference to dental not just professional claim; p.77 should also include that this segment is not needed for dental," p. 79 Medical Record Identification should not be needed for dental
				Yes	Periodontal Attachment - Comment: Regarding the upcoming attachment for a periodontal attachment, the reference should be for a periodontal chart---not periodontal care. A payer may need to request full mouth radiographs and clinical narrative in additional to the periodontal chart in order to make accurate contractual payment. In no way should a payer be limited to requesting only the named attachments in order to accomplish payment.

Submitter :

Date: 11/18/2005

Organization : **Illinois Healthcare & Family Services**

Category : **State Government**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-0050-P-36-Attach-1.DOC

Illinois Healthcare and Family Services
File Code CMS-0050-P
Public Comments Submitted on November 18, 2005

File Code	Page #	Issue Identifier	Comment
CMS-0050-P	55994	EFFECTIVE DATES	Because of the complexity of this transaction, the use of two different standards, and the other major HIPAA implementations that are underway, Illinois Medicaid would like to see the effective date extended by 1 year to allow a 36 month implementation period. We understand that there will always be competing projects, but Illinois will be starting from the ground up with this transaction and really feel the extra time is needed for successful implementation.
CMS-0050-P	55995	Overview of Clinical Document Architecture	We cannot comment on the merits of adopting CDA Release 2.0 over CDA Release 1.0, however, we are concerned about a scenario in which we would have to use and support both releases, or change releases immediately after implementation.
CMS-0050-P	55998	Combined Use of Two Different Standards	Combining the use of two standards will cause some unique issues that did not exist for the other transactions. Currently, our translator is not able ot handle the HL7 portion of these proposed transactions. We are unclear if this functionality will be in place when this final rule is posted. We will likely have to separate the HL7 portion of the transaction and find another way to check it for compliance. This will require more time and additional cost to implement and maintain. We ask that this be considered when evaluating the need to extend the effective date.
CMS-0050-P	56001	Provider VS Plan Perspective	"...a health care provider may direct a health plan to send any request for additional documentation to it or its business associate in standard form, for those attachment types for which a standard has been adopted here, and the health plan must do so." This seems to contradict the provision for unsolicited attachments. If a health plan gives instruction in their companion guide requesting attachment information for certain types of claims, does this mean the provider can ignore that instruction and require a 277 request transaction for each claim? Does this force the health plan to put a claim on hold and send a 277 instead of rejecting a claim with a reason of 'additional information required'? We would like clarification on the intent of this statement.

Illinois Healthcare and Family Services
File Code CMS-0050-P
Public Comments Submitted on November 18, 2005

File Code	Page #	Issue Identifier	Comment
CMS-0050-P	55999	Solicited vs. Unsolicited Attachments	"...health plans may solicit only one electronic attachment request transaction which would have to include all of their required or desired 'questions' and/or documentation needs relevant to that specific claim." We understand that the intent of this restriction is to prevent health plans from delaying payment by continuously asking for additional information. However, we do not feel that this is the appropriate place to address that issue. There is a complaint process to deal with these payers. This restriction is not going to hurt the health plans. If they do not get the information they need, they will be forced to reject the claim. This restriction will lead to a higher number of rejections which will only hurt the providers. We would like to see this language removed in the Final Rule.
CMS-0050-P	56000	Impact of the Security Rule	There will be a tremendous impact to security by implementing this proposed standard. Even though compliance with the security rule will be required prior to implementing this standard, this will change how the security rule is applied. This impact should be acknowledged in the Final Rule. None of the other standard transactions allow separate files to be submitted in a variety of formats. Allowing users to upload file attachments, particularly within the same interchange as the 837 transactions, puts internal systems at a much higher risk for viruses and other external hazards, as well as, creates the potential for the claims systems to be held up because of the file sizes of the attachment transmissions. We would like to see security issues evaluated and addressed in the final rule.

File Code	Page #	Issue Identifier	Comment
CMS-0050-P		Approval of future attachment types	Throughout this NPRM review process we have heard that a number of organizations are in favor of bypassing the NPRM process for future attachment types. We at Illinois Medicaid have mixed feelings about this. Certainly, we can understand that this transaction is different from the others and the full NPRM process seems excessive and time consuming just to implement a new type. However, we are concerned that bypassing the NPRM process and allowing DSMO approval to mandate a transaction for the industry is setting a dangerous precedent. We would like to urge careful consideration when making this decision, and if it is decided to allow DSMO approval to be the final decision, a very specific plan for industry notification and allowance of public input needs to be included in the final rule. There should be some document to take the place of the Final Rule, which the entire industry can refer to when questions arise about what exactly is required. There needs to be a public comment period so that organizations and individuals who are not members of HL7 or X12 have the ability to give input.
CMS-0050-P		Content overlap between 837 transactions and claims attachments	There are some data elements that overlap between the 837 transactions and the claims attachments. We are concerned about how this will be handled. If the elements are removed from the 837 transactions, health plans may have to request claims attachments where they never needed them before. It is difficult to see how this could "simplify" business processes for providers or health plans. We would like to see specific documentation in the final rule as to how these overlapping data elements will be handled.
CMS-0050-P	55999	Coordination of Benefits	Language should be added to the Coordination of Benefits section of the Final Rule to state that primary health plans are not allowed to send attachment data on to secondary health plans. It should not even be an option to forward this information.

Submitter : Susan McClacherty **Date: 11/18/2005**

Organization : Division of Health Policy and Finance

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-0050-P-37-Attach-1.DOC

Kansas Medicaid's Comments Regarding Ambulance Claim Attachment

Document Number	Page #	Par/Sec or Fed Reg Column	LOINC (if appropriate)	Comment or Suggested Change	Business Justification
Ambulance AIS CDAR1AIS0001R021	15	Table 5.1	HL79000	Add values to HL79000: Air Ambulance used instead of ground ambulance because 1) Patient condition not stable enough for ground, 2) ground travel hazardous to patient condition, 3) Delay in treatment would result in adverse affect on patient	Providers need to justify why a air ambulance is used versus a ground ambulance.
Ambulance AIS CDAR1AIS0001R021	15	Table 5.1	HL79000	Add capability to submit free-form text as justification for trip.	This is if the above is not granted as providers must justify why air ambulance is used versus a ground ambulance.

Submitter : **Ms. Deborah Belcher** **Date: 11/18/2005**

Organization : **IDX Systems Corporation**

Category : **Health Care Industry**

Issue Areas/Comments

GENERAL

GENERAL

IDX Systems Corporation is honored to have the opportunity to submit the attached document with our comments on the NPRM for HIPAA claims attachment standards.

Submitter : Ms. Deborah Belcher **Date:** 11/18/2005

Organization : IDX Systems Corporation

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

'See Attachment'
This may be a duplicate of comment 43381. When I printed that one it did show that the attachment was linked to it.

IDX Systems Corporation is honored to have the opportunity to submit the attached document with our comments on the NPRM for HIPAA claims attachment standards.

CMS-0050-P-39-Attach-1.DOC

Making a Difference in Healthcare

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November 18, 2005

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

Dear Ms. Doo:

Subject: Comments on 45 CFR Part 162 HIPAA Administrative Simplification: Standards for Electronic Health Care Claims Attachments; Proposed Rule

On behalf of IDX Systems Corporation, I am honored to have the opportunity to submit the enclosed comments on the NPRM for HIPAA Administrative Simplification: Standards for Electronic Health Care Claims Attachments. We are excited that these proposed standards for claims attachments have been published and we look forward to the final rule, as we think that the transactions offer substantial cost savings to the healthcare industry, both for healthcare providers and for health plans. Such cost savings ultimately reduce the cost of care for patients.

Founded in 1969, IDX Systems Corporation provides information technology solutions to maximize value in the delivery of healthcare, improve the quality of patient service, enhance medical outcomes, and reduce the costs of care. IDX supports these objectives with a broad range of complementary and functionality rich products installed at 3,300 customer sites.

Please contact me directly if you wish to discuss our comments.

Respectfully submitted,

Deborah J. Belcher
Principal Software Designer
(802) 859-6078
deborah_belcher@idx.com

Submitter :

Date: 11/18/2005

Organization : **Craig Hospital**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

ELECTRONIC CLAIMS ATTACHMENT TYPES

We strongly request that durable medical equipment (DME) attachment types be included with the six attachment types already selected. DME is so closely tied to our rehabilitation services. It does not make sense to exclude DME at this time when significant work has already been done on DME attachment standards and it would require going through the usual rulemaking process to get them added in the future. Let's get it right the first time and not require DME standards to be unnecessarily delayed, possibly for years.

Submitter : **Mr. Abhay Mainkar** **Date: 11/18/2005**

Organization : **Montefiore Medical Center**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

Please see attached MS-Word document title:Montefiore Medical Center - Comments on 275 NPRM.doc

Thank you.

Abhay Mainkar
Montefiore Medical Center.
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CMS-0050-P-41-Attach-1.DOC

45 CFR Part 162, [CMS-0050-P], RIN 0938-AK62
HIPAA Administrative Simplification Standards for Electronic Health Care Claims Attachments

Comment Number	NPRM or Tech.Spec Page #	NPRM Column (L,C, R)	Section	IDX Systems Corporation Comment on NPRM
1	56023 56024 56024	C C R	Subpart S 162.1002 (LOINC) 162.1915 162.1925 Standards and Implementation Specifications	**Proposed Standards** IDX is in agreement with the proposed X12 and HL7 standards for claims attachments, including the use of both the human decision variant (HDV) and computer decision variant (CDV) methods. We also agree with the selection of the LOINC code set to be used to identify the questions and answers, as outlined in the implementation guides and AIS booklets.
2	56024	C R	Subpart S 162.1915 and 162.1925 Standards and Implementation Specifications	**Add LOINC Modifiers to Standards** IDX recommends that 'LOINC modifier' be specifically cited as a standard in Sections 162.1915 and 162.1925.
3	55997	C	II.C.6 Format Options	**FORMAT OPTIONS** **Human Decision Variant (HDV) and Computer Decision Variant (CDV)** IDX recommends that both the HDV and the CDV methods of the CDA attachments recommendation be named in this Final Rule. The HDV allows electronic claims attachments to be implemented by both providers and payers in the near term. The CDV allows extended benefits to be obtained as both provider and payer systems separately evolve to have and use more structured data. Allowing both HDV and CDV concurrently gives the industry the option to implement them in parallel. It allows the benefits to be obtained through independent incremental business decisions. Each business can determine the benefit of the CDV to their business and when it is best to move to the CDV model, rather than have to react to a "one size fits all" regulatory mandate. Additionally, the provider sender controls whether to build the attachment in either the HDV or CDV format, while the payer can render it using either format.

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4	55999	R	II. C. 2 Overview of Clinical Document Architecture	**Clinical Document Architecture (CDA) Release 1 vs. Release 2** IDX recommends that the HL7 AIS guides be updated to move them to Clinical Document Architecture Release 2. We understand that HL7 will need to make changes to the HL7 IG and each AIS developed to be based on CDA release 2. We encourage and will support HL7 intention and work to make all necessary specification changes in as timely a manner as is possible. The benefits of using CDA Release 2 are: 1. Vendors can develop using a single version of CDA, rather than developing in two different versions with ongoing support of multiple versions. 2. CDA release 2 is consistent with all new standards coming from HL7 and is the release being used to develop EHR systems. 3. Providers who implement EHRs would benefit from CDA release 2 because they could take advantage of software solutions in their EHRs to create the electronic attachments. Most EHR vendors are developing CDA Release 2 implementations, not CDA Release1 implementations. 4. CDA Release2 is consistent and compliant with the U.S. Federal Consolidated Healthcare Informatics initiative and the proposed HIE standards.
5	55996 56024	C L	II.C.5 Electronic Claims Attachment Types Subpart S 162.1910 (C)	**ELECTRONIC CLAIMS ATTACHMENT TYPES** **Six Proposed Attachment Types** IDX supports the six initial attachment types being proposed as standards.
6	56001	R	II, E Attachment Content and Structure	**ATTACHMENT CONTENT AND STRUCTURE'** **BIN segment size** IDX supports the correction in the preamble by X12 on the recommended size limit of 64 MG to be a limitation per BIN segment, not per 275 transaction. Given the constantly changing landscape of technology, IDX does not want any specific size to be set as a standard, as it can quickly become outdated. We recommend that the 64 MB per BIN segment either be removed from the implementation guides. Or if it is left in the guides, then have it be a recommendation only. It should not be either a maximum limit or a standard.

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7	55993 56023	R R	II. A Definitions Subpart S 162.103	**DEFINITIONS** IDX recommends the definitions provided in the preamble also be the definitions that are given in the regulatory text. We note that some of the definitions do not seem complete in the regulatory text.
	55994 56006	L C	II.A.3 IIG.3.d	IDX recommends that the definition of "Clinical Reports" be expanded to point out that it does not include the actual medical diagnostic image, such as a cat scan or MRI. It does include the written report of the results of such tests.
	55994	L	II.A.4	IDX recommends that the definition of "Emergency Department" be clarified or expanded to include other health care services that may be provided in such a setting. It could currently be interpreted to only include services for "critical or life-threatening situations." However, many other services are provided in such as setting and may require the use of claims attachments.
8	56023	R	Subpart S 162.1900 Definitions	**DEFINITIONS** IDX recommends that LOINC and LOINC modifiers be included in the definition section of the preamble and the Final Rule.
9	56024	R	Subpart S 162.1920 (d)	**Use of LOINC codes in the 275 claim attachment transaction** NPRM section 162.1920 paragraph (d) states "A health care provider that sends scanned images and text documents in the attachment transaction, for the human decision variants, is not required to use the LOINC codes as the response, other than to repeat the LOINC codes used in the 277 request."
	56005	R	II.G.3 Electronic Health Care Claims Attachment Transaction	Additionally, the NPRM states "Information conveyed by the HL7 message would be the specific AIS provided in response to the LOINC code or codes contained in the request, or as an unsolicited (but pre-arranged) electronic attachment submission. Each electronic attachment type is identified by a unique LOINC code that indicates its name and appears in the header of the message for identification purposes; for example, psychiatric rehabilitation has its own unique LOINC code of 18594–2. Other LOINC codes used in the body of the message will specify the specific information related to that service that is desired (for example, the psychiatric rehabilitation plan)." IDX recommends clarification is obtained from X12 and HL7 on the following situations and that the final rule include specifics on how to handle all these situations in the 275 attachment transaction.

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9 (cont'd)	56006	R	II.G.4 Examples of How Electronic Health Care Claims Attachments Could Be Implemented	1. When the 275 is in response to a 277, then IDX agrees that the X12 portion of the 275 should include the LOINCs sent in the 277. The LOINC would be returned in the STC segment(s). 2. However, the LOINC code in the CDA header of that 275 attachment transaction may not be the same as the LOINC sent in the 277 request. An example is a request in the 277 for a specific data element. That data element can exist in a scanned image that include additional information and is classified as a whole with a different LOINC code than the one that is sent in the 277. Example is a request for a specific lab result where the information is included at the provider as part of a scanned progress note. There will be many other types of examples. 3. The 277 request may contain multiple LOINCs, with each LOINC from a different AIS booklet. How will we able to tell which LOINC code belongs to which AIS booklet? And therefore, if there must be a direct link between the 277 LOINC code and the CDA <document_type_cd> element in the associated 275, how do we determine which to use? 4. Paragraph d only covers the solicited model. The unsolicited model is not covered, where there would be no LOINC codes received since there is no 277. 5. IDX recommends that HL7 clarify the use of LOINC codes in the CDA header of the CDA <document_type_cd> element so that the same scanned document image can be classified once but used for multiple purposes, such as claims attachments and other uses, such as sharing between clinical providers. 6. IDX recommends that the final rule remove paragraph (d)'s reference to the LOINC code methodology and refer to the X12 and HL7 standards for this level of detail
10	55997 56014	L L	II.C.5 Electronic Claims Attachment Types III. Modifications to Standards, A & B. 1st paragraph	**ELECTRONIC CLAIMS ATTACHMENT TYPES MODIFICATIONS TO STANDARDS AND NEW ATTACHMENTS'** Standards Additions and Modifications Process IDX agrees with the recommendations from WEDI, X12 and H7 regarding changes to the standards adoption process for new AIS and for version changes. This will move the regulatory and the industry adoption process for changes much more quickly than the current process.

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10 (cont'd)				Repetition of the comments from WEDI, HL7 and X12. Comment 1: Our main goal is to move the regulatory process forward more quickly. For new attachment types* (AIS), we recommend that the DSMO be authorized to adopt those that are developed, balloted and published by HL7 through the DSMO process. Stop the process here and do not go through the full regulatory process. This overall process will include provisions for outreach and comments in the HL7 SDO processes. In addition, notification and rollout time between adoption and implementation date needs to be added after the HL7 publication. More time is needed to implement new types than for changes to existing ones. Comment 2: Additionally, we recommend that the initial six AIS be adopted as standards. Comment 3: Our main goal is to move the regulatory process forward more quickly. For new versions of standards by HL7 or X12, we recommend that the DSMO be authorized to adopt those that are developed, balloted and published by HL7 or X12 through the DSMO process. Stop the process here and do not go through the full regulatory process. This overall process will include provisions for outreach and comments in the SDO processes. In addition, notification and rollout time between adoption and implementation date needs to be added after publication. Provisions for sunsetting older versions of the standards after a transition period must be included. Additionally HL7 and X12 recommend that the Implementation timeframes of new HL7 AIS booklets should allow six months, minimum, for new attachment types, and 12 months for new versions of existing attachment types. The timeframe begins once the DSMO has completed its review/approval process.

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11	56014	L	III. Modifications to Standards, A & B	**LOINC code usage in each AIS booklet** IDX agrees with the recommendations from HI7 and WEDI regarding clarification in the regulation and in the implementation guides on the use of LOINC codes. IDX asks for clarification from HL7 and/or the Regenstrief Institute on how to identify in the LOINC database which LOINC codes apply to each AIS booklet. There are some fields in the LOINC database that seem to meet this need, but we would like an explanation as to how we can determine this for certain. The following are the comments from WEDI and HL7 Comment 1: because LOINC is adopted as a medical code set, the regulation needs to clarify the use of which LOINCs are used in each of the AIS documents. Recommendation that the regulation be clarified as follows: 1. Those AIS documents that contain static content (e.g. ambulance, ED, Rehab, Medication) the regulation must be clear that only the LOINCs enumerated in the AIS are allowed. 2. those AIS documents that reference the LOINC database (Lab results, clinical reports) the regulation should clarify that only the LOINC class as described in the LOINC DB (such as Lab results or clinical reports) defined for the AIS is allowed. Comment 2: Recommend a technical correction to the HL7 AIS booklets that reference the LOINC database to clarify how to determine the appropriate subset of the LOINC codes.
12	56025	C	Subpart S 162.1930 Initial Compliance Dates	**EFFECTIVE DATES** IDX thinks that the proposed timeline of 24 months from the final rule publication date to the effective date is feasible. Extending the effective date only defers the benefits that can be gained by the industry from implementing these transactions

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13	56001	C	II, D, 9 HC Clearinghouse perspective	Healthcare Clearinghouse Perspective Industry Readiness and Sequencing If the proposed rule is to be phased in according to the organization type, IDX recommends that health plans and clearinghouses need to be ready first. This does mean that vendors supporting these businesses will need to be ready to support them. Provider organizations would follow. In order to implement, all parties (vendors and covered entities) will need to do testing to show compliance with the final rule. IDX does not support any form of mandatory or official certification, as in our experience it added cost but no significant value to specific implementations. IDX does support voluntary use of reliable, low-cost testing that can be used by all parties that wish to use such services as part of their testing process. Perhaps this could be a new part of the 'Integrating the Healthcare Enterprise' (IHE) financial transactions domain, or a similar platform that could be established. This would allow payors, providers, clearinghouses, and vendors to test their implementations of the standard, and serve as a platform to help resolve rule interpretation discrepancies between trading partners in a collaborative, cost-effective and transparent manner.
14	56000	C	II , D.6 Connection to Signatures	**Electronic Signature** IDX concurs that there is no interoperable standard for electronic signatures today. Since there is no interoperable industry standard in the United States, we recommend that the final rule be silent on this topic, aligned with the HIPAA security standard.
15	55999 56024	L L	II.D.2 Solicited vs. Unsolicited Attachments Subpart S 162.1910 (a)(3)	**SOLICITED vs. UNSOLICITED ATTACHMENTS** The proposed regulation states the following condition under which providers may send unsolicited attachments: "Through instructions for a specific type of health care claim which permit a health care provider to submit attachment information on an unsolicited basis each time such type of claim is submitted." The WEDI/X12/HL7/AFEHCT 2005 claims attachment show that a substantial percentage (56%) of providers are currently sending unsolicited attachments. From IDX's conversations with providers, their highest priority to improve the attachment process is to be able to send unsolicited attachment, as the process speeds up the claims cycle. The survey on the health plans showed that many plans do provide information to providers today when they receive unwanted unsolicited attachments. 36% said they

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15 (cont'd)				Almost Always or Frequently published their attachment requirements. Only 34% said they sent policy messages to all providers (these could contain many of the same group, as respondents were allowed to select all modes that applied). 14% Almost Always or Frequently sent requests to specific providers, and only 12% specified the information in provider contracts. But more alarming was the 14% of payer respondents indicated that when they received undesired attachments they Almost Always, Frequently or Sometimes *refrained from notifying providers altogether.* This rule as written, using the term "instructions" puts all the control for unsolicited attachments in the hands of the health plan and allows the possibility for a health 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. The goal of all parties should be for attachments that are always requested to have health plans provide that information in advance to providers, so that the overall adjudication process becomes faster. Health plans should provide this information with easily accessible methods to providers, such as though web based materials or written materials. The final rule should permit advance instructions electronically and should be permitted to be conveyed over the Internet. For less common attachments, a health plan may work with specific providers to determine the conditions when an attachment is required. However, these types of arrangements could be through past experience, and therefore not formal contracts. Arrangements should not be limited to a formal negotiation process between trading partners, as this will add cost and time to the process. IDX 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

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15 (cont'd)				unsolicited attachment. 2. If a plan receives an unsolicited attachment, it may not later request the same attachment. 3. Health plans should publish advance instructions for attachment requirements to providers so that they are readily available.
16	N/A	N/A	N/A	**Claim Denials** Some health plans currently use a business process that will deny a claim for a reason of "needing additional clinical information", i.e. needing information that would be in a claim attachment. They do use either the unsolicited or the solicited model for additional clinical information. IDX would like clarification on that process. From a policy perspective with the new standards, can the use of denials only continue? Can the provider request that the health plan provide either the unsolicited or the solicited method or both? If this denial process can continue, how will the provider know the details of what additional clinical information to submit? The 835 remittance advice supplies only general claim adjustment reason or remarks codes, such as "needs additional information". Once they have the information on what clinical information to send, the provider is currently resubmitting the claim with that information. This may be done with both the claim and the attachment as paper. Or the claim might be an 837, while the attachment is on paper. Which electronic transactions would be used to send in the additional information post the denial? For this situation, can the unsolicited attachment model be used? Does the denial constitute advance instructions?
17	56024	C	**Subpart S – 162.1915 Standards and implementation specification for the electronic health care claims attachment request transaction**	**Standards Version** IDX recommends that the more recent version 5010 of the X12 guides for the 277 and for the 275 be named as the standards for these transactions. Knowledge gained since the 4050 version were published and comments received during this NPRM process can then be incorporated into the final 5010 version by work at X12.

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18	56024	C	Subpart S – 162.1915 Standards and implementation specification for the electronic health care claims attachment request transaction Also the X12 v4050 275 Implementation Guide - Section 1.3.2	**Unsolicited Attachment Uncoupled from the Claim** IDX recommends that the regulation allow for the ability to send the unsolicited 275 attachment separately from the 837 claim. The two should not be required to be bundled in the same interchange or transmission file (ISA/IEA). This change to allow sending of the separate transactions is in the version 5010 of the X12 Implementation Guide for the 275, so it can be incorporated into the regulation by naming version 5010 as the standard. A threshold that allows up to at least 3 days for timing between of the submission of the 837 claim and the associated 275 claim attachment should be included in the regulation. To avoid the need for negotiations and companion guides by every payer, payers should not be able to mandate the provider or clearinghouse to submit the 275 within the same business day, as this may not be feasible in all cases.
19	55999	R	II, D, 3 Coordination of Benefits	**Coordination of Benefits** IDX supports the proposed method for use of attachments with COB, in that payers should not send claims attachments that they receive on to subsequent payers. The final rule should have language that specifically states that If a payer receives an attachment, they are not required to send it on to the subsequent payers.
20	55999 – 56000	R L	II, D, 4 Impact of Privacy Rule	**Impact of Privacy Rule** IDX thinks the Privacy Rule is fully applicable and this rule should not contain more privacy language. IDX thinks that a requirement for providers to black out sections of a scanned document that includes more than the minimum necessary information will be so costly, as to inhibit adoption of electronic claims attachments. Clearinghouses are intermediaries between the provider and the health plan. IDX would like clarification on whether clearinghouses should keep claim attachment clinical data or should clearinghouses specifically not keep this data? IDX recommends that clearinghouses not be required to retain attachment data beyond business requirements.

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21	NA	NA	X12 and HL7 Implementation Guides	**Acknowledgement Transactions** The current paper claims attachment process includes much finger-pointing between providers and payers as to whether an attachment was sent or received. Therefore, IDX recommends that the Implementation Guides all include the use of acknowledgement transactions as audit trail for receipt and acceptance. We recommend that the 275 Implementation Guide be changed to remove the use of the X12 102 transaction. Change the reference in the 275 Implementation Guide to recommend the use of the X12 999 for syntax errors, and the use of the X12 824 TR3 to acknowledge both the X12 and HL7 content. To acknowledge the 277, we recommend the use of the X12 999 for syntax errors, and the use of the X12 824 TR3 to acknowledge the X12 content. This is in line with the WEDI Acknowledgements PAG recommendations.
22	56024	R	Subpart S 162.1920 Electronic healthcare claims attachment response transaction	**Electronic healthcare claims attachment response transaction** IDX recommends that this section be named "Electronic healthcare claims attachment transaction." The 275 attachment transaction is not always a response to a 277, such as in the unsolicited model. Remove "response" from the section title as well as any of the paragraphs in that section.
23	55999	L	II.D.1 Electronic Health Care Claims Attachments vs. Health Care Claims Data	**Clinical Data Elements in the 837 Claim** IDX requests that X12 clarify what will happen to clinical data elements that are currently in the 837 claims. Some of these elements overlap with data that is now in an AIS or will possibly be in a future AIS. This will result in confusion on when to use which transaction and it may result in differing interpretations by different health plans. Providers and payers will need clear direction for using the claims attachment transaction with the current 4010A 837. Additionally, what is the intent for future versions; will clinical data elements be removed from the 837 claims? If providers do not have to implement attachments, what happens when data elements are removed from the 837 claim?

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24	56000	R	II.D.5. Impact of the Security Rule	Impact of the Security Rule IDX recommends that the final rule include the option to transmit the attachments transactions using broadband access over the internet. This method must be secure, use open standards, and be accessible by multiple trading partners who wish to communicate via this method. The final rule should not disallow the internet as a communication vehicle for these transactions nor for any other transactions. Allowing this use of the internet will improve communications speed.
25	55998 56000 29	L R	II.C.7 Combined Use Of Two Different Standards Through SDO Collaboration II.D.7 Connection to Consolidated Health Informatics Initiatives HL7 Implementation Guide Section 3.3.4	**COMBINED USE OF DIFFERENT STANDARDS** IDX supports the use of X12 and HL7 as the appropriate standards organizations to develop these transactions, as they each represent the appropriate content experts for administrative and clinical information. **Future View – Connection to Consolidated Clinical Informatics** IDX supports the future use of URL as a reference pointer to attachment content in the provider's system as another method to access this clinical information. This would include appropriate security and trading partner agreement. This method is allowed in the CDA standard. While is it not currently used in the 6 named AIS, it may be in the future. IDX believes that, in the future, claims attachments will be a use case for the appropriate sharing of clinical information from EHR systems between health plans and providers that can use the same methodologies that are and will be used between multiple providers. IDX recommends that the regulation not specifically exclude the use of URL in the future, as this may be a technology method that will be used by various NHII to access information. The methods allowed for accessing clinical information should not be completely different for claims attachment purposes, since it will duplicate efforts and methods to sometime retrieve the same data.
26	1		HL7 AIS for LOINC Modifiers - section 1 X12 277 Implementation Guide	**Usage of LOINC modifiers in 277** The AIS_R021 Modifier Code booklet specifies that STC10 is supposed to contain time window modifiers and STC11 should contain item selection modifiers. The X12 277 guide has no such restriction, just that the modifiers can come in here in any order. Can STC11 be filled in without STC10? Why does it matter what kind of modifier comes in as long as STC10 and STC11 only have modifiers?

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27			HL7 Implementation Guide CDAR1AIS0000R021	**Reduce repetition of same BIN image** For the same claim, health plans may request multiple LOINC codes. The answer to each LOINC question may be the exact same document image in the HDV. This was the case in some of the pilot testing at Empire. IDX recommends changing the HDV method in the HL7 Implementation guide to allow the identification that the BIN segment answer is included in a previous BIN segment for the same claim (i.e. same 275). The additional BIN segments would refer to a permanent name instead of sending the same document image multiple times, thus reducing the size of the transaction.
28			X12	**Use of the 277 request for information (RFI) in conjunction with the 276/277 claim status transactions** IDX would like to have X12 clarify the use of the 277 RFI in conjunction with the use of the 276/277 Claim Status transaction. Possible scenario 1: The provider sends a 276 Claim Status request. The payer should respond with the 277 Claim Status Response that could say that the claim is pended and include a claim status reason code that is generic in nature, such as "additional information needed". Will the health plan also send a 277 Request for Information, which details what information is needed? Possible scenario 2: The health plan has already sent the provider a 277 RFI, requesting a 275 claim attachments. Prior to sending that 275, the provider sends a 276 Claim Status request. The payer should respond with the 277 Claim Status Response, which will say that the claim is pended and include a claim status reason code that is generic in nature, such as "additional information needed". Can the health plan send a second 277 Request for Information, which details what information is needed?
	55999	C	II.D.2 Solicited vs. Unsolicited Attachments	**SOLICITED vs. UNSOLICITED ATTACHMENTS** Will scenario 2 conflict with the NPRM proposal that "for each claim, health plans may solicit only one electronic attachment request transaction…"
	56024	C	Subpart S 162.1910 C	

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Centers for Medicare and Medicaid Services
Department for Health and Human Services
Attention: CMS-0050-P

References: 45 CFR Part 162
HIPAA Administration Simplification:
Standards for Electronic Health Care Claims Attachments; Proposed Rule
70 FR 184 9/23/05 pages – 55989-56025

The following comments are submitted to you for consideration by Montefiore Medical Center (MMC). MMC was one of the participants to pilot this pair of HIPAA transaction sets (277/275) in both Part A and Part B settings in collaboration with Empire Medicare Services (EMS). We would want to accentuate strongly that the document titled 'Evaluation of the Electronic Claims Attachments Pilot' being prepared by EMS for submission to CMS be reviewed thoroughly as part of the public comments. We recommend additional pilot testing that would include more variation in terms of reports, unsolicited 275s and CDV based testing.

Please note that MMC agrees with and supports the comments submitted by NUCC and NUBC as well as HL7 and X12.

Thank you,

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Montefiore Medical Center Comments to:
45 CFR Part 162 HIPAA Administrative Simplification:
Standards for Electronic Health Care Claims Attachments; Proposed Rule

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55994		II-B. Effective Dates	The timeframe outlined is aggressive but possible for the implementation of the claims attachment transaction. The fact that the solution allows various grades of technical specifications should facilitate implementation and allow a measured progression from a simple imaged document to a fully automated and codified adaptation.
55995		II-C-2 Overview of Clinical Document Architecture	The XSD's and name space provided in the HL7 documentation, as posted on their website (HL7.org), did not have technical corrections applied and resulted in incorrect name spaces in the CDA standards document. If HL7 CDA Release 1 is legislated, the technical corrections must be applied. We recommend using CDA release 2 if it has been properly adopted by HL7.
55996	L	5. ELECTRONIC CLAIMS ATTACHMENT TYPES	The large image sizes typical of TIFF images and the repetition of images throughout various BIN segments in a single 275 may cause difficulty in the FTP process due to long processing and transmission times. The same sets of images may often be the most appropriate for answering various LOINC codes The 275/CDA IG should clarify that when the same attachment answers multiple LOINCs in the attachment, it be sent once and the subsequent LOINCs should be answered with a "URN" to allow a pointer back to the first

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			BIN that contained the data.
55996 - 7		5. Electronic Claims Attachment Types	Recommend a large scale survey be done in the health care industry to determine the current types of claims attachments be used and the frequency with which they are used. This survey could be further expanded to gather data on the costs and savings related to the implementation of electronic claims attachment transactions.
55996 - 7		5. Electronic Claims Attachment Types	The NPRM is requesting input on the types of claims attachments that might be required in the next 5 to 10 years. Some of the examples are: As part of solicited 275 - DME reports, periodontal care, home care, secondary payer questionnaire, non-clinical documents such as coordination questionnaire/data, explanation of benefits, itemized bills etc. As part of unsolicited 275 - appeal letters, consent forms etc.
55997		5. Electronic Claims Attachment Types	Clinical reports can be broadly or narrowly defined. We recommend the broad definition to include multiple report types in order to offer flexibility during implementation.
55997		II-C-5 Electronic Claims Attachment Types	Recommend moving to CDA release 2, assuming that there is a pilot that uses the next version. The benefits of using CDA Release 2 would be: 1. More streamlined technical standard from HL7 with respect to various reporting

PAGE	COL.	SECTION	DISCUSSION
			2. Better vendor ability to develop functionality to allow providers a choice of off-shelf software being developed by these health care vendors 3. Better CDV components 4. Consistent with the U.S. Federal Consolidated Healthcare Informatics initiative
55997 - 8		6. Format Options (Human vs. Computer Variants) for Electronic Claims Attachments	The HDV allows economic benefits given the limitations of current provider/payer systems. The CDV allows extended benefits to be obtained (for attachment types ambulance, emergency department, rehabilitation services, lab results, medications, and clinical reports) as provider and payer systems evolve to have and use more structured data. Allowing both, and giving the industry the option to implement them in parallel, allows the extended benefits to be obtained gradually through incremental business decisions, which is far sooner than the benefits could be obtained through a "one size fits all" regulatory mandate. Please note that the pilot project used only HDV and a CDV approach was not used.
55998		II-D Electronic Health Care Claims Attachment Business Use	Strongly propose to include all post-adjudication requests/processes as part of the final rule. Claim attachment process should include activities requiring document request and submission not part of traditional adjudication process.
55998	L	II C 7 Combined use of Different Standards	We support the combined development of X12 and HL7 in the standard. HL7 and X12 should continue to refine the standard to meet technical and operational needs. Please refer to the Empire Medicare Service Evaluation of

PAGE	COL.	SECTION	DISCUSSION
			the Electronic Claims Attachment Pilot for specific HL7, X12, MIME, XML and base64 edits technical comments.
55999		4. Impact of Privacy Rule	Department of Health and Human Services (HHS) needs to provide more formal guidance on the impact of privacy in the specific areas of "minimum necessary" and patient's rights, especially when the providers are using HDV to scan documents that may contain more data on the same page/image than "minimum necessary". In addition, the NPRM does not address the responsibilities of receivers for maintenance of the data and use of the data.
55999		3. Coordination of Benefits	Support the potential of the claims attachment process to further streamline the adjudication process. For instance, with regard to the coordination of benefits, it would be beneficial to have an electronic attachment for a secondary payer questionnaire. We are in support of the language in the preamble that states that any secondary health plan may send an attachment request separate from a request made by the primary health plan since the requirements of the additional documentation may be different for the payers. We would like to see it clarified and restated in the regulatory text.
55999		2. Solicited vs. Unsolicited Electronic Health Care Claims Attachments	Unsolicited claims attachments provide more efficiency in the claims adjudication process when the provider is able to send documentation along with the claim when it is known from the prior experience that such a documentation is necessary for that payer. We recommend that the regulatory text be modified to allow a provider, based on prior arrangement and/or experience with a health plan, to be able to send unsolicited

PAGE	COL.	SECTION	DISCUSSION
			attachments until a health plan either issues advance instruction to clarify its requirements or explicitly instructs the provider that any attachment is not required for the type of claim in question. If the plan instructs the provider that an attachment is not required for certain services but resumes requesting the attachment, the provider may resume sending an unsolicited attachment for those services. Please note that the pilot project did not include testing of unsolicited claims attachments.
56001		8. Health Care Provider vs. Health Plan Perspective	Support the language that "a health care provider may direct a health plan to send any request for additional documentation to it or its business associate in a standard form, for those attachment types for which a standard has been adopted, a health plan must do so."
56001		E. Electronic Health Care Claims Attachment Content and Structure	With regards to file size, the 64 megabytes of data for a single transaction was acceptable for the text-based scanned images exchanged during the pilot. Given the complexities and resolution details of the images that may have to be sent, we strongly recommend that this limit be reassessed to include sizing for more complex images that include color, PET scans, MRI images, etc. During the pilot an attempt was made to submit a color image by one of the participants but the quality of the transmitted image was insufficient for an appropriate review due to lack of photographic details.
56012		H. Requirements (Health Plans, Covered Health Care Providers	The preamble of the NPRM states that "No other electronic transaction format or content would be permitted for the identified transactions." In addition,

PAGE	COL.	SECTION	DISCUSSION
		and Health Care Clearinghouses)	the regulatory text in Section 162.1905 states that when using "electronic media" a covered entity must comply with the applicable standards. We need more clarification on what constitutes "other electronic transactions" and "electronic media" when the NPRM and regulatory text in 162.1905 mention these terms.
56014		III. Modifications to Standards ,A & B. 1st paragraph	In order to move the regulatory process forward more quickly, we recommend that the appropriate DSMOs be authorized to adopt new versions of standards by HL7 or X12. This overall process will include provisions for outreach and comments in the SDO processes. The clarification on provisions for deactivating older versions of the standards after a transition period and period between notification and implementation must be included.
56018		4. Costs and Benefits	MMC expects to realize the ROI within a year of implementation of this transaction set. The cost savings on receiving/responding the attachment requests and appealing denials if the response could not be sent in timely manner, as well as a number of paper requests lost in transit that now would be managed, would pay for the project implementation costs quickly.
56024		162.1910	We support the language in Section 162.1910 (a) (2) that indicates that an attachment can be sent in advance of a health care claim. A more detailed guidance and clarification on the topic should be included (probably in the preamble).

Submitter : pam dixon **Date:** 11/18/2005

Organization : World Privacy Forum, EFF, EPIC, U.S. PIRG, PRC, PA

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-0050-P-42-Attach-1.PDF

HIPAA Administrative Simplification: Standards for Electronic Health Care Claims Attachment, Proposed Rule [45 CFR Part 162]

Comments of the World Privacy Forum, Electronic Frontier Foundation (EFF), Electronic Privacy Information Center (EPIC), PrivacyActivism, Privacy Rights Clearinghouse, and U.S. Public Interest Research Group (U.S. PIRG)

Via http://www.cms.hhs.gov/regulations/ecomments and express mail.

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

November 18, 2005

Re: HIPAA Administrative Simplification: Standards for Electronic Health Care Claims Attachment, Proposed Rule. [45 CFR Part 162] [CMS-0050-P]

Pursuant to the notice published in the Federal Register on September 23, 2005 regarding HIPAA Administrative Simplification: Standards for Electronic Health Care Claims Attachment, Proposed Rule [45 CFR Part 162] [CMS-0050-P], the World Privacy Forum and the Electronic Frontier Foundation (EFF), Electronic Privacy Information Center (EPIC), PrivacyActivism, Privacy Rights Clearinghouse, and U.S. Public Interest Research Group (U.S. PIRG), ("The Submitters") respectfully submit the following comments.

The comments are divided into three sections. Section one, "General Comments," includes general comments about the Notice of Proposed Rule Making (NPRM). Section two "Specific Comments" includes comments relating to specific sections of the NPRM. Each comment in section two begins with a label per the NPRM instructions, such as DEFINITIONS, or COSTS and includes the outline number and page number as it appears in the NPRM. Section three is a brief conclusion.

I. General Comments on the Notice of Proposed Rulemaking

The Department of Health and Human Services (HHS) seeks to assist the transition of the healthcare sector from a paper-based process to an electronic data interchange (EDI) based process.[1] The submitters contend that not enough attention has been paid to protecting patient privacy, choice, and security in this process. Specific areas of concern in the Healthcare Claims Attachment NPRM include those relating to the impact on the Privacy Rule, the standards making process, balancing goals of EDI adoption with privacy, protecting the minimum necessary rule in spirit and in practice, issues related to solicited attachments, and cost and savings assumptions, among other issues.

A. General Comments on the Standards Process and Outcomes

We understand that the NPRM reflects years of work by the many individuals, corporations, and stakeholders involved in the standards processes discussed in the NPRM. However, the shortcomings in this standards process have excluded some stakeholders, in particular, stakeholders in the privacy community.

Few, if any, non-profit privacy organizations have the practical ability to actively participate in the standards process due to the costs associated with such participation. Membership in ASC X12N for nonprofit organizations is $2,500 a year. In addition to this recurring fee, there are additional costs of attending the X12 meetings, which are held around the country and add thousands more dollars in travel-related costs. Participating in HL7 would add another tier of membership and travel costs. While these costs may be manageable for some large non-profit organizations, privacy groups are typically small organizations with budgets that do not realistically allow for such expenditures.

To actively participate even as a non-member is also expensive. For example, to simply read the X12 and UN/EDIFACT publications costs thousands of dollars, according to ASC X12N. Some of these documents are free for members or are offered at a lower price for members. For non-members, the fees can be substantial.

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[1] In our use of the term Electronic Data Interchange or EDI in these comments, we using it in its broadest sense and are including XML in our definition.

Thus, the standards processes that HHS relies upon in setting basic rules that directly affect privacy and security of patient information are structured so that privacy perspectives are unrepresented. This exclusion of privacy perspectives may not be intentional, but the result is the same. Important perspectives are absent, and that absence damages the legitimacy of the standards process, leads to unbalanced results, and may ultimately impede public acceptance of HHS actions that rely on standards. As HHS moves toward the establishment of increased computerization and networking of health records, it cannot afford to allow relevant views to be routinely overlooked as standards are developed.

Privacy must be incorporated into the standards making process from the beginning of the process all the way through to the final outcomes. While the privacy community values the NPRM process and the rights the process affords, in the case of NPRMs that incorporate industry consensus standards, the standards process must be genuinely and practicably open from the beginning, or the stated goal of conducting an "open" standards process cannot be met. It is insufficient that privacy groups can only comment after the standards process is complete – privacy is not something that can simply be tacked on at the end of a long process.

The best way to accomplish an open standards process that includes privacy is to involve privacy organizations from the beginning of that standards making process, and to incorporate privacy viewpoints throughout the standards setting process. We request that HHS remedy the shortcomings in this process in such a way that will ensure the participation of interested privacy organizations.

To accomplish this, we specifically ask that HHS insist that standards groups incorporate more privacy awareness in the standards through the direct involvement of privacy groups in the standards process, and by reaching out actively to the privacy groups. We also ask HHS to mandate that standards groups affirmatively disclose all privacy, patient, and consumer groups that participated in the standard development. We also ask HHS to require standards groups to document their affirmative steps to bring privacy, consumer, and patient groups within the process.

B. General Comments on Goals of Standardization

The goals HHS articulates in the NPRM of having a more automated, standardized approach to health care information exchange must be balanced by privacy, patient choice, and security concerns. Finding a way to protect privacy, patient choice, and security is particularly important as health information formats transitions to automatically adjudicated models. This includes healthcare claims attachments.

C. General Comments on Cost

The cost estimates set forth in the NPRM are not appropriately substantiated and are therefore not reliable. HHS' estimates of cost savings is based on a single 1993 WEDI report coupled with "conservative assumptions" from the Transaction rule to predict costs and savings. The NPRM states that some of the cost estimates were based on "informal discussions with industry representatives of health plans and vendors."

A grouping of 12-year old data, "conservative assumptions," and informal discussions with industry members is not an appropriate factual basis upon which to rest either a broad assertion of cost saving or specific costs and savings assumptions. Another concern is that HHS did not use an important August 2005 WEDI report on healthcare claims attachments in its estimates, a report that if used would have changed the cost estimates, particularly the savings.

D. General Comments on the Privacy Rule and the Minimum Necessary Standard

The current approach of the NPRM does not adequately protect the minimum necessary standard because health providers are not always able to redact electronic content at a sufficiently granular level due to limitations imposed by some vendors' systems. The minimum necessary standard, as articulated in the Privacy Modification Final Rule [§164.502 (b)(1)] requires a covered entity to make reasonable efforts not to use, disclose, or request more than the minimum amount of Protected Health Information (PHI) than is necessary to accomplish the intended purposes of the use or disclosure. As HHS promulgates rules promoting broad adoption of electronic interchanges of data, the minimum necessary standard needs to be protected in all interchange scenarios, including

digital formats. To accomplish this in practice in healthcare claims attachments, it will be necessary for health providers to be able to easily redact unnecessary information from electronic documents at a very specific level, for example, editing content line by line – something that is currently challenging for many providers.

It is, for example, a common practice of physicians when dealing with paper medical files and related records to remove the paper documents that are unnecessary for the adjudication of a health care claim. The patient correspondence section of a medical file will not always be necessary to send to a health plan. If such a correspondence is relevant, only the relevant pieces of correspondence would be sent.

However, in electronic format, the information selection and "publication," or "printing to an electronic file" process [2] has many imperfections due to restrictions imposed by some vendor software. In the EDI environment, providers do not always have the ability to create an electronic medical file with control over specific content at a sufficiently granular level, as opposed to control over which entire sections of a file should be included in the file.

For example, a provider may need to submit the central medical data set from a file to a health plan along with an attachment. As previously discussed, in a paper format, providers can manually remove the pieces of paper in the data set and attachments that are not necessary. However, when a provider has to "publish" and share the central medical data set and attachments electronically, the provider may not be able to edit the content level of the data to a deep enough level to permit the removal of unnecessary information embedded within the data set. For example, in some major vendor software, a physician can only include an entire data set or attachment with no content-level edits in the electronic version of the medical file. That is, the physician cannot remove unnecessary information at the paragraph level.

As a result, information that a provider would not have sent in paper format often is sent in electronic format. This issue is frequently beyond the control of the provider. This problem is further exacerbated in the case of scanned documents that may contain abundant data not directly connected to a claim.

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[2] The term "publishing" in these comments refers to a term or art that providers use when changing a medical file into one or more electronic formats for internal use or for use in billing and providing patient care.

The end result of these challenges is that the "minimum necessary" standard is being diluted in the EDI environment. Providers do not intentionally set out to dilute or circumvent the minimum necessary rule, and many providers struggle with software systems and vendors in their efforts to comply with the rule. But vendors do not have motivation to change their systems.

We ask that HHS include in the healthcare claims attachments rulemaking a requirement that health providers have the capability of line-level editing and paragraph-level editing throughout the entire content of a published electronic medical file or health record or attachment. If HHS does not mandate this capability, then vendors will not have to make it available. We recognize there will be a cost associated with this requirement, but the cost will be amortized over millions of records and over a long period of time. This requirement does not need to go into effect immediately, but the requirement should be stated in the final rulemaking and industry should be allowed sufficient time to comply. At a minimum, HHS should mandate that new systems include granular editing capabilities. If it is not practical to mandate the same requirements for some or all legacy systems, HHS should nevertheless define the requirements for the future.

HHS has the opportunity with this rulemaking to give those making healthcare decisions the power and ability to carefully edit at a granular, paragraph by paragraph level, electronically published health records and attachments. Health care providers need and require more detailed control over the content aspect of electronic publication of medical files. This will enhance privacy for patients, and may help to increase patient trust in electronic systems.

II. Comments on Specific Elements of the NPRM

In our specific comments, we have retained the original NPRM outline numbers for clarity, and we have used the HHS section descriptions where available. The page numbers refer to the original NPRM page numbers.

Section II: Provisions of the Proposed Regulations p. 55993

A. DEFINITIONS p. 55993

(3.) Clinical reports definitions p. 55994

Scanned files that become claims attachments introduce special problems in regards to rigorously excluding psychotherapy notes from clinical reports in actual practice. The NPRM states that: "Clinical reports means reports, studies, or notes including tests .... Clinical reports do not include psychotherapy notes" (p. 55994). In the case of covered entities that choose to use scanned images (documents) as attachments, there is the possibility that a scanned document with necessary information such as lab reports or studies may also contain psychotherapy notes. It is unreasonable to expect that that this situation will never arise, particularly in the case of scanned files.

Compounding this fundamental challenge, a further difficulty arises after the attachments are sent to a health plan. A majority of respondents in the August 19, 2005 WEDI/HL7/X12/AFEHCT National Healthcare Claims Attachment Survey Final Report stated that scanned attachments, after being sent to a health plan, are "Almost Always" saved and stored (WEDI 2005 Survey, p. 44).

Scans stored in a database can lead to increased potential for misuse or patient harm beyond the initial claims attachment adjudication process. Unfortunately, there are already examples of health plan database breaches. Medica Health Plans (Minnesota) experienced a database breach in 2005 that affected 1.2 million individuals. In this situation, hackers stole sensitive and confidential data from Medica's computer system two times in January 2005 and shut down parts of the system on four other occasions, exposing members' SSNs, addresses, dates of birth, employment information, and names of relatives.[3]

We urge HHS to acknowledge the challenges scanned files introduce and find a way of addressing this problem in the final rulemaking so that psychotherapy notes do not get inadvertently attached as an image file of a larger document and then subsequently stored at a health plan. HHS may need to mandate fine-grained editing capacities for software tools so that psychotherapy notes can be redacted. It may also be

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[3] See <http://www.securityinfowatch.com/online/Cabling--and--Connectivity/Medica-Health-Plan-Alleges-that-Former-Employees-Hacked-Sensitive-Data/4484SIW422>.

advisable to require periodic audits of stored records to purge psychotherapy notes.

C. OVERVIEW OF KEY INFORMATION FOR ELECTRONIC HEALTH CARE CLAIMS ATTACHMENTS p. 55994

It is not feasible to properly evaluate HHS' claims regarding the impact of increased computerization and networking without better information. The NPRM states that: "This proposal has the potential for helping the industry attain desired efficiencies, expedite payments, reduce fraud and abuse, and improve the accuracy of medical information" (p. 55995 paragraph 2).

If attaining efficiency, expediting payments, reducing fraud and abuse, and improving the accuracy of medical information are the stated goals of the NPRM, then a formal study and regular, public reporting of specific outcomes in all of these areas should be mandatory in order to provide a factually determined basis for these statements. We therefore request that HHS formally undertake a sector-wide study and subsequently publicly report on the efficiency, abuse and fraud reduction, and accuracy improvement claims made in this NPRM.

It is also essential that more information be available on the costs and benefits of health information systems. If HHS ultimately contemplates the expenditure of tens of billions of dollars on health care information technology, then HHS must prove to the public that these dollars will be well spent.

(5.) ELECTRONIC CLAIMS ATTACHMENT TYPES p. 55996

The process of deciding on the six types of claims attachments went through a multi-year process and through pilot programs with a great deal of industry input. While this is completely appropriate, any future electronic claim attachment types need to be decided upon after greater outreach to smaller stakeholders and a wider variety of stakeholders, including the privacy community. HHS should establish a specific and verifiable process to ensure that privacy stakeholders are affirmatively included in these longer decision- making processes.

(6.) FORMAT OPTIONS p. 55997

The NPRM notes two primary functional models using a variety of format options, the human decision variants and the computer decision variants. We see the human decision variant as described in the NPRM as a helpful "stopgap" measure during a transitional time from paper to electronically adjudicated claims. Even though the human decision variant represents a transitional process, the reality of HIPAA implementation is that even decades from now some providers may still be using the human decision variant. For this reason, it is important to pay attention to all details of the transitional system, which we have commented on in more detail below.

D. ELECTRONIC HEALTH CARE CLAIMS ATTACHMENTS BUSINESS USE p. 55998

(2.) SOLICITED VS. UNSOLICITED ATTACHMENTS p. 55999

We agree with HHS's decision to restrict unsolicited attachments, and to require solicited attachments insofar as this supports the minimum necessary standard and eases challenges with document storage, retrieval, and handling. However, we are concerned about the proposal to allow for the solicitation of only one attachment. The NPRM states:

> "We also propose that for each specific claim, health plans may solicit only one electronic attachment request transaction which would have to include all of their required or desired 'questions' and /or documentation needs relevant to that specific claim. Health care providers would be required to respond completely to the request, using one response transaction" (p. 55999).

We do not oppose the one-attachment policy as a policy matter. We are concerned about its privacy consequences. In order to comply with the one-attachment rule, it is probable that more data than is necessary will often be included in that attachment. Allowing only one solicitation may effectively reverse or undermine the minimum necessary standard.

Further, allowing a health provider to rely on a health plan's "request" as meeting the minimum necessary rule is problematic when taken together with the fact that only one solicitation will be allowable. We urge HHS to deny health care providers the ability to rely on health plan requests that are not consistent with the minimum necessary rule.

The purpose is to ensure that the rule for one solicitation does not become a solicitation for all documentation in one fell swoop, even unnecessary documentation.

We recognize the inherent tension between providing for only one solicited attachment and asking that providers "consider" the minimum necessary rule. HHS needs to recognize that tension as well. We request HHS to articulate a way for providers to share information in that one solicited attachment in a way that respects privacy *and* the minimum necessary rule. HHS's commitment to privacy will be judged by how it resolves this tension. The need for a careful and privacy-protective resolution to this issue is magnified in importance by the fact that this is all a precursor to the NHIN, which will magnify the risks to privacy.

(4.) IMPACT OF THE PRIVACY RULE p. 55999

Reliance upon requestor should not apply in all circumstances

The NPRM allows a health care provider to rely upon a health plan's request for information as meeting the minimum necessary requirement:

> "A health care provider may rely, if such reliance is reasonable under the circumstances, on a health plan's request for information, or specific instructions for unsolicited attachments, as the minimum necessary for the intended disclosure" (p. 56000).

To the extent that a request is consistent with a standard or a practice within an industry, relying on a request appears to be readily acceptable. But – the reliance will only be acceptable to the extent that a requester understands and complies with the minimum necessary standard. When a request goes beyond normal bounds, the ability to rely upon the request should no longer apply.

If health care providers are allowed to rely on a request to meet the standard, this leaves the door open to many abuses, particularly in the EDI environment. We request that HHS prohibit health care providers from relying upon requests that are not consistent with the minimum necessary rule. We understand that the NPRM gives providers the ability to retain the discretion to make their own minimum necessary determination, which is fine. However, the reliance loophole should be closed or narrowed.

Further, the policy allowing reliance runs the risk that industry practice will overwhelm the minimum necessary rule. If all insurers decide to insist on extraneous data elements, then the industry practice standard will mean that disclosure is acceptable even though the minimum necessary rule is not otherwise met. HHS needs to ensure that the creeping demands of administrative convenience do not overwhelm the intent of the minimum necessary policy.

Scanned documents and challenges to the minimum necessary rule

The NPRM states that in the case of submitting scanned documents, "efforts will be need to be made to ensure that those documents do not contain more than the minimum necessary information." When an attachment is sent as an image, adjudication will have to be accomplished manually using an image viewer or a web browser. Because this option represents the least organizational change in moving to electronically transmitted attachments, we expect that it will be a popular option. However, scanned documents represent a substantial challenge to the minimum necessary rule and pose many potential problems.

Providers do not always have the ability in the EDI environment to publish, or "print to electronic file" a medical file with precise control over specific content, as opposed to broad control over sections of a file. For example, a provider may need to submit the central medical data set to a health plan with an attachment. In a paper format, providers will frequently manually remove inapplicable pieces of paper in the central medical data set and attachments. By doing so, providers are able to comply with the minimum necessary rule. However, when a provider has to "publish" a data set electronically (ie, create it in electronic format) , the provider may not be able to edit the content level of the data sets to a deep enough level in order to remove unnecessary data elements embedded within the data set. This is particularly true in the case of scanned documents, which may contain abundant data not connected to a claim.

Shortcomings of technology can undermine minimum necessary rule. We support HHS's efforts to continue application of the minimum necessary rule to scanned documents. We encourage HHS to broaden that rule to include all attachments.

(5.) Impact of the Security Rule p. 56000

We agree that all claims attachments must abide by the Security Rule, including scanned documents. We have concerns about the storage of attachments, particularly scans. We encourage HHS to consider long-term storage of attachments sent to health plans in any upcoming modifications to the Security Rule. This would include, for example, long term storage of attachments in databases.

(6.) Connection to Signatures p. 56000

The NPRM solicited input from industry on how "electronic signatures" should be handled when an attachment is requested and submitted electronically. The NPRM states in its discussion of "electronic signatures" that "a consensus standard does not presently exist that we could propose to adopt ..." (p. 56000). It is true that HHS could not adopt the current standard – which is a W3C standard -- due to HHS' restriction of adopting standards from only ANSI-accredited Standards Development Organizations specifically designated by HHS to manage the maintenance of the EDI standards adopted under HIPAA. [4] But there is nevertheless an industry consensus standard on (cryptographic) digital signatures. [5]

The W3C *xmldsig* is the widely recognized foundation for digital signatures. In order to replicate a paper signature block, *xmldsig* is included in the schema and the bit of meta data in a traditional signature block is added. That is the way digital signatures are created and used currently. Reliance on this specification is nearly universal in XML messaging.

The W3C *xmldsig* is a consensus standard. The *xmldsig* is a W3C recommendation, which means it is approved by W3C members.[6] It has been incorporated into OASIS' WS-Security specification, which itself has been approved by OASIS' members, which has in turn been profiled by WS-I (in final stages of review). Whether something is taken

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[4] ANSI is the acronym for the American National Standards Institute < http://www.ansi.org>; W3C is the World Wide Web Consortium < http://www.w3.org/Consortium/ >.

[5] We are using the term *digital signature(s)* to refer to cryptographic digital signatures. "Electronic signatures" can mean many things, including insecure, noncryptographic forms of signatures that would be inappropriate for use in handling healthcare claims attachments due to security vulnerabilities.

[6] See <http://www.w3.org/TR/xmldsig-core/>.

up by WS-I and whether it is finally approved depends on what the organization calls an "N-1" consensus.

In its November 7, 2005 final rule, the Centers for Medicare and Medicaid Services adopted "foundation standards" for Medicare e-prescribing with its publication of its 42 CFR Part 423 Medicare Program; E-Prescribing and the Prescription Drug Program. The standards, which will be adopted January 1, 2006 include:

- Version 5.0 of the National Council for Prescription Drug Standards (NCPDP) Script standard, which allows physicians to transmit prescriptions to pharmacies;
- ASC X12N 270/271 Version 4010, which allows providers to check eligibility for benefits; and
- NCPDP Telecommunications Standard 5.1, which pharmacies can use to check eligibility.

Although the e-prescribing standards are officially adopted "foundation standards," these standards will not be adequate for use in healthcare claims attachments. Because the W3C *xmldsig* standard is already in use by large financial institutions and insurance companies, including in their use of attachments, it is entirely reasonable to expect that large commercial software vendors, as they write software to mesh billing and medical applications, will rely on the developed consensus standard in actual use, that is W3C *xmldsig*. If this happens on a wide scale, then hospitals, in order to use the software available to them, will likely use the defacto standard, *xmldsig*.

In light of its silence on digital signatures in electronic healthcare claims attachments, it is entirely possible that HHS will not be able to realistically change this outcome. We foresee a possibility of HHS needing to adopt the W3C standard at a future date. On one hand, ignoring the standard may work, at least in the short term. But because W3C is not among the organizations designated to manage the maintenance of the EDI standards adopted under HIPAA, if the standard was eventually adopted, there may be some challenges.

Instead of ignoring the complex set of issues surrounding digital signatures, we urge HHS to find a reasonable way either to pilot test the existing W3C standard – and bring privacy stakeholders into that process – or to bring ASC X12N into the W3C process in a more robust way and find a way of making that process move faster and

work more efficiently, or to employ a combination of the above. Because of rapid developments on adoption of digital signatures, it is unrealistic to expect that vendors will wait to build digital signatures into billing and other applications that hospitals can use until a standard is set by an HHS-designated ANSI-accredited standards organization.

We request that HHS face this issue head-on and work to incorporate the viewpoints of all stakeholders in the outcome.

G. PROPOSED STANDARDS p. 56004

In the general introduction to these comments, we discussed the challenges associated with adopting "industry consensus standards" as regulation without input from all stakeholder groups. It is difficult to come in at the late date of an NPRM and evaluate code sets for privacy and security considerations, much less effect any substantive change to enhance privacy and security at that point. We repeat our assertion that privacy stakeholders need to be involved in the standards making process, and that HHS require the standards bodies to show how they are working to involve privacy groups.

H. REQUIREMENTS p. 56012

I. SPECIFIC DOCUMENTS AND SOURCES p. 56013

VI. REGULATORY IMPACT ANALYSIS p. 56014

After the healthcare claims attachment rule is in effect for one year, we request that HHS prepare and make available to the public an analysis of the impact of this rulemaking on the privacy and security rule. HHS might ask the National Committee on Vital and Health Statistics to play a role in defining or conducting the analysis.

B. COSTS AND BENEFITS p. 56016

(4.) Cost and benefit estimates p. 56018

We question the HHS cost and benefit estimates. The specific estimates of cost savings from HIPAA transaction standards were, according to the NPRM, based on a single 1993 WEDI report coupled with "conservative assumptions" from the Transaction rule to predict costs and savings. The NPRM further states that some of the cost estimates were based on "informal discussions with industry representatives of health plans and vendors." A grouping of 12-year old data, "conservative assumptions," and informal discussions with industry members is not an appropriate factual basis upon which to rest either a broad assertion of cost saving or specific costs and savings assumptions.

Further, it is strange that the NPRM did not take into account the landmark WEDI/HL7/X12/AFEHCT National Healthcare Claims Attachment Survey Final Report in its proposed rulemaking. This report was published August 19, 2005, which gave HHS enough time to correct or at least inform some of the foundational errors in its calculations.

HHS relied upon the 1993 WEDI figure that 25 percent of all health care claims required support by an attachment or additional documentation. This figure has changed, as documented by the 2005 WEDI report. In the August 2005 WEDI report, the majority of health plan respondents surveyed stated that only 1 to 5 percent of claims required attachments. The next largest group of respondents stated that only 5 to 10 percent of claims required attachments (WETA 2005 Survey, p. 39). These numbers, if used, along with others, would have provided different cost and savings outcomes.

To begin to document and provide realistic and fact-based cost and savings analysis in this area, we request that HHS prepare and publish a sector-wide study to determine actual costs and actual savings of the implementation of the healthcare claims attachments rule prior to promulgating the final rule. It is important to accurately determine costs and savings in the electronic environment, given the HHS focus on transitioning to an EDI-based process in many aspects of healthcare data collections and flows.

III. Conclusion

A recent national consumer survey found that "[C]onsumers continue to have

serious misgivings about the security of their personal health information. Without strong safeguards, reliable privacy protection, and vigilant enforcement of privacy laws, public support for the national effort to develop a health care network could be in jeopardy" (National Consumer Health Privacy Survey 2005, California Health Care Foundation, November 2005, p. 2).

This conclusion is based in part on the response of 67 percent of 2100 people surveyed who stated they were "'somewhat' or 'very concerned' about the privacy of their personal medical records. In addition, the survey found that recent high-profile information privacy breaches have contributed to both the public's level of awareness about how much of their personal information is held by entities over which they have no control and how vulnerable that information is. This in turn has increased public concern about the privacy of medical records.

The adoption of standards for health claims attachments does not grab as many headlines as, for example, the NHIN. However, the health claims attachments standards will be widely used and will substantially impact patients' privacy. HHS must protect patient privacy, choice, and security in this process by maintaining the integrity of the minimum necessary standard in spirit and in practice, making the standards process more inclusive and fair, and generally balancing goals of EDI adoption with privacy. How HHS balances its goals of efficiency with protecting patient choice, privacy, and security will be an important test of how it will handle other issues such as the NHIN. The outcome will ultimately help or hurt patients' trust in the privacy of their medical records.

Respectfully submitted,

Pam Dixon
Executive Director
World Privacy Forum

and

Lee Tien
Senior Staff Attorney
Electronic Frontier Foundation

Melissa Ngo
Staff Counsel
Electronic Privacy Information Center

Linda Ackerman
Staff Counsel
PrivacyActivism

Beth Givens
Director
Privacy Rights Clearinghouse

Ed Mierzwinski
Consumer Program Director
U.S. Public Interest Research Group (U.S. PIRG), National Association of State PIRGs

Submitter : Dr. S. Jerome Zackin
Organization : Dr. S. Jerome Zackin
Category : Other Practitioner

Date: 11/19/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
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.

Submitter : Dr. S. Jerome Zackin **Date:** 11/19/2005

Organization : Dr. S. Jerome Zackin

Category : Other Practitioner

Issue Areas/Comments

GENERAL

GENERAL

It is important to realize that dentistry is not medicine. While vast numbers of claims are filed, most are for relatively small amounts. The overwhelming majority do not require information beyond what is contained on the claim form. While claims for periodontal procedures constitute only 5-6% of all dental claims, the majority of third party dental benefits carriers require documentation prior to adjudicating claims for many of them. While an increasing number of these are submitted electronically, most still accompany paper claims. A continuing problem among dentists is the separation of attachments from claims by carriers so they are not available for review by the consultant. All too often, the same information is requested from the dentist. The result is a three to four weeks delay in claims processing and frustration and added expense in the dental office. Because of these delays and the added expense associated with them, an increasing number of dentists are refusing to accept assignment of benefits or to file dental claims on behalf of their patients. Documentation and a completed claim form are given to the patient who is told to file them him/herself. Electronic submission of claims and documentation avoids many of these problems. Development of standardized electronic documentation for each periodontal procedure would allow the dentist to simplify matters in his/her office, thereby reducing expenses. It also would allow carriers to access needed information at the time the claim is adjudicated, simplifying the process and reducing their expenses.

To allow carriers to reject unsolicited electronic documentation would bring the claims adjudicating process back to well before the current paper claims. Carriers would receive an electronic claim and then solicit the documentation which currently accompanies claims.
Weeks-long delays would be built into the system. On a practical basis, though, the result would be a refusal by many dentists to file claims, either electronically or on paper, on behalf of their patients, thereby defeating the whole simplification process. It would seem that dentistry (and our patients) and the dental benefits industry would be well served by exempting them from the proposed regulation and allowing development of standardized documentation requirements for each periodontal procedure.

Submitter : Peter Preziosi **Date:** 11/19/2005

Organization : American Association for Medical Transcription

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-0050-P-45-Attach-1.DOC

AAMT
AMERICAN ASSOCIATION FOR MEDICAL TRANSCRIPTION

November 19, 2005

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

On behalf of the American Association for Medical Transcription (AAMT), we are submitting comments related to the proposed rule CMS-0050-P specifically issues in the section "ATTACHMENT CONTENT AND STRUCTURE." AAMT is the professional association that represents business associates in the medical transcription field and advocates on behalf of the profession to ensure that quality medical documentation and patient safety remains a high priority for the healthcare system.

AAMT supports an XML-based standard for electronic healthcare claims information that would increase the use of XML as a document standard for a wide variety of data and concur with the proposed named electronic attachment types specified in the administrative transactions outlined in the proposed rule. The Clinical Document Architecture specifications of HL7 will increase the use of XML as a document standard in healthcare documentation as well as increase the likelihood of reaching a point of standardized reports. Such a move has the potential to decrease the cost of healthcare transcription because standardized formats would eliminate the need for every facility and physician from having their own style of organizing a report.

Standardized reports in transcription support patient safety and document integrity by ensuring that data is consistently captured and displayed in the same record field, thereby increasing healthcare compliance and uniformity throughout the care team. Widespread use of XML-based standards also has the potential of improving the revenue cycle, as the data tags would make extracting information for coding and billing easier to do increasing the productivity and accuracy of medical transcriptionists and coders. We applaud the authors on creating a workable standard for the industry and believe this will add value to the administrative simplification process.

Sincerely,

Peter Preziosi, PhD, CAE
Executive Director
American Association for Medical Transcription

AMERICAN ASSOCIATION FOR MEDICAL TRANSCRIPTION
100 SYCAMORE AVENUE, MODESTO, CALIFORNIA 95354-0550
PHONE: 209-527-9620 • FAX: 209-527-9633 • EMAIL: aamt@aamt.org • WEB: www.aamt.org

Submitter : alan shugart **Date:** 11/21/2005

Organization : HHS/CMS/CMSO/FSBG/Divsion of State Systems

Category : Federal Government

Issue Areas/Comments

GENERAL

GENERAL

The Division of State Systems within the Center for Medicaid State Operations, which has federal oversight of the the State's Medicaid Management Information System (MMIS) completely supports the attached document that contains the comments to the Claims Attachment NPRM from the National Medicaid EDI HIPAA (NMEH)workgroup. The NMEH is comprised of representatives from the 50 state Medicaid agencies and their fiscal intermediaries/agents. Approximately 35 states participated in the formulation of these comments. These are comments where a consensus was reached among the states. Individual states will also be submitting comments individually.
The attachment submitted represent comments and suggested changes that would should apply to all Medicaid State Agencies and Programs and is totally supported by the Division

CMS-0050-P-46-Attach-1.DOC

NMEH Comments to: CMS-0050-P
NPRM Release: 9/23/2005
Comments Due: 11/22/2005

Commenting Organization: ___ National Medicaid EDI HIPAA Workgroup (NMEH)_
Date Comments Submitted: ___ November 17, 2005_

Contact Person Name: __ Penny Sanchez and Mary Kay McDaniel (NMEH Claims Attachment SWG Co-chairs)_
Contact Person Telephone: __(916) 636-1168 / (602) 417-4307
Contact Person e-mail: _____penny.sanchez@eds.com / Marykay.Mcdaniel@azahcccs.gov

#	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	N/A	The National Medicaid EDI HIPAA (NMEH) workgroup would like to request that the 60 day public comment period for CMS-0050-P be extended from 60 days to 120 days adding an additional 60 days. This is to ensure that a thorough review of the numerous standards documents and the NPRM policy statements can be made for impact to our systems and processes. This rule will play a significant role in our claims adjudication process and ensuring that the data contents of the attachments adequately meets our needs will require a clinical review our of individual state policy requirements. In addition, the policy statements outlined in the NPRM need to be reviewed for comment and feedback. The NMEH would like to be able to provide substantiated feedback to some of the questions posed by the department in the NPRM. We believe that the additional time will allow us to make this thorough review and provide the type of feedback the department is looking for.	This has already been sent in by Robert Pozniak on behalf of the NMEH.

#	Document Number and ISSUE IDENTIFIER	Page #	Par/Fed Reg Column	LOINC (if appropriate)	Comment or Suggested Change	Business Justification
2	Federal Register	N/A	N/A		The Final Rule should make it clear that Prior Authorization attachments are not included as part of this regulation, but could be done using a similar approach not governed by HIPAA.	
3	X12 275 (004050X151)	9	1.3.2		The NMEH recommends that the final rule adopt the 5010 versions of the X12 275 and 277 Implementation Guides for the following reasons: 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 if 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. 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.	Willing trading partners should be able to send the 275 separate from the 837 for unsolicited attachments.
4	Federal Register CDA R1 vs R2	55995	siiC2: col3		The NMEH supports the adoption of CDA Release 2 if it is in alignment with recommendations from Health Level Seven.	

#	Document Number and ISSUE IDENTIFIER	Page #	Par/Fed Reg Column	LOINC (if appropriate)	Comment or Suggested Change	Business Justification
5	Federal Register ELECTRONIC CLAIMS ATTACHMENT TYPES	55997	sii C5: col1		Please clarify in the final rule that providers and health plans can continue to do attachments not named in the regulation voluntarily using the proposed standards or by any other means.	Some people have interpreted this proposal to mean that only attachments named in this rule will be accepted.
6	Federal Register OVERVIEW OF KEY INFORMATION	55997	sii C5: col 1		If a revision to one of the six proposed attachment standards is balloted and approved by HL7, can the revision be used by willing trading partners prior to adoption of the applicable final rule?	The use of additional clinical information contained in an attachment revision would improve efficiency in claims processing.
7	Federal Register FORMAT OPTIONS	55997	sii C6: col 3		The NMEH supports the concept of both the HDV and CDV allowing that each entity has the option to choose which varaint they will implement for each attachment type.	
8	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.	There is at least one vendor who has indicated they will not be supporting the combined use of the transaction. For the organization to continue, a new vendor must be found - or another solution found outside the current data flow for the organization. Either way, disruptive and requires resolution.

#	Document Number and ISSUE IDENTIFIER	Page #	Par/Fed Reg Column	LOINC (if appropriate)	Comment or Suggested Change	Business Justification
9	Federal Register BUSINESS USE	55998	siiD: col3		Regulation should not disallow health plans from collecting information via the claims attachment process for purposes other than claims adjudication, such as post payment review, fraud and abuse mitigation, quality control and reporting.	
10	Federal Register	59999	sii D1: Col 1		It is recommended that the regulation text include instruction on how the industry should implement standard attachments that have data content that overlaps elements within the claims transactions. The final rule should also provide information about a migration or roll-out plan for handling these data overlaps and the entity(ies) who should define this migration plan.	
11	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? We recommend that a health plan be able to request additional information after the initial set of attachment data is received if more data is needed to adjudicate the claim.	We understand the purpose of only allowing a single iteration for the request and response would stop providers and health plans from piecemealing the attachment information; however, if the data sent with the original reponse is not adequate to adjudicate the claim or prompts additional questions, this should not prohibit the health plan from asking for more information.

NMEH Comments to: CMS-0050-P
NPRM Release: 9/23/2005
Comments Due: 11/22/2005

#	Document Number and ISSUE IDENTIFIER	Page #	Par/Fed Reg Column	LOINC (if appropriate)	Comment or Suggested Change	Business Justification
12	Federal Register SOLICITED VS UNSOLICITED ATTACHMENTS	55999	sii D2: col1		The NMEH supports the need for both the unsolicited and solicited models. Both models should be allowed.	
13	Federal Register COB	55999	sii D3: col3		The NMEH recommends that the primary payer should not be allowed to send attachment information on to the secondary payer when the payer to payer COB model is used.	The needs of the secondary payer may be different then that of the primary payer.
14	Federal Register SOLICITED VS UNSOLICITED	55999	sii D2: col2		Please clarify: If a health plan customarily denies a claim for lack of the supporting additional information, does this constitute the business practice of requesting additional information?	
15	Federal Register PRIVACY/MINIMUM NECESSARY	56000	sii D4: col 1		There is a statement in the preamble that says "the covered health care provider always retains the discretion to make its own minimum necessary determination." If a health plan requests additional information to support the adjudication of a health care claim and the provider deems that it does not meet their definition of minimum necessary, what resources does the health plan have to obtain the additional information necessary to adjudicate the claim? The final rule should make it clear that a health plan can still adjudicate the claim as appropriate per their policy based on the information received.	

#	Document Number and ISSUE IDENTIFIER	Page #	Par/Fed Reg Column	LOINC (if appropriate)	Comment or Suggested Change	Business Justification
16	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.	For example, the physical therapy and occupational therapy rehabilitation attachments could be necessary for processing a power wheelchair claim and the laboratory results attachment might be needed for an enteral nutrition claim.
17	Federal Register SIGNATURES	56000	sii D6: col 3		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, the NMEH requests clarification from CMS wether allowance of on image of the "wet" signature within an electronic claims attachment would satisfy the federal regulatory requirement requiring that Medicaid agencies obtain certain signatures for consent forms. Currently Medicaid's must require these attachments via paper in order to obtain the federally mandated signature.	Other Federal Requirements require that we must receive

#	Document Number and ISSUE IDENTIFIER	Page #	Par/Fed Reg Column	LOINC (if appropriate)	Comment or Suggested Change	Business Justification
18	Federal Register PROVIDER VS PLAN PERSPECTIVE	56001	sii D8: col1		Request clarification on the following: The preamble states: "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." 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 submitted claim (unsolicited), does this rule require that a health plan implement a process to request additional information if the provider asks them to.	If yes, this would require that a health plan enter into a business process they have never performed before.
19	Federal Register ATTACHMENT CONTENT AND STRUCTURE	56001	sii E: col3, par3		File size. 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 link multiple attachments together if the need for more than 64 megabytes of data is required. AND there needs to be a way within the transaction to alert the receiver when a file larger than 64 megabytes is being 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? Must have a way to handle from the beginning rather than try to figure out when you are there.
20	Federal Register PROPOSED STANDARDS	56004	sii G1: col2		We need a clear understanding of the maintenance and update schedule of the LOINC code set.	

#	Document Number and ISSUE IDENTIFIER	Page #	Par/Fed Reg Column	LOINC (if appropriate)	Comment or Suggested Change	Business Justification
21	Federal Register PROPOSED STANDARDS	56006	sii G3: col2		The NMEH encourages the completion and adoption of the following attachment types as quickly as possible: Children's Preventive Health Services, Durable Medical Equipment, Consent Forms (Abortion, Hysterectomy and Sterilization) and Non-Ambulance Transportation. The NMEH also recommends that the Patient Information Unspecified Content be named for optional use.	
22	Federal Register PROPOSED STANDARDS	56006	sii G3: col2		There needs to ba a way to easily identify and extract attachment concepts for each attachment type from the LOINC database for easy integration into adjudication systems.	
23	Federal Register MODIFICATIONS TO STANDARDS AND NEW ATTACHMENTS	56014	siii B: col1		There needs to be a streamlined process to adopt new attachment types as they are developed by HL7. For new Additional Information Specifications (AIS), we recommend that the DSMO be authorized to adopt approved published HL7 AIS documents through the DSMO process without going through full federal regulatory process. This would need to include appropriate provisions for full industry input to the outreach process at HL7 during the development phase of the attachment and public input into the comment period during the HL7 ballot process. Appropriate notification and roll-out time between adoption and the required implementation date is also required.	

#	Document Number and ISSUE IDENTIFIER	Page #	Par/Fed Reg Column	LOINC (if appropriate)	Comment or Suggested Change	Business Justification
24	Federal Register MODIFICATIONS TO STANDARDS AND NEW ATTACHMENTS	56014	siii B: col1		There needs to be a streamlined process to adopt revised versions of existing attachment standards that are developed by HL7 and X12. We recommend that the DSMO be authorized to adopt revised versions of approved published HL7 and X12 standards for attachments through the DSMO process without going through full federal regulatory process. This would include provisions for industry outreach during the development of the proposed standard and appropriate public comment period during the HL7 and X12 ballot/approval process. Appropriate notification and roll-out time between adoption and the required implementation date is also required.	
25	Federal Register COSTS AND BENEFITS	56018	svi B3: col1 & col3		At this time, the states have not had the resources and time to conduct cost benefit analysis to quantify projected savings with the conversion to electronic claims attachments under this model. In addition, most states have not done a thorough enough assessment to determine implementation impacts/costs for both technical and operational.	

#	Document Number and ISSUE IDENTIFIER	Page #	Par/Fed Reg Column	LOINC (if appropriate)	Comment or Suggested Change	Business Justification
26	Federal Register REG TEXT - DEFINITIONS	56023	162.1900		The final rule should clarify the differences between the form-based and the non-form based AIS. The Clinical Reports AIS only references a subset of the available LOINCs for Clinical Reports. The entire list of available LOINCS for Clinical Reports is obtained from the LOINC database. In addition, the LOINCS 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. This should be fully explained in the final rule.	
27	Federal Register REG TEXT	56024	162.1915 and 1925		The NMEH supports the proposed combined solution using the X12 and HL7 standards for electronic claims attachments. In addition, the NMEH supports the use of LOINC to identify the questions and answers on the attachment.	
28	Federal Register REG TEXT	56024	162.1905		In general, we would like to see 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 using claims attachments.	

Submitter : Mr. David Feinberg **Date:** 11/21/2005

Organization : Rensis Corporation - A Consulting Company

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment -- which is a four page letter. Should the attachment need format clean-up, the following page setup values should be used: top_margin=0.5", bottom_margin=0.5", left_margin=1.0", right_margin=1.0", gutter=0.0", header_from_edge=0.5", footer_from_edge=0.5", and gutter_position=left.

CMS-0050-P-47-Attach-1.DOC

David A. Feinberg, C.D.P.
3662 SW Othello Street • Seattle, Washington 98126-3246
206 617-1717 • DAFeinberg@computer.org

21 November 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0050-P

via: Electronic Comments @ http://www.cms.hhs.gov/regulations/ecomments

References: (a) 70 FR 184, 9/23/2005, pages 55989-56025
(b) CMS-0050-P
(c) RIN 0938-AK62

After almost seven weeks of review and analyses of this Notice of Proposed Rule Making (NPRM) and its incorporated Implementation Specifications, and based on my many submitted, but still uncompleted, comments, the following SUMMARY conclusions are inescapable.

I. There needs to be one way – and **one way only** – to communicate each attachment; by type, subtype, or other objective criteria if necessary.
- No variants.
- No options.
- No trading partner agreements.

II. Each attachment type and subtype should be specified with a single appropriate way to codify the applicable data; which would likely be categorized as:
- discrete numeric or one-two word values and attributes, or distinct short textual phrases
- lengthy reports or impressions.

Different *situational* ways for different attachment types, subtypes, or other clearly determinable cases could be specified.

(continued on next page)

III. This NPRM and its incorporated HL7 Additional Information Specifications do not presently provide sufficient specificity. Current documentation is too broadly written. Too many needed precise policies and technical details are absent.

IV. Detailed policies and technical specifications for attachments should be focused on communications formats and technologies – not receiver – *i.e.*, health plan – processes that might be used to perform adjudication or to transform what is communicated into desired formats to perform adjudication. These processes are business decisions, and should not be included in transactions standards.

V. Detailed policies and technical specifications need to accommodate what can be created, sent, received, and processed today while at the same time not precluding economic processing options potentially available in the near future.

- Discrete data elements as presently used in all other HIPAA-adopted transactions are a certainty.
- Properly distinguished data in free ASCII text that allows for the possibility for near future intelligent parsing into distinct data items that could support automated adjudication would potentially be reasonable.
- Scanned images provide the least likely possibilities for decoding into distinct data items that could support automated adjudication, and therefore should not be specified.

VI. An estimate of the costs and other impacts of requiring health care providers and their vendors to implement and operate the completely new implementation specification paradigm – *i.e.*, CDA – proposed in this NPRM needs to be performed. That the CDA happens to originate from a HIPAA Standards Setting Organization is of no consequence whatsoever to those organizations that already have a functioning clinical information messaging architecture – *i.e.*, HL7 version 2 – that could more cost-effectively be used to communicate claims attachments data.

(continued on next page)

VII. There is no verifiable body of knowledge that can demonstrate with any certainty that the proposed, hugely complex, technologies will even work in the necessary nationwide industrial-strength environment. The very minimal static highly-constrained one-time proof-of-concept pilot simply does not provide sufficient data for a rational extrapolation. Nobody has sufficient data to know what additional significant changes to Implementation Specifications may still be needed, or the costs they may impose.

In fact:

- the very limited Empire Medicare Services pilot is the one and only time even a portion of the complete set of implementation specifications with all the variabilities proposed by this NPRM have ever been actually implemented and executed;
- only a handful of production status CDA implementations of any kind exist at all anywhere in the United States;
- there are no known standalone implementations of any of HL7's Additional Implementation Specifications as transactions independent of how they are proposed for use with X12's 275 transaction in this NPRM; and
- there are no known implementations at all of X12's 275 transaction set in any form – based or not based on the proposed 004050X151 or its one predecessor Implementation Guides.

Regrettably, this NPRM isn't about standardizing multiple uses of already well-proven technology. As written, this NPRM actually is proposing to turn the entire United States health care industry into a gigantic claims attachments test environment in parallel with daily production activities for documenting and obtaining payment for rendered services, procedures, and supplies.

(continued on next page)

VIII. This NPRM and its incorporated Implementation Guides and Additional Information Specifications simply are not yet ready for what is needed by our industry. Consequently ...

- **This NPRM should be abandoned.**
- **More precise, more cost-effective, case-by-case Additional Information Specifications should be written – in concert and coordinated with explicit and more precise NPRM policies.** Completing fully operational parallel-with-current-operations pilot projects might be one way to develop and validate these materials.
- **A Notice should be published in the Federal Register stating that this NPRM is being abandoned, and explicit and more precise coordinated policies and technical specifications are about to be written and fully tested, and will be published in a future NPRM – not an uncommentable final rule – when they are ready. The Notice should also detail mechanisms, including new federal advisory panels or such, whereby the public has an opportunity to freely participate in all of these revitalized efforts – including policy creation.**

Thank you for considering these conclusions and suggested action. Please use any of the methods shown on the first page of this letter should you wish to contact me.

Yours truly,

David A. Feinberg

David A. Feinberg, C.D.P.
President, Rensis Corporation

Submitter : Lynne Gilbertson **Date:** 11/21/2005

Organization : NCPDP

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-0050-P-48-Attach-1.DOC

National Council for Prescription Drug Programs
NCPDP

November 21, 2005

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

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

Dear Centers for Medicare & Medicaid Services:

The National Council for Prescription Drug Programs (NCPDP) is pleased to submit the following comments regarding the HIPAA Administrative Simplification: Standards for Electronic Health Care Claims Attachments NPRM.

NCPDP is a non-profit ANSI-accredited Standards Development Organization consisting of more than 1,400 members who represent computer companies, drug manufacturers, pharmacy chains and independents, drug wholesalers, insurers, mail order prescription drug companies, pharmaceutical claims processors, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, service organizations, government agencies and other parties interested in electronic standardization within the pharmacy services sector of the health care industry.

While the topic of claims attachments does not directly affect NCPDP, the general topic of attachments does because of the work of an industry task group. At the November 2004 Work Group meeting, NCPDP's Work Group 11 ePrescribing & Related Transactions formed the Prior Authorization Workflow-to-Standards Task Group in response to testimony to the National Committee on Vital and Health Statistics (NCVHS) and recommendations from NCVHS to the Department of Health and Human Services on aspects of electronic prescribing. This industry task group consists of representatives from ASC X12N, HL7, NCPDP and interested parties. Its objectives are to:

- Promote standardized automated adjudication of prior authorization
- Coordinate the further development and alignment of standards
- Identify additional needed standards

II. Provisions of the Proposed Rule

C. Overview of Key Information for Electronic Health Care Claims Attachments

6. Format Options (Human vs. Computer Variants) for Electronic Claims Attachments "FORMAT OPTIONS" (F.R. Page 55997)

NCPDP Recommendations:

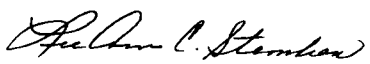
NCPDP supports the adoption of both the Human Decision and Computer Decision Variants. The flexibility afforded by this option allows providers to gain the advantages of electronic submission of additional information without the necessity of immediate large investment in systems and technology. This ability to build in phases to a fully automated process, in addition to affirming the benefits, will allow the systems vendors additional time to develop and make

available fully integrated electronic health record, referral and billing systems. The Prior Authorization Workflow to Standards Task Group noted above is focusing on the use of the computer decision variant for prior authorizations of medications, but recognizes that not all providers with electronic prescribing capabilities have integrated systems that can handle the flow between the standards i nvolved in the solution. By using the model developed for claims attachments, this is not an obstacle.

7. Combined Use of Two Different Standards Through Standard Development Organization (SDO) Collaboration "COMBINED USE OF DIFFERENT STANDARDS"(F.R. Page 55998)

NCPDP Recommendations:
NCPDP supports the collaboration of ASC X12 and HL7 and the use of the two standards in the claims attachment environment. The Prior Authorization Workflow to Standards Task Group noted above is using this same model for building prior authorization functionality. In addition, NCPDP supports the use of Logical Observation Identifiers Names and Codes (LOINC®).

Sincerely,



Lee Ann C. Stember
President
National Council for Prescription Drug Programs (NCPDP)
9240 E. Raintree Drive
Scottsdale, AZ 85260
(480) 477-1000 x 108
lstember@ncpdp.org

cc: NCPDP Board of Trustees

Submitter : Bill Pankey
Organization : Tunitas Group
Category : Individual

Date: 11/21/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-0050-P-49-Attach-1.RTF

"RELATIONSHIP TO PRVACY RULE" the requirement that plans submit 'complete' requests for *ALL* of the information needed to adjudicate the claim is inconsistent with the minimum necessary expectations of the Privacy Rule and otherwise inefficient. The business rule requirement of 162.1910(c) will result in Plans requesting more information than is necessary to adjudicate the claim.

For example, a plan has a rule allowing reimbursement for a specific treatment only when patient exhibits condition A, or in the absence of condition A, condition B. The above HIPAA Rule allows the plan to make a single request for information, so the plan will, by necessity, request information about condition A and about condition B.

Say that the presence of condition A is the ordinary circumstance, then the HIPAA Rule would require that the plan request information that it ordinarily does not need to adjudicate the claim. Furthermore, providers will be required to collect and transmit information that is otherwise not necessary, were it not for the HIPAA Rule.

The net result of the Rule will be to support the Plan tendency to request 'all the information'.

Submitter : Ms. Stacey Barber
Date: 11/21/2005
Organization : NCHICA
Category : Other
Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-0050-P-50-Attach-1.DOC

November 21, 2005

Centers for Medicare and Medicaid Service,

Department of Health and Human Services,

Attention: CMS-0050-P

Post Office Box 8014

Baltimore, MD 21244-8014

The North Carolina Healthcare Information and Communications Alliance, Inc (NCHICA) is submitting the comments contained in this document on 45 CFR Part 162 HIPAA Administrative Simplification: Standards for Electronic Health Care Claims Attachments; Proposed Rule. NCHICA is a nonprofit consortium of over 235 organizations dedicated to improving healthcare by accelerating the adoption of information technology. These comments were prepared by the NCHICA HIPAA Transactions, Code Sets, and Identifiers (TCI) Claims Attachments Task Force. The task force is represented by health care providers, health plans, and software vendors who support North Carolina covered entities.

Comments to NPRM Text

Page 55993 center 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, claims transactions (837 version 4010-1a)..."

The adopted HIPAA guides are most commonly referred to as 4010A1, not 4010-1a.

"EFFECTIVE DATES"

Page 55994

There are mixed feelings within the NCHICA membership regarding the effective date. There are some members who feel that 24 months is more than enough time to implement, while other members feel that 24 months is not enough time.

The majority consensus of the NCHICA TCI task force feels that a 24 month implementation period is not enough time for the industry to implement. The NCHICA TCI task force believes that a 36 month implementation would be more reasonable. The task force offers the following reasons for a 36 month implementation:

1. Most software vendors have large customer bases and the rollout could be extensive. The NCHICA TCI task force knows that one large national vendor who supports several of North Carolina providers typically has a three year rollout period for new software releases
2. The task force feels that there will be a learning curve in the industry to adopt the LOINC codes.

Deleted: 11/21/2005

3. Payers are not all going to be ready at the same time and the additional year will allow for a smoother transition.
4. Although there are not as many transactions as compared to the initial implementation of HIPAA administrative transactions, experience from that implementation proved that industry could not adopt the transactions in a 24 month period.

Page 55995 2. Overview of Clinical Document Architecture

The NCHICA TCI task force is concerned with moving to Clinical Document Architecture (CDA) release 2 without the industry having the opportunity to review and comment on the HL7 specification prior to them being named in a rule. The task force does support the ability for that comment period to be conducted outside of an NPRM such as during the HL7 ballot period.

"ELECTRONIC CLAIMS ATTACHMENT TYPES"

Page 55996/55997

The NCHICA TCI task force requests clarification that the final rule is not limiting the types of claims attachments that can be conducted in the industry. Is the rule stating that if one of the named attachments is done electronically, that attachment type must be conducted using the standards?

The task force agrees with the attachment types that have been named, and also recommend that attachments for Durable Medical Equipment (DME) and Home Health Services be considered for inclusion.

"FORMAT OPTIONS"

Page 55997

The NCHICA TCI task force supports both the Human Decision Variant (HDV) and the Computer Decision Variant (CDV). In addition, we feel strongly that there be no mandate on any covered entity to use the CDV since the CDV has the ability to render a HDV. The decision of a covered entity to fully automate adjudication of attachments using the CDV should be at the discretion of that covered entity.

"COMBINED USE OF DIFFERENT STANDARDS"
Page 55998

The NCHICA TCI task force supports both X12N and HL7 transactions. The industry is familiar with X12N transactions, and they will provide a mechanism to wrap the HL7 CDA for transport.

1. Electronic Health Care Claims Attachments vs. Health Care Claims Data
Page 55999

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

Deleted: 11/21/2005

The NCHICA TCI task force suggests that "required" in the previous statement be changed to "supported".

The task force also requests additional clarification of the previous statement. There are some attachments being proposed that the data is supported in both the 837 transaction and in the attachment. For example, for ambulance attachments there is data in the 837 that is also represented in the ambulance attachment specification. Is the intent that if the ambulance information is sent in the 837, that it be omitted from the attachment?

"SOLICITED vs. UNSOLICITED ATTACHMENTS"

The NCHICA TCI task force generally supports the ability to send unsolicited attachments when there is a business justification for it.

Page 55999 center column:
"We also propose that for each specific claim, health plans may solicit only electronic attachment request transaction which would have to include all of their required or desired "questions" and/or documentation needs relevant to that specific claim. Health care providers would be required to respond completely to the request, using one response transaction."

The NCHICA TCI task force understands the intent of a single iteration for requesting additional information and responding to that request. However, we do have concern that this requirement will result in:

1. more information than necessary being requested by a plan to ensure they receive all the data necessary to adjudicate the claim which is in conflict with the HIPAA Privacy Rule's minimum necessary requirements, or
2. an increase in the claim denial rate due to lack of information.

The request for additional information is going to be based on the data the plan has at the time the additional information is requested. The additional information provided could drive the need to request even more information.

The task force agrees that the process should not be stuck in an endless loop of requesting additional information, but believes there needs to be some flexibility to ensure that the correct data is obtained to properly adjudicate the claim without receiving unnecessary data.

3. Coordination of Benefits
Page 55999

The NCHICA TCI task force supports that in health plan-to-health plan COB, the primary health plan is not expected to forward attachments to a secondary payer.

Deleted: 11/21/2005

4. Impact of Privacy Rule
Page 56000 left column

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

The NCHICA TCI task force understands sensitivity of PHI and that only the minimal necessary information should be provided in a scanned image. However, the task force is recommending this statement be modified to state ..., reasonable efforts....

By adding the word reasonable, a provider, who does not have sophisticated imaging software, could send one page of a medical record that contains more data than is necessary without the need to print that page of the medical record, black out the additional data, and rescan before sending the electronic attachment. The task force feels that this would defeat the intent and would cause undue burden. There is minimal risk because the health plan is also a covered entity.

6. Connection to Signature (Hard Copy and Electronic)
Page 56000

The NCHICA TCI task force recommends that the provider maintain signed copies and only provide the hard copy with signature when requested by the plan.

"ATTACHMENT CONTENT AND STRUCTURE"

Page 56001 right column.

"The implementation guide for the X12 275 response transaction permits up to 64 megabytes of data in a single transaction." This statement contradicts the 275 Implementation Guide (IG). In the IG it is only recommended that the BIN segment be limited to 64 megabytes. Please clarify that willing trading partners can agree to conduct transactions for which the BIN segment could exceed 64 megabytes.

"ALTERNATIVE CONSIDERED: CANDIDATE STANDARDS"

b. Health Care Claims Attachment Response Transaction
page 56002 center column, right column

" ...(2) the ability to transmit large amounts of information within the BIN segment of the transaction, which can contain up to 64 megabytes of data."

The IG only recommended that the BIN segment be limited to 64 megabytes. Please clarify that willing trading partners can agree to conduct transactions for which the BIN segment could exceed 64 megabytes

1. Code Sets
page 56004

The NCHICA TCI task force supports the use of LOINC codes.

2. Electronic Health Care Claims Attachment Request Transaction

Deleted: 11/21/2005

3. Electronic Health Care Claims Attachment Response Transaction
Page 56005

The NCHICA TCI task force supports the use of the ASC X12N 277 – Health Care Claim Request for Additional information and the ASC X12N 275 – Additional Information to Support a Health Care Claim or Encounter transactions. However, we do recommend that version 5010 of these IGs be adopted over 4050 for the following reasons:

1. there are numerous errors in the 4050 guides being proposed which have been corrected in 5010
2. by the time the final rule is promulgated, 4050 will be an outdated standard
3. 5010 removes the requirements of an unsolicited attachment being sent in the same interchange as the 837.

Additional comments not pertaining to a specific section of the NPRM:

The NCHICA TCI task force feels that language needs to be included in the final rule encouraging the use of acknowledgements. The use of acknowledgements assists in the prevention of duplicate attachments being sent, probably on paper. We are not recommending that a specific standard acknowledgement be named. However, we do feel that if acknowledgements are encouraged in the final rule, trading partners will implement some mechanism of acknowledging receipt of the attachments.

Comments to ACS X12N 004050X150 277 Health Care Claim Request for Additional Information

General comments:

1. Some of the header and footers are incorrect and reference a different guide.
2. The situational rules between the subscriber loop and the dependent loop are not consistent for certain data elements and should be. Example: NM105
3. In Loop 2000D/2200D some segments contain rules to use when the subscriber is the patient, while other segments do not have this note. We recommend that the situational rule "when the subscriber is the patient" be specific to the HL and not the individual segments within that HL.
4. In Loop 2000E/2200E some segments contain rules to use when the patient is not the subscriber, while other segments do not have this note. We recommend that the situational rule "when the patient is not the subscriber" be specific to the HL and not the individual segments in that HL.

page 22 last line – REF in the last line should be DTP.

Page 24 2.2.3.2.2 PER03=ED -
We recommend that it be clarified that the health plan can recommend that the attachment be sent electronically, but that the provider is not required, in accordance with the NPRM, to submit the attachment electronically.

Deleted: 11/21/2005

Page 24 2.2.3.2.4 -
Notes indicate it is not required, but recommended. Wouldn't this information be required to indicate the address where the provider would send a paper attachment? Same comment 2.2.3.2.4 – Segments within loop should be required so that the provider will always know where to send an attachment in the event the provider is able to send an electronic attachment.

Page 24 2.2.3.2.5 - "occurences" should be "occurrences"

Page 25 2.2.3.3 STC*R4:18660-1:LOI*20030824****R4:18790-6:LOI -

Verify the example. The example does match with the required data elements in the STC segment.

Page 26-27 2.2.3.3.2 STC Segment at the 2220 Loop -

Although this section is headed as being at the 2220 loop, the explanations and examples on page 27 pertain to the claim level STC segment at the 2200 loop. It is an exact copy of the 2.2.3.1.2 section. Since the STC at the claim level and the service line level have different requirements, this section needs to be modified.

Page 26 2.2.3.3.2 Last paragraph -

"When questions are only asked regarding specific service line information the STC segment at the claim level contains date of the payer's request in STC02. When this occurs STC01 is used. STC01-1 will always contain the value "R0", STC01-2 will always contain "19016-5", and STC01-4 will always contain "LOI"."

This paragraph is somewhat confusing. The segment note on page 71 clarifies what is trying to be conveyed. We would recommend replacing this note in the front matter with the note from the segment at loop 2200D page 71:

"When questions are only asked regarding specific service line information, the STC segment at the Claim Level only conveys the Status Information Effective Date. When this occurs STC01 is used. STC01-1 will only contain the value "R0" and STC01-2 will only contain "19016-5", and STC01-4 will always contain "LOI"."

Page 28 2.3.3 The Health Care Patient Information (275) Transaction Set - This section does not appear to be complete.

Page 54 - We recommend adding a note to this segment to clarify who the information receiver is intended to be.

Page 58 - The note on XX may need to be revised to add "and the receiver is a provider". According to the note for the segment, other types of entities receiving the request on behalf of a provider may be identified in this segment (clearinghouse, a service bureau, an agency, an employer).

Page 61 - It might be helpful to tie this back to a specific provider element – in the professional claim, is it the billing provider or the rendering provider on the claim or is the guide giving the payer a choice of whichever one they want to send?

Page 64 - It would be helpful to add "dependent" after (HL03=23) to clarify what 23 means.

Deleted: 11/21/2005

Page 75 REF01 – We recommend that the same note to the EJ qualifier that is included on the REF01 at the dependent level be included at the subscriber level as well.

Page 83 - On a professional claim, what would equal the Statement Date?

Page 96 N402 Note "on the claim" does not fit for this segment - Maybe it should be "on the claim request for additional information"

Page 112 Notes on NM104, NM105, and NM107 - There is no need to say "when the value in NM102 is 1" NM102 only support the value of 1.

Page 114 - Payer Claim Identification Number - Note 1 This is ambiguous and needs to be clarified about when it should be sent.

Page 117 -

STC01-1 Note: "This is a category code and is required if STC01 is used" is not needed since STC01 is a required field and will always be used. The next note mentions that this is a category code.

STC01 – 4 Note: To be consistent with the same field at the subscriber level, add "This value indicates that STC01-2, STC10-2, STC11-2 is a Logical Observations Identifiers Names and Codes (LOINC)."

STC11 Note should match the STC10 note.

STC11-1 note should have the following added to be consistent "This data element must contain the same value as STC01-1.

Page 124 note 1 - we suggest changing the note to: "Required when the Medical Record Number is submitted on the claim. If not required, do not send."

Page 128 – segment note contradicts the segment note for the DTP at 2200D loop. We do not fell that you can necessarily require it when the patient is not the subscriber. Depending on the type of claim you may not have claim level dates. On a professional claim, what would equal the Statement Date?

Page 143 - HC Health Care Financing Administration Common Procedural Coding System (HCPCS) Codes qualifier code note – Delete up to 110157 and begin the note with Because.

page 155 - These attachment examples are being used to show how to code the 275. Shouldn't the reference be to how to code the 277?

Page 174 – we feel this example is more appropriate in the 275 guide instead of the 277.

Section 4 contains only examples for institutional claims. We recommend that examples be included for professional claims as well.

Deleted: 11/21/2005

Comments to ACS X12N 004050X151 275 Additional Information to Support a Health Care Claim or Encounter

General comment:
There are multiple places in the guide that refer the implementer to the 277 guide. It cannot be assumed that everyone in the industry is going to know what 277 is being referenced. Therefore, we recommend the guide be specific about what 277 it is instructing the implementer to reference.

Page 9 Section 1.3

First bullet – The NCHICA TCI task force recommends that guidance be provided in the front matter on how providers are supposed to respond to requests made on paper.

Second bullet - The NCHICA TCI task force supports the ability to send unsolicited claims attachments, but do not support that it must be sent with in the same transmission with the claim. Most practice management systems are not able to support different transaction sets within the same transmission. This could pose an implementation issue for providers.

Page 13 - 2.2.1.1 last paragraph - The NCHICA TCI task force supports the ability to send attachments unsolicited, but not within the same transmission.

Page 18 STC segment, first paragraph - The NCHICA TCI task force recommends that the guide be specific as to what 277 Implementation Guide should be referenced (e.g. 277 Health Care Claim Request for Additional Information).

Page 49 - What is meant by the service provider? Is this the same as the billing provider in the 837 or would it be the equivalent of the rendering provider? The NCHICA TCI task force feels that this needs to be clarified within the segment or in the front matter so that there is no confusion as to what provider would be represented in Loop 1000C. It is clear what to use when NM108 value is equal to SV, but for the other NM108 values it is not clear.

Page 55 - NM104/NM105/NM107 situational rules need to be changed. The only available value in NM102 is 1.

Page 57 REF segment - The segment is required yet there is a situational note. Is the segment required or situational? The NCHICA TCI task force believes the intent is that the segment is required.

Page 66 note 2 TRN segment - needs to be clarified - What is the definition of a unique attachment?

Comments to the HL7 Attachment Specification

At this time, the NCHICA TCI task force does not have any specific comment to the attachment specifications. The task force will continue to review these documents during the extended comment period.

Deleted: 11/21/2005

Submitter : Jean Narcisi **Date:** 11/22/2005

Organization : American Medical Association

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-0050-P-51-Attach-1.DOC

NUCC
National Uniform Claim Committee

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Member Organizations

Alliance for Managed Care

American Association for Homecare

America's Health Insurance Plans

American Medical Association

American National Standards Institute Accredited Standards Committee X12 Insurance Subcommittee

Blue Cross and Blue Shield Association

Centers for Medicare and Medicaid Services

Dental Content Committee

Health Level Seven

Medical Group Management Association

National Association of State Medicaid Directors

National Uniform Billing Committee

American Academy of Physician Assistants

Public Health/ Health Services Research

Centers for Disease Control and Prevention (Federal)

Midwest Center for HIPAA (State)

State Medical Association
Minnesota Medical Association
Texas Medical Association

November 22, 2005

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

RE: File Code CMS-0050-P
HIPAA Administrative Simplification: Standards for Electronic Health Care Claims Attachment; Proposed Rule

Dear Sir or Madam,

The National Uniform Claim Committee (NUCC) is pleased to provide the Centers for Medicare and Medicaid Services (CMS) our comments on the proposed rule for the Standards for Electronic Health Care Claims Attachments published in the Federal Register at page 55,990 Volume 70, Number 184, on September 23, 2005.

The NUCC was formally organized in May 1995. The goal of the NUCC is to promote the development of a uniform electronic claim "form" for use by the non-institutional health care community to transmit related claim and encounter information to and from all third-party payers. The NUCC is chaired by the American Medical Association (AMA), in consultation with CMS. The committee includes representation from key provider and payer organizations, as well as standards setting organizations, and the National Uniform Billing Committee. As such, the committee is intended to have an authoritative voice regarding national standard data content and data definitions for non-institutional health care claims in the United States.

The following are our comments on the Claims Attachment NPRM.

DEFINITIONS (p. 55993)

We are in agreement with the definitions of the terms as stated in the preamble of the proposed rule. We would like to see these same definitions repeated in Section 162.1900 of the regulation text.

EFFECTIVE DATES (p. 55994)

We find that, although the timeframe outlined may seem adequate for the implementation of the claims attachment transaction, concerns have been expressed regarding the industry's need for training, budgeting, and testing. The Department of Health and Human Services (HHS) should consider other significant HIPAA and health information technology projects at the time the final rule is published and adjust effective and implementation dates taking these things into consideration.

As discussed in the NPRM, covered entities have already implemented other X12 transactions and set up the business agreements for translator services, submission and receipt protocols, and testing. Since this standard is being implemented as the second-round of transaction standards, we believe that most of the infrastructure should already be in place. The fact that the solution allows various grades of technical specification should facilitate implementation and allow a measured progression from a simple imaged document to a fully automated and codes adaptation.

We are basing our opinion, in part, on the fact that the Electronic Claims Attachment Project through Empire Medicare Services was able to implement and conduct claims attachment transactions within a six-month period of time. Although we recognize that this project was much more limited in scope, we believe that it demonstrates the ability for the industry to implement the proposed transactions within the timeframe specified in the rule.

In addition, we support the work of the WEDI SNIP Claims Attachment Workgroup in developing an implementation plan for the industry related to this standard.

OVERVIEW OF CLINICAL DOCUMENT ARCHITECTURE (p. 55995)

We recommend moving to CDA Release 2, assuming that there is an adequate pilot of Release 2 that demonstrates its acceptable functionality. It is our understanding that the following are benefits of CDA Release 2:

- More technical consistency with all new standards coming from HL7 including, but not limited to genomic reporting, adverse event reporting, and the care record summary used for continuity of care.
- More consistency with code being developed by EHR developers (vendors and users) for standard and other applications based on the CDA
- More ability to use off-shelf software being developed by health care vendors
- Improved technology for validating computer-decision variant instances of attachments (when this is required)
- Compliance with the U.S. Federal Consolidated Healthcare Informatics initiative

TRANSACTIONS FOR TRANSMITTING ELECTRONIC ATTACHMENTS (p. 55996)

We strongly support the use of structured, as opposed to unstructured, content in electronic data interchange and we believe that the HL7 standards provided this much needed structure.

In reviewing the language in the preamble, we noted that the language regarding Binary Data (BIN) segments does not specify that it conveys the HL7 CDA standard. We believe that this clarification should be made so that implementers are clear that the HL7 standards are required for use in the BIN segment. Absent specific language to this effect, implementers may think that imaged data and text, for example, could be in the BIN segment without the CDA structure. This clarification is needed with each reference that is made to the BIN segments throughout the proposed rule.

ELECTRONIC CLAIMS ATTACHMENT TYPES (p. 55996)

We support the six attachment types being proposed in the NPRM. In addition, we recommend industry education on the existing processes to identify future attachment needs as they arise.

FORMAT OPTIONS (p. 55997)

We strongly support the flexibility being allowed in the proposed rule for using either the human or computer decision variant options of the HL7 CDA. We noted that the language regarding the human and computer decision variants does not specify that they are part of the HL7 CDA standard and we believe that this clarification should be made in the final rule.

COMBINED USE OF DIFFERENT STANDARDS (p. 55998)

We strongly support the use of standards for electronic data interchange, versus non-standard approaches. We support the collaborative efforts of HL7 and X12 in developing the format and content of the transactions in this proposed rule.

ELECTRONIC HEALTH CARE CLAIMS ATTACHMENT BUSINESS USE (p. 55998)

We encourage the voluntary use of the attachment standards for additional electronic transaction processes such as post-adjudication, prior authorization for e-prescribing, pre-certification, and public health reporting.

ELECTRONIC HEALTH CARE CLAIMS ATTACHMENT VS. HEALTH CARE CLAIMS DATA (p. 55999)

We want to see a strengthening of the reporting of claims data in the claims process. We want the claims attachments to remain as an exception and not become a rule with each claim. We believe that the Designated Standards Maintenance Organizations (DSMOs) should be an integral part of the review for the necessity of claims attachments. We recommend that the final rule name the DSMOs for this review process.

SOLICITED vs. UNSOLICITED ATTACHMENTS (p. 55999)

1. We believe that the use of unsolicited claims attachments provides for more efficiency in the claims adjudication process. We recommend changing the word in Sections 162.1910 and 162.1920 from "instructions" to "prior arrangement." We also recommend that the regulatory text be modified to allow a provider, based on prior arrangement with a health plan, to be able to send unsolicited attachments.

2. We find the language in the preamble allowing the health plan to submit only one request for additional information to be too restrictive. This allowance does not appear to be repeated in the regulatory text in 162.1910 (c) and this needs to be clarified.

   The regulatory text states that the health plan's request must be "complete". The regulatory text does not specifically state that the health plan can only make one request. It is possible for the health plan to make a "complete" request initially, but upon receipt of the response, identify a further need for information. The language in the preamble would not allow for the health plan to make a subsequent request, but the regulatory text is not as clear about this.

   Although we have concerns about a potential for endless requests by the health plan resulting in the need for the provider to respond, we also recognize that there may be a genuine need for a subsequent request by a health plan. We believe that the final rule should allow for a subsequent request by the health plan to avoid a potential denial by the health plan because they do not have enough information to adjudicate the claim. We recognize that the appeals process adds administrative burden to both the health plans and health care providers and would like to avoid any potential situation that could cause an increase in their occurrence.

COORDINATION OF BENEFITS (p. 55999)

We see the potential of the claims attachment process to further streamline the adjudication process. For instance, with regard to the coordination of benefits, it would be beneficial to have an electronic attachment for a secondary payer questionnaire.

We are in support of the language in the preamble that states that any secondary health plan would send an attachment request separate from a request made by the primary health plan. In other words, Payer #1 is not required to forward the attachment information to Payer #2. We would like to see this reiterated in the regulatory text.

IMPACT OF PRIVACY RULE (p. 55999)

We would like to see further clarification in the final rule on "reasonable effort" when a medical record page needed for an attachment contains additional information than what is being requested. We propose that "reasonable effort" should allow for scanning the entire page(s), so long as the page includes the information that is being requested. In addition, we propose that the receiver must protect all data that is received.

IMPACT OF THE SECURITY RULE (p. 56000)

We believe that any efforts to comply with the Security Rule should be effectively incorporated into electronic attachment processing. With this new standard, there is a need for HHS to provide further guidance to the industry to help with understanding the additional concerns on security, as well as privacy, specific to the claims attachment process.

CONNECTION TO SIGNATURES (HARD COPY AND ELECTRONIC) (p. 56000)

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:

- simply transmitting a data field that indicates that the sender has a "wet" signature on file
- 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"
- transmitting an image of a document, or a portion thereof, that includes a wet signature
- strongly authenticating a computer user and using digital signature technologies to record the electronic act of signing a document and associate it with the electronic document itself in a manner that allows subsequent verification that only the authorized signer could have performed the act of signing and the electronic document has not been subsequently altered.

The choice of approach depends on the specific business use, applicable legislation and governmental regulations and the policies of the parties exchanging electronically signed documents.

We further concur that there is an important business requirement to share signatures electronically as information in support of a healthcare claim. The signature that must be shared is often not the signature of the author of the electronic attachment document. For example, a consent signature is generally that of the patient or the patient's agent and a rehabilitation plan may include the signatures of multiple providers not all of whom are the authors of the plan.

The <signature_cd> element of CDA Release 1 is only defined for case (b), above, and only describes the signature of the author of the CDA document.

It is important that the standard for additional information in support of a claim support multiple approaches to signature so that the correct approach may be chosen that is practical, cost-effective and consistent with the federal, state and local legislation, regulations and policy. For example, there are regulatory and practical concerns that rule out approaches (a), (b) and (d) for consent forms, since policy makers have indicated that a "wet signature on file" is not adequate and it is unlikely that the person providing the signature will usually be an authenticated user of a healthcare provider's electronic system, much less a strongly authenticated user.

We would propose, therefore, that the final rule and commentary either be silent on electronic signature or indicate that individual attachments should specify the approach to electronic signature appropriate to the business needs for that attachment.

ATTACHMENT CONTENT AND STRUCTURE (p. 56001)

We do not have the expertise to recommend the amount of data permitted in a transaction. We do support that the health plans and clearinghouses be required to adhere to the maximum size allowed in the final rule.

CODE SET (p. 56004)

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

- For those AIS documents that contain static content (e.g., Ambulance, Emergency Department, Rehabilitation, Medications), the regulation must be clear that only the LOINCs enumerated in the AIS are allowed.
- For those AIS documents that reference the LOINC database, the regulation should clarify that only the LOINC class as described in the LOINC database (i.e., Laboratory or Clinical Reports) defined for that AIS is allowed.

In addition, we need a clear process on how to access the LOINC codes used for the HIPAA specific code set. We also need the final rule to indicate the LOINC code set update schedule.

ELECTRONIC HEALTH CARE CLAIMS ATTACHMENT RESPONSE TRANSACTION (p. 56005)

We recommend that HHS develop a survey and ongoing process to track the utilization of the named and any unnamed attachment types to determine which attachment types are most needed by the health care industry.

REQUIREMENTS (HEALTH PLANS, COVERED HEALTH CARE PROVIDERS AND HEALTH CARE CLEARINGHOUSES) (p. 56012)

1. The preamble of the NPRM states that "No other electronic transaction format or content would be permitted for the identified transactions." In addition, the regulatory text in Section 162.1905 states that when using "electronic media" a covered entity must comply with the applicable standards. We would like further clarification of what constitutes "other electronic transactions" and "electronic media." Currently, some health plans and health care providers have systems in place in which the health plan can access patient information from the provider through a web portal. In this situation, there is no exchange of information between the health plan and provider. The health plan is able to obtain the information they need through the viewing capability. In addition, some providers respond to requests for additional information by emailing the scanned document to the health plan. We would like to see more specific language in the final rule that addresses whether or not these types of information exchanges will be allowed under the claims attachment final rule.

2. We request clarification of the second paragraph in this section, which states that the "use of the standard electronic health care claims attachment would not preclude the health plan from using other processes or procedures to verify the information reported in the attachment documentation." If the intent of this language is to address a post-payment review, then this should be more clearly stated. If the intent is to allow for non-electronic verification of claims attachment information without any specific limitations to when the verification can be requested, then there would be an undue burden to the health care provider to respond to the claims attachment request and later verify the attachment information either via the phone or paper submission.

COSTS AND BENEFITS - GENERAL ASSUMPTIONS, LIMITATIONS, AND SCOPE (p. 56016)

We believe that it is not safe to make the assumption that attachments are usually requested after the claim has been submitted, specifically if this assumption is being used in the cost and/or savings estimates. Conversations that committee members have had with health plans and health care providers regarding the claims attachment process has indicated that providers will likely send a large number of attachments at the time the claim is submitted.

162.1910 (p. 56024)

We would like clarification of the language in Section 162.1910 (a) (2) that indicates that an attachment can be sent in advance of a health care claim. The process being allowed by this language is not a workflow that was considered in the development of the standard.

162.1920 (d) (p. 56024)

The final rule text reads that "Response information may be free text, scanned documents, or an embedded document within the BIN segment of the response transaction." The language should be "In accordance with the HL7 CDA, response information may be free text, scanned documents, or an embedded document within the BIN segment of the response transaction."

The NUCC appreciates this opportunity to provide you with our comments on the Claims Attachment NPRM. Should you have any questions concerning our comments, please contact me directly at (312) 464-4713.

Sincerely,

Jean Narcisi
Chair, National Uniform Claim Committee

Cc: Lorraine Doo, CMS

Submitter : Jean Narcisi **Date:** 11/22/2005

Organization : National Uniform Claim Committee

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-0050-P-52-Attach-1.DOC

NUCC

National Uniform Claim Committee

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Member Organizations

Alliance for Managed Care

American Association for Homecare

America's Health Insurance Plans

American Medical Association

American National Standards Institute Accredited Standards Committee X12 Insurance Subcommittee

Blue Cross and Blue Shield Association

Centers for Medicare and Medicaid Services

Dental Content Committee

Health Level Seven

Medical Group Management Association

National Association of State Medicaid Directors

National Uniform Billing Committee

American Academy of Physician Assistants

Public Health/ Health Services Research

Centers for Disease Control and Prevention (Federal)

Midwest Center for HIPAA (State)

State Medical Association
Minnesota Medical Association
Texas Medical Association

November 22, 2005

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

RE: File Code CMS-0050-P
HIPAA Administrative Simplification: Standards for Electronic Health Care Claims Attachment; Proposed Rule

Dear Sir or Madam,

The National Uniform Claim Committee (NUCC) is pleased to provide the Centers for Medicare and Medicaid Services (CMS) our comments on the proposed rule for the Standards for Electronic Health Care Claims Attachments published in the Federal Register at page 55,990 Volume 70, Number 184, on September 23, 2005.

The NUCC was formally organized in May 1995. The goal of the NUCC is to promote the development of a uniform electronic claim "form" for use by the non-institutional health care community to transmit related claim and encounter information to and from all third-party payers. The NUCC is chaired by the American Medical Association (AMA), in consultation with CMS. The committee includes representation from key provider and payer organizations, as well as standards setting organizations, and the National Uniform Billing Committee. As such, the committee is intended to have an authoritative voice regarding national standard data content and data definitions for non-institutional health care claims in the United States.

The following are our comments on the Claims Attachment NPRM.

DEFINITIONS (p. 55993)

We are in agreement with the definitions of the terms as stated in the preamble of the proposed rule. We would like to see these same definitions repeated in Section 162.1900 of the regulation text.

EFFECTIVE DATES (p. 55994)

We find that, although the timeframe outlined may seem adequate for the implementation of the claims attachment transaction, concerns have been expressed regarding the industry's need for training, budgeting, and testing. The Department of Health and Human Services (HHS) should consider other significant HIPAA and health information technology projects at the time the final rule is published and adjust effective and implementation dates taking these things into consideration.

As discussed in the NPRM, covered entities have already implemented other X12 transactions and set up the business agreements for translator services, submission and receipt protocols, and testing. Since this standard is being implemented as the second-round of transaction standards, we believe that most of the infrastructure should already be in place. The fact that the solution allows various grades of technical specification should facilitate implementation and allow a measured progression from a simple imaged document to a fully automated and codes adaptation.

We are basing our opinion, in part, on the fact that the Electronic Claims Attachment Project through Empire Medicare Services was able to implement and conduct claims attachment transactions within a six-month period of time. Although we recognize that this project was much more limited in scope, we believe that it demonstrates the ability for the industry to implement the proposed transactions within the timeframe specified in the rule.

In addition, we support the work of the WEDI SNIP Claims Attachment Workgroup in developing an implementation plan for the industry related to this standard.

OVERVIEW OF CLINICAL DOCUMENT ARCHITECTURE (p. 55995)

We recommend moving to CDA Release 2, assuming that there is an adequate pilot of Release 2 that demonstrates its acceptable functionality. It is our understanding that the following are benefits of CDA Release 2:

- More technical consistency with all new standards coming from HL7 including, but not limited to genomic reporting, adverse event reporting, and the care record summary used for continuity of care.
- More consistency with code being developed by EHR developers (vendors and users) for standard and other applications based on the CDA
- More ability to use off-shelf software being developed by health care vendors
- Improved technology for validating computer-decision variant instances of attachments (when this is required)
- Compliance with the U.S. Federal Consolidated Healthcare Informatics initiative

TRANSACTIONS FOR TRANSMITTING ELECTRONIC ATTACHMENTS (p. 55996)

We strongly support the use of structured, as opposed to unstructured, content in electronic data interchange and we believe that the HL7 standards provided this much needed structure.

In reviewing the language in the preamble, we noted that the language regarding Binary Data (BIN) segments does not specify that it conveys the HL7 CDA standard. We believe that this clarification should be made so that implementers are clear that the HL7 standards are required for use in the BIN segment. Absent specific language to this effect, implementers may think that imaged data and text, for example, could be in the BIN segment without the CDA structure. This clarification is needed with each reference that is made to the BIN segments throughout the proposed rule.

ELECTRONIC CLAIMS ATTACHMENT TYPES (p. 55996)

We support the six attachment types being proposed in the NPRM. In addition, we recommend industry education on the existing processes to identify future attachment needs as they arise.

FORMAT OPTIONS (p. 55997)

We strongly support the flexibility being allowed in the proposed rule for using either the human or computer decision variant options of the HL7 CDA. We noted that the language regarding the human and computer decision variants does not specify that they are part of the HL7 CDA standard and we believe that this clarification should be made in the final rule.

COMBINED USE OF DIFFERENT STANDARDS (p. 55998)

We strongly support the use of standards for electronic data interchange, versus non-standard approaches. We support the collaborative efforts of HL7 and X12 in developing the format and content of the transactions in this proposed rule.

ELECTRONIC HEALTH CARE CLAIMS ATTACHMENT BUSINESS USE (p. 55998)

We encourage the voluntary use of the attachment standards for additional electronic transaction processes such as post-adjudication, prior authorization for e-prescribing, pre-certification, and public health reporting.

ELECTRONIC HEALTH CARE CLAIMS ATTACHMENT VS. HEALTH CARE CLAIMS DATA (p. 55999)

We want to see a strengthening of the reporting of claims data in the claims process. We want the claims attachments to remain as an exception and not become a rule with each claim. We believe that the Designated Standards Maintenance Organizations (DSMOs) should be an integral part of the review for the necessity of claims attachments. We recommend that the final rule name the DSMOs for this review process.

SOLICITED vs. UNSOLICITED ATTACHMENTS (p. 55999)

1. We believe that the use of unsolicited claims attachments provides for more efficiency in the claims adjudication process. We recommend changing the word in Sections 162.1910 and 162.1920 from "instructions" to "prior arrangement." We also recommend that the regulatory text be modified to allow a provider, based on prior arrangement with a health plan, to be able to send unsolicited attachments.

2. We find the language in the preamble allowing the health plan to submit only one request for additional information to be too restrictive. This allowance does not appear to be repeated in the regulatory text in 162.1910 (c) and this needs to be clarified.

   The regulatory text states that the health plan's request must be "complete". The regulatory text does not specifically state that the health plan can only make one request. It is possible for the health plan to make a "complete" request initially, but upon receipt of the response, identify a further need for information. The language in the preamble would not allow for the health plan to make a subsequent request, but the regulatory text is not as clear about this.

   Although we have concerns about a potential for endless requests by the health plan resulting in the need for the provider to respond, we also recognize that there may be a genuine need for a subsequent request by a health plan. We believe that the final rule should allow for a subsequent request by the health plan to avoid a potential denial by the health plan because they do not have enough information to adjudicate the claim. We recognize that the appeals process adds administrative burden to both the health plans and health care providers and would like to avoid any potential situation that could cause an increase in their occurrence.

COORDINATION OF BENEFITS (p. 55999)

We see the potential of the claims attachment process to further streamline the adjudication process. For instance, with regard to the coordination of benefits, it would be beneficial to have an electronic attachment for a secondary payer questionnaire.

We are in support of the language in the preamble that states that any secondary health plan would send an attachment request separate from a request made by the primary health plan. In other words, Payer #1 is not required to forward the attachment information to Payer #2. We would like to see this reiterated in the regulatory text.

IMPACT OF PRIVACY RULE (p. 55999)

We would like to see further clarification in the final rule on "reasonable effort" when a medical record page needed for an attachment contains additional information than what is being requested. We propose that "reasonable effort" should allow for scanning the entire page(s), so long as the page includes the information that is being requested. In addition, we propose that the receiver must protect all data that is received.

IMPACT OF THE SECURITY RULE (p. 56000)

We believe that any efforts to comply with the Security Rule should be effectively incorporated into electronic attachment processing. With this new standard, there is a need for HHS to provide further guidance to the industry to help with understanding the additional concerns on security, as well as privacy, specific to the claims attachment process.

CONNECTION TO SIGNATURES (HARD COPY AND ELECTRONIC) (p. 56000)

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:

- simply transmitting a data field that indicates that the sender has a "wet" signature on file
- 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"
- transmitting an image of a document, or a portion thereof, that includes a wet signature
- strongly authenticating a computer user and using digital signature technologies to record the electronic act of signing a document and associate it with the electronic document itself in a manner that allows subsequent verification that only the authorized signer could have performed the act of signing and the electronic document has not been subsequently altered.

The choice of approach depends on the specific business use, applicable legislation and governmental regulations and the policies of the parties exchanging electronically signed documents.

We further concur that there is an important business requirement to share signatures electronically as information in support of a healthcare claim. The signature that must be shared is often not the signature of the author of the electronic attachment document. For example, a consent signature is generally that of the patient or the patient's agent and a rehabilitation plan may include the signatures of multiple providers not all of whom are the authors of the plan.

The <signature_cd> element of CDA Release 1 is only defined for case (b), above, and only describes the signature of the author of the CDA document.

It is important that the standard for additional information in support of a claim support multiple approaches to signature so that the correct approach may be chosen that is practical, cost-effective and consistent with the federal, state and local legislation, regulations and policy. For example, there are regulatory and practical concerns that rule out approaches (a), (b) and (d) for consent forms, since policy makers have indicated that a "wet signature on file" is not adequate and it is unlikely that the person providing the signature will usually be an authenticated user of a healthcare provider's electronic system, much less a strongly authenticated user.

We would propose, therefore, that the final rule and commentary either be silent on electronic signature or indicate that individual attachments should specify the approach to electronic signature appropriate to the business needs for that attachment.

ATTACHMENT CONTENT AND STRUCTURE (p. 56001)

We do not have the expertise to recommend the amount of data permitted in a transaction. We do support that the health plans and clearinghouses be required to adhere to the maximum size allowed in the final rule.

CODE SET (p. 56004)

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

- For those AIS documents that contain static content (e.g., Ambulance, Emergency Department, Rehabilitation, Medications), the regulation must be clear that only the LOINCs enumerated in the AIS are allowed.
- For those AIS documents that reference the LOINC database, the regulation should clarify that only the LOINC class as described in the LOINC database (i.e., Laboratory or Clinical Reports) defined for that AIS is allowed.

In addition, we need a clear process on how to access the LOINC codes used for the HIPAA specific code set. We also need the final rule to indicate the LOINC code set update schedule.

ELECTRONIC HEALTH CARE CLAIMS ATTACHMENT RESPONSE TRANSACTION (p. 56005)

We recommend that HHS develop a survey and ongoing process to track the utilization of the named and any unnamed attachment types to determine which attachment types are most needed by the health care industry.

REQUIREMENTS (HEALTH PLANS, COVERED HEALTH CARE PROVIDERS AND HEALTH CARE CLEARINGHOUSES) (p. 56012)

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The NUCC appreciates this opportunity to provide you with our comments on the Claims Attachment NPRM. Should you have any questions concerning our comments, please contact me directly at (312) 464-4713.

Sincerely,

Jean Narcisi
Chair, National Uniform Claim Committee

Cc: Lorraine Doo, CMS

Submitter : **Ms. Rochelle Archuleta** **Date: 11/22/2005**

Organization : **American Hospital Association**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-0050-P-53-Attach-1.DOC

American Hospital Association

Liberty Place, Suite 700
325 Seventh Street, NW
Washington, DC 20004-2802
(202) 638-1100 Phone
www.aha.org

November 22, 2005

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, S.W.
Room 445-G
Washington, DC 20201

Re: Quality Standards for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, Supplies (DMEPOS) and Other Items and Services

Dear Dr. McClellan:

The American Hospital Association (AHA), on behalf of our 4,700 member hospitals and health care systems, and our 31,000 individual members, appreciates the opportunity to comment on the draft quality standards for suppliers of durable medical equipment, prosthetics, orthotics, supplies (DMEPOS) and other items and services. These draft standards were developed as part of the transition to DME competitive bidding, as required by the Medicare Modernization Act of 2003 (MMA). **The AHA is very concerned with the particular draft quality standard in Appendix I that would restrict the types of practitioners who may provide prosthetics and orthotics services.**

Appendix I of the draft standards would restrict the types of practitioners who can provide orthotics and prosthetics services to individuals "certified or licensed as an orthotist, prosthetist, and/or staff certified by the American Board for Certification in Orthotics and Prosthetics or the Board for Orthotist/Prosthetist Certification." This provision is inconsistent with both the current standard of care for orthotics/prosthetics and the current Medicare provider guidelines that establish the types of practitioners qualified to provide orthotics and prosthetics services. In Section 1384 H1(F) of the Social Security Act, physical therapists (PT) and occupational therapists (OT) are included among the approved orthotics and prosthetics providers for Medicare, yet these draft standards would specifically exclude PTs and OTs. **Without justification, this proposed restriction would significantly reduce care for the patients who rely on PTs and OTs for these services.**

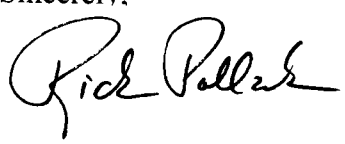
Today, thousands of OTs and PTs provide orthotics and prosthetics services in hospital outpatient departments and many other settings. Their services include evaluating patients; designing and fabricating orthotics (and limited prosthetics); dispensing orthotics and prosthetics; and providing patient education on how to apply and remove orthotics and prosthetics, and related issues. **It is essential that PTs and OTs retain the ability to provide these services in hospitals and other settings, as allowed in the statute.**

CMS should specifically state that Medicare-certified health care practitioners, such as hospital PTs and OTs, that provide DMEPOS are exempt from those draft quality standards for DMEPOS suppliers that are duplicative of existing Medicare quality and operational standards. Such an exemption is appropriate since these providers already are subject to extensive quality and operational requirements within the Medicare conditions of participation and other laws and regulations, in such areas as clinical protocols, facility operations, quality safeguards, etc. Therefore, most of these draft standards would be unnecessary and burdensome for hospitals, given current quality and other regulations.

The draft standards should be modified by striking the provision in Appendix I of the draft standards that states, "These standards address customized orthotics and prosthetics that *require the qualification and expertise of a certified or licensed as an orthotist, prosthetist, and/or staff certified by the American Board for Certification in Orthotics and Prosthetics or the Board for Orthotist/Prosthetist Certification.*" If this sentence is kept in the final guidelines, it should be expanded to include PTs and OTs.

We strongly urge CMS to modify Appendix I as recommended to preserve the ability of PTs and OTs to provide orthotics and prosthetics and related health services in hospitals and other settings. Doing so will help ensure that Medicare beneficiaries retain access to these important services under the new competitive bidding process. The AHA appreciates the opportunity to submit these comments. If you have any questions, please contact me or Rochelle Archuleta, senior associate director for policy, at (202) 626-2320.

Sincerely,



Rick Pollack
Executive Vice President

Submitter : Tish Kohler **Date:** 11/22/2005

Organization : Ameritas Life Insurance Corp.

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-0050-P-54-Attach-1.DOC

To: The Office of the Secretary, HHS
From: Ameritas Life Insurance Corp.
RE: Comments to proposed HIPAA Administrative Simplification: Standards for Electronic Health Care Claims Attachments

File Code – CMS-0050-P
Page number – 55999
Section – II D, number 2. Solicited vs. Unsolicited Electronic Health Care Claims Attachments

It is proposed that health care providers may submit an unsolicited electronic attachment with a claim only when a health plan has given them specific instructions pertaining to that type of claim or service.

We propose that providers be allowed to submit any electronic attachment they deem necessary to accompany the 837D. This will assist in the ease of workflow for each provider's office. Based on the clinical data compiled, attachments should be submitted as each provider deems necessary. Each health care plan has its own specific review process, and required attachments can be completely different from one covered group to another. The only commonality is the review process itself. If specific instructions are given, there needs to be a specific place, common to all health care plans, where the provider can easily access information needed to process the claim by that particular plan. An updated version of attachment needs is also a concern. Limiting the amount of attachments may defeat the purpose of review. We feel that this needs to be addressed now due to this process setting a precedent by which later attachments will be implemented.

File Code – CMS-0050-P
Page number – 55996
Section – II C, number 5. Electronic Claims Attachment Types

It is proposed that there are six specific electronic attachment types. None of these six types are appropriate for Dental.

We propose that they include X-rays and Periodontal Charting for dental claims. The six specific listed attachment types could be inclusive for dental, however, need to be as specific as they are for medical. There are no LOINC code references for either X-rays or Periodontal Charting. LOINC codes are for medical coding only. We feel this needs to be addressed now due to this process setting a precedent.

Submitter : Mr. Bill Moon

Date: 11/22/2005

Organization : Blue Cross and Blue Shield of Alabama

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-0050-P-55-Attach-1.DOC

BlueCrossBlueShield
of Alabama

November 22, 2005

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

Attention: **CMS-0050-P**

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

Dear Dr. McClellan:

Blue Cross and Blue Shield of Alabama (BCBSAL) appreciates the opportunity to comment on the Proposed Rule to adopt standards for electronic claims attachments under title XI of the Social Security Act subpart C Administrative Simplification.

BCBSAL participated in numerous industry forums and discussions. As a result, we are uniquely aware of the proposed comments made by such organizations as the Workgroup for Electronic Data Interchange (WEDI), Data Interchange Standards Association (DISA) – American Standards Committee (ASC) X12 Electronic Data Standards, Health Level Seven (HL7), and the Blue Cross and Blue Shield Association (BCBSA). BCBSAL supports the comments submitted by these organizations. In addition to those comments, BCBSAL would like to comment on a few more specific issues provided in our formal comments.

First, we strongly support the decision to limit unsolicited electronic attachments to situations already pre-arranged between providers and payers. We believe this to be necessary for many reasons, including the accurate re-association of claims attachment information with a claim for specific service(s) provided. We believe that the unsolicited electronic attachment should be permitted to arrive either with the electronic claims transaction or in the same processing day as the electronic claims transaction.

BCBSAL also supports language not requiring payers to provide attachment information to secondary and tertiary payers.

BCBSAL supports a national initiative to develop a mapping of claims information (procedure code, diagnosis code, etc) to LOINC request codes. This would eliminate duplicity among health plans in developing how to automate requests as well as assist providers by better aligning information that various health plans may typically need for claims adjudication.

BCBSAL supports the list of ***permissible file types*** defined in the AIS Implementation Guide (CDAR1AIS0000R021) on page 34. However, we would ask that CMS consider this list as a "maximum available" list of file types and provide covered entities, through trading partner agreements or companion documents, the ability to agree to use a sub-set of that list.

BCBSAL would ask that CMS provide clarification to the language found in 162.1910 (a) (2) (page 56024) of the NPRM stating "A health plan may make such a request (for additional information)...***in advance of submission of the health care claim***". This language appears to contradict the intent of an unsolicited attachment as well as a post claim request/response (277/275).

BCBSAL has additional concerns with respect to the proposed rules that include the following:

- Maintenance to LOINC codes for ambulance services, emergency department services, rehabilitation services, and medications maintained requiring Federal Regulatory action.
- Industry feedback/comment and dissemination during maintenance activity to LOINC codes for clinical reports and laboratory results.
- Overlapping/duplicate information found in the claim transaction (837) and the attachment transaction (275) (i.e., ambulance information).
- Requirement of health plan to submit a complete request for additional information, identifying all attachment information required to adjudicate the claims.
- Time limit for comment period and final rule implementations.
- Unnecessary re-definition of minimum necessary provisions proposed in the NPRM.

We appreciate the opportunity to offer these comments. Please find attached additional detailed comments provided as requested in the NPRM. As with this and all other issues relating to HIPAA Administrative Simplification, we look forward to working with you and your staff.

Sincerely,

Bill Moon (bmoon@bcbsal.org)
Vice President, Systems Resources
Blue Cross and Blue Shield of Alabama

BlueCrossBlueShield
of Alabama

November 22, 2005

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

As requested by the Center for Medicare and Medicate Services (CMS), BCBSAL comments to the proposed rule are organized by the section of the proposed rule to which they apply with the "issue identifier" labeling each comment for that section. Comments are presented in the order they appear in the NPRM. Page number references are to the NPRM as published in the Federal Register on September 23, 2005.

Provisions of the NPRM

Effective Dates (Page 55994)

Proposed Rule: Covered entities must comply with the standard within 24 months from the effective date of the final rule.

Issues: Other HIPAA initiatives, such as implementation of the national provider identifier, upgrade to version 5010 for other transactions, national payer identifier, e-prescribing, and updates to major code lists (i.e., ICD 9 to ICD 10) may be active concurrently.

BCBSAL Recommendation: CMS, at the time the final rule is published, should take into consideration other concurrently running HIPAA initiatives and adjust effective and implementation dates accordingly.

G. Proposed Standards – Code Set (Page 56004)

Proposed Rule: Under the proposed rule, LOINC code maintenance for Laboratory results and Clinical reports is unclear with respect to soliciting industry comment and facilitating industry dissemination.

Issues: Maintenance to LOINC codes for Laboratory results and Clinical reports appear to be done within the control of the Regenstrief Institute under the direction of Health Level Seven (HL7) for those considered as HIPAA codes. This maintenance falls outside of the regulatory

process as well as a typical code set maintenance process. It is unclear if this maintenance would follow a process that adequately solicited input from the stakeholders as well as provide the outcome of that maintenance process to the stakeholders.

BCBSAL Recommendation: We recommend that language be added outlining how stakeholders will be able to provide feedback/comment within the process of maintaining HIPAA related LOINC Codes. We also recommend that language be added describing the procedure for dissemination to the industry when LOINC code activity occurs for Clinical and Laboratory codes used under HIPAA.

Electronic Health Care Claims Attachment vs. Health Care Claims Data(Page 55999)

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

Issues: In certain cases, overlapping/duplicate information is found on the claim transaction (837) that could also be contained in the claim attachment transaction (275), such as ambulance information. Because providers are not mandated to use electronic attachments, this information cannot be removed from the electronic claim transaction (837), which creates confusion as to where this information should be reliably obtained when an unsolicited attachment is received and both transactions have this information populated.

BCBSAL Recommendation: CMS should offer guidance regarding what to do if/when this overlapping/duplicate information is encountered.

Impact of Privacy Rule on Scanned Attachment Content (Page 56000)

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

Issues: The distinction between paper and electronic attachments, with respect to content conforming to the minimum necessary provisions of the Privacy Regulation, is a mute point. The test for exceeding minimum necessary is not dependant on the format by which that information is conveyed or transmitted; rather it is dependant on the actual content of that document. The decision as to a scanned documents content being subject to tests for minimum necessary should be no different than if the document were simply faxed or mailed manually. That test is already established via the Privacy Regulation and should not be further defined in this NPRM.

BCBSAL Recommendation: Language regarding scanned documents and minimum necessary should either be removed or merely refer to the HIPAA Privacy Rule for guidance.

Solicited and Unsolicited Attachments (Page 55999)

Proposed rule: For each specific claim, health plans may solicit only one electronic attachment request transaction which would have to include all of their required or desired "questions" and/or documentation needs relevant to that specific claim.

Issues: In certain cases, the content of the initial response from a provider may alert a health plan to circumstances unknown at the time of receipt of the claim which may require additional information be provided for claim adjudication. Limiting to only one electronic request would prevent health plans from pursing further clarification electronically forcing manual interventions, which in turn may be unavailable to the health plan if the provider requires that all attachment requests be electronic (as defined in the NPRM). This may leave health plans with no other recourse than to deny the claim.

BCBSAL Recommendation: We recommend that language be added stating that health plans should provide as complete of a request possible by asking all know questions at the initial request, with the understanding that further questions may be asked based on the response to the initial request.

Submitter : Mr. Thomas Wilder **Date:** 11/22/2005

Organization : America's Health Insurance Plans

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-0050-P-56-Attach-1.DOC

America's Health Insurance Plans

601 Pennsylvania Avenue, NW
South Building
Suite Five Hundred
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202.778.3200
www.ahip.org

November 22, 2005

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

Re: Comments in Response to the Notice of Proposed Rulemaking: HIPAA Administrative Simplification: Standards for Electronic Health Care Claims Attachments

Dear Sir/Madame:

America's Health Insurance Plans (AHIP) is writing to offer comments in response to the Notice of Proposed Rulemaking (NPRM) regarding Standards for Electronic Health Care Claims Attachments under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The NPRM was published in the *Federal Register* on September 23, 2005 (70 Fed. Reg. 55990).

AHIP is the national trade association representing the private sector in health care and our nearly 1,300 member companies provide health, long-term care, dental, vision, disability, and supplemental coverage to more than 200 million Americans. Almost all of AHIP's members are covered entities for purposes of the HIPAA administrative simplification provisions.

Our members support the use of electronic health care claims attachments to increase administrative efficiencies for health plans, health care providers, and clearinghouses. The proposed regulations, however, raise a number of concerns for our members. We have outlined our concerns and recommendations to address these issues in the attached discussion paper (Attachment A). Our main recommendations include the following key points:

- We recommend that HHS issue an interim final rule to allow covered entities additional time to develop implementation plans and become familiar with the electronic health care claims attachment standards. HHS should then issue a final rule that requires covered entities to come into compliance with the standards in 24 months from the effective date of the final rule (small health plans will have 36 months to come into compliance).
- We encourage HHS to develop an overall implementation strategy to enable covered entities to implement the claims attachment standards and other HIPAA regulatory requirements in a reasonable timeframe without disrupting business operations.

- The final regulations should allow covered entities to develop trading partner agreements that address many of the technical formatting requirements.
- To ensure administrative efficiency and timely implementation, the final rule must name only one version (i.e., the 4050 or the 5010 version) for the X12N 277 transaction.
- The final regulation should not restrict the number of attachment requests that can be solicited by health insurance plans.
- The final regulations should defer to the Designated Standard Maintenance Organizations for validation about whether the proposed data sets and elements are sufficient for claims attachment transactions.

We appreciate the opportunity to provide comments. Please contact me at (202) 778-3255 or at twilder@ahip.org if you have any questions.

Sincerely,

Thomas J. Wilder
Vice-President, Private Market Regulation

Attachment

ATTACHMENT A
America's Health Insurance Plans
Comments and Recommendations
Notice of Proposed Rulemaking: Electronic Health Care Claims Attachments
November 22, 2005

The following are comments and recommendations on behalf of America's Health Insurance Plans (AHIP) in response to the Notice of Proposed Rulemaking (NPRM) for Administrative Simplification Under the Health Insurance Portability and Accountability Act of 1996 (HIPAA): Standards for Electronic Health Care Claims Attachments. The NPRM was published by the Department of Health and Human Services (HHS) in the *Federal Register* on September 23, 2005 (70 Fed. Reg. 55990).

I. Definitions

Issue: The proposed rule includes a new definition for "clinical reports" which needs to be clarified when the final rule is issued.

Discussion: Several new terms and definitions were proposed for the claims attachment standards including a definition for "clinical reports." The proposed definition, however, is vague because it fails to explain whether certain types of health information would qualify as a clinical report. For example, it is unclear if a radiological image such as an x-ray would meet the criteria listed in the proposed definition.

No standard transaction currently exists for radiological images, although HL7 may develop a standard attachment transaction in the future. The proposed definition and the corresponding regulations do not adequately explain whether radiological images are covered by the claims attachment rules.

Additionally, the proposed definition includes information that is "used to analyze and/or document an individual's medical condition." The definition does not appear to include information that is developed and compiled as a prospective plan for an individual (e.g., a provider's treatment plan for an individual patient).

Finally, the proposed definition includes the phrase "medical condition" but does not explain whether the phrase is intended to capture a broad range of health conditions. For example, the proposed definition is unclear about whether it includes dental information.

Recommendation: The definition of "clinical reports" should be revised to clarify whether radiological images, information that is developed and compiled as a prospective treatment plan for an individual, and dental information are included in the definition. The revised definition should be closely aligned with the information contained in the Additional Information Specification (AIS).

Additionally, if radiological images are included in the definition, the final rule should explain that there is no standard transaction named for radiological images at this time.

II. Effective Dates

Issue: Covered entities should be provided sufficient time to comply with the claims attachment standards once a final rule is published.

Discussion: The proposed rule requires covered entities to 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. These timeframes are listed in the HIPAA statute.

The timeframes, however, are problematic for several reasons. Covered entities, which include health insurance plans, are currently undertaking a number of initiatives including implementation of the National Provider Identifier and other HIPAA mandated standards, evaluating potential ICD-10 conversion, developing electronic and personal health records, and establishing electronic prescribing programs for the new Medicare Part D benefit.

These projects require significant administrative and technical resources that will likely include financial investments in hardware and software, and implementing system upgrades. To require covered entities to also comply with new requirements for claims attachments in the proposed timeframes places additional strain on available resources and budgets.

Additionally, we are concerned that the industry does not have adequate experience with electronic claims attachments that would guarantee a smooth transition to the new standards. The proposed standards are based on the experience of only one existing pilot project. Additional pilot projects may be needed to evaluate the business and operational implications of using electronic claims attachments in real-life and diverse business settings.

Recommendation: We recommend that HHS issue an interim final rule for the claim attachments standard to allow covered entities additional time to develop implementation plans and become familiar with the electronic health care claims attachment standards. HHS should then issue a final rule that requires covered entities to come into compliance with the standards in 24 months from the effective date of the final rule (small health plans will have 36 months to come into compliance).

We encourage HHS to develop an overall implementation strategy to enable all covered entities to implement the claims attachments and other regulatory requirements in a reasonable timeframe without disrupting business operations. This strategy should include additional pilot tests to expand the knowledge base for and industry experience with the claims attachment standards.

III. Electronic Health Care Claims Attachments

Issue(1): The proposed regulations incorporate specific computer languages by reference but do not reference them in the regulations.

Discussion(1): Each HL7 Additional Information Specification (AIS) for the electronic claims attachment standards includes information about the appropriate computer languages and how they will work together to display images and information. The preamble to the proposed regulations discusses the following computer languages:

- Extensible Markup Language (XML). This language provides the intelligence for electronic documents for content, semantics, and format.
- Hypertext Markup Language (HTML). This is a presentation language that describes how the context of a page should be displayed and is used for creating documents for display on the Internet.
- Extensible Stylesheet Language (XSL). This language allows the display of information in different media, such as a computer screen or a paper copy, and enables the user to view the document according to preferences and abilities. XSL (Version 1.0) can convert an XML document into Extensible HTML which can be understood by web browsers and other common applications.

Although these languages may be used within the health care industry, other technical images, formats, or solutions may be appropriate for claims attachments as the industry progresses and covered entities gain more experience with them. For example, Joint Photographic Experts Group (jpeg), Tagged Image File Format (tiff), and Graphics Interchange Format (gif) may be more suitable for future use with some health care claims attachments.

Information about the computer languages that can be used for transmitting and receiving health care claims attachment is a necessary component of the regulations. We agree with HHS' approach to incorporate this information by referencing the AIS documents.

Recommendation(1): HHS, in conjunction with the National Committee on Vital and Health Statistics and the Designated Standard Maintenance Organizations, should continue to monitor technological developments related to encoding and transmitting health care claims attachments. Before final regulations are released, and in the first year following implementation of the standard, HHS should issue guidance and/or modify regulations, when appropriate, to incorporate any new applicable technical solutions into the health care claims attachments standards and corresponding regulations. In the alternative, HHS should clarify that health plans can negotiate the use of image formats and technical formatting requirements through trading partner agreements.

Issue(2): HHS requested comments about the appropriate version for the HL7 Clinical Document Architecture (CDA) that should be required in the standard.

Discussion(2): The HL7 Clinical Document Architecture (CDA) Release 1.0 is an approved document markup standard encoded in XML that specifies the format and content of clinical documents for information exchange used in electronic or printed format. HL7 CDA Release 2.0 is under review. HHS recognizes, but cannot guarantee, that the 2.0 release version will be approved by HL7 before a final rule is issued.

An XSL stylesheet is also being developed that would permit interoperability between Release 1.0 and Release 2.0. While the proposed regulations do not suggest adoption of either Release 1.0 or Release 2.0, the preamble indicates that CDAs may be included in future proposed rules.

We do not offer comments about whether HL7 CDA Release 2.0 is more appropriate than Release 1.0 because we do not have enough experience with either version to form a reasonable opinion. We do, however, encourage HHS to adopt final standards that allow covered entities the flexibility to develop implementation plans and to use transactions that best apply to their business operations.

The most reasonable approach for HHS is to permit covered entities to use either CDA release. Once the industry has more experience with using these releases, HHS can evaluate whether future rulemaking is needed.

Recommendation(2): The final rule should allow covered entities the option to use either CDA Release Version 1.0 or 2.0, as long as HL7 develops a stylesheet within a reasonable time of the regulation's effective date.

Issue(3): Health insurance plans can be adversely affected if providers are given unlimited authority to send imaged documents in claims attachments.

Discussion(3): The preamble to the proposed regulation states that an important feature of the CDA is that it allows the entire body of an XML document to be replaced by an actual image so that clinical content can be conveyed by either an image or a text document. While this approach appears to give providers formatting options, it can create significant issues for health insurance plans.

Administrative simplification will not result if health insurance plans will be expected to receive imaged versions for any and all claims attachment responses from providers. The information technology storage and administrative systems needed to support imaged documents can be costly for health insurance plans. Health insurance plans need some ability to forecast the volumes of imaged documents that they can expect to receive from providers. It is possible that the resulting costs of receiving and storing large volumes of imaged documents would be equal to or exceed the costs of performing the claims attachment transactions via paper.

Depending on the services performed and the health care claim submitted, a health insurance plan will evaluate whether supplemental information is needed for proper adjudication. When a health insurance plan sends a claims attachment request transaction, the plan often has an expectation about whether the requested information must be sent by the provider as an imaged or text document. Providers should not have independent discretion to determine the electronic format for the information contained in the response transaction.

In some cases, unreadable, imaged documents may be received by a health insurance plan. Health insurance plans should have the ability to develop processes that prohibit certain providers from sending imaged documents as opposed to text documents in claims attachment

response transactions when the health insurance plan has experienced prior technical difficulties with the provider's attachment formats.

Recommendations(3): The final regulations should allow covered entities to develop trading partner agreements that address technical formatting requirements. These agreements could specify whether a provider's response transaction should contain: (1) text-only information; (2) image-only information; or (3) a text or imaged format, at the option of the provider.

The final regulations should also recognize that health insurance plans and providers may enter into written contracts that prohibit providers from sending imaged documents in claims attachment response transactions if the health insurance plan has experienced prior technical difficulties with the provider's attachment formats.

Issue(4): Two transactions (version 4050 of the X12N 277 request and version 4050 of the X12N 275 response) are proposed to carry the attachment related questions and the related answers or responses. However, version 4050 for the X12N 277 transactions may be outdated by the time a final rule is released.

Discussion(4): The X12N 277 version 4050 transaction transmits information about a particular claim along with the question codes. The X12N 275 version 4050 transaction returns the claim identification information and transports the responses to each question with the response codes, narrative text, or imaged documents. The preamble explains that the X12N transactions are flexible enough to be used for either manual processing or computer automated processing.

According to information obtain from the Workgroup for Electronic Data Interchange (WEDI), the 4050 version of the X12N 277 is under review and the 5010 version may be published before a final rule is issued. If this happens, the latest version should be named so that health insurance plans are not expected to simultaneously support two different versions of the same claims attachment transaction.

Recommendation: Before issuing a final rule, HHS should name the most current published version of the X12N 277 as appropriate for use within the health care industry. To ensure administrative efficiency and timely implementation, the final rule must name only one version for this transaction type.

IV. Business Uses

Issue: The proposed rule does not provide sufficient guidance about post-adjudication processes.

Discussion: The preamble states that post-adjudication requests for claims-related data are not covered by the proposed regulations because these requests are not part of the claims payment process. The proposed regulation, however, does not provide sufficient information about: (1) the definition of a "post-adjudication request;" (2) examples of what constitutes a post-adjudication request; and (3) how post-adjudication requests or processes that may affect a previously-adjudicated claim will be handled once the claims attachment regulations are in

effect. Examples of these post-adjudication processes can include: subrogation procedures; state appeals and grievance processing; internal and external review processes; antifraud and abuse investigations; and compliance with the Employee Retirement Income Security Act (ERISA) claims processing requirements.

Health insurance plans are particularly concerned about potential disruption to anti-fraud investigations. Health care providers may not be aware that a post-adjudication request for additional information is being made as part of a fraud investigation. Although the provider would be aware that a request for additional information has been made by a health insurance plan, the provider will likely be confused about why the request for information was not covered by the electronic health care claims attachment regulations. A provider could also be "tipped off" that he or she is under investigation for potential fraud and may be unwilling to cooperate in providing the requested information to the health insurance plan.

Health insurance plans are also concerned about the potential disruption to post-adjudication claims review processes. If providers are confused about whether the electronic health care claims attachment requirements apply to these situations, delays can result and necessary information may be omitted from the review documents and processes.

Recommendation: The final health care claims attachment regulations should specifically exempt post-adjudication processes and procedures from the scope of the final claims attachment standards. The final regulations should include: (1) a definition of a "post-adjudication request;" and (2) examples of what constitutes a post-adjudication request. The preamble to the final regulations should discuss how post-adjudication requests or processes may be handled once the claims attachment regulations are in effect.

V. Solicited vs. Unsolicited Attachments

Issue(1): The proposed regulation allows health insurance plans to make only one attachment request for additional information.

Discussion(1): The proposed regulations include a requirement that health insurance plans may solicit only one electronic attachment request transaction which should include all of the required or desired questions and/or requests for documentation relevant to the specific claim. The regulation states:

> Sec. 162.1910 Electronic health care claims attachment request transaction.
>
> (a) The health care claims attachment request transaction is the transmission, from a health plan to a health care provider, of a request for attachment information to support the adjudication of a specific health care claim. A health plan may make such a request -
> (1) Upon receipt of the health care claim;
> (2) In advance of submission of the health care claim; or
> (3) Through instructions for a specific type of health care claim which permit a health care provider to submit attachment information on an unsolicited basis each time such type of claim is submitted.
> (b) If a health plan conducts a health care claims attachment request transaction using electronic media and the attachment information requested is of a type described at Sec. 162.1905, the plan must conduct the transaction in accordance with the appropriate provisions of Sec. 162.1915.
> (c) A health plan that conducts a health care claims attachment request transaction using 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.
> (d) The health care claims attachment request transaction sent using electronic media, is comprised of two component parts:
> (1) The general request structure that identifies the related claim; and
> (2) The LOINC codes and LOINC modifiers identifying the attachment information being requested.

The language of subsections (a)(2) and (3) of the proposed regulation are problematic because it can be interpreted to cover informal or informational requests that can be issued to providers. For example, many health insurance plans issue bulletins or newsletters to help providers understand the health insurance plan's business rules and claims processing requirements. Under the proposed regulation, such informational communications could count as a request for information, even though no claim for services is submitted to the health insurance plan for review and payment.

Recommendation(1): The final regulation should clarify that informational communications between a health insurance plan and health care providers do not count as a request for claims

attachment information if no claim for services has been submitted to the health insurance plan for review and payment.

Issue(2): Health insurance plans are limited to soliciting only one request for additional information.

Discussion(2): Section 162.1910(c) of the proposed regulation is overly restrictive because it limits health insurance plans to issuing only one request for information. In many cases, claims attachment information is requested and received by the health insurance plan which then prompts additional questions or the need for more information.

As an example, if a claim is received that includes services for both medical and dental procedures, multiple business units may be involved to review the claim, issue requests for information to justify either a medical or dental benefit, adjudicate the claim, and issue appropriate member or provider notices regarding payment or denial. In this scenario, the claim for services may be "split" between the medical and dental units and each business unit need to request specific information based on the services under review. Allowing only one request for attachment information undermines the administrative efficiencies that the health insurance plan developed for its claims adjudication process.

Health insurance plans must comply with both federal and state statutory and regulatory requirements that set timeframes for claims processing and accompanying notice requirements. Restricting health insurance plans to one request for information can result in health insurance plans not being able to receive the necessary information to support payment for a claim. This lack of information can also result in higher claims denial rates resulting in increased frustration for providers. A more reasonable approach would be to allow health insurance plans to send any number of claims attachment requests, as long the established statutory and/or regulatory timeframes for claims adjudication have not expired.

Recommendation(2): The final regulation should not restrict the number of attachment requests that can be solicited by health insurance plans. The final regulation should allow requests for claims attachment information to be sent, as long as the established federal and/or state statutory and/or regulatory timeframes for claims adjudication have not expired.

VI. Attachment Content and Structure

Issue: Covered entities should be allowed to specify submission options and file size issues in trading partner agreements.

Discussion: Both the request and response transactions contain administrative information that identifies the individual, date of service, and other information. The proposed electronic attachment standards specify:

- The administrative information contained in the request and response;
- The attachment information (i.e., the additional information specification) contained in the response;

- A code set for specifically describing the attachment information;
- A code set modifier for adding specificity to the request; and
- The format that will contain all of this information.

The size of the file in the response transaction will be impacted by the option the health care provider chooses for the submission because imaged documents are generally larger than text files. Additionally, smaller providers who lack access to high speed transmission lines may have difficulty sending larger files. The implementation guide for the X12 275 response transaction permits up to 64 megabytes of data in a single transaction. The final regulations should allow covered entities to establish submission options based upon business rules of the health insurance plan and a provider's technical capabilities.

Recommendation: As stated earlier, the final regulations should allow covered entities to address issues regarding submission options and file size issues in their trading partner agreements.

Submitter : **Ms. Heidi Margulis** **Date: 11/22/2005**

Organization : **Humana Inc.**

Category : **Health Plan or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-0050-P-57-Attach-1.DOC

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HUMANA.
Guidance when you need it most

November 22, 2005

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

Re: HIPAA Administrative Simplification: Standards for Electronic Health Care Claims Attachments

Dear Dr. McClellan:

The purpose of this letter is to comment on the Department of Health and Human Services' (HHS) proposed rule regarding HIPAA Administrative Simplification: Standards for Electronic Health Care Claims Attachments.

Humana Inc., headquartered in Louisville, Kentucky, is one of the nation's largest publicly-traded health benefits companies. We have approximately 7 million health plan members. Humana offers a diversified portfolio of health insurance products and related services -- through traditional and consumer-choice plans – to employer groups, government-sponsored plans, and individuals.

Humana is also a member of America's Health Insurance Plans (AHIP), the principal national trade association representing companies that provide health benefits to consumers and employers throughout the United States. We provided technical input into the AHIP's comments regarding the proposed Standards for Electronic Health Care Claims Attachments and want to express our support for and agreement with the comments and recommendations submitted by this organization.

The Administrative Simplification provisions included in Title II of the Health Insurance Portability and Accountability Act (HIPAA) have promoted increased efficiencies and cost savings for our health care system by providing uniform

standards for the electronic exchange of certain health information. Humana is committed to advancing administrative simplicity to improve our claims processing systems, streamline administrative tasks and support real-time capabilities for our members and business partners. We have invested significant resources in technology for the development of on-line tools and resources to support these efforts, including automated claims processing systems to process claims in a timely and efficient manner. The development of standards to transmit claims attachments electronically will foster additional savings and efficiencies in the system.

While the intent of the proposed standards for electronic claims attachments is to encourage the use of more cost-effective electronic health care transactions, some provisions contained in the proposed regulation could adversely impact current claims processing systems and result in increased costs. One major concern is the provision that would limit health plans to soliciting only one electronic attachment request transaction for each specific claim. The preamble states:

> "A health plan would not be able to extend adjudication through a lengthy process of multiple individual attachment requests for the same claim...We propose this because it seems contrary to the goals of administrative simplification for covered entities to engage in a continuous loop of query and response in order to have a claim processed."

While we are sensitive to provider concerns over payment delays and have established procedures to pay claims in a timely manner, it is important to emphasize that health plans request additional information only if it is necessary to process a claim. Last year Humana processed approximately 39 million medical and dental claims. Nearly 72% of these claims were received electronically, and processed through an automated claims processing system which required no human intervention. We estimate that the cost of processing an automated claim averages less than a dollar as compared to more than three dollars for manually processing a claim. Cost increases or savings are ultimately passed on to our members. As a result, health plans strive to design their claims systems in ways that will take full advantage of automated and electronic processes while still satisfying regulatory requirements and customer needs.

However, all claims cannot be processed automatically, especially if a provider submits a claim with missing, incomplete or incorrect information. When this occurs, health plans must further investigate the claim before it can be accurately processed, including requesting additional information from the provider. We receive approximately 375,576 medical and dental claims attachments per month. S ome of the top reasons for requesting additional information for medical claims include investigations for services potentially involving pre-existing conditions, emergency room situations, medical necessity, and cosmetic services. Common reasons for dental claims include the request for X-rays and periodontal charting to determine dental necessity. While health plans attempt to limit the number of requests they make to providers, sometimes the information a provider submits to the health plan

generates additional questions that must be addressed to ensure the claim is processed correctly.

Here is an example of a medical claim that could necessitate more than one request for clinical records:

> A provider submits a claim for a service that could be a cosmetic procedure or treatment for a medical condition. The health plan would request medical records related to the service to make an appropriate benefit determination. The records submitted by the provider indicate that other treatment for the same condition was rendered to the patient on a separate date, but the health plan has not received a claim for such service. The health plan would not have known to request records for dates of service disclosed in the provider's records since it had not received a claim. Even though the service was provided on a different date, it could be relevant to the overall treatment of the condition and impact the benefit determination. The health plan would need to request this additional information from the provider to properly process the claim.

Additionally, as many health plans process both medical and dental claims, some dental claims include expenses that may be covered under a medical policy. In these situations additional information may be requested separately from both the medical and dental business units to make coverage determinations. This process would be disrupted by the proposed provision limiting health plans to only one attachment request. To further complicate this matter, internal procedures set up to comply with the HIPAA Privacy Rule's minimum necessary requirements may impede health plans' ability to coordinate the collection of protected health information across different product lines that are marketed by the same carrier.

Health plans must comply with existing federal and state requirements that establish time frames for promptly paying a claim. If health plans are unable to request additional information, it could result in an incorrect or overpayment to a provider and increase costs for health plans and their members. The costs of recovering overpayments made in error can be substantial.

<u>Due to the potential impact this proposal would have on existing claims procedures, we recommend the provision be removed from the final rule. Health plans should be permitted to make more than one request for claims attachments if such requests are necessary to process the claim and if the health plan adheres to the applicable federal and state timeframes for claims payment.</u>

In addition to the concerns mentioned above, we have outlined other issues for your consideration in the attached comments. We appreciate the Department's efforts to increase the use of electronic claims attachments based on uniform standards and look forward to working with you on this important issue.

Again, thank you for the opportunity to comment on the proposed rule. If you have any questions, please do not hesitate to contact me.

Sincerely,

Heidi Margulis

Heidi Margulis
Senior Vice President, Government Relations
Humana Inc.

Humana Comments

Applicability

Issue: It is unclear whether the proposed standards are applicable to dental claims.

Recommendation: We recommend the Department delay the inclusion of dental claims in the proposed rule until sufficient Logical Observation Identifiers Names and Codes (LOINC) are developed and finalized to support such transactions.

Comments: While dental claims were included within the scope of the HIPAA Electronic Transactions and Code Set standards, the proposed rule on the Electronic Claims Attachments does not specifically reference the applicability to dental claims. Many dental offices still lag behind in technology and lack the resources to transmit information electronically. It is also our understanding that dental and periodontal codes, which are necessary to perform these transactions, are still under development. We believe delaying the inclusion of dental claims within the scope of the proposed rule is warranted until sufficient technology standards are in place to support the transmission of electronic dental claims attachments.

Definitions

Issue: The term "clinical reports" is defined as "Reports, studies, or notes, including tests, procedures, and other clinical results, used to analyze and/or document an individual's medical condition. These include discharge summaries, operative notes, history, physicals, and diagnostic procedures (radiology reports, electrocardiograms (for example, EKG), cardiac echoes, gastrointestinal test, pathology, etc.)..."

Recommendation: We suggest the agency clarify that x-rays are included within the definition of clinical reports. Additionally, the definition should also clarify the inclusion of teeth and periodontal charts which are often used to make dental benefit determinations if the proposed rule applies to dental claims.

Comments: The definition of clinical reports includes a reference to radiology reports, but does not specifically list x-rays. While we presume x-rays are intended to be within the scope of this definition, clarification on this issue would be helpful to the industry.

Effective Dates

Issue: The proposed regulation indicates covered entities must comply with the claims attachment standards 24 months from the effective date of the final rule, except for small health plans. Small health plans must comply 36 months from the effective date of the final rule.

Recommendation: We suggest the final rule specify that covered entities must begin "testing" the new standards 18 months from the effective date of the final rule to facilitate a smooth transition and ensure compliance can be met within the 24 month time frame. Small health plans would begin testing at 30 months.

Comments: We are very concerned that the 24-month compliance requirement will not provide adequate time for health plans to develop, test and implement these new standards based on prior experience implementing the HIPAA Electronic Transaction Standards. Unexpected difficulties implementing and complying with the HIPAA Electronic Transaction Standards were due, in part, to delays in overall readiness and testing of the transactions with a sufficient number of other covered entities and business associates. The health care industry has also committed significant administrative, financial and IT resources to other health information technology (HIT) efforts, including the implementation of the HIPAA National Provider Identifier, evaluation of the ICD-10 procedure codes and other state and regional HIT initiatives related to the development of electronic health records. We believe the Department should consider these activities before issuing a final regulation. In an effort to minimize the burden on covered entities and avoid potential implementation delays, we also believe it would be useful to specify when advance testing of the new standards must begin for all covered entities. This will ensure more successful and timely compliance with the new transaction standards.

Overview of Key Information for Electronic Health Care Claims Attachments

Issue: The Preamble (Section C. Overview of Key Information for Electronic Health Care Claims Attachments, paragraphs 2. through 3.) discusses the Clinical Document Architecture (CDA) and how Extensible Markup Language (XML) is applied within the CDA.

Recommendation: We recommend that the Preamble encourage the use of compressed image formats and indicate that health plans have the ability to negotiate the use of these formats in the trading partner agreements.

Comments: While the Overview of Extensible Markup Language (XML) in the Preamble mentions various computer languages, including XML, Hypertext Markup Language (HTML) and Extensible Style sheet Language (XSL), the language concerning image formats is very generic. The use of compressed image formats, such as Tag Image File Format (TIFF), Graphic Interchange Format (GIF) or Joint Photographic Experts Group (JPEG) is a more efficient format for storing and exchanging data images than other technologies, such as Bitmap (BMP).

Additionally, while we do not believe the regulation should require the use of a specific technology as it could become obsolete in a short period of time, we do recommend the Preamble clarify the ability of health plans to negotiate the use of efficient image formats and technical formatting in trading partner agreements.

Transactions for Transmitting Electronic Attachments

Issue: The proposed rule recommends the use of two transactions to carry the attachment related questions and answers: 1) version 4050 of the X12N 277 request and 2) version 4050 of the X12N 275 response.

Recommendation: We suggest adoption of the 5010 version of both transactions rather than the 4050 version.

Comments: It is our understanding the 5010 version is complete, but the implementation guides are still under development. We suggest the Department consider what standard is expected to be available when these proposed regulations are finalized and become effective rather than adopting a standard that might be obsolete by that time. The 5010 version will support enhanced functionality and additional data elements (e.g., expanded diagnosis coding standard, functional status, etc.) that better meet evolving business practices and needs. It would be burdensome and costly if covered entities were forced to build the necessary technology capabilities for one standard and then be required to adopt a newer standard within a short period of time.

Electronic Health Care Claims Attachment Business Use

Issue: The Preamble of the proposed rule states the standards would not encompass post-adjudication requests for claims related data (e.g., post-adjudication reviews for quality control, fraud and abuse or reporting requirements).

Recommendation: We seek clarification on whether this strategy is consistent with the requirements for initial claim benefit determinations under the ERISA Claims Procedure Regulation and state prompt pay requirements. We also suggest that clarification be provided that subrogation, post-service grievance and appeal internal reviews, external reviews and back-end claims adjustments are considered "post-adjudication" requests are excluded from the scope of the proposed rule.

Comments: More clarity is necessary to ensure there is no conflict between the proposed rule and other state and federal requirements that are related to the claims process, such as the ERISA Claims Procedure Regulation and state prompt pay requirements. Additionally, while the Preamble notes the Department does not consider post-adjudication requests for claims-related data to be part of the claims payment process, there is little guidance on this issue. Processes such as subrogation, post-service grievance and appeal internal reviews, external reviews and back-end claims adjustments are generally performed after the claim has already been paid. Providing these additional examples of what processes constitute "post-adjudication" would be beneficial to the industry and prevent confusion over the intent of this provision.

Submitter : **MaryAnne Zingaro** **Date: 11/22/2005**

Organization : **BlueCross BlueShield of FL**

Category : **Health Plan or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-0050-P-58-Attach-1.WPD

CMS-0050-P-58-Attach-2.WPD

D R A F T

COMMENTS / ISSUES ON CLAIMS ATTACHMENTS PROPOSED RULE

November 21, 2005

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

Dear Sir/Madam:

Blue Cross Blue Shield of Florida (BCBSF) appreciates the opportunity to comment on the Proposed Rule to adopt standards for electronic claims attachments under Title XI of the Social Security Act Subpart C Administrative Simplification. Our organization provides healthcare services to over 4 million members statewide.

BCBSF strongly supports the adoption of health information technology, including the use of electronic claims attachments, to improve the cost effectiveness of healthcare delivery. We believe that the use of electronic attachments will improve workflow and control of claims attachments between providers and payers. We further believe that electronic claims attachments will reduce errors, reduce costs, and streamline communications within the healthcare industry.

The attached comments are provided for your consideration. Please do not hesitate to call MaryAnne Zingaro at 904-905-6599 if there are any questions concerning our comments.

Sincerely,

Joe Hayes
Program Director

D R A F T

COMMENTS / ISSUES ON CLAIMS ATTACHMENTS PROPOSED RULE

November 21, 2005

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

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The attached comments are provided for your consideration. Please do not hesitate to call MaryAnne Zingaro at 904-905-6599 if there are any questions concerning our comments.

Sincerely,

Joe Hayes
Program Director

Submitter : Ms. Cynthia Brown **Date:** 11/22/2005

Organization : American College of Surgeons

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-0050-P-59-Attach-1.DOC

November 22, 2005

The Honorable Michael O. Leavitt
Secretary
Department of Health and Human Services
Attention: CMS-0500-P
P.O. Box 8014
Baltimore, MD 21244-8014

RE: CMS-0500-P: HIPAA Administrative Simplification: Standards for Electronic HealthCare Claims Attachments

Dear Secretary Leavitt:

On behalf of the 70,000 Fellows of the American College of Surgeons, the following comments are submitted in response to the proposed rule on standards for heath care claims attachments published in the September 23, 2005 *Federal Register*. The rule proposes three things:

- The use of two transactions standards--one to request additional information and the other to respond to that request.
- The use of Health Level 7 specifications for the content and format of communicating the actual clinical information.
- The use of Logical Observation Identifiers Names and Codes (LOINC) for identification of the information being requested and for answers to the request.

The proposed effective date for compliance is two years after the date of publication of the final rule.

Definitions

We agree with the definitions of attachment information and clinical reports. The attachment information is supplemental health

information needed to support a specific claim. Clinical reports cover the broad spectrum of summaries, notes, and diagnostic tests. We have a problem with emergency department, which is now defined as providing care "primarily in critical or life-threatening situations." Emergency departments clearly render care that is not needed in "critical or life-threatening situations." For example, treating a broken finger is not life-threatening, yet many broken fingers are treated in emergency departments. It is also not clear whether the emergency department covers places rendering urgent care.

Effective dates

We recommend that the effective date for non-small health plans not be any shorter than two years from the date of the final rule. There is still a great deal to be done to make electronic attachments a reality for a significant number of physicians before the effective date.

Electronic claims attachment types

You requested comments on the types of claims attachments that are most frequently used by our members and whether the six types of attachments developed to date are adequate. Fellows of the College definitely have to submit operative notes as attachments to claims frequently. Payors also may request progress notes and the results of laboratory and other diagnostic tests. We believe the six types of claims attachments are adequate for surgery.

Format options

We are grateful that you performed pilot testing of the request and response transactions and the LOINC coding system. The pilot is testing the request for information and three variants of responses: a scanned document, a keyed response, and a computer generated response that would be coded. We agree with the format for the request and responses that the pilot test is demonstrating because it gives physicians' practices of all sizes and settings the ability to submit attachments electronically or manually. If they are using an electronic medical record, they also have the ability to integrate the electronic medical record and electronic attachment

processes. We believe that all three formats should remain available to all physicians for the foreseeable future.

Solicited vs. unsolicited attachments

The proposed rule states that unsolicited attachments be furnished with the claim only if the health plan has given advance notice that an attachment should be submitted with a claim. You cite the privacy rule's provision that health plans can only request the minimum necessary amount of information as the primary reason for this restriction. We understand and support the reasoning. However, we would urge that in writing the final regulation and related instructions the Centers for Medicare & Medicaid Services (CMS) make it clear to health plans that they should be as all-inclusive as possible in giving advance notice. There should not just be procedure code specific notices but there should also be modifier specific notices and provider specific notices. This will permit additional claims to be considered "clean" for purposes of prompt payment statutes and will not cause requests and responses to be generated needlessly.

We are especially concerned about the modifier specific notices because surgeons often use the technique of attaching modifier -22 to the procedure code to indicate that an unusual procedural service was rendered. This modifier is used to indicate such things as lysis of extensive adhesions or dealing with abnormal anatomy that makes the operation take much longer than usual. Normally, the health plan wants a copy of the operative note to see that the operation was in fact more difficult than the normal operation. Provider specific notices would permit a provider on pre-payment medical review to submit the required additional documentation with the initial claim.

CMS also proposes to allow only one request transaction for all relevant documentation for a claim. Likewise, it would be incumbent upon the physician to provide all the requested documentation in one response transaction. Presumably, the health plan would deny the claim if an incorrect or incomplete response was received and the physician's office would have to appeal the claim, supplying the correct or complete information with the appeal. We understand and appreciate that CMS is trying to avoid having an extended exchange of multiple transactions and, indeed, this would appear to be helpful to physicians. However, we have some concerns about the proposal.

We believe that a lot of honest mistakes are going to be made at all points in the claims attachment system, especially when the system is new. The health plan might make some. The physician's staff might make some, especially in a small office where a single person has multiple responsibilities. Some, such as a failure to transmit some or all of the message, might be made by the hardware and software systems involved. It seems foolish that these kinds of things would cause a physician to have to appeal the claim. One approach would be to have a data set that says "You made an error." and describe what the error was. Surely in the final rule, CMS can find a reasonable compromise that would better serve both health plans and providers.

CMS also requested comments on how providers who choose to submit scanned documents can comply with the standard of the privacy rule so that no more than the minimum amount of data necessary be received by the health plan. We can foresee two things that can be done, with a physician's office choosing one or the other depending on the amount and placement of the extraneous material. For relatively short pieces of extraneous material, the physicians' office staff can photocopy the document and, on the photocopy, mark through the extraneous material with a heavy black pen before scanning it. Another approach, for longer pieces of extraneous material, would be to photocopy the document, blocking the extraneous material with paper, and then scanning the photocopy.

Provider vs. plan perspective

CMS states in its proposed rule that if a provider wishes to use the claims attachment standard, health plans must comply and must also accept the standard response. We agree with the statement, and believe this provision is essential if we are to have standard transactions.

Conclusion

The American College of Surgeons is very supportive of the view CMS took in preparing this notice of proposed rule-making, specifically in allowing any of three response modes--a scanned document, a keyed response and a computer generated response. This will allow any physicians office the opportunity to use this electronic transaction. We hope the final rule will make it clear that advance notices that an

attachment is needed with a claim can be for modifiers and physicians as well as the procedure code. Finally, we believe CMS' proposed policy that only one request and one response may be made for additional information on a claim is unduly restrictive. We are certainly looking forward to working with CMS on claims attachments.

Sincerely,

Cynthia A. Brown

Cynthia A. Brown,
Director
Division of Advocacy and Health Policy

WO:cb:jh//td

Submitter : bill pankey
Date: 11/22/2005
Organization : tunitas group
Category : Individual
Issue Areas/Comments

GENERAL

GENERAL

"ELECTRONIC SIGNATURE" See attachment

CMS-0050-P-60-Attach-1.RTF

A failure in HHS leadership with respect to promulgation of an electronic signature standard will diminish the benefit that the industry can achieve from electronic transactions.

While in most circumstances, requesters do not need the practitioner's signature that authenticates the claim attachment, there are circumstances where they do require them. For example, Medicare requires a physician to certify thru an original signature the accuracy of clinical information provided on forms such as HFCA 2728 or DEMRC 484.2. Medicare's requirement for the assurance provided by these signatures is so strong that 'facsimile' signatures are explicitly prohibited; some ESRD networks go so far as to specify the color of ink that must be used for the signature. While these forms are called 'certifications', they clearly involve the transmission of 'attachment information' as defined in §162.1900 of the proposed Rule. Other plans with similar assurance requirements will also require receipt of the practitioner's signature. Should the Final attachment rule not support the transmission of electronic signature, providers would be obligated to create, transmit, process and store paper records which contain information that is otherwise subject to the attachment rule. Similarly plans would have to create exception processes to handle attachment information for which they require the assurance given by receipt of an original signature. This inefficiency will be exacerbated by 'full' adoption of the electronic record as paper copies will have to be created for the sole purpose of collecting a signature that can be transmitted to the plan. Clearly, the attachment process is improved should there be a generally accepted signature standard and process.

Currently, health care providers implement a de facto standard for the practitioner's electronic signature on the records that are likely to be the subject of an attachment request. Specification for electronic signature is found in the medical practice acts of many states, JCAHO IM standards, and in Medicare COP. This standard typically involves entry of an assigned PIN when the practitioner wants to electronically sign a record or order. While the validity of such signatures can be ensured through the security of the record system and the practitioner's faithful protection of PIN confidentiality, there is no mechanism by which 3rd parties can validate the signature short of an audit of the providers' record system. Furthermore, such signatures are not transportable, which is to say, that there is no manifestation of the signature which can be communicated to 3rd parties. Digitized facsimile signature images are sometime programmatically attached to documents to indicate signature, but such facsimile have been (and should be) rejected by plans. Use of facsimile is subject to widespread abuse as they allegedly were in the famous case involving Magee-Women's Hospital. As it stands, the industry's de facto signature mechanism is insufficient to provide high degrees of assurance to plans. This is not surprising since this signature mechanism was developed to support a provider's internal control over documents and was never intended to directly support reimbursement transactions.

Without the impetus of regulation, it is unlikely that the industry will adopt a standard electronic signature mechanism for attached clinical information. This is easy to see, for in lieu of regulation, as the parties that must be assured of record authenticity, i.e. plans, necessarily will set their own requirements for the electronic signature. The burden falls to the providers though that must adopt solutions that satisfy the plan requirements. There is no reason to believe that plans will specify consistent electronic requirements as clearly they did not do so with other aspects of healthcare EDI.[1] In that absence of consistent plan requirements, providers will support electronic signature only where it has the most compelling business interest. However, the overall, business interest in electronic signature will be diminished as additionally management overhead must be exerted to determine which payer's electronic signature mechanism must be applied to the document. Furthermore, because the payer or payers are often not known at the time the clinical record is created; redundant workflow has to be applied once the payer is known. As a practical matter then, lack of standardization so reduces the economic benefit of implementing a transportable electronic signature in support of reimbursement that few if any providers will implement the same. That is the case today. There is nothing in the mere passage of time that will change this basic value

[1] Hence, the rationale for Administrative Simplification under HIPAA.

inequality. It is unlikely that emergence of a widely adopted electronic signature appropriate to claim attachments will emerge merely by 'waiting upon events'.

Contrary to the statements of the NPRM, there is a consensus standard for electronic signatures that readily support data formats mandated under the Proposed Rule. Furthermore that consensus standard provides for electronic signatures that are transportable and interoperable and meet as well the requirements that providers must satisfy under state licensing and JCAHO rules. The collection of standards developed by the IETF and W3C provides a flexible format for the digital signature of xml formatted records.

For purposes of electronic claims attachments this standard is not complete however. The standard does not define specifically what data objects must be signed. Furthermore the standard is flexible with respect to the methods by which 'trust' in the electronic signature key is established. Both of these issues however are appropriate matters for trading partner negotiation. Congress called for a HIPAA standardization of methods for the *transmission and verification* of electronic signature used with the reimbursement transactions. XML-DSIG does this.

At minimum, in the absence of further electronic signature support, the Rule should exempt requests for information that require explicit authentication by the practitioner as in the cited HHS 'certifications'. Otherwise, the economic analysis of the Rule should include the costs impacts due to the Rule preclusion of the use of some conventional fraud prevention mechanisms.

Submitter : Mr. Tristan North

Date: 11/22/2005

Organization : American Ambulance Association

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-0050-P-61-Attach-1.DOC

AMERICAN AMBULANCE ASSOCIATION

American Ambulance Association
8201 Greensboro Drive, Suite 300
McLean, Virginia 22102
Phone: (703) 610-9018
Fax: (703) 610-9005
Website: www.the-aaa.org

"The American Ambulance Association promotes health care policies that ensure excellence in the ambulance service industry and provides research, education, and communications programs to enable members to effectively address the needs of the communities they serve."

November 22, 2005

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

RE: Proposed Rule, CMS-0050-P

Dear Sir or Madam:

The American Ambulance Association (AAA) is pleased to submit our comments to the proposed rule (70 Federal Register 55990) issued on September 23, 2005 by the Office of the Secretary of the Department of Health regarding standards for electronic attachments to support claims. While members of the AAA are primarily organizations that provide emergency and/or non-emergency ambulance services, it is important to note that we also have members who are software companies and billing agents for ambulance service providers. It is therefore on behalf of the diverse membership of the AAA that we submit these comments.

1. **Attachment**

We believe the attachment proposed should not be a mandatory field when claims are submitted. Instead, it should only be used when the carrier/intermediary seeks additional information or documentation.

2. **Attachment Content (Issue Identifier II – E)**

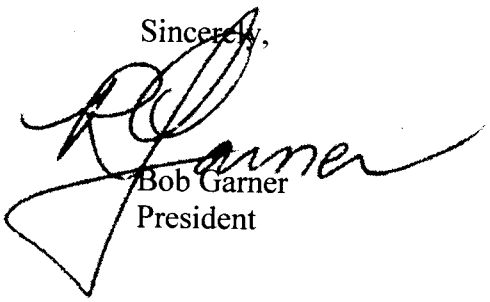
The file attachment is 64 megabytes. We agree that this is sufficient space to provide information or documentation requested.

3. **Cost**

In order to submit attachments, software changes will be needed, e.g. internet connectivity, scanning, etc. to interface with billing software. Many of our members are small providers who may not be able to afford the costs involved. Therefore, we highly recommend that electronic attachments be made available, but not mandatory.

Thank you for the opportunity to comment on this Proposed Rule.

Sincerely,



Bob Garner
President

Submitter : Mr. Dennis Harsh

Date: 11/23/2005

Organization : MedAmerica Billing Services, INC

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-0050-P-62-Attach-1.DOC

ELECTRONIC CLAIMS ATTACHMENT TYPES:
We are a large medical billing company that bills for 150,000 emergency room visits a month for over 60 hospitals.

In Section II, C, 5 (page 55997:
There are 6 **attachment types** mentioned (Ambulance services, Emergency department, Rehabilitation services, Clinical reports, Laboratory results and Medications).

Under paragraph 162.1905 (page 56024):
There are 3 types of **services** (Ambulance, Emergency and Rehabilitation) and 3 **types of information** listed (Clinical reports, Laboratory results and Medications)

Clarification on these 6 items is needed because you are referring to them differently in different places in the document. We also need clarification on how do we classify chart elements received from hospitals. See the following example and questions.

Our hospitals charts are composed of from 2 to 6 different chart elements/documents (Insurance card, Dictation, Nurses Notes, Face Sheet, Discharge or Fee Ticket, and a Smart Chart or Ed Record or Doctor Notes). Are you going to allow us to combine all of these different chart elements into 1 of the 6 **document types**? If so, do we use Emergency or Clinical reports? If we have to use both what should be placed in each?

If we can not combine chart elements/documents, then there will be problems with where to place the inconsistent chart elements/documents in the data stream. Some hospitals use document templates that combine information and others do not as you can see from the 6 chart elements/documents most hospitals send us.

The most feasible solution for Emergency Physician groups would be to supply all available information and documentation regarding the emergency department visit, including all procedures, as the following under the LOINC Users' Guide – June 1, 2005

Initial Document Type Submissions

Short Name	Kind of Document	Type of Service	Setting	Training/ Prof. Level	Subject Matter Domain	Code Mappings	Comments
Emergency Department Note	Clinical Note	Evaluation & Management	Emergency Department				

The Clinical Term Class should be "Emergency Department (DEEDS)". Abbreviation "ED.
The Attachment Term Classes should be "Emergency department attachment". Abbreviation "ATTACH.ED"

The final ruling should allow for latitude in how documents are indexed and stored within the physician groups' repository. Otherwise, the physician group can be greatly burdened by the costs, including labor, of identifying and separating the various components of the emergency department record. The shortfall is that in some cases, the minimum necessary in accordance with HIPAA privacy,

could be jeopardized. However, until there is greater standardization or output and better abilities to integrate systems, the physician group should be allowed to submit the entire emergency department record as a single attachment as documented above in cases where absolutely necessary. Otherwise the ruling is forcing physicians to absorb the costs and burden associated with today's systems that don't inherently store and easily transfer documents representing separately identifiable chart components.

Overtime, as the interoperability to standardization of systems is improved, the regulations could be revised to ensure that these improvements are taken advantage of ensuring that the minimal necessary is supplied.

Submitter : Dr. Jeffrey Kaufman **Date:** 11/24/2005

Organization : vascular services of western new england

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Based on early experience with EHR problems, three key issues were not addressed in the early regulations for HIPAA: A robust patient identifier that was machine readable; a document type taxonomy; an identifier for the document source. All of these issues pertain to the regulations for attachments, because all of these must be used by the claims-processing system.

First, the issue of an identifier, which is either understood by text fields with XML markers as noted in the proposed rule, or by some sort of bar code, is very important. The system must have formatting rules or be created such that machine logical systems can intuit the data in a variety of formats, to address the key issues of name, birthdate, address, all without using social security numbers, which are increasingly forbidden. This is not a trivial issue. For those of us still generating paper documents, we need to know just what formatting of the document must be afforded and where to allow systems to do either OCR conversion or to allow the computer to look for parts of the document that are the identifier.

Second, claims processing must know what type of document they are using as an appendage, so that it is handled properly. We have no national taxonomy so far, but the basic concept would distinguish between operation reports and discharge summaries, between lab reports and radiology reports, in order to assist in adjudication of claims. We need this type of taxonomy for proper storage of data in any computerized system, so your standards for claim attachments should be consistent on this.

If a paper attachment comes from a physician office, it will usually have a header and/or footer containing the source information, and it will be signed. There is no standard for placement of tags or other machine-readable identifiers as to what the source is. Claims attachments should have their processing assisted by having automatic uploading of this information: for example, the practice name and the specific doctor generating the information should be considered. It seems logical in the standards being addressed to have fields for the upcoming NPI's. I do not think we should all throw away our office stationery, but there could easily be rules created to code the information line by line to identify what field it would go into for the purposes of identifying the document source, and there could be standards for font, font size, font density which might assist this process.

I think we are heading for a standard where much of this information is placed in either bar codes or other machine-readable fields at the top or bottom of the document, as if it were a check to be processed. The technology to do this is available now, and the cost is minuscule. It is a matter of thought and standards that allow both those with EHR's in the office and those still using typewriters to embed the data.

Submitter : Ms. Barbara Marone **Date:** 11/29/2005

Organization : American College of Emergency Physicians

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHMENT

CMS-0050-P-64-Attach-1.DOC

American College of
Emergency Physicians®

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202-728-0610
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www.acep.org

November 21, 2005

Attention: CMS-0050-P

The Honorable Michael O. Leavitt
Secretary, Department of Health and Human Services
445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-0050-P: Administrative Simplification: Standards for Electronic Health Care Claims Attachments Proposed Rule.

Dear Secretary Leavitt:

On behalf of the American College of Emergency Physicians (ACEP), I am pleased to submit comments on the proposed Standards for Electronic Health Care Claims Attachments published in the Federal Register on September 23, 2005. ACEP is a national medical specialty society with more than 23,000 members, dedicated to improving the quality of emergency care through continuing education, research, and public education. We appreciate the opportunity to provide the Department with our comments on this latest set of requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

ACEP supports the current Administration efforts to move rapidly to a total electronic health record system. We also support this effort to establish standards for electronic claims attachments and we encourage rapid adoption by vendors and payers. As stated in the proposed regulation, covered entities must comply with the requirements 24 months after the rule is finalized. We believe this timeframe is not realistic or feasible.

Currently, most hospital EDs and ED system vendors do not have information systems in place to accommodate the robust set of data elements specified in CDAR1AIS0002R021, Additional Information Specification 0002: Emergency Department Attachment, Release 2.1, based on HL7 CDA Release 1.0. Once the proposed rule is finalized, it may take more then 5 years and as much as $ .5 million per facility to achieve full compliance. Therefore, the current implementation timeline is much too aggressive and unsupportable by the current information system vendor market. The time frame needs to be reevaluated in light of exiting infrastructure and economic impact to hospitals and healthcare software vendors.

The current claims attachment is largely derivative of a very dated specification (DEEDS 1.0) published in 1997 which is currently being revised by the "Health Level 7 Emergency Care Special Interest Group" (HL7 EC SIG). DEEDS requires a complete overhaul to fix many problems, add new data types and to specify its content using current HHS Consolidated Health Informatics Initiative adopted terminologies and standards. Therefore, significant review and revision by the HL7 ED SIG is inevitable and the specification should not be finalized until this review and revision has passed HL7 ballots and whatever harmonization process there is with X12N. HHS should fund

DEEDS revisions and completion of the specifications for version 3 messages by HL7 EC SIG. In addition, HHS should fund updating LOINC to comply with any new DEEDS specification requirements and for SNOMED-CT adding additional concepts required for ED use.

ACEP opposes the proposed penalty structure for inability to comply with the specification. This places an excessive and unfair burden upon hospitals and emergency care providers due to shortcomings in the information systems vendor industry which is outside of the provider's control. EDs represent a crucial component of the healthcare safety net and the frontline for identification, management, and treatment of disease pandemics, terrorism, bioterriorism, and natural disasters. At the same time, many EDs are extremely crowded, experiencing difficulty obtaining appropriate specialty consultations, facing increasing personnel shortages, and experiencing rising numbers of the uninsured who have no other healthcare provider. ACEP is very concerned that the inclusion of penalties in the ED Attachment requirement will create serious problems in an already precarious emergency care system.

ACEP supports federal funding of pilot programs involving multiple emergency department information systems (EDIS) vendors and multiple payers. Implementation deadlines should be delayed until after pilots are completed, proven to be functional and DHHS has analyzed the results.

ACEP supports a phased-in approach and federal funding of a payment adjustment to physicians and providers to help compensate for the additional cost of compliance. We also believe that better communications between DHHS and information system vendors on these standards is necessary to achieve wide adoption and support for these requirements at the provider level.

ACEP appreciates the opportunity to offer these comments and looks forward to continuing to work cooperatively with the Department in order to address these important issues. Please do not hesitate to contact Barbara Marone, ACEP's Federal Affairs Director at (202) 728-0610 ext. 3017 if you have any questions about our comments and recommendations.

Sincerely,

Frederick C. Blum, MD, FACEP, FAAP
President

American College of
Emergency Physicians®

Washington, D.C. Office
2121 K Street, NW
Suite 325
Washington, D.C. 20037-1801

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November 21, 2005

Attention: CMS-0050-P

The Honorable Michael O. Leavitt
Secretary, Department of Health and Human Services
445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-0050-P: Administrative Simplification: Standards for Electronic Health Care Claims Attachments Proposed Rule.

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DEEDS revisions and completion of the specifications for version 3 messages by HL7 EC SIG. In addition, HHS should fund updating LOINC to comply with any new DEEDS specification requirements and for SNOMED-CT adding additional concepts required for ED use.

ACEP opposes the proposed penalty structure for inability to comply with the specification. This places an excessive and unfair burden upon hospitals and emergency care providers due to shortcomings in the information systems vendor industry which is outside of the provider's control. EDs represent a crucial component of the healthcare safety net and the frontline for identification, management, and treatment of disease pandemics, terrorism, bioterriorism, and natural disasters. At the same time, many EDs are extremely crowded, experiencing difficulty obtaining appropriate specialty consultations, facing increasing personnel shortages, and experiencing rising numbers of the uninsured who have no other healthcare provider. ACEP is very concerned that the inclusion of penalties in the ED Attachment requirement will create serious problems in an already precarious emergency care system.

ACEP supports federal funding of pilot programs involving multiple emergency department information systems (EDIS) vendors and multiple payers. Implementation deadlines should be delayed until after pilots are completed, proven to be functional and DHHS has analyzed the results.

ACEP supports a phased-in approach and federal funding of a payment adjustment to physicians and providers to help compensate for the additional cost of compliance. We also believe that better communications between DHHS and information system vendors on these standards is necessary to achieve wide adoption and support for these requirements at the provider level.

ACEP appreciates the opportunity to offer these comments and looks forward to continuing to work cooperatively with the Department in order to address these important issues. Please do not hesitate to contact Barbara Marone, ACEP's Federal Affairs Director at (202) 728-0610 ext. 3017 if you have any questions about our comments and recommendations.

Sincerely,

Frederick C. Blum, MD, FACEP, FAAP
President

Submitter : **Lynne Gilbertson** **Date: 12/22/2005**

Organization : **NCPDP**

Category : **Other Association**

Issue Areas/Comments

GENERAL

GENERAL

See attachment of 20051222

CMS-0050-P-65-Attach-1.DOC

Comments submitted 12/22/2005:

NCPDP recommends that this rule exempt retail pharmacy due to the named standards and conditions under which this industry operate. Retail pharmacy's use of on-line real-time claims adjudication processing would be negatively impacted by the use of the recommended electronic health care claims attachment standards. We do not believe HHS intended this, but request it be clearly stated that retail pharmacy is exempted from this rule. If the intent was that retail pharmacy might be included, HHS must conduct a thorough analysis, studying how these attachments would impact 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 resulting in the inability to provide pharmaceutical care (prescriptions) to healthcare beneficiaries.

Submitter : **Kristina Pelletier** **Date: 12/23/2005**

Organization : **DoD/Heath Affairs/TMA**

Category : **State Government**

Issue Areas/Comments

GENERAL

GENERAL

Attachment

CMS-0050-P-66-Attach-1.PDF

Notice of Proposed Rule Making Claims Attachments
Comments

NPRM Claims Attachments Section Header	Page	Comments	
Definitions			
		None	
Effective Dates			
		None	
Overview of the Clinical Architecture			
Overview of Clinical Document Architecture	55995	Agree that the option to include imaged or text information is important to healthcare providers that do not have computer-based patient record systems, as we believe this to be the case for physician offices and small facilities such as ambulance providers.	Agree that the option to include imaged or text information is important to healthcare providers that do not have computer-based patient record systems, as we believe this to be the case for physician offices and small facilities such as ambulance providers.
Electronic Claims Attachment Types			
Electronic Claims Attachment Types	55996	The federal rulemaking process need to be timelier.	With claims attachments, new booklets and updates to current booklets will need a timelier process to keep up with changes in policy and industry standard. The current process is not efficient enough to keep up with the need of the industry.
Electronic Claims Attachment Types	55996	Flexibility to continue the exchange of paper processes is necessary in the event the attachment types or the AIS do not cover a plan's business need.	In the event the attachment types or the AIS do not cover a plan's business need. For example, when provider bills a span of dates for any therapy, we would need to develop for a breakdown of services (specific service dates). We don't feel that the AIS booklets accommodate this.
Electronic Claims Attachment Types	55997	Agree with the 6 proposed attachment types for this rule. Additional attachment types such as DME and Home Health would like to be seen in the future	
Format Options			
Format Options (Human vs. Computer Variants) for Electronic Claims Attachments	55997	Clarification is needed with respect to the receivers option to auto-adjudicate and not a requirement of the plan if the attachment is sent as a Computer Decision Variant.	
Format Options (Human vs. Computer Variants) for Electronic Claims Attachments	55997	PGBA supports both the HDV and the CDV of the CDA attachments recommendation be named in this Final Rule.	While some payers may think allowing the CDV will require them to process those documents as computer readable (should a provider choose to implement the CDV) they can be rendered as human readable with the style sheet. This will not place an extra burden on the payer.
Use of CDA Release 2	55995	HL7 Attachments Special Interest Group (ASIG) implementation guides should be updated to the current release of CDA, Release 2, May, 2005.	Release 2.0 is fully derived from the HL7 Reference Information Model (RIM) and supports full semantic interoperability. Release 1.0 was only partially RIM-derived with limited interoperability. Further, there is no significant legacy of Release 1.0 documents in the US. The industry focus on Release 2.0 is clear from the activity of the HIMSS EHR Vendors Association and others implementing CDA – all are using Release 2.0. We see no need for a Release 1.0/Release 2.0 conversion mechanism because of the lack of Release 1.0 legacy and the industry concensus around adoption of Release 2.0.
Combined Use of Different Standard			

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NPRM Claims Attachment Section Header	Page	Comment	Justification
Combined Use of Different Standard	55998	HHS solicits industry input regarding the strategy of using X12 and HL7 together to address both the administrative and clinical aspects of the attachment transactions from a format and content perspective. This strategy is acceptable for this proposed rule.	We are not aware of any objectives to this strategy that have been raised by TMA.
Post Adjudication	55998	Anything that involves the actual payment or processing of the claim should be included in this rule. Does post adjudication include adjustments to previously processed claims.	
Solicitated vs Unsolicited Attachments			
Solicited vs. Unsolicited Attachments	55999	HHS solicits industry input regarding whether, for each specific claim, health plans should be allowed to submit only one electronic attachment request transaction which would have to include all of their required or desired "questions" and/or documentation needs relevant to that specific claim.Agree with HHS' intent to limit ongoing requests for information, and encourages accumulating questions and asking once. However, is there also (or will there also be) language that would restrict health plan/payers from using other media (paper, phone, fax, etc.) to solicit additional attachments after the one electronic attachment request transaction was transmitted? The language we see in the NPRM appears to only restrict the health plan's/payer's use of electronic transactions to one. If plans/payers are still allowed to use other modes of transmitting requests for attachments, in addition to the one electronic attachment request transaction, then HHS' reasons for establishing the stated restriction may not be met. We also suggest that HHS include a provision to denote that there will be allowances for "second electronic reque	On page 56012, under "H. Requirements (Health Plans, Covered Health Care Providers and Health Care Clearinghouses)", the NPRM appears to provide language that would allow supplemental paper, phone, fax requests for attachments when it says "Under the proposed rule, health plans may continue to use manual processes (such as paper forms, letters, faxes, etc.) to request additional documentation from a health care provider, even for the attachment types listed in this proposal. However, whenever such a request is made electronically, it must be made using the standard. Furthermore, if the health care provider asks that the transaction be sent using the standard, the health plan must comply."
Solicitated vs Unsolicited Attachments	55999	The NPRM states: "Health care providers would be required to respond completely to the request, using one response transaction."Suggest changing this sentence to read, "Health care providers that are using X12n 277/275 electronic transactions would be required to respond in accordance with the cardinality of the request, using one response transaction."	Referencing that providers must respond based on the rules of cardinality clarifies that responding "completely" may be different than sending everything the health plan/payer requests.
Solicited vs. Unsolicited Attachments	55999	Paragraph 4, Solicited: In regards to the verbiage, *"We also propose that for each specific claim, health plans may solicit only one electronic attachment request transaction which would have to include all of their required or desired 'questions' and/or documentation needs relevant to that specific claim."* we question the number of times plans are restricted to request.	The concept of requesting information under the minimum necessary standard will not reasonably answer all decision information once that information on the original request is returned. The information returned may require additional requests for information dependent on service. For example, if a claim is received with an unlisted surgical procedure 17999, a request is done for a valid procedure code or description of service rendered. If the response to that request identifies the procedure as cosmetic, additional information regarding medical necessity, history & physical, pathology report or office notes would then be needed. With the review of the claim, there may be multiple departments that view the claim for different levels of information. It is not always apparent, upon the initial review of the claim, what additional information is needed to complete processing.
Solicited vs. Unsolicited Attachments	55999	This section states that the provider may only submit an unsolicited electronic attachment when the health plan has given them advance instructions. If the health plan has not defined advanced instructions for a type of claim or service and the provider submits an unsolicited electronic attachment, which the health plan does not consider based on the fact, advance instructions were not defined, will the health plan be restricted from requesting the claims attachment information on this claim from the provider?	
Solicited vs. Unsolicited Attachments	55999	When doing Unsolicited claims attachments, and the attachment does not answer all questions, are we allowed to send a 277 request for the additional information?	
Coordination of Benefits			

NPRM Claims Attachments Discussion Topic	Page	Comment	Justification
Coordination of Benefits	55999	For COB in general, if we have *solicited* attachment information, is the primary health care plan required or permitted to forward this information?	
Coordination of Benefits	55999	For COB in general, if we have unsolicited attachment information, is the primary health care plan required or permitted to forward this information?	
Coordination of Benefits	55999	If a payer receives an attachment as a scanned image (jpg), and internally must store the document in a different format (tif), can the payer forward the additional information for COB in the stored format if all data from the original format is present? Must the attachment be forwarded in the same format as it was received?	
Impact of Privacy Rule			
Impact of Privacy Rule	56000	HHS solicits 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.Under the human variant of the electronic attachment standards, application of the minimum necessary standard would essentially remain unchanged for provider responses to requests for claims attachments. However; it appears that for a computer variant request, data retrieval, and response on behalf of providers; either extensive automated check and balance safeguard mechanisms or continued human review and approval may be necessary to ensure responses to requests for information do not exceed the standard for minimum necessary data.	Unless there is a means to ensure that plans/payers take steps to narrow their use of LOINC values to actually identify the minimum data necessary for what the plan/payer really needs, then the NPRM (and real world practice) appears to put the workload (effort) on the provider to evaluate each incoming request against the minimum necessary standard. Sending only the minimum necessary information would benefit the provider as printing, scanning and manhour time would be reduced.
Connection to Signatures			
Connection to Signatures (Hard Copy and electronic)	56000	PGBA concurs 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 the 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.	
Provider vs Plan Perspective		None	
Attachment Content and Structure			

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NPRM Claims Attachment Section/Header	Page	Comment	Justification
Reusability	56001	Insert Attachment Control Number (ACN) into 275 with reference to the CDA document identifier	One advantage of the CDA format for electronic claims attachments is that providers can reuse the documentation produced for the patient chart to support the claim for payment fo services. As proposed, the CDA implementation guides support reusability, with the exception of the requirement of an attachments-specific Attachment Control Number (ACN) in the header of the CDA. This data element is specific to this proposal and will require that each document be created de novo for claims adjudication. The ACN matches the attachment with the associated claim. We suggest that an alternative mechanism, based on the unique identifier in the CDA header be substituted for the ACN and that the association be made within the 275. Under this alternate mechanism, matching can be against the globally-unique CDA identifier required in each document header and there is no need to regenerate documents from a patient chart that may already contain all information reqiured for adjudication.
Alternatives Considered:Candidate Standards			
Code Sets	56003	With regard to transaction size limitation the NPRM needs to be corrected to show 64 MB size limit on BIN segment. Correction needed to the preamble - should be limitation per BIN segment not per transaction.	
	56004	Need a clear process on how to access the LOINC codes used for the HIPAA specific code set.	
	56003	We need clear understanding of the maintenance and update schedule of the LOINC code set.	
	56004	Because LOINC is adopted as a medical code set, the regulation needs to clarify the use of which LOINCs are used in each of the AIS documents. There is a concern that absent this clarification entities may attempt a legalistic position that any LOINC code may be used for any attachment.	
	56005	Recommend a technical correction to the HL7 AIS booklets that reference the LOINC database to clarify how to determine the appropriate subset of the LOINC codes.	
Modifications to Standards and New Attachments			
		None	
Impact Analysis			
		None	
Costs and Benefits			
		None	
General			

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NPRM Claims Attachment Section Header	Page	Comment	Justification
II, E Attachment Content and Structure	56001	File size in X12 275 recommends 64mb for the BIN segment. NPRM indicates maximum size of 275 should not be greater than 64mb. Rule should reflect the X12 275 verbiage as a recommendation size o the BIN, not a maximum of the entire transaction.	
Covered Healthcare Providers	56012	Paragraph 2: Reads 'These 'unsolicited' electronic attachments should not be sent without prior agreement or understanding between trading partner's Need clarification of the word 'agreement'. Is thi a physically signed agreement between provider/payer? For plans to obtain an additional signed trading partner agreement from providers wishing to utilize the attachment process will not be cost effective for the provider or the payer due to the additional steps necessary to secure signed agreements	
II, H Requirements (HP, CH, Providers 1st column)	56012	Paragraph 2: "The use of the standard electronic health care claims attachments would not preclude the health plan from using other processes or procedures to verify the information reported in the attachment documentation." Recommend changing the word 'verify' to 'clarify'. Verify infers a confirmation of the information rather than clarification of the information	
Subpart S – 162.1920 Electronic health care claims attachment response transaction	56024	Item D does not require the use of HL7 CDA for the human decision variant. This is in disagreement with the pre-amble and the HL7 specifications. It is recommended that this section is revised to include the HL7 CDA requirement for the human decision variant. This section should be revised to state that in the HDV repeat the LOINC codes in CDA and that the free text, scanned images or embedded documents must be in HL7 CDA within the BIN segment.	
Subpart S – 162.1925 Standards and implementation specification for the electronic health care claims attachment response transaction	56024	The X12 275 version 4050 Implementation Guide is named in this section. Since this version is a final published guide and no changes can be made to this version, it is recommended to adopt the X12 275 version 5010 for various reasons: 1) In Unsolicited attachments using version 4050 275, the sender is limited to sending the X12 837 and 275 within the same interchange. This could impose limitations on the providers ability to transmit data separately which may be due to file size restrictions or an applications inability to combine the two transactions, thus decreasing the number of implementers.	The draft version 5010 275 Implementation Guide does not include the limitation that an unsolicited 275 must be sent within the same interchange as the 837 transaction. This allows receivers to define specific timing rules to their business by allowing the corresponding unsolicited attachment to be sent within the same business cycle or within 3 days of the X12 837 claim submission. This leniency allows cushion in the event , 1) The business process and software applications of the 837(claim) and X12 275 (attachment) are not housed in the same business area, therefore not linked.
		For new attachment types, recommend that the DSMO be authorized to adopt those that are developed, balloted and published by HL7 through the DSMO process. Stop the process here and do not go through the full regulatory process. This overall process will include provisions for outreach and comments in the HL7 SDO processes. In addition, notification and rollout time between adoption and implementation date needs to be added after the HL7 publication.	More time is needed to implement new types than for changes to existing ones.
		Recommend that the 275 IG be changed to remove the use of the 102. Change the reference in the 275 IG to recommend the use of the X12 999 for syntax errors, and the use of the X12 824 TR3 to acknowledge both the X12 and HL7 content.	This is in line with WEDI Acknowledgements PAG recommendations.
		The preamble of the NPRM references style sheets incorrectly and PGBA recommends clarifying this in the Final Rule. The individual attachment AIS's (booklets) do not include a stylesheet; the stylesheet is provided separately by HL7. It should also be noted that at this time, one style sheet works for all 6-attachment types.	
Reference Documents Comments			

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Comments

NPRM Claims Attachment Section Number	Page	Comment	Justification
AIS Rehabilitation; Ambulance; and Emergency Department booklets		The Rehabilitation; Ambulance; and Emergency Department booklets reference a practitioner or treatment plan author identifier using UPIN, NPI, or state license numbers. US territories utilize 3-digit country codes, therefore the reference to 'XX' 2-digit US Postal abbreviations is not correct for identifying licensed practitioners in US territories.	
AIS booklet:Psychiatric Rehabilitation Services		Comment: TRICARE Policy Manual Chapter 11, Section 3.9 requires that for each claim for their services a pastoral counselor must certify that a written communication has been (or will be) made to the referring physician of the treatment results. There is no provision for documentation of this written communication in the Psychiatric Rehabilitation Services Attachment. Suggested wording for requesting/providing documentation: Written communication with the referring physician Response: Yes No	
AIS Laboratory Results		Page 11, section 3.1.1 should be 3.1.4 since there is already a 3.1.1 on page 9.	