OCT 13 2005

UROLOGY ASSOCIATES OF SOUTH BEND, P.C.

A. PHILIP DE PAUW, M.D., F.A.C.S.
JOHN A. HUDAK, M.D.
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KATHLEEN DELNAY, M.D.
SCOTT A. BLICKENSDERFER, D.O.
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JAN C. GREEN, M.D., F.A.C.S., Emeritus

707 E. CEDAR STREET, SUITE 450
SOUTH BEND, INDIANA 46617
PHONE: 574 234 4100
FAX: 574 282 1739

October 6, 2005

Re: Electronic Claims Attachments Rule

Procedures filed with the modifiers –22 (Unusual procedural services)and –62 (Two Surgeons) as well as unlisted procedure codes (example: 53899) need to bypass the attachment ruling.

We know in advance each of these claims is non-payable without additional documentation.

We are in Indiana and have applied for a waiver for these types of claims; however, the waiver is for a period of 120 days so that we may get our computer up to snuff. After that period of time, I worry that an already complex payment system will become even more so and my physicians will be forced to wait unnecessarily long periods of time for reimbursement for services provided.

Alice M Kater, CPC
Alice M. Kater, CPC
Urology Associates of South Bend, PC

2.

Columbia Surgical Associates, Inc.

OCT 13 2005

1605 East Broadway, Suite 110, Columbia, MO 65201
Telephone (573) 443-8773, Fax (573) 875-4972

Walter R. Peters, M.D.
Paul W. Humphrey, M.D.
Joe D. Starke, M.D.
James B. Pitt, D.O.
John G. Adams, M.D.
Richard D. Coats, M.D.

October 6, 2005

CMS
Dept of Health and Human Services
Attention: CMS-0050-P
PO Box 8014
Baltimore MD 21244-8014

GP ID #990001337

RE: **ELECTRONIC CLAIMS ATTACHMENTS RULE**

Dear Sirs:

Per the Federal Register dated September 23, 2005, the above stated proposed rule would not allow physicians' offices to attach documentation electronically to claims we have submitted. Although we understand the motivation for this ruling, it can only complicate the processing of claims/payments. There would be an increase in the number of calls necessary to track these claims as it would be impossible to know if the documentation had been received. That would mean longer "hold times" for everyone involved.

The following CPT code 37205 (Transcatheter Placement of an Intravascular Stent, Percutaneous: Initial Vessel) elicits additional documentation. It seems reasonable to add this code to a "blanket" attachment order so the documentation would be sent automatically, not when requested. This would reduce possible delays in processing and payment of claims.

We thank you for your careful consideration in this matter.

Sincerely,

Sharon K. Smith

Sharon K. Smith
Practice Manager

OCT 17 2005

Desert Pain Institute

P. O. Box 20310 • Mesa, AZ 85277-0310 • 480-325-3802

October 11, 2005

To: CMS-0050-P
Re: Proposed Electronic Claims Attachments rule

Comment:

As pain management specialists, we treat many implanted pain pump patients. Per the Noridian carrier, whenever we fill/refill the pump reservoir with a compounded drug, we must file with an unlisted CPT J3490, and attach the drug invoice to the claim. The refill codes CPT 95990 or 95991 must always accompany the J3490 code.

We would suggest adding these codes to be covered under a "blanket" attachment order. This would enable us to electronically submit our claim with the invoice on the first filing, instead of submitting claim electronically, then waiting for the request for the invoice.

Thank you for your consideration of this comment.

Lynda Von Stein, CPC
Billing Reimbursement Specialist
480-325-3802 Ext 337

OCT 20 2005

T · A · O · S
ORTHOPAEDIC
INSTITUTE

James H. Lubowitz, M.D. *Director*
Dan Guttmann, M.D. *Associate Director*

Telephone **505.758.0009**
Facsimile **505.758.8736**

1219-A Gusdorf Road · Taos, New Mexico 87571

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

To Whom It May Concern:

This letter is in regards to the proposed standards for electronic health care claims attachments. Below are our comments in regards to specific aspects of the proposal.

ELECTRONIC CLAIMS ATTACHMENT TYPES

We wish to comment on some electronic claims attachment types which we feel are just as pressing as the six proposed electronic claim attachment types. The first attachment we propose to have added is that of EOBs for secondary payers. Most secondary payers require a copy of the EOB received from the first payer before they will process and pay the claim. We believe that all health care providers need to send attachments of this type and would like a method of sending such claims electronically. This would help speed up payment of the claim and allow providers to track such claims.

A second attachment we would like to have added is that of appeals for denied claims. Most health care providers need to send appeals to insurance companies and enabling such appeals to be sent electronically would help hasten the appeals process as well as provide a means of tracking such appeals.

SOLICITED vs. UNSOLICITED ATTACHEMENTS

We wish to comment on you proposal that health care providers may submit an unsolicited electronic attachment with a claim only when a health plan has given them specific advance instructions pertaining to that type of claim or service. We disagree with this proposal in that health care plans do not always give specific advance instructions for claims that we know will be denied unless specific information is attached. There are claims which are consistently denied because they lack progress notes or operative notes and while the health care plans do not give us advance notice of the need for such attachments, nonetheless such attachments are needed for the claim to be paid. Rather than wait for the health care plan to request such attachments, it would be beneficial if we could send such attachments with the original claim. This would enable quicker payment of such claims.

We also wish to comment on your proposal that for specific claims health care providers would be required to respond completely to the request using one response transaction. Inevitably a health care provider will send a response to a request and later realize that in error they left out part of the request. Health care providers should at least be allowed two transactions to respond the request in the case of such errors. It would also be beneficial to allow more than one transaction in the case where part of the required information is not immediately available to be sent, but it is believed that sending the information that is available would allow the health care plan to pay part of the claim. This would allow us to receive partial payment or denial for part of the claim in a timely manner.

We hope that our comments are helpful in determining the final standards for electronic health care claims attachments.

Sincerely,

Grace Tafoya

Grace Tafoya
HIPAA Compliance Officer

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NHIA

National Home Infusion Association

Providing solutions for the infusion therapy community

October 17, 2005

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0500-P, Mail Stop C4-26-05
Baltimore, MD 21244-1850

Ref: CMS-0500-P Proposed HIPAA Rule on Claims Attachments
Request for Extension of Comment Period

Dear Dr. McClellan:

The National Home Infusion Association ("NHIA") is intending to submit comments on the proposed rule for HIPAA Claims Attachments as issued in the Federal Register on September 23, 2005.

NHIA is a national membership association for clinicians, managers and organizations providing infusion therapy services for patients in home care and outpatient settings. Our members include independent local and regional home infusion pharmacies; national home infusion provider organizations; and hospital-based home infusion organizations. Generally, infusion pharmacies can be defined as pharmacy-based, decentralized patient care facilities that provide care in alternate sites to patients with either acute or chronic conditions. Currently, NHIA has more than 2,000 members.

NHIA appreciates the substantial work on development of standards for claims attachments and proposal of a rule by CMS and all others involved in development of the proposed standards, especially within the X12 and HL7 standards organizations. We understand this has been a very lengthy seven year effort by many parties.

From our initial efforts to analyze the proposed rule including all ten of the technical documents incorporated by reference, we have realized understanding and commenting on what is proposed involves review of at least 1,000 pages of material. Much of this material presents new and complex technology such as XML/CDA and standards for which many are generally unproven by use, which will have highly significant cost-benefit tradeoff impact for all participants in the health care industry. Of course, NHIA is especially concerned with impact on home infusion providers and their technical vendors. We note that our constituency fulfills a critical role in a segment of alternate-site health care that typically has unique needs as compared other categories of health care providers.

Given that development of these complex standards and proposed rule have taken seven years and the very high potential impact on the entire health care industry, NHIA urges CMS to extend the comment period by at least 120 more days, i.e. a 180 day comment period. This delay is essential for CMS to receive thorough and quality comments from all parties that would be involved in using these HIPAA standards—to ultimately achieve the desired benefits.

Sincerely,

Bruce E. Rodman
Director, Health Information Policy

100 Daingerfield Road • Alexandria, VA 22314 • *Phone:* 703.549.3740 • *Fax:* 703.683.1484 • www.nhianet.org

OCT 26 2005

wedi™ *Partnering for Electronic Delivery of Information in Healthcare*

October 18, 2005

Lorainne Doo
Senior Policy Advisor
Centers for Medicare and Medicaid Services
Office of e-Health Standards and Services
531 Piccadilly Rd.
Baltimore, MD 21204

Dear Ms. Doo:

The Workgroup for Electronic Data Interchange (WEDI) is named as an advisor to the Secretary of the Department of Health and Human Services in the Health Insurance Portability and Accountability Act of 1996 (HIPAA). It is in the role of advisor to the Secretary that I write to you today.

As you know, on September 23, 2005 the Department of Health and Human Services (HHS) published the Claims Attachments Proposed Rule under HIPAA. The NPRM provides the healthcare industry with a 60 day window for submitting public comments. WEDI has been working proactively and collaboratively with other healthcare industry groups such as the Association for Electronic Healthcare Transactions (AFEHCT), X12, HL7, and NCPDP on the topic of Claims Attachments for more than a year. WEDI is a key participant on a claims attachment pilot funded by CMS. It is through that work that WEDI has been exposed to the efforts to date. WEDI will also be holding a Policy Advisory Group later this month to develop WEDI comments on the Claims Attachments NPRM that will eventually be passed on to HHS.

However, the complex nature of combining clinical standards with administrative standards will have a profound impact on all healthcare stakeholders and will need careful review. It is the view of the WEDI Board of Directors that such complexity will require an additional 30 days for comment to allow for a meaningful review and response by all affected healthcare stakeholders. If you need more information, WEDI representatives would be more than happy to meet with you at your convenience. You may contact WEDI's Executive Vice President and CEO Jim Schuping at (703) 391-2716.

Respectfully Submitted,

Mark R. McLaughlin
Chair, WEDI Board of Directors

Enclosure
cc: Dr. Mark McClellan, Administrator, Centers for Medicare and Medicaid Services,
Dr. Simon Cohn, Chair, National Committee on Vital and Health Statistics

12020 Sunrise Valley Drive, Suite 100, Reston, VA 20191

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OCT 26 2005

NMEH

National Medicaid
EDI Healthcare
Workgroup

October 7, 2005

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

Dear Sir or Madam:

The National Medicaid EDI HIPAA (NMEH) workgroup requests the 60 day public comment period for CMS-050-P be extended from 60 days to 120 days adding an additional 60 days. This is to ensure a thorough review of the numerous technical standards documents and NPRM policy statements can be made to assess the impact to our systems and processes. This rule will play a significant role in our claims adjudication process and ensuring that the data content of the attachments adequately meets our needs will require a Centers for Medicare & Medicaid Services
clinical review of our individual state policy requirements. 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 informative feedback the department is seeking.

Sincerely,

Robert C. Pozniak, Chair
National Medicaid EDI Healthcare Workgroup

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OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
HEALTH AFFAIRS
SKYLINE FIVE, SUITE 810, 5111 LEESBURG PIKE
FALLS CHURCH, VIRGINIA 22041-3206

TRICARE
MANAGEMENT
ACTIVITY

OCT 18 2005

To: Centers for Medicare & Medicaid Services, Department of Health and Human Services

From: TRICARE Management Activity Privacy Office, Department of Defense (Health Affairs)

Re: Comments of CMS-0050-P, HIPAA Administrative Simplification: Standards for Electronic Health Care Claims Attachments, Proposed Rule

CMS-0050-P, §II.D.2., "Solicited vs. Unsolicited Attachments"

We agree with the proposal for health care providers to submit an unsolicited electronic attachment with a claim only when a health plan has given them specific advance instructions pertaining to that type of claim or service. As long as both the health plan and the provider ensure that the data request on file is the minimum necessary amount of data needed for adjudicating that type of claim or service, this standard procedure meets the intent and requirements of the minimum necessary implementation specifications in §(s) 164.514(d)(3) and 164.514(d)(4) of the Department of Health and Human Services final Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule.

However, we are concerned that the proposal for health plans to solicit only one electronic attachment request and for providers to submit only one response will lead to violations of the minimum necessary requirements. Some health plans, either intentionally or otherwise may not request all of the information needed the first time. Because only one request and response is permitted, those claims may be denied due to the lack of sufficient information. The appeals process can be a time consuming experience that may be costly both financially and emotionally for providers and their affected patients. Conversely, in an effort to ensure that a claim will not be denied for a lack of needed information, some providers may include more information than is needed to adjudicate the claim thus violating the minimum necessary requirements of the HIPAA Privacy Rule and the privacy rights of the patient.

Thank you for the opportunity to comment.

Samuel P. Jenkins
TMA Privacy Officer

Administrative
Uniformity
Committee

October 27, 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

Dear Sir/Madame:

On behalf of the members of the Administrative Uniformity Committee and the Minnesota HIPAA Collaborative, I would like to formally request an extension of sixty (60) days to the current November 22, 2005 deadline for submission of comments on the above-referenced Notice of Proposed Rule Making (NPRM) for the establishment of national standards for electronic claim attachments. We request that the new deadline be January 22, 2006.

We are very supportive of the adoption of national standards for the submission of electronic claim attachments. But we believe that the newness of the topic, the level of complexity of the subject matter of the proposed standards, and the number, size and complexity of the reference documents that constitute the proposed standards makes it extremely challenging for the industry to conduct a review and to submit comments in the original 60-day comment period provided.

In particular, we fully concur with your assessment that the proposed AIS documents were drafted several years ago under different business practices related to claim attachments, and that it is imperative now to engage health plans and health care providers in a process to carefully evaluate the maximum data set that constitute these standards and the questions and cardinality of the elements for each AIS. We believe this thorough review will not be able to be achieved within the original 60-day period, even in states like Minnesota that for years have actively engaged payers and providers in the review and comment of all HIPAA-related proposed regulations. We are currently engaged in such a collaborative review and comment effort for this NPRM.

Should you have any questions regarding this request please contact Kristin Loncorich from the Minnesota Department of Health at (651) 282-6343 or via email at: Kristin.Loncorich@state.mn.us.

Sincerely,

Stacey Alsdurf

Stacey Alsdurf
Chair, Administrative Uniformity Committee
Minnesota Department of Human Services

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Docket Management Comment Form

Docket: CMS-0050-P - Standards for Electronic Health Care Claim Attachments

Temporary Comment Number: 42623

Submitter: Matt Klischer **Date:** 11/01/05

Organization: CMS

Category: Federal Government

Issue Areas/Comments

General

see attachment

Attachments

CMS-0050-P-T42623-Attach-1.doc

Print | Comment on Another Docket | Exit

Print - Print the comment
Exit - Leave the application

Comments on the Claims Attachment NPRM from CMS

Comment Number	Page Number	Section	Comment	Response
1	55990	(Dates)	To ensure complete analysis of the NPRM to the Medicare contractor processing environment, we request extending the comment period an additional 60 days.	

//

Cerner Corporation
2800 RockCreek Parkway
MD W0831
Kansas City, MO 64117-2551

NOV 15 2005

November 3, 2005

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

Dear Sir or Madam,

Cerner Corporation, a leading supplier of clinical and management information systems with more than 1,000 application installations at healthcare organizations worldwide, appreciates the opportunity to submit comments for the *HIPAA Administrative Simplification Standards for Electronic Health Care Claims Attachments* proposed rule CMS-0050-P dated September 23, 2005.

I would first like to provide some detail about our company in order to help you understand how the proposed regulation affects Cerner Corporation. Cerner Corporation designs, develops, markets, installs and supports patient-focused clinical and patient financial information systems and services. We are a business associate to many hospitals and health care organizations in the U.S. As such, our systems provide for automation of the clinical processes that support patient care as well as the revenue cycle processes that support patient billing. We also provide the electronic medical record infrastructure for many of our clients. We foresee our information systems solutions assisting provider organizations in managing requests made from payers for claims attachments, fulfilling the request in terms of the supply of clinical information necessary to respond, and for those providers who desire to implement it with payer agreement for acceptance of such transactions, submitting "unsolicited" claims attachments to payers at the same time health care claims are submitted.

Cerner Corporation expresses our strong support for the intent of the proposed rule to reduce the administrative costs of the request and reply for claims attachments, and for the potential for the paperless claims adjudication process the proposed rule envisions. This bears the promise of great benefit for both the provider and the payer to reduce the personnel costs and processing costs involved in the manual and phone based process in use today for these types of requests.

In support of the proposed rule, Cerner wishes to make the following comments on particular aspects of it:

1. The use of LOINC as the basis for standardizing clinical data references between systems

Cerner fully supports the use of LOINC as a standardized medical codification system for sending and receiving systems to understand clinical data references. The sender of the request for the claims

attachment can use it to clearly articulate the desired clinical data, and the responder can use it to determine if the desired information is within its possession. Further, as the early state of effort of implementation may depend on the provider to draw information not only from one source but many across its paper and electronic based systems, LOINC also should provide the means for the system receiving the request from the payer to be able to turn around and make requests of other systems to obtain clinical information that may be held in any given system. It may also be possible to create workflow around the fulfillment process to respond to requests for claims attachments so providers can manage such requests when information is not immediately available in electronic form (such as may be required when scanning of paper based records may be necessary).

2. The design of the 277/275 transaction exchange, and the use of XML and HL7's Clinical Document Architecture (CDA)

Cerner also supports the use of the proposed 277 and 275 transactions for the request and reply, and of the use of XML and HL7's CDA v.1.0 as the basis for the exchange of claims attachments. The flexibility afforded by the use of these standards for providers to respond in the manner that their then current state information systems and paper based medical records may allow should prove invaluable in inviting adoption. At the same time, Cerner advocates providers and payers take steps towards full automation of the request and reply in order to realize completely the benefits of implementation, and not to remain in an intermediate state that requires human intervention to both reply to a request as well as to adjudicate a claim subject to a claims attachment. This would serve to sub-optimize the cost savings and workflow benefits that could be supported. So in the efforts to see the proposed rule implemented when final, Cerner encourages the Secretary to promote the use of these transactions vigorously in this regard, and to take a leading role in promoting best practice types of exchanges for adoption in the appropriate forums. The promise of cost savings in general for HIPAA standard transactions remains to be realized for many other transactions, and we encourage a more activist approach to encourage adoption by the Secretary particularly relative to federal health insurance programs and their own compliance efforts as a leader by example (and those of their contractors and intermediaries).

3. The use of the HL7 CDA and AIS Specification as an Implementation Specification

Cerner strongly supports the use of the HL7 CDA and AIS specification as the basis for an implementation specification for a provider to respond with the clinical information necessary to fulfill a claims attachment request. Cerner urges the Secretary to strongly defend this position provided that it truly means that payers will not be permitted the latitude to implement companion guide documents that add additional requirements or that serves to change the meaning of the AIS specification documents. It is our opinion that both providers and payers are given significant latitude to request for and reply with the clinical data desired in order to adjudicate the claim without additional requirements for this basis of standard. It is our opinion that the adoption rates for standard transactions have been significantly slowed by the existence of companion guides relative to other transaction standards. They have served to exacerbate implementation costs for providers, and have served to place additional compliance burdens on providers that beyond what an otherwise compliant adoption of other standard transactions would require. If the HL7 specification documents are to truly serve as standards in the manner that they are, they should be the basis for adoption without adulteration.

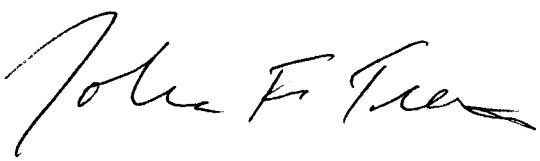
4. The requirement for a singular request and a singular reply

Cerner also greatly advocates the requirement that a payer may make one and only one request for additional information per claim, and that a provider should reply with all that they possess in one and only one response. This will serve to limit the cycles of adjudication that many providers see as an excessive delay tactic employed by payers to slow down the payment cycle. Providers should make efforts to fully comply with the response they give to requests with an emphasis on providing discrete actionable responses to payers where possible so that adjudication costs and cycle time can be minimized. It is in both the payer and provider interest to see that the cycle time goes down, and that steps be taken towards auto adjudication where possible. The administrative costs of both parties are

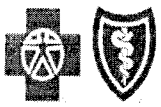
reduced, accuracy of request and reply is improved, and the need for human decision making (and potential for error) can be reduced.

As an overall benefit, the experience that the industry promises to gain through implementation of the claims attachment transactions will serve to help pave the way for other manners of clinical data exchange that is standards based. It will provide an insight into the ability of the industry to adopt other standards based exchanges of clinical information that will be vital to the adoption of community based electronic health records, and it will serve to raise the bar some for vendors of clinical information systems to realize the importance of interoperability around common medical code set vocabularies for such information exchanges. The industry cannot solve interoperability problems through clearinghouse strategies for the long term, and clinical information systems vendors have to enable point to point information exchanges between not only providers and payers but also between providers and with community or regional clinical information databases to truly enable e-health in support of national and regional initiatives for an effective health information infrastructure.

Sincerely,



John Travis
Solution Management Director and Compliance Strategist
Cerner Corporation



Arkansas
BlueCross BlueShield
An Independent Licensee of the Blue Cross and Blue Shield Association

Attention: **CMS-0050-P**

Comments from Arkansas Blue Cross Blue Shield on 45 C.F.R. Part 162 (HIPAA Administrative Simplification: Standards for Electronic Health Care Claims Attachments)

Proposed Rule issued Federal Register / Vol. 70, No. 184 / Friday, September 23, 2005 p. 55990

Submitted via electronic mail: November 18, 2005

Arkansas Blue Cross Blue Shield (ABCBS) appreciates the opportunity to respond to the HHS Office of the Secretary request for comments regarding the HIPAA Electronic Health Care Claim Attachment proposed rule. ABCBS is a mutual insurance company serving over 900,000 individuals in Arkansas and across the nation. We agree that the adoption of electronic standards for health care claim attachments has the potential for streamlining processes, which may eventually lead to an overall reduction in operating costs in Arkansas provided adoption by covered entities reaches certain levels.

Section II.D.2 --- Solicited vs. Unsolicited Attachments (pg. 55999)

Proposed Rule: 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.

Issue: There are common situations within the health care industry where the provider's response to a request from a health plan for additional information leads to more questions. In other situations, a provider's response leads to a need for information from another provider. As stated in the proposed rule, it is also possible for a provider to invoke a HIPAA Privacy "minimum necessary" judgement that is in fact less information than the health plan requires.

ABCBS feels strongly that in practice, limiting requests to one transaction will force health plans to 1) routinely ask for the entire patient medical record to ensure enough information will be received to adjudicate the claim, or 2) deny the claim citing a need for additional information, or 3) request additional information through a manual process. All of these options would unnecessarily increase administrative workload when an efficient electronic mechanism would be in place to address the need for additional information.

Please note that all Blue Cross and Blue Shield licensees are business associates of one another. In coordination of benefits processing, it could appear to a provider that they have received multiple requests for claim information from the same health plan, but in fact, the subsequent request was from another Blue plan with slightly different claim information requirements. In this case, the subsequent request for additional information is actually being made by a business associate of the second plan.

ABCBS Recommendation: The final rule should require the initial request from a health plan be a complete request to the best of the plan's knowledge at the time of the request. If it should be discovered at a later time that additional information is required to correctly adjudicate the claim, additional requests for information and additional responses would be permitted electronically.

Section II.D.3 – Coordination of Benefits (pg. 55999)

Proposed Rule: Assumption that primary health plan will request only the attachments it needs to adjudicate its portion of the claim.

Issue: There could be significant issues relating to the HIPAA Privacy "minimum necessary" requirements if health plans were required to pass claim attachment information to plans paying in a secondary position. However, health plans should be permitted to exchange attachment information provided that HIPAA Privacy requirements are met.

ABCBS Recommendation: The final rule should state that health plans are not required to pass claim attachment information to other plans paying in a secondary or tertiary position. Health plans should be permitted to share claim attachment information provided that HIPAA Privacy requirements are met and a business relationship has been established.

Section II.D.4 – Impact of Privacy Rule (pg. 56000)

Proposed Rule: The covered health care provider always retains the discretion to make its own minimum necessary determination.

Issue: The original HIPAA Transaction and Code Set rule states that "minimum necessary" requirements do not apply to covered HIPAA transactions. This provision was established so that computer systems could be designed to transmit all of the "required" data and help ensure efficient processing on the receiver's system. A similar approach will be needed in the claim attachment rule if efficiencies are to be realized.

Perhaps there are instances today when a health plan requests excessive information by unnecessarily requesting entire medical records. The HIPAA Enforcement Rule complaint process should be utilized in those cases to resolve the suggested abuse. With the proposed requirement to use LOINC codes for claim attachment requests, there may be times when the amount of information requested comes into question. However, to achieve the desired efficiencies, providers will need to rely on the health plans to an additional degree for determining if the appropriate amount of information was requested.

Ease of implementation will be key to provider adoption of this rule. Providers should not be required to "black out" certain data items on claim attachments that were not specifically requested. As required today, the health plan receiving the request would be required under the HIPAA Privacy rule to protect all PHI in its possession.

ABCBS recommendation: The final rule should state that health plans are required to use the most specific LOINC codes available to request the "minimum necessary" amount of information needed for adjudication of a claim. As systems become increasingly capable of responding to electronic requests, providers should be encouraged to reply automatically to the request. If a provider perceives a pattern of abuse by a health plan that routinely requests too much information, they should follow the HIPAA Enforcement provisions to resolve the potential violation.

Section II.H – Covered Health Care Providers (pg. 56012)

Proposed Rule: If they [providers] choose to receive and send requests and responses electronically for any of the six proposed attachments.

Issue: The proposed rule could be interpreted to mean that a provider may choose to implement one or more of the 6 proposed claim attachments, but not all. If this is the case, health plans must not only keep up with whether a provider participates in the electronic claim process, but also for which claim attachments they are capable of responding. This will lead to additional administrative overhead and potential for errors.

ABCBS recommendation: The final rule should state that providers participating in the electronic claim attachment process must accept all requests for health care claim attachments electronically. Providers participating in the electronic claim attachment process should respond electronically to any of the claim attachment types named in the final rule.

Section II.H – Covered Health Care Providers (pg. 56012)

Proposed Rule: In either case, covered health care providers would continue to have the option of using electronic or manual means of conducting business, including responding to a request for attachment information electronically or on paper.

Issue: To realize the expected efficiencies of the health care claim attachment rule, the complete model designed by WEDI must be followed. Permitting a provider to elect electronic claim attachment requests but also permitting responses via paper will lead to numerous implementation issues. For instance, a health plan may show that an electronic request has been sent, but an electronic reply has never been received. Conversely, allowing a provider to respond to a manual request electronically may also result in the manual process not detecting that a response has been received.

Providers should not be permitted to partially participate in the electronic claim attachment process based on the media type for which the original health care claim submitted. Permitting this option would lead to additional administrative overhead and increase processing errors.

ABCBS Recommendation: For the named claim attachment types, covered health care providers participating in the electronic claim attachment process must accept requests electronically and respond electronically. This requirement should exist regardless of how the original claim was submitted, either on paper or electronically. For claim attachment types not named in the final rule, trading partners are permitted to define business rules for conducting those transactions.

Section VI.B.1 – General Assumptions, Limitations, and Scope (pg. 56017)

Proposed Rule: 50 percent of all claims attachments are likely to be represented by the six attachment types named here.

Issue: ABCBS feels that the six named claim attachment types will accommodate over 80 percent of the requests currently needed for our business rules. This is a good first step in the implementation process. Trading partners should be free to implement other attachment types once the core system changes have been installed and tested.

ABCBS Recommendation: Mandated adoption of new claim attachments and version changes should always go through the formal rule making process. Successful implementation of HIPAA transactions relies on the health care industry having an opportunity to comment on potential business issues and industry impacts which are not thoroughly addressed within the DSMO

process. The industry also needs clear compliance dates for these changes so that implementation is as smooth as possible during transition periods to new format versions.

162.1910 – Request Transaction (pg. 56024)

Proposed Rule: A health plan may make such a request (1) upon receipt of a health care claim (2) in advance of submission of a health care claim (3) through instructions for a specific type of health care claim which permit a health care provider to submit attachment information on an unsolicited basis each time such type of claim is submitted.

Issue: Permitting the submission of a claim attachment in advance of submission of a claim (#2) would be problematic for health plans since the claim attachment would be in reference to a claim that is unknown to the plan. This option seems to be contrary to the model defined by WEDI and was not included in the claim attachment pilot sponsored by CMS.

ABCBS agrees with the proposed rules regarding unsolicited claim attachments (#3) and strongly feels that unsolicited claim attachment submissions without clear instructions from the health plan will lead to unnecessary administrative overhead. In our organization, there is a very small number of business cases where additional information is "always" needed for a certain type of claim. Providers may have a sense for this requirement, but should wait for clarification from a health plan prior to submission of unsolicited claim attachments. Unsolicited claim attachments will most likely be a violation of the HIPAA Privacy rule "minimum necessary" provision. Health plans generally need an opportunity to perform basic claim edits prior to determining if additional information is required. For example, claims are edited to ensure that the patient has active coverage at the time of service before additional adjudication steps are performed.

ABCBS Recommendation: The final rule should state that health plans may make a request for claim attachment information (1) upon receipt of the health care claim (2) through instructions for a specific type of health care claim which permits a health care provider to submit attachment information on an unsolicited basis each time such type of claim is submitted.

162.1920 – Response Transaction (pg. 56024)

Proposed Rule: The proposed rule does not standardize acknowledge transactions.

Issue: Transactions pertaining directly to the payment of health care claims should include acknowledgment of receipt. Specifically, a health plan sending a request for claim attachments should be notified that the request was received to aid in researching issues where responses to those requests are not received. We believe the 102 acknowledgement listed in the HL7 AIS guides would not met the need of most systems currently exchanging X12 transactions.

ABCBS Recommendation: Providers participating in the claim attachment process should return a TA1 or 997 transaction, as appropriate, upon receipt of an ANSI 277 transaction. A health plan receiving an ANSI 275 transaction should return a TA1 or 997 transaction, as appropriate.

162.1925 – Response Implementation Standards (pg. 56024)

Proposed Rule: The following are permissible file types: .txt, .htm, .html, .jpg, .jpeg, .pdf, .png, .gif, .rft, .tif.

Issue: It is agreed that covered entities should be capable of exchanging these named image types. However, as technology advances, new image types are likely to be developed and may be superior in both clarity and size requirements than are the named types.

ABCBS Recommendation: The final rule should state that health plans should be required to accept, at a minimum, the image format types listed. Covered entities are permitted to exchange image types other than those listed if there is a mutual agreement to do so.

Section VI.B – Costs and Benefits

Affected Entities (pg. 56016) – Since health care providers have the option of continuing to submit paper attachment information…

ABCBS Response: This implementation model increases costs on health plans since they will need to maintain two independent processes – one for HIPAA-compliant providers and one for manual processing.

Affected Entities (pg. 56016) – Health plans will be able to automate the processing of attachment information.

ABCBS Response: This is highly unlikely since the entity sending the attachment (the provider) chooses whether to adopt the human-decision variant or the computer-decision variant. From a health plan perspective, the computer-decision variant is not cost justified without significant provider adoption of this variant and providers are unlikely to voluntarily accept this additional cost.

Cost and Benefit Analysis (pg. 56017) – The 1993 study by WEDI suggested that 25 percent of all health care claims required support by an attachment or additional documentation. […] If current attachment statistics exist, we hope the industry and/or its representatives will provide those data during the comment period.

ABCBS Response: Basing cost and benefit decisions on a study produced 10 years prior to the compliance date of the HIPAA Transaction and Code Set rule is likely to lead to a gross mis-expectation of the return-on-investment for the proposed rule. A 2005 study by our organization revealed that less than 2 percent of all health claims processed by our organization required additional information.

Cost and Benefit Analysis for Covered Health Care Providers (pg. 56018) – Covered health care providers may incur the following implementation costs: Programming systems to accommodate the new transaction types, messaging standards, and codes; Software and/or vendor fees; Practice management system vendor fees and charges; Health care clearinghouse fees.

ABCBS Response: Since the implementation date of the HIPAA Transaction and Code Set rule, observations within Arkansas have revealed that provider organizations do not typically "program" new functionality for their systems. Providers typically either purchase vendor system solutions or accept health care clearinghouse fees for translating formats. The number of direct connections with providers has been on a steady decline and providers are increasingly utilizing clearinghouse capabilities since 2002. Without significant vendor pressure to create electronic claim attachment solutions, providers will most likely continue the current manual process.

Benefits of Implementation (pg. 56020) – Next, we assume a fairly optimistic rate of adoption for the electronic health care claims attachment transactions, because, based on Medicare's experience, two years past the compliance date for the original set of transactions, 99 percent of the claims being submitted are in HIPAA compliant formats.

ABCBS Response: The assumed adoption rate will be off target by a wide margin for a few reasons. First, the vast majority of providers were already creating electronic claim transactions prior to HIPAA. The process after HIPAA generally relied on health care clearinghouses to

convert these into HIPAA-compliant formats; which tended to increase the overall cost to the health care industry as a whole. Clinical information needed for the proposed rule is not typically in electronic format today. Second, comparing the adoption of administrative transactions to the adoption of clinical transactions is not relevant. The six named attachment types will require information from systems that typically will not be currently associated with practice management systems. The integration of these disparate systems will be costly and therefore will not be voluntarily assumed by the provider community.

In summary, ABCBS certainly believes that electronic claim attachment transactions have a potential for return on investment. However, the rule, as proposed, will simply add to overall health care administrative overhead and drive up costs for all Americans. These additional costs either lead to increase in out-of-pocket expenses for the patient, or worse, cause employer groups to reduce employee benefits leaving the individual unprotected.

ABCBS Recommendation 1: The final rule should expand the definition of "business associate" to include software vendors of health care administrative and clinical systems. Software vendors that market systems that produce electronic health claim transactions should be capable of producing claims transactions as well as the other covered HIPAA transactions designed for providers in HIPAA compliant formats.

ABCBS Recommendation 2: The final rule should mandate adoption of the named electronic claim attachments by large providers. "Large" providers should be defined in the same manner as "large' health plans under HIPAA rules; which is annual revenue exceeding $5 million.

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NOV 17

North Carolina Department of Health and Human Services
2001 Mail Service Center • Raleigh, North Carolina 27699-2001
Tel 919-733-4534 • Fax 919-715-4645

Michael F. Easley, Governor

Carmen Hooker Odom, Secretary

November 9, 2005

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

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

To Whom It May Concern:

The North Carolina Department of Health and Human Resources (NC DHHS) would like to request that the public comment period for CMS-0050-P be extended from 60 days to 120 days. This 60 day extension would ensure that a thorough review of the policy statements in the Claims Attachments Notice of Proposed Rule Making (NPRM) and the numerous associated standards documents can be conducted to assess the impact to our systems and processes. Since the proposed rule will play a significant role in our claims adjudication process, a clinical and technical review within NC DHHS will be necessary to ensure that the data content of the claims attachments adequately meets our needs.

NC DHHS would also like to be able to provide substantiated feedback to some of the questions posed by HHS in the NPRM. We believe that the requested additional time will allow us to conduct this thorough review and provide the appropriate level of feedback HHS is anticipating. Thank you for your consideration in this matter.

Sincerely,

Carmen Hooker Odom

Carmen Hooker Odom

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

American Academy of Dermatology Association

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Ronald A. Henrichs, CAE
Executive Director & CEO

November 15, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS—0550—P
P.O. Box 8014
Baltimore, MD 21244–8014

RE: Proposed Rule: HIPAA Administrative Simplification: Standards for Electronic Health Care Claims Attachments – 45 CFR Parts 162 RIN 0938 – AK62

Dear CMS Representative:

On behalf of the 14,000 members of the American Academy of Dermatology Association, we appreciate this opportunity to comment on the proposed standards for the HIPAA electronic claims attachment transactions. While the Academy shares the long-term goals of standard-based, electronic data transactions, enabling electronic health care information to be sent and received more efficiently and effectively, we have some concerns regarding their practical applications and experience to date.

Before commenting on specific aspects of the proposed electronic claims attachment standards, we would like to share a number of general observations. First, as CMS moves towards implementing electronic claims attachment standards, such an effort should be informed by and unfold within the context of its larger push to promote health information technology solutions. Specifically, the contemplated transactions, messaging, and data content standards should be harmonized and reconciled with the wider effort to identify, developed, and implement interoperable standards for electronic health records, personal health records, and other emerging health information technology standards and solutions.

Second, while the Academy recognizes that these proposed provisions may ultimately facilitate easier electronic exchange of clinical and administrative data, we feel that important lessons can be learned from the previous round of the HIPAA Transaction and Code Sets (TCS) standards implementation that should be applied to this current proposed rule. Many payers and clearinghouses implemented contingency plans in 2003 causing delays in widespread adoption of the TCS standards and rules, and still continue to apply the TCS standards in a selective and arbitrary manner using their own companion guides, thereby undercutting some of the obvious electronic transaction benefits.

The first generation TCS produced an enormous variation in the interpretation of the TCS rules and guidelines by private payers, resulting in a missed opportunity to capture the benefits of streamlined and uniformed electronic transactions, compounded by a frustratingly slow and uneven adoption rate, and producing an unmanageable number of proprietary payer business rules and companion guides. Notwithstanding, the current proposed claims attachment rule should preempt any repeat of the past by limiting the scope for interpretation by payers as they implement the final electronic clinical attachment standards. Private payers should be discouraged from adding additional technical complexities and confounding business rules to these proposed transactions to minimize further hassles currently experienced in electronic data exchanges. When properly implemented, these standards can serve to educate and benefit all stakeholders involved in healthcare delivery and financing. Therefore, by linking the difficult and disappointing lessons from the previous TCS implementation experience, and harnessing the current proposed attachment standards to the future promise of automating health information technology, CMS would help physicians, especially those in small- and medium-size practice settings, deliver safe, quality-based, and cost-effective patient care. We are hopeful that the proposed claims attachment provisions, addressing the adoption of a set of standards to facilitate the electronic exchange of clinical and administrative data, will improve the claims adjudication process based on additional documentation.

ELECTRONIC CLAIMS ATTACHMENT TYPES

As dermatology practices face an increasing demand for both medical and surgical dermatologic services, we expect payers to respond by requesting additional electronic clinical information. Of the six proposed clinical electronic attachment types—ambulance services, emergency medicine, rehabilitation services, clinical report, laboratory results, and medications—only the latter three impact the specialty directly. Therefore, to help dermatologists, and other office-based medical professionals, gain perspective on and to boost confidence in the proposed electronic claims attachment process, the Academy believes that CMS should release the results of and identify the lessons learned from the claims attachment pilot testing program it authorized in July 2004. Such information can help our members better understand the practical aspects involved with this relatively complex electronic health care data transaction.

We are particularly keen on learning what the test pilot program revealed in terms of the level of effort and experience of medium- and small practices in handling requests and responses to relevant electronic claims attachments. Dermatologists' experience indicates that claims that reflect the use of modifiers (indicating a separately identifiable service was provided to a patient along with a surgical procedure and evaluation and management service on the same date, or multiple dermatologic surgeries or even surgeries followed by repairs on same date of service) are more often subject to requests for additional information for adjudication by payers. Given the constant changing business practices and claims edit rules instituted by payers, we feel that the proposed claims attachment transactions can help educate payers as to the scope of medical and surgical services provide by dermatologists to their patients presenting with skin, hair, and nail conditions.

Prospectively, we anticipate that electronic clinical reports sent as electronic attachments should accommodate digital or graphic imaging of the skin, hair, and nail that can be included in any new electronic attachment specification that will be developed and implemented in the future would be without restriction to or limitation by format, content, or size of a data file.

FORMAT OPTIONS

We concur with the Department of Health and Human Services' assessment that while small physician practices are not yet fully automated, they nonetheless wish to do so in a manner that is sustainable, given their level of resources and viable, given technological limitations. We applaud the Department's efforts to make sure that the adoption and implementation of the claims attachment transactions standards be flexible and scalable enough to conform to the fiscal, technical, and administrative realities of small-size practices. To the extent that the health care claims attachment allows for the transmittal of data in either the two proposed human decision variants (transmission of scanned page image and/or a typed, narrative text response) or a computer decision variant (based on structured and coded data), we are confident that such flexible options will ensure that the transactions evolve in a user-friendly fashion, thereby encouraging faster compliance.

COMBINED USE OF DIFFERENT STANDARDS

We appreciate the latitude afforded to medical professionals and their practice staff on how to submit the requested information—in either narrative text, scanned documents, or with fully formatted and coded data. We believe that such a margin of flexibility will further incentivize our members to recognize the benefits of integrating their clinical records with their practice management billing software, as they move toward adoption of electronic health records, making auto-adjudication a more achievable goal the in process. We believe instances of post-adjudication should be covered in the scope of this proposed rule. It would address any potential disputes arising between contracted health care professionals and plans to reduce any confusion, especially in light of health plans' business policies governing claims edit rules that often ignore standard AMA-CPT coding conventions and eliminate the misrepresentation of the level of services provided to the patient. Extending the claims attachment standard to episodes of post-adjudication claims appeal process, would provide for fair and prompt reimbursement for services and further enhance the benefits of the proposed standards.

SOLICITED vs. UNSOLICITED ATTACHMENTS

The prospects of having to submit attachments concomitantly with each claim filed would impose an unfair and significant burden on medical practices, undermining their confidence in any economies to be achieved by electronic data exchange. Therefore we agree with the Department's proposal to restrict such unsolicited electronic attachments (with original claims) to instances wherein the payer gives specific advance notice and instructions related to a particular type of claim or service. We also welcome and support the Department's efforts to restrict payers to only one electronic attachment request transaction, which would include explicitly all their required/desired questions and or documentation relevant only to the specific claim in question. We believe this can effectively forestall the likelihood of payers extending claim adjudication by a lengthy process of multiple individual attachment requests for the same claim. We applaud the Department's recognition of the risk of creating never-ending loops of query that threaten to undermine the benefits of the administrative simplification process.

ATTACHMENT CONTENT AND STRUCTURE

The proposed transactions associated with the claims attachment—request for documentation and, in turn, a response attachment—capture what we believe are specific elements and data fields that serve to identify unambiguously a patient, their date of service and any other pertinent information required for a specific individual and claim. Finally, while the proposed rule does not disallow payers from continuing to request additional documentation by manual manner (i.e., paper form request, letters, faxes), we applaud the Department's effort to remind payers of their duty to obey the claims attachment standards fully when making an electronic request for information, and requiring the payer to comply with the standards when asked by a medical professional to do so.

The Academy is confident that the proposed health care electronic claim attachment provisions will help reduce miscommunication, avoid instances of multiple requests for information and provide for particular limits to the content of the attachment. We believe that the HIPAA administrative simplification provision can contribute towards the goal of developing a national electronic health information infrastructure that can deliver on the promise of significantly improving the quality of care and providing cost savings and workflow efficiency gains.

We appreciate the opportunity to provide comment regarding these important HIPAA provisions. Thank you for reviewing these comments. If you have any questions regarding our recommendations, please contact Jayna Bonfini at jbonfini@aad.org at 202-712-2614, or William Brady at wbrady@aad.org or 847-240-1824.

Sincerely,

Brett Coldiron, MD, FACP
Chair/AADA Health Care Finance Committee

Robert Kirsner, MD, PhD
Chair/AADA Practice Management Task Force

Cc: Clay J. Cockerell, MD, President, AADA
Stephen P. Stone, MD, President-Elect, AADA
David M. Pariser, MD, Secretary-Treasurer, AADA
Ronald A. Henrichs, CAE, Executive Director and CEO, AADA
John D. Barnes, Deputy Executive Director, AADA
Judith Magel, Director, Health Policy and Practice, AADA
Laura Saul Edwards, Director, Federal Affairs, AADA
Cyndi Del Boccio, Director, Executive Office, AADA
Jayna Bonfini, Assistant Director, Federal Affairs, AADA
Norma Border, Senior Manager, Coding and Reimbursement, AADA
Sandra Peters, Senior Manager, Workforce, Insurance and Practice Issues, AADA
William Brady, Manager, Practice Management, AADA

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

14 November 2005

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

via: Priority Mail

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

Enclosed are one original and two copies of my written comments on the proposed rule for HIPAA Administrative Simplification Standards for Electronic Health Care Claims Attachments. Note that my 67 pages of comments are printed on both sides of each sheet of paper, *i.e.*, duplexed, to reduce materiel costs.

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, C.D.P.
President, Rensis Corporation

Comment Number: Rensis-1.01

Regarding: FORMAT OPTIONS
(Human vs. Computer Variants)

Human Decision Variants are not permitted.

A. A health plan will be in violation of the law when using Human Decision Variants; thus making them unusable by providers or clearinghouses as well.
{PL 104-191 §1175 (a) (1) (C)}

B. The legislation does not permit adopting implementation specifications that contain non-discrete data element provisions unique to Health Claims Attachments.
{PL 104-191 §1173 (a) (2)}

C. Human Decision Variants are in conflict with definitions of Data Condition, Data Content, and Data Element already promulgated in other, final, portions of Part 162.
{45 CFR 162.103}

D. Human Decision Variants have been repeatedly prohibited for use in other adopted transactions. As but one example, see any of the many presentations by government spokespersons over the past five or so years regarding the non-compliance of computer-to-computer facsimiles; which use TIF format.

Comment Number: Rensis-1.03

Regarding: FORMAT OPTIONS
(Human vs. Computer Variants)

The absence of any policy regarding who controls when and whether to use Human Decision Variants versus Computer Decision Variant is in conflict with already promulgated other, final, portions of Part 162 for all other HIPAA transactions which unambiguously state precisely which Format must be followed.
{45 CFR 162.103}
{45 CFR 162.923 (a)-(b)}

Comment Number: Rensis-1.04

Regarding: FORMAT OPTIONS
(Human vs. Computer Variants)

The absence of any policy regarding who controls when and whether to use Human Decision Variants versus Computer Decision Variant is contrary to years of work by non-HL7 Standards Setting Organizations – fully supported by federal government representatives – to remove all unspecified variations in transmitted transactions formats and contents. {*e.g.*, Accredited Standards Committee X12 Implementation Guide (IG) Handbooks}

Comment Number: Rensis-2.01

Regarding: PROPOSED STANDARDS

There is no Medical Data Code Set for Drugs and Biologics for the environments in which the proposed rule would apply; *i.e.*, professional claims, institutional claims, and dental claims.
{45 CFR 162.1002 (b) (2)}
{68 FR 34, 2/20/2003, pages 8385-8387}
Therefore the Computer Decision Variant for Medications Attachments is not usable until a national standard for drugs and biologics is adopted.
{CDAR1AIS0006R021}

Comment Number: Rensis-2.02

Regarding: PROPOSED STANDARDS

The Human Decision Variant for Medications Attachments is not permitted.

A. A health plan will be in violation of the law when using Human Decision Variants; thus making them unusable by providers or clearinghouses as well.
{PL 104-191 §1175 (a) (1) (C)}

B. The legislation does not permit adopting implementation specifications that contain non-discrete data element provisions unique to Health Claims Attachments.
{PL 104-191 §1173 (a) (2)}

C. Human Decision Variants are in conflict with definitions of Data Condition, Data Content, and Data Element already promulgated in other, final, portions of Part 162.
{45 CFR 162.103}

D. Human Decision Variants have been repeatedly prohibited for use in other adopted transactions. As but one example, see any of the many presentations by government spokespersons over the past five or so years regarding the non-compliance of computer-to-computer facsimiles; which use TIF format.

Comment Number: Rensis-2.03

Regarding: PROPOSED STANDARDS

Since neither the Computer Decision Variant nor Human Decision Variants for the Medications Attachments are possible, this AIS is not implementable, and, therefore, should not be included in any final rule for Health Claims Attachments.
{Comment Number Rensis-2.01}
{Comment Number Rensis-2.02}
{CDAR1AIS0006R021}

Comment Number: Rensis-2.04

Regarding: PROPOSED STANDARDS

The proposed X12 version for solicited attachments transactions is 004050. The mandated X12 version of applicable claims transactions is 004010. The requirement to use, and thus implement, two different versions of X12 transactions adds cost, and can be particularly onerous when the a claim using version 004010 is accompanied by an unsolicited attachment using version 004050. Consequently, a single X12 version for all applicable adopted transactions – particularly, but not limited to, claims and claims attachments – is strongly recommended; perhaps version 005010.

Comment Number: Rensis-2.05

Regarding: PROPOSED STANDARDS

In the Electronic Health Care Claims Attachment Response Transaction section, the sentence

"Other LOINC codes used in the body of the message will specify the specific information related to that service that is desired ... ."

is in direct conflict with proposed §162.1920(d) that 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 request.".

Given that Human Decision Variants are not permitted by the HIPAA legislation for use by health plans {PL 104-191 §1175 (a) (1) (C)}, recommend modifying the proposed §162.1920(d) to remove this conflict by requiring discrete standard data elements within the body of all attachments.

Comment Number: Rensis-2.06

Regarding: PROPOSED STANDARDS

The LOINC Modifier Codes booklet is missing from the list of those referenced in the section covering the Electronic Health Care Claims Attachment Request Transaction.

Comment Number: Rensis-3.01

Regarding: SUMMARY

This summary is incomplete.

A. The summary does not mention Human Decision Variants – which are not EDI as commonly defined and understood in the industry.

B. The summary does not explain how the intent of Administrative Simplification to enhance solely computer-to-computer – without human intervention – communications between health plans and other entities is achieved using Human Decision Variants.

C. The summary does not mention the various scanned image standards which are incorporated into the NPRM by the incorporation of the HL7 CDAR1AIS0000R021 Additional Information Specification Implementation Guide, Release 2.1, May 2004, §3.5.1 and §3.5.3.

D. The summary does not mention that, according to HL7 CDAR1AIS0000R021 Additional Information Specification Implementation Guide, Release 2.1, May 2004, §3.5.3, additional Human Decision Variant file types 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.

E. The summary does not mention that, according to HL7 CDAR1AIS0000R021 Additional Information Specification Implementation Guide, Release 2.1, May 2004, §3.5.3, additional implementation specifications (*e.g.*, DICOM with its many optional mix-and-max Supplements) 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.

Comment Number: Rensis-3.02

Regarding: LEGISLATION

This section is incomplete.

A. This section does not mention the standards incorporated into the NPRM by the incorporation of the HL7 CDAR1AIS0000R021 Additional Information Specification Implementation Guide, Release 2.1, May 2004, §3.5.1 and §3.5.3, that are established by non-ANSI organizations.

B. The section does not mention that, according to HL7 CDAR1AIS0000R021 Additional Information Specification Implementation Guide, Release 2.1, May 2004, §3.5.3, additional Human Decision Variant file type standards 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.

C. The summary does not mention that, according to HL7 CDAR1AIS0000R021 Additional Information Specification Implementation Guide, Release 2.1, May 2004, §3.5.3, additional implementation specifications (*e.g.*, DICOM with its many optional mix-and-max Supplements) 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.

Comment Number: Rensis-3.03

Regarding: STANDARDS SETTING ORGANIZATIONS

This section is incomplete.

A. This section does not mention or describe the applicability, appropriateness, or suitability of any of the organizations that established standards incorporated into the NPRM by the incorporation of the HL7 CDAR1AIS0000R021 Additional Information Specification Implementation Guide, Release 2.1, May 2004, §3.5.1 and §3.5.3.

B. The section does not discuss that, according to HL7 CDAR1AIS0000R021 Additional Information Specification Implementation Guide, Release 2.1, May 2004, §3.5.3, additional Human Decision Variant file types 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.

C. The summary does not mention that, according to HL7 CDAR1AIS0000R021 Additional Information Specification Implementation Guide, Release 2.1, May 2004, §3.5.3, additional implementation specifications (*e.g.*, DICOM with its many optional mix-and-max Supplements) 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.

Comment Number: Rensis-3.04

Regarding: INDUSTRY STANDARDS, IMPLEMENTATION GUIDES, AND ADDITIONAL INFORMATION SPECIFICATIONS

This section is incomplete.

A. This section does not mention any of the specifications that are incorporated into the NPRM by the incorporation of the HL7 CDAR1AIS0000R021 Additional Information Specification Implementation Guide, Release 2.1, May 2004, §3.5.1 and §3.5.3.

B. This section does not mention how to obtain any of the specifications that are incorporated into the NPRM by the incorporation of the HL7 CDAR1AIS0000R021 Additional Information Specification Implementation Guide, Release 2.1, May 2004, §3.5.1 and §3.5.3.

C. Neither this section nor the HL7 CDAR1AIS0000R021 Additional Information Specification Implementation Guide, Release 2.1, May 2004, §3.5.1 and §3.5.3 specify which versions of the specifications that are incorporated into the NPRM by the incorporation of the HL7 CDAR1AIS0000R021 Additional Information Specification Implementation Guide, Release 2.1, May 2004, §3.5.1 and §3.5.3 are to be used.

D. The section does not discuss that, according to HL7 CDAR1AIS0000R021 Additional Information Specification Implementation Guide, Release 2.1, May 2004, §3.5.3, additional Human Decision Variant file types 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.

E. The summary does not mention that, according to HL7 CDAR1AIS0000R021 Additional Information Specification Implementation Guide, Release 2.1, May 2004, §3.5.3, additional implementation specifications (*e.g.*, DICOM with its many optional mix-and-max Supplements) 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.

Comment Number: Rensis-3.05

Regarding: DEFINITIONS

This section is incomplete.

A. This section does not define any of the terms or formats incorporated into the NPRM by the incorporation of the HL7 CDAR1AIS0000R021 Additional Information Specification Implementation Guide, Release 2.1, May 2004, §3.5.1 and §3.5.3.

B. The section does not discuss that, according to HL7 CDAR1AIS0000R021 Additional Information Specification Implementation Guide, Release 2.1, May 2004, §3.5.3, additional Human Decision Variant file types 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.

C. The summary does not mention that, according to HL7 CDAR1AIS0000R021 Additional Information Specification Implementation Guide, Release 2.1, May 2004, §3.5.3, additional implementation specifications (*e.g.*, DICOM with its many optional mix-and-max Supplements) 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.

Comment Number: Rensis-3.06

Regarding: COST AND BENEFIT ANALYSIS FOR HEALTH PLANS

This section is incomplete.

A. This section does not cover any of the standards incorporated into the NPRM by the incorporation of the HL7 CDAR1AIS0000R021 Additional Information Specification Implementation Guide, Release 2.1, May 2004, §3.5.1 and §3.5.3.

B. The section does not discuss that, according to HL7 CDAR1AIS0000R021 Additional Information Specification Implementation Guide, Release 2.1, May 2004, §3.5.3, additional Human Decision Variant file types 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.

C. The summary does not mention that, according to HL7 CDAR1AIS0000R021 Additional Information Specification Implementation Guide, Release 2.1, May 2004, §3.5.3, additional implementation specifications (*e.g.*, DICOM with its many optional mix-and-max Supplements) 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.

Comment Number: Rensis-3.07

Regarding: COST AND BENEFIT ANALYSIS FOR COVERED HEALTH CARE PROVIDERS

This section is incomplete.

A. This section does not cover any of the standards incorporated into the NPRM by the incorporation of the HL7 CDAR1AIS0000R021 Additional Information Specification Implementation Guide, Release 2.1, May 2004, §3.5.1 and §3.5.3.

B. The costs of acquiring, installing, and updating software to create Human Decision Variant scanned images 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.

C. The costs of acquiring and installing hardware (*e.g.*, scanners, additional memory, cables, *etc.*) to create Human Decision Variant scanned images are not listed. This is a particular concern for smaller providers.

D. The section does not discuss that, according to HL7 CDAR1AIS0000R021 Additional Information Specification Implementation Guide, Release 2.1, May 2004, §3.5.3, additional Human Decision Variant file types 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.

E. The summary does not mention that, according to HL7 CDAR1AIS0000R021 Additional Information Specification Implementation Guide, Release 2.1, May 2004, §3.5.3, additional implementation specifications (*e.g.*, DICOM with its many optional mix-and-max Supplements) 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.

Comment Number: Rensis-3.08

Regarding: COST AND BENEFIT ANALYSIS FOR COVERED HEALTH CARE PROVIDERS

It is questionable how savings can accrue for the use of standardized, predictable attachments and formats when there is no NPRM policy stating how providers and health plans determine which variant and which options and unbounded non-XML formats within Human Decision Variants will be used and processed. At the present time, in the absence of any such clear NPRM policy, the effect – particularly for providers – will be the same as the current situation of numerous proprietary forms associated with individual health plan requirements. In other words, if trading partner agreements are required to determine what format to use, providers – as they have historically – will have to comply with whatever the health plans dictate in order to be paid.

As but one example, what would it cost a provider to comply with a health plan dictated requirement to send audio (*e.g.*, .wav) attachments when presented with such a requirement as a component of an overall trading partner agreement? This is presently permitted by this NPRM and the HL7 CDAR1AIS0000R021 Additional Information Specification Implementation Guide, Release 2.1, May 2004, §3.5.3.

Comment Number: Rensis-3.09

Regarding: COST AND BENEFIT ESTIMATES

This section is incomplete.

A. This section does not cover any of the standards incorporated into the NPRM by the incorporation of the HL7 CDAR1AIS0000R021 Additional Information Specification Implementation Guide, Release 2.1, May 2004, §3.5.1 and §3.5.3.

B. The section does not discuss that, according to HL7 CDAR1AIS0000R021 Additional Information Specification Implementation Guide, Release 2.1, May 2004, §3.5.3, additional Human Decision Variant file types 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.

C. The summary does not mention that, according to HL7 CDAR1AIS0000R021 Additional Information Specification Implementation Guide, Release 2.1, May 2004, §3.5.3, additional implementation specifications (*e.g.*, DICOM with its many optional mix-and-max Supplements) 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.

Comment Number: Rensis-3.10

Regarding: PROPOSED §162.920 AVAILABILITY OF IMPLEMENTATION SPECIFICATIONS AND GUIDES

This section is incomplete.

A. This section does not cover any of the standards incorporated into the NPRM by the incorporation of the HL7 CDAR1AIS0000R021 Additional Information Specification Implementation Guide, Release 2.1, May 2004, §3.5.1 and §3.5.3.

B. The section does not discuss that, according to HL7 CDAR1AIS0000R021 Additional Information Specification Implementation Guide, Release 2.1, May 2004, §3.5.3, additional Human Decision Variant file types 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.

C. The summary does not mention that, according to HL7 CDAR1AIS0000R021 Additional Information Specification Implementation Guide, Release 2.1, May 2004, §3.5.3, additional implementation specifications (*e.g.*, DICOM with its many optional mix-and-max Supplements) 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.

Comment Number: Rensis-3.11

Regarding: PROPOSED §162.1925 STANDARDS AND IMPLEMENTATION SPECIFICATIONS FOR ELECTRONIC HEALTH CARE CLAIMS ATTACHMENT RESPONSE TRANSACTION

This section is incomplete.

A. This section does not cover any of the standards incorporated into the NPRM by the incorporation of the HL7 CDAR1AIS0000R021 Additional Information Specification Implementation Guide, Release 2.1, May 2004, §3.5.1 and §3.5.3.

B. The section does not discuss that, according to HL7 CDAR1AIS0000R021 Additional Information Specification Implementation Guide, Release 2.1, May 2004, §3.5.3, additional Human Decision Variant file types 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.

C. The summary does not mention that, according to HL7 CDAR1AIS0000R021 Additional Information Specification Implementation Guide, Release 2.1, May 2004, §3.5.3, additional implementation specifications (*e.g.*, DICOM with its many optional mix-and-max Supplements) 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.

Comment Number: Rensis-3.12

Regarding: LEGISLATION

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 DICOM and its many optional mix-and-match Supplements.
{PL 104-191 §1173 (a) (1)}

Comment Number: Rensis-4.01

Regarding: OVERVIEW OF KEY INFORMATION FOR ELECTRONIC HEALTH CARE CLAIMS ATTACHMENTS

The statement "Clinical Document Architecture (CDA), which was a significant enhancement over the HL7 version 2.4" is unsubstantiated.

A. From a technical perspective this may or may not be the situation. It is newer, but that does not automatically translate into better; particularly given the proposed implementation specifications' absence of integration with HL7's Reference Information Model (RIM).

B. From a business and economic perspective this is certainly not the situation in the United States; particularly given the industry's virtually universal absence of conversion to CDA from their current fully paid-for implementations of HL7 version 2 series messaging – despite years of HL7 marketing and entreaties.

Comment Number: Rensis-4.02

Regarding: OVERVIEW OF KEY INFORMATION FOR ELECTRONIC HEALTH CARE CLAIMS ATTACHMENTS

Human Decision Variants allow no easily attainable, let alone affordable, capability to automatically (*i.e.*, without human intervention) validate that "standardized data elements" have in fact been created and/or used for electronic claims attachments.
{*WEDI Attachments Workgroup Report, Initial Findings*, recommendation (a) as stated in the NPRM}

As but one pair of examples, how are the handwritten scrawls shown in the HL7 CDAR1AIS0000R021 Additional Information Specification Implementation Guide, Release 2.1, May 2004, pages19-20, to be processed?

Comment Number: Rensis-4.03

Regarding: OVERVIEW OF KEY INFORMATION FOR ELECTRONIC HEALTH CARE CLAIMS ATTACHMENTS

How can Human Decision Variants, particularly scanned images, "be processed ... through automation"? At what cost if even technically feasible?

As but one pair of examples, how are the handwritten scrawls shown in the HL7 CDAR1AIS0000R021 Additional Information Specification Implementation Guide, Release 2.1, May 2004, pages19-20, to be processed?

Comment Number: Rensis-5.01

Regarding: ELECTRONIC CLAIMS ATTACHMENT TYPES

In the thus far absence of a final report on the EMS Pilot, but based on the presentation referenced below, no ongoing operational execution of the proposed Health Claims Attachment methodology has yet been achieved. The EMS Pilot was a "proof of concept and not a working model". It is thus not yet proven that the proposed standards are workable in production.

{"Claims Attachment Pilot", Empire Medical Services by Mary Lynn Bushman, 9/28/2005 at the Accredited Standards Committee X12 Trimester Meeting in Atlanta, Georgia.}

Comment Number: Rensis-5.02

Regarding: ELECTRONIC CLAIMS ATTACHMENT TYPES

In the thus far absence of a final report on the EMS Pilot, but based on the presentation referenced below, only a very small number of test cases – 20 requests and 89 *accepted* responses – were even attempted. This is hardly a ringing endorsement of an industrial strength standard. It is thus not yet proven that the proposed standards are workable in production.

{"Claims Attachment Pilot", Empire Medical Services by Mary Lynn Bushman, 9/28/2005 at the Accredited Standards Committee X12 Trimester Meeting in Atlanta, Georgia.}

Comment Number: Rensis-5.03

Regarding: ELECTRONIC CLAIMS ATTACHMENT TYPES

In the thus far absence of a final report on the EMS Pilot, but based on the presentation referenced below, only the scanned image Human Decision Variant was tested; *i.e.*, none of the free text Human Decision Variant nor the Computer Decision Variant have yet been piloted. It is thus not yet proven that the entire ranges of options and variants in the proposed standards are workable.

{"Claims Attachment Pilot", Empire Medical Services by Mary Lynn Bushman, 9/28/2005 at the Accredited Standards Committee X12 Trimester Meeting in Atlanta, Georgia.}

Comment Number: Rensis-5.04

Regarding: ELECTRONIC CLAIMS ATTACHMENT TYPES

In the thus far absence of a final report on the EMS Pilot, but based on the presentation referenced below, transmission times for the tested documents were quite long. While the presentation does not state what speed communications line(s) were used, analysis of the size of the transmitted documents appears to indicate that high speed, dedicated connections are going to be required to obtain reasonable speeds – at best. Obtaining and using such high speed lines will likely add additional costs to all but the largest providers. Moreover, the psychological barrier of obtaining such connections for the bulk of mostly already not EDI capable smaller providers could prove a further inhibitor to use of the proposed standards – keeping these providers on paper.

{"Claims Attachment Pilot", Empire Medical Services by Mary Lynn Bushman, 9/28/2005 at the Accredited Standards Committee X12 Trimester Meeting in Atlanta, Georgia.}

Comment Number: Rensis-5.05

Regarding: ELECTRONIC CLAIMS ATTACHMENT TYPES

In the thus far absence of a final report on the EMS Pilot, but based on the presentation referenced below, numerous technical issues were identified:

- Large BIN Segment
- Carriage Return Line Feed – Data communication Text versus Binary
- MIME wrapping program for HL7 CDA
- Multiple BIN segments with the same attachment.

Until such time as resolutions to the above issues are identified, analyzed, tested, and incorporated into the documents proposed by this NPRM and this NPRM itself, it is not yet proven, or even known, that the proposed standards are workable.

{"Claims Attachment Pilot", Empire Medical Services by Mary Lynn Bushman, 9/28/2005 at the Accredited Standards Committee X12 Trimester Meeting in Atlanta, Georgia.}

Comment Number: Rensis-6.01

Regarding: ELECTRONIC CLAIMS ATTACHMENT TYPES

There is no Medical Data Code Set for Drugs and Biologics for the environments in which the proposed rule would apply; *i.e.*, professional claims, institutional claims, and dental claims.
{45 CFR 162.1002 (b) (2)}
{68 FR 34, 2/20/2003, pages 8385-8387}
Therefore the Computer Decision Variant for Medications Attachments is not usable until a national standard for drugs and biologics is adopted.
{CDAR1AIS0006R021}

Comment Number: Rensis-6.02

Regarding: ELECTRONIC CLAIMS ATTACHMENT TYPES

The Human Decision Variant for Medications Attachments is not permitted.

A. A health plan will be in violation of the law when using Human Decision Variants; thus making them unusable by providers or clearinghouses as well.
{PL 104-191 §1175 (a) (1) (C)}

B. The legislation does not permit adopting implementation specifications that contain non-discrete data element provisions unique to Health Claims Attachments.
{PL 104-191 §1173 (a) (2)}

C. Human Decision Variants are in conflict with definitions of Data Condition, Data Content, and Data Element already promulgated in other, final, portions of Part 162.
{45 CFR 162.103}

D. Human Decision Variants have been repeatedly prohibited for use in other adopted transactions. As but one example, see any of the many presentations by government spokespersons over the past five or so years regarding the non-compliance of computer-to-computer facsimiles; which use the TIF format.

Comment Number: Rensis-6.03

Regarding: ELECTRONIC CLAIMS ATTACHMENT TYPES

Since neither the Computer Decision Variant nor Human Decision Variants for the Medications Attachments are possible, this AIS is not implementable, and, therefore, should not be included in any final rule for Health Claims Attachments.
{Comment Number Rensis-6.01}
{Comment Number Rensis-6.02}
{CDAR1AIS0006R021}

Comment Number: Rensis-7.01

Regarding: SOLICITED VERSUS UNSOLICITED ATTACHMENTS

The proposed X12 version for solicited attachments transactions is 004050. The mandated X12 version of applicable claims transactions is 004010. The requirement to use, and thus implement, two different versions of X12 transactions adds cost, and can be particularly onerous when the a claim using version 004010 is accompanied by an unsolicited attachment using version 004050. Consequently, a single X12 version for all applicable adopted transactions – particularly, but not limited to, claims and claims attachments – is strongly recommended; perhaps version 005010.

Comment Number: Rensis-7.02

Regarding: SOLICITED VERSUS UNSOLICITED ATTACHMENTS

Must a provider submit an unsolicited claims attachment at the same time as the claim is submitted when a specific advance instruction has been given, or may the provider elect, at its sole discretion, to not submit an unsolicited attachment and wait for the appropriate attachment request?

Comment Number: Rensis-8.01

Regarding: IMPACT OF PRIVACY RULE

For Human Decision Variants, there is no reasonably automated methodology to select only those data elements that are minimally necessary. As a consequence, such selections must be done manually. Ongoing manual determinations are more expensive than automated ones, and are thus much less likely to be done. As a consequence, similar to what is done today when sending "entire medical records" when only some of the information contained therein is actually needed, Human Decision Variants are very likely to cause the sending of more than minimally necessary data. This will tend to "gut" the intent of HIPAA Privacy regulations. Moreover, such over-sending will, also over time, lead to more privacy complaints, which will lead to higher costs for complaint investigations and resolutions.

Comment Number: Rensis-8.02

Regarding: IMPACT OF PRIVACY RULE

For Human Decision Variants, there is no reasonably automated methodology to confirm that only those data elements that are minimally necessary are received. As a consequence, such confirmations must be done manually. Ongoing manual confirmations are more expensive than automated ones, and are thus much less likely to be done. As a consequence, similar to what is done today when receiving "entire medical records" when only some of the information contained therein is actually needed, Human Decision Variants are very likely to cause the receiving of more than minimally necessary data. This will tend to "gut" the intent of HIPAA Privacy regulations. Moreover, such over-receiving will, also over time, lead to more privacy complaints, which will lead to higher costs for complaint investigations and resolutions.

Comment Number: Rensis-8.03

Regarding: IMPACT OF PRIVACY RULE

HL7 Cardinality rules divide data to be communicated into only "required" and "optional". There are no general specification paradigms for "situationally required". Thus the HL7 implementation specifications, in general, require transaction-by-transaction case-by-case minimum necessary analyses. The needs for such transaction-by-transaction case-by-case minimum necessary analyses – almost always manual – will increase costs for both senders and receivers, and when imperfectly performed, lead to more privacy complaints, which will lead to higher costs for complaint investigations and resolutions.
{ CDAR1AIS0000R021 Additional Information Specification Implementation Guide, Release 2.1, May 2004, §2.10}

Comment Number: Rensis-9.01

Regarding: PROVIDER VERSUS PLAN PERSPECTIVE

Using the scanned image option of Human Decision Variants, what are the policies and procedures for providers

- ensuring that the original document is legible and/or even decipherable? and

health plans

- dealing with a received document that is illegible and/or not decipherable – in part or even in whole?

Note that for scanned images, there are no NPRM or implementation specification requirements that require machine-written materials – they could be *hand written.*

Comment Number: Rensis-9.02

Regarding: PROVIDER VERSUS PLAN PERSPECTIVE

Using the free text option of Human Decision Variants, what are the policies and procedures for health plans

- dealing with a received document that is unintelligible and/or not decipherable – in part or even in whole?

Note that for free text, there are no NPRM or implementation specification requirements that require the free text to be coherent.

Comment Number: Rensis-9.03

Regarding: PROVIDER VERSUS PLAN PERSPECTIVE

The NPRM does not provide an explicit policy as to whether a health plan must accept any of the variants and format options within Human Decision Variants that may be sent by a provider.

Comment Number: Rensis-9.04

Regarding: PROVIDER VERSUS PLAN PERSPECTIVE

May a health plan constrain and accept only its pre-determined variants and format options within Human Decision Variants that may be sent by a provider?

Comment Number: Rensis-9.05

Regarding: PROVIDER VERSUS PLAN PERSPECTIVE

The NPRM does not provide an explicit policy as to whether a provider is free to send any of the variants and format options within Human Decision Variants and that the provider may expect every health plan to accept whatever it sends – at no additional costs to the provider.

Comment Number: Rensis-9.06

Regarding: PROVIDER VERSUS PLAN PERSPECTIVE

The NPRM does not provide an explicit policy as to whether, if every health plan is free to pre-determine only those variants and format options within Human Decision Variants that it will receive, how a provider will be compensated for the complexities of negotiating and tracking which form of attachment transaction is to be transmitted to each and under what conditions.

In fact, it is the removal of such variability for providers that is *the* lynchpin of HIPAA Transactions and Code Sets standards and adding such variability back into the mix for Health Claims Attachments is a huge step in the wrong direction!

Comment Number: Rensis-10.01

Regarding: ATTACHMENT CONTENT AND STRUCTURE

Building on the Ambulance attachment example, if a scanned image is sent by the ABC Ambulance Company without embedded LOINC codes {proposed §162.1920(d)}, how would the health plan

- uniquely and without doubt locate the proper value for weight reported by the individual from amongst potentially many values that could be present in the scanned image?
- discern weight reported by the individual from other forms of patient weight (*e.g.*, observed, measured) should more than one value for weight be included in the scanned image? and,
- positively confirm that weight reported by the individual was actually the value sent rather than some other value that may have been used instead?

Obviously, the above would not be issues if only a single value were present in the scanned image; however, this seems an unlikely scenario given that any scanned image would normally be expected to consist of a report-like document that displays many pieces of information about the patient. Such reports, when sent electronically, may not include column or row headings included automatically by and during actual hardcopy printing.

Comment Number: Rensis-11.01

Regarding: ALTERNATIVES CONSIDERED: CANDIDATE STANDARDS
(Code Sets)

There is no standard code set for Drugs and Biologics for the environments in which the proposed rule would apply; *i.e.*, professional claims, institutional claims, and dental claims.

{45 CFR 162.1002 (b) (2)}

{68 FR 34, 2/20/2003, pages 8385-8387}

LOINC does not have codes that uniquely and unambiguously identify Drugs and Biologics.

Thus, given the present state of medication identification terminology with its frequent use of synonyms (*e.g.*, generic name versus brand name versus constituent compounds) it is not possible to communicate medications in a way that does not present a potential for misunderstanding. Therefore, a final rule for Medication Attachments is not advised at this time.

Comment Number: Rensis-12.01

Regarding: ALTERNATIVES CONSIDERED: CANDIDATE STANDARDS

Note that the 15 June 1998 NCVHS vetting of HL7 was prior to creation of the current HL7 Additional Information Specifications; which efforts didn't begin until four and a half years later in 2003. Thus NCVHS' approval is no longer applicable to the approach proposed in this NPRM. Given the law's absolute requirement for discrete standard data elements, it's highly unlikely that the Human Decision Variants approach proposed in this NPRM would or even could obtain NCVHS approval.

Comment Number: Rensis-12.02

Regarding: ALTERNATIVES CONSIDERED: CANDIDATE STANDARDS

Note that the 15 June 1998 NCVHS vetting of HL7 was for the version of these standards that remains broadly and almost universally in use within the industry: version 2. No such vetting for the CDA version of HL7 proposed by this NPRM has taken place. Thus, the NCVHS has not approved the approach proposed in this NPRM.

Comment Number: Rensis-12.03

Regarding: ALTERNATIVES CONSIDERED: CANDIDATE STANDARDS

Note that the 15 June 1998 NCVHS vetting of HL7 was for the use of short, highly constrained, free text (*e.g.*, "no contraindications") as a response to a particular request for single piece of information. No vetting was for unrestricted and un-codified free text [options 2 and 3] containing multiple responses *in lieu* of discrete standard data element structures. Thus, the NCVHS has not approved the approach proposed in this NPRM. Given the law's absolute requirement for discrete standard data elements, it's highly unlikely that the Human Decision Variants approach proposed in this NPRM would or even could obtain NCVHS approval.

Comment Number: Rensis-12.04

Regarding: ALTERNATIVES CONSIDERED: CANDIDATE STANDARDS

Note that the 15 June 1998 NCVHS vetting of HL7 did not consider nor include any use of scanned images *in lieu* of discrete standard data element structures. Thus, the NCVHS has not approved the approach proposed in this NPRM. Given the law's absolute requirement for discrete standard data elements, it's highly unlikely that the Human Decision Variants approach proposed in this NPRM would or even could obtain NCVHS approval.

Comment Number: Rensis-13.01

Regarding: REQUIREMENTS (HEALTH PLANS, COVERED HEALTH CARE PROVIDERS AND HEALTH CARE CLEARINGHOUSES)

A. The NPRM needs to explicitly state that a health plan must receive and process any variant and format option specified in proposed § 162.1925. As presently written this section is not clear that the variant and format option being used to send a Health Claims Attachment transaction is solely at the discretion of the sending provider.

B. If the above is not the intent of this NPRM, then analyses of complexities and associated costs of providers having to send Claims Attachments transactions using differing variants and format options based on undocumented, in this NPRM, criteria need to be performed.

C. Note that the removal of the described variability for providers is *the* lynchpin of HIPAA Transactions and Code Sets standards and adding such variability back into the mix for Health Claims Attachments is a huge step in the wrong direction! This section is written as if there is only one standard for sending a Health Claims Attachment, but, in reality, there are too many:

- two variants
- unlimited number of Human Decision Variant formats as the HL7 CDAR1AIS0000R021 Additional Information Specification Implementation Guide, Release 2.1, May 2004, §3.5.1 and §3.5.3 allow for any format, or even new implementation specifications (*e.g.*, DICOM with its many optional mix-and-match Supplements) to be established by trading partner agreement; *i.e.*, potentially forced upon a provider by a health plan business contract.

This variability is anathema to the provider community and the very situation HIPAA Transactions and Code Sets standards are intended to alleviate!

Comment Number: Rensis-14.01

Regarding: SPECIFIC DOCUMENTS AND SOURCES

There are no references or discussions in the body of this NPRM regarding additional standards needed to comply with this proposed rule that are first and only listed within Human Decision Variants implementation specifications; particularly HL7 CDAR1AIS0000R021 Additional Information Specification Guide, Release 2.1, May 2004. Such references and discussions need to be added.

Comment Number: Rensis-15.01

Regarding: MODIFICATIONS TO STANDARDS AND NEW ATTACHMENTS

There are no references or discussions in the body of this NPRM regarding how to obtain, request, or process modifications to the additional standards needed to comply with this proposed rule that are first and only listed within Human Decision Variants implementation specifications; particularly HL7 CDAR1AIS0000R021 Additional Information Specification Guide, Release 2.1, May 2004. As but one example, PDF can be updated approximately annually. Such references and discussions need to be added.

Comment Number: Rensis-15.02

Regarding: MODIFICATIONS TO STANDARDS AND NEW ATTACHMENTS

Would requests for modifications to the additional standards needed to comply with this proposed rule that are first and only listed within Human Decision Variants implementation specifications; particularly HL7 CDAR1AIS0000R021 Additional Information Specification Guide, Release 2.1, May 2004 have to go through the DSMO?

Comment Number: Rensis-15.03

Regarding: MODIFICATIONS TO STANDARDS AND NEW ATTACHMENTS

Have the authors of the additional standards needed to comply with this proposed rule that are first and only listed within Human Decision Variants implementation specifications; particularly HL7 CDAR1AIS0000R021 Additional Information Specification Guide, Release 2.1, May 2004 been contacted to determine their opinions and desires regarding being named as standards under HIPAA and the associated impacts to their operations that could result?

Comment Number: Rensis-16.01

Regarding: COSTS AND BENEFITS
(Cost and Benefit Analysis for Covered Health Care Providers)

With the exception of a handful of CDA implementations in the United States, the provider community already universally uses HL7 version 2 series messaging to communicate the same or similar data described in the AIS' included in this NPRM. Marketing and entreaties by HL7 over the years has failed to move providers to CDA – primarily for economic reasons. Thus, it would seem reasonable to add additional cost and benefit analyses that are based on excluding or reducing the following implementation costs:

- learning about and training staff on new HL7 technology (*i.e.*, CDA instead of version 2)
- programming systems to accommodate new messaging standards (*i.e.*, CDA instead of version 2)
- some software and vendor fees
- some practice management system vendor fees and charges
- purchasing or expanding server space (*i.e.*, HL7 version 2 messages are far more compact than CDA)
- acquiring XML expertise
- purchasing or enhancing translator software (*i.e.*, health care provider covered entities already have X12 and HL7 version 2 series translators)
- telecommunications expansions (*i.e.*, HL7 version 2 messages are far more compact than CDA and already readily accommodated in health care providers existing infrastructures)

Comment Number: Rensis-16.02

Regarding: COSTS AND BENEFITS

Given the language not presently included in this NPRM, it's unclear how costs can be reduced by

- health plans receiving consistent response information, and
- health care providers use of standardized, predictable attachments and formats rather than numerous proprietary forms associated with individual health plan documents?

The Human Decision Variants are essentially electronic paper and free text transcription; albeit wrapped in standardized "envelopes". As proposed in §162.1920(d), there would be no encoding of discrete or standard data elements within the Human Decision Variants. Thus any forms and formats could be used.

Additionally there are no policies proposed in this NPRM that specify which variants and formats are to be used. There also are no policies proposed in this NPRM that specify that health plans must receive and process any specified variant and format sent by a health care provider. The HL7 CDAR1AIS0000R021 Additional Information Specification Implementation Guide, Release 2.1, May 2004, §3.5.1 and §3.5.3 allows for any format or implementation specification to be established by trading partner agreement; *i.e.*, potentially forced upon a provider by a health plan business contract.

All of these variabilities remove the possibilities of reducing costs as a consequence of the points noted.

Comment Number: Rensis-16.03

Regarding: COSTS AND BENEFITS

Which party bears the programming efforts and costs required to adjust non-XML file sizes when a mismatch occurs?
{ PROPOSED CDAR1AIS0000R021 §3.5.3}

Comment Number: Rensis-16.04

Regarding: COSTS AND BENEFITS

What happens when a plethora of differing non-XML file size requirements occur between multiple trading partner pairs? There need to be some rules. Leaving this to trading partner agreement essentially means that the provider will be at the mercy of each and every health plan to comply with whatever each wants in order to be paid.
{ PROPOSED CDAR1AIS0000R021 §3.5.3}

Comment Number: Rensis-16.05

Regarding: COSTS AND BENEFITS
(Cost and Benefit Analysis for Health Plans)

The Human Decision Variants are essentially electronic paper and free text transcription; albeit wrapped in standardized "envelopes". As proposed in §162.1920(d), there would be no encoding of discrete or standard data elements within the Human Decision Variants. Thus any forms and formats could be used. It is unclear how electronic paper – as opposed to physical or facsimile paper

- eliminates paper documents and the manual efforts to process the attachment documents
- supports the ability to electronically adjudicate.

Comment Number: Rensis-16.06

Regarding: COSTS AND BENEFITS
(Cost and Benefit Analysis for Covered Health Care Providers)

Analyses should be performed and calculations adjusted to compare theoretical reductions in postage and mailing costs to the potential added costs for expanded or new computing equipment and ongoing high speed telecommunication lines to handle the large sized CDA message formats, and particularly scanned image Human Decision Variants.

Comment Number: Rensis-16.07

Regarding: COSTS AND BENEFITS

The estimated savings from use of Health Claims Attachments are highly suspect if health care providers decline to use electronic communications due to the high degree of variability and unpredictability of the proposed standard – which isn't a single standard as intended by HIPAA Administrative Simplification but a family of variants and formats with no policies on which single one to use. There is a huge possibility that health care providers will simply abstain from participating in electronic Health Claims Attachments transactions rather than expend the efforts and costs to negotiate trading partner agreements with every health plan and consequently program their computing systems to comply with a plethora of variations in order to satisfy all the potential differences in variant and format that could be imposed on them for every attachment type, subtype, and/or data variation.

In other words, the calculations should also include the possibility that health care providers will not participate in droves due to the absence of predictability and consistency for the transaction standard***s*** proposed in this NPRM.

Comment Number: Rensis-16.08

Regarding: COSTS AND BENEFITS

Expenditures and the partial results achieved to date by all participants in the pilot project should be used to extrapolate another overall estimate of the costs of implementing the approach proposed in this NPRM.

Comment Number: Rensis-17.01

Regarding: GUIDING PRINCIPLES FOR STANDARD SELECTION

The policies and standards proposed in this NPRM are not "consistent and uniform with the other HIPAA standards ... ."

A. The other HIPAA standards use a variable length, delimited message structure while the proposed HL7 standards use either a XML tagged message format (CDA) or free ASCII text or scanned images of paper documents. Thus the standards proposed in this NPRM do not "support the regulatory goals of consistency and avoidance of incompatibility ... ."

Comment Number: Rensis-17.02

Regarding: GUIDING PRINCIPLES FOR STANDARD SELECTION

The policies and standards proposed in this NPRM are not "consistent and uniform with ... other private and public sector health data standards."

A. With the exception of handful of situations, in the United States the industry-wide paradigm for communicating clinical information is HL7 version 2 series messages. These messages use a variable length, delimited message structure while the proposed HL7 standards use either a XML tagged message format (CDA) or free ASCII text or scanned images of paper documents. Thus the standards proposed in this NPRM do not support the regulatory goals of consistency and uniformity.

B. No other standards transactions in actual use to communicate health care information in the United States (*e.g.*, IEEE, DICOM, ASTM, NCPDP, X12, and even HL7 as implemented today) presently use un-codified (*i.e.*, without data element identifiers) free text or un-codified scanned images for communication of numeric and simple text data elements. [DICOM does allow such scanned images for pictures of body parts – which are not fundamentally numeric or simple text data in the first place; however, at the present time, that does not seem to be included in this NPRM's proposed standards other than by voluntary or imposed trading partner agreement.]
{ CDAR1AIS0000R021 Additional Information Specification Implementation Guide, Release 2.1, May 2004, §3.5.3}

Comment Number: Rensis-17.03

Regarding: GUIDING PRINCIPLES FOR STANDARD SELECTION

The policies and standards proposed in this NPRM do not "have low additional development and implementation costs relative to the benefits of using the standard."

A. In spite of many years of HL7 marketing and entreaties, United States health care providers have almost universally declined to convert from their present HL7 version 2 series messages to CDA – primarily for economic reasons as regardless of any technical benefits that may accrue, they are insufficient to justify the costs.

B. HL7 spent many years following its version 2 introduction explaining to health care providers the reasons for ceasing to use free text messages (DSP segments) in preference to discrete data elements of data (OBX segments). Over time – approximately ten years or so ago now – health care providers and their vendors made this conversion from free text to discrete data elements. Given this history and its rationale, there seem to be no economic benefits to asking the provider community and their vendors to switch back to free text.

C. Even if the HL7 standards proposed in this NPRM were adopted, there is no reason to assume that health care providers and their vendors would cease to use HL7 version 2 series messages that are already operational; *i.e.*, it isn't broken so they're likely not to fix it. Thus, health care providers and their vendors would be required, if the proposed HL7 standards are adopted, to maintain two or more different versions of messaging formats for clinical data: the one they will continue to use for internal transactions and whichever multiple ones they're obligated to use for Claims Attachments. This is obviously more expensive than continuing to maintain only the one HL7 version series that is already in use.

Comment Number: Rensis-17.04

Regarding: GUIDING PRINCIPLES FOR STANDARD SELECTION

The free text and scanned image standards (*i.e.*, Human Decision Variants) proposed in this NPRM are not "precise and unambiguous ... ."

A. Free text is dependent on the skills of each transcriptionist. There is no consist way to predict or electronically control, edit, or necessarily accurately discern the content – whether by human, let alone computer.

B. Scanned images are limited by the content and clarity of the underlying paper document. Without very expensive image enhancement software, such "electronic paper" has no additional features for controlling content or readability than actual paper. Again, there is no consistent way to predict or electronically control, edit, or necessarily accurately discern the content – whether by human, let alone computer. If the original image is hard to read, so will be the electronic one.

C. There seems to be an unstated assumption that Human Decision Variants will actually be well-formed and readily legible in all cases. No such requirement exists in this NPRM or its proposed implementation specifications. Given the provisions of proposed §162.1920(d), there's also not even a reliable presumption that data items will be in any particular sequence within a Human Decision Variant transaction. Thus, it's possible given the present language of this NPRM and its proposed implementation specifications for a Human Decision Variant transaction to simply contain an unordered list of values which are totally indecipherable by anybody at the health plan without further discussions with somebody at the provider.

Comment Number: Rensis-17.05

Regarding: GUIDING PRINCIPLES FOR STANDARD SELECTION

The free text and scanned image standards (*i.e.*, Human Decision Variants) proposed in this NPRM will not "support the regulatory goals of cost-effectiveness and avoidance of burden."

A. Free text is dependent on the skills of each transcriptionist. There is no consist way to predict or electronically control, edit, or necessarily accurately discern the content – whether by human, let alone computer. The usefulness and cost-effectiveness of an attachment sent in this manner is no different than had it been sent by facsimile or simply paper copy.

B. Scanned images are limited by the content and clarity of the underlying paper document. Without very expensive image enhancement software, such "electronic paper" has no additional features for controlling content or readability than actual paper. Again, there is no consist way to predict or electronically control, edit, or necessarily accurately discern the content – whether by human, let alone computer. If the original image is hard to read, so will be the electronic one. The usefulness and cost-effectiveness of an attachment sent in this manner is no different than had it been sent by facsimile or simply paper copy.

C. There seems to be an unstated assumption that Human Decision Variants will actually be well-formed and readily legible in all cases. No such requirement exists in this NPRM or its proposed implementation specifications. Given the provisions of proposed §162.1920(d), there's also not even a reliable presumption that data items will be in any particular sequence within a Human Decision Variant transaction. Thus, it's possible given the present language of this NPRM and its proposed implementation specifications for a Human Decision Variant transaction to simply contain an unordered list of values which are totally indecipherable by anybody at the health plan without further discussions with somebody at the provider. Such situations result in additional costs for the use of electronic Human Decision Variants that would be avoided if the two parties just got together non-electronically in the first place.

(Comment continued on next page.)

D. Adding the overhead of HL7 CDA formatting only adds cost to sending Human Decision Variants. Free text or scanned images – assuming for the moment that they even make sense in the first place – can just as easily simply be sent within only the X12 275 transaction binary (BIN) segment without any need for HL7 syntax at all.

Comment Number: Rensis-17.06

Regarding: GUIDING PRINCIPLES FOR STANDARD SELECTION

The HL7 standard***s*** proposed in this NPRM do not "support the regulatory goals of cost-effectiveness".

A. The HL7 standards proposed are not a single standard that can just be implemented. The HL7 standards proposed consist of variants and formats for which no policies regarding which or when to use are presently proposed. Thus, there is no "standard", but rather many standards without any usage guidance. Consequently, trading partner agreements, or equivalent, will likely be required between every trading partner pair to define the particular specifics of what variant and format to use – conceivably for every attachment type, subtype, and/or data variation. The need to prepare such trading partner agreements adds undesired costs in and of itself. Maintaining different instances of the many standards based on differing trading partner agreement requirements not only potentially adds great costs to all parties, but is 180° counter the reason and purpose of HIPAA Administrative Simplification Transactions and Code Sets in its most basic intent.

Comment Number: Rensis-17.07

Regarding: GUIDING PRINCIPLES FOR STANDARD SELECTION

Human Decision Variants do "not improve the efficiency and effectiveness of the health care system".

A. With the exception of principle #10, apply the same logic to Human Decision Variants, plus all their potential formats, as was applied to exclude NSF from adoption for the current set of HIPAA standard transactions.
{63 FR 88, 5/07/1998, page 25288, second column}

B. With the exception of principle #10, apply the same logic to Human Decision Variants, plus all their potential formats, as was applied to exclude UB92 from adoption for the current set of HIPAA standard transactions.
{63 FR 88, 5/07/1998, page 25288, third column}

Comment Number: Rensis-17.08

Regarding: GUIDING PRINCIPLES FOR STANDARD SELECTION

There is no "precise and unambiguous" Medical Data Code Set for Drugs and Biologics for the environments in which the proposed rule would apply; *i.e.*, professional claims, institutional claims, and dental claims.
{45 CFR 162.1002 (b) (2)}
{68 FR 34, 2/20/2003, pages 8385-8387}
Therefore, the regulatory goals of predictability and simplicity are not satisfied by the standards proposed in this NPRM.

Comment Number: Rensis-18.01

Regarding: GUIDING PRINCIPLES FOR STANDARD SELECTION

The HL7 standards names in this NPRM do not "compare favorably with typical ...HL7 standards ... ease of use and cost".

A. In spite of many years of HL7 marketing and entreaties, United States health care providers have almost universally declined to convert from their present HL7 version 2 series messages to CDA – primarily for economic reasons as regardless of any technical benefits that may accrue, they are insufficient to justify the costs.

B. HL7 spent many years following its version 2 introduction explaining to health care providers the reasons for ceasing to use free text messages (DSP segments) in preference to discrete data elements of data (OBX segments). Over time – approximately ten years or so ago now – health care providers and their vendors made this conversion from free text to discrete data elements. Given this history and its rationale, there seem to be no economic benefits to asking the provider community and their vendors to switch back to free text.

C. Even if the HL7 standards proposed in this NPRM were adopted, there is no reason to assume that health care providers and their vendors would cease to use HL7 version 2 series messages that are already operational; *i.e.*, it isn't broken so they're likely not to fix it. Thus, health care providers and their vendors would be required, if the proposed HL7 standards are adopted, to maintain two or more different versions of messaging formats for clinical data: the one they will continue to use for internal transactions and whichever multiple ones they're obligated to use for Claims Attachments. This is obviously more complicated and expensive than continuing to maintain only the one HL7 version series that is already in use.

Comment Number: Rensis-19.01

Regarding: PROPOSED §162.1915 STANDARDS AND IMPLEMENTATION SPECIFICATIONS FOR THE ELECTRONIC HEALTH CARE CLAIMS ATTACHMENT REQUEST TRANSACTION

The LOINC Modifier Codes booklet is missing from the list of those standards and implementation specifications proposed for adoption.

Comment Number: Rensis-19.02

Regarding: PROPOSED §162.1900 DEFINITIONS

The definition of ambulance service is not specific enough. It seems to read that anybody can operate as such a service so long as they transport; *e.g.*, a general purpose taxicab seems to be included in this definition. Is this what is intended or was the intent to apply only to licensed or otherwise designated ambulance organizations?

Comment Number: Rensis-19.03

Regarding: PROPOSED §162.1900 DEFINITIONS

The definition of attachment information could perhaps be strengthened by adding the phrase "not already included with a claim" as discussed in the "Electronic Health Care Claims Attachment vs. Health Care Claims Data" section of this NPRM.

Comment Number: Rensis-19.04

Regarding: PROPOSED §162.1900 DEFINITIONS

A category of medications seems to be missing: already ordered for the patient but which the patient is not taking. This occurs all the time – particularly for outpatients!

For medications, there are key distinctions between

- what is ordered / prescribed,
- what is dispensed, and
- what is administered / taken.

The definition of medications and the medications attachment AIS need to acknowledge each of these situations, and be clearer as to when and whether medications in each of these states is relevant.

Comment Number: Rensis-19.05

Regarding: PROPOSED §162.1910 ELECTRONIC HEALTH CARE CLAIMS ATTACHMENT REQUEST TRANSACTION

What's the difference between §162.1910 (a) (2) and §162.1910 (a) (3) ?

Comment Number: Rensis-19.06

Regarding: PROPOSED §162.1920 ELECTRONIC HEALTH CARE CLAIMS ATTACHMENT RESPONSE TRANSACTION

Paragraph §162.1920 (b) and paragraph §162.1920 (d) appear to be somewhat contradictory. Paragraph (b) requires use of the implementation specifications listed in §162.1925, however paragraph (d) states that "response information may be free text, scanned documents, or an embedded document within the BIN segment of the response transaction" without any restrictions.

Comment Number: Rensis-19.07

Regarding: PROPOSED §162.1920 ELECTRONIC HEALTH CARE CLAIMS ATTACHMENT RESPONSE TRANSACTION

Paragraph §162.1920 (d) states that for Human Decision Variants a provider is "not required to use LOINC® codes as a response other than to repeat the LOINC® codes used in the request". Such an approach can all-to-easily lead to indecipherable, unreadable, and/or unintelligible attachments – thus defeating the entire purpose of this NPRM.

A. Free text is dependent on the skills of each transcriptionist. There is no consist way to predict or electronically control, edit, or necessarily accurately discern the content – whether by human, let alone computer. The usefulness and cost-effectiveness of an attachment sent in this manner is no different than had it been sent by facsimile or simply paper copy.

B. Scanned images are limited by the content and clarity of the underlying paper document. Without very expensive image enhancement software, such "electronic paper" has no additional features for controlling content or readability than actual paper. Again, there is no consist way to predict or electronically control, edit, or necessarily accurately discern the content – whether by human, let alone computer. If the original image is hard to read, so will be the electronic one. The usefulness and cost-effectiveness of an attachment sent in this manner is no different than had it been sent by facsimile or simply paper copy.

C. There seems to be an unstated assumption that Human Decision Variants will actually be well-formed and readily legible in all situations. No such requirement presently exists in this NPRM or its proposed implementation specifications. Given the provisions of proposed §162.1920 (d), there's also not even a reliable presumption that data items will be in any particular sequence within any Human Decision Variant transaction. Thus, it's possible given the present language of this NPRM and its proposed implementation specifications for a Human Decision Variant transaction to simply contain an unordered list of values which are

(Comment continued on next page.)

totally indecipherable by anybody at the health plan without further discussions with somebody at the provider. Such situations result in additional costs for the use of electronic Human Decision Variants that would be avoided if the two parties just got together non-electronically in the first place.

For example, the following free text option for a Human Decision Variant laboratory result attachment is presently possible:

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

To alleviate such potential gobbledygook, this NPRM and its proposed implementation specifications will have to be changed to require some form of "standard data element" {PL 104-191 §1175 (a) (1) (C)} coding for each value communicated in Human Decision Variants. Such encoding would necessarily require a specified data element coding format along with, if the rest of this proposed NPRM is carried forward, use of LOINC® codes as each data element identifier. This means

- every free text Human Decision Variant would have to be transcribed using a decipherable and intelligible data element identifier, data element value, and, where applicable, data element units and other attributes format;
- every free text Human Decision Variant would have to be transcribed using LOINC® codes as the data element identifier;
- every scanned image Human Decision Variant would have to be originally stored using a decipherable and intelligible data element identifier, data element value, and, where applicable, data element units and other attributes format; and
- every scanned image Human Decision Variant would have to be stored using LOINC® codes as the data element identifiers.

All of a sudden, all of the purported advantages and cost benefits of Human Decision Variants in and of themselves evaporate – at the least!

Comment Number: Rensis-19.08

Regarding: PROPOSED §162.1920 ELECTRONIC HEALTH CARE CLAIMS ATTACHMENT RESPONSE TRANSACTION

Paragraph 162.1920(e) does not clearly indicate whether a provider must submit an unsolicited claims attachment at the same time as the claim is submitted when a specific payer advance instruction – *i.e.*, trading partner agreement – has been given, or may the provider elect, at its sole discretion, to not submit an unsolicited attachment and wait for the appropriate attachment request?

Comment Number: Rensis-20.01

Regarding: PROPOSED CDAR1AIS0000R021
PROPOSED CDAR1AIS0001R021
PROPOSED CDAR1AIS0002R021
PROPOSED CDAR1AIS0003R021
PROPOSED CDAR1AIS0004R021
PROPOSED CDAR1AIS0005R021
PROPOSED CDAR1AIS0006R021

There is no standard mechanism specified in any of the proposed implementation specifications for a provider to precisely and unambiguously indicate that no data is available for a required data item; *i.e.*, a data item with cardinality of **1,1** or **1,n**. This is particularly critical if an attachment request or a previously agreed-to health plan advance instruction precisely requests a specific piece of information with this "required" cardinality. Merely sending an attachment with nothing present would likely be considered un-precise and/or ambiguous.

This same issue also exists, but to a somewhat lesser extent, when optional cardinality – **0,1** or **0,n** – is specified.

There is no definition of "local markup" as used in the proposed implementation specifications and this phrase implies situation-by-situation differences that are likely to regularly occur.

Multiple appropriate standard mechanisms for explicitly stating that no data is available are critical for the Computer Decision Variant plus all options of Human Decision Variants.

Of additional concern is how, when a specific piece of information is requested that is not available, a scanned image will be either modified or economically created to accomplish this. Or, will one variant and/or option be used when the required data value is present and can be sent, and a different variant and/or option be used when it is not? This could become very confusing and expensive!

Some NPRM and implementation specification policies for another public review are needed here.

Comment Number: Rensis-21.01

Regarding: ACKNOWLEDGEMENT TRANSACTIONS FOR ELECTRONIC HEALTH CARE CLAIMS ATTACHMENT RESPONSE TRANSACTION

Accredited Standards Committee X12 detailed acknowledgement transactions – *e.g.*, 999, 997, 824 – are dependent on being able to precisely and unambiguously identify the X12, or potentially HL7 version 2, loop, segment, and/or data element that is being processed. How would this occur when attempting to identify a "bad" piece of information conveyed in Human Decision Variant transactions?
{004050X151 §2.3}

Comment Number: Rensis-21.02

Regarding: ACKNOWLEDGEMENT TRANSACTIONS FOR ELECTRONIC HEALTH CARE CLAIMS ATTACHMENT RESPONSE TRANSACTION

Accredited Standards Committee X12 detailed acknowledgement transactions – *e.g.*, 999, 997, 824 – are dependent on being able to precisely and unambiguously identify the X12, or potentially HL7 version 2, loop, segment, and/or data element that is being processed. What changes to these transactions would be required to make them work with the proposed CDA and XML-based Computer Decision Variant?
{004050X151 §2.3}

Comment Number: Rensis-22.01

Regarding: PROPOSED CDAR1AIS0000R021 §3.5.3

There appears to be an incorrect reference to Table 5. Should the reference be to "Table 4: Acceptable File Types for <non xml>"?

Comment Number: Rensis-22.02

Regarding: PROPOSED CDAR1AIS0000R021 §3.5.3

Which party bears the programming efforts and costs required to adjust non-XML file sizes when a mismatch occurs?

Comment Number: Rensis-22.03

Regarding: PROPOSED CDAR1AIS0000R021 §3.5.3

What happens when a plethora of differing non-XML file size requirements occur between multiple trading partner pairs? There need to be some rules. Leaving this to trading partner agreement essentially means that the provider will be at the mercy of each and every health plan to comply with whatever each wants in order to be paid.

Comment Number: Rensis-22.04

Regarding: PROPOSED CDAR1AIS0000R021 §3.7.4.2

References to ICD-10 need to be added.

Comment Number: Rensis-23.01

Regarding: PROPOSED CDAR1AIS0002R021 EMERGENCY DEPARTMENT SERVICES, §5.20 AND ALL OTHER PORTIONS THAT REFERENCE §5.20

NDC has been eliminated as a HIPAA Medical Data Code Set for the environments in which the proposed AIS would be used; *i.e.*, professional claims, institutional claims, and dental claims. As a consequence, it should not be specified in this AIS.

{45 CFR 162.1002 (b) (2)}
{68 FR 34, 2/20/2003, pages 8385-8387}

Therefore the data items for transmitting codified medication identification should be removed until a national standard for drugs and biologics is adopted.

Comment Number: Rensis-23.02

Regarding: PROPOSED CDAR1AIS0002R021 EMERGENCY DEPARTMENT SERVICES, §5.20 AND ALL OTHER PORTIONS THAT REFERENCE §5.20

The statement regarding the suitability of NDC has been proven inaccurate for the environments in which the proposed AIS would be used; *i.e.*, professional claims, institutional claims, and dental claims. As a consequence, it should not be specified in this AIS.

{45 CFR 162.1002 (b) (2)}
{68 FR 34, 2/20/2003, pages 8385-8387}

Therefore the data items for transmitting codified medication identification should be removed until a national standard for drugs and biologics is adopted.

As a consequence, this NPRM and its proposed Claims Attachments Response standards should be abandoned. Their purported advantages are actually their worst failings. This NPRM is the antithesis of TCS as intended and thus far implemented – particularly all of this NPRM's presently unbounded so-called flexibilities and variants and options and file types – and a fresh start on mechanisms for communicating additional information from providers to health plans to support claims needs to be undertaken.

Comment Number: Rensis-99.04

Regarding: DATES

It's unfortunate that at the time these comments are being submitted that there is insufficient time to further analyze the interplay between the policies in this NPRM itself and the technical materials it names. There're a lot of materials to cross-check with what are brand new NPRM policies being seen – or more precisely for this NPRM, not seen – for the first time. It's hoped that following consideration of these and all other comments received that (a) significant changes are made and (b) another opportunity for public comment is provided through a second very different NPRM and significantly revised technical materials.

Comment Number: Rensis-99.05

Regarding: DATES

The comments in this package – some of which are a bit rough and less coordinated than preferred – are the best that could be managed given the available time! Should a sufficient extension to the present NPRM comment period – as requested by me and others – be granted subsequent to the date these comments are submitted, further analytical efforts could be performed.

END OF WRITTEN COMMENTS

S. Jerome Zackin, D.M.D.
7621 Preserves Court
Sarasota, Florida 34243

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.

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Rec'd 11/21/05
L.M.M.

November 18, 2005

Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-8050

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

Dear Dr. McClellan:

The College of American Pathologists (CAP) is pleased to respond to the proposed rule on HIPAA Administrative Simplification Standards for Electronic Health Care Claims Attachments (CMS-0050-P).

The CAP represents 16,000 physician pathologists that practice in community hospitals, independent laboratories, academic medical centers and federal health facilities. CAP is the owner of SNOMED Clinical Terms® (SNOMED CT®) a dynamic, scientifically validated clinical terminology and infrastructure that makes healthcare knowledge more usable and accessible. SNOMED CT provides a common language that enables a consistent way of capturing, retrieving, sharing and aggregating health data across specialties of sites of care. Applications for SNOMED CT include, but are not limited to: electronic medical records, ICU monitoring, clinical decision support, medical research studies, clinical trials, computerized physician order entry, disease surveillance, public health reporting, image indexing, and consumer health information services.

The CAP, an ANSI standard development organization, is committed to advancing excellence in patient care through encouraging the adoption of SNOMED CT by clinicians, researchers and patients to share health care knowledge worldwide across clinical specialties and sites of care.

As you are aware, through a July 2003 agreement with the National Library of Medicine (NLM), the CAP currently provides SNOMED CT free of charge to all interested US parties for use for any purpose within the US. Shortly thereafter, in November 2003, the National Center on Vital Healthcare Statistics (NCVHS) recommended SNOMED CT as a core terminology standard for the Patient Medical Record Initiative (PMRI). As stated in the NCVHS report, this

recommendation was made on the basis of SNOMED CT's "breadth of content, sound terminology model and widely recognized value as a general purpose terminology for the purpose of exchange, aggregation, and analysis of patient medical information."

Also, as recognized in the proposed HIPPA regulation, SNOMED CT was selected as an HHS standard for the Consolidated Health Informatics (CHI) Initiative. The CHI initiative established a portfolio of existing clinical vocabularies and messaging standards to allow federal agencies to build interoperable federal health data systems. This activity has helped to reach consensus that the time is right to establish universal clinical vocabulary and messaging standards. Leaders in the health care industry have communicated how important the federal government's leadership role is in the adoption of standards. As the federal government is involved in providing and paying for health care, standards that the government adopts will significantly influence the decisions on standards adopted by the rest of the health marketplace. This CHI initiative should be the framework from which any new entity or activity should build.

In the years since SNOMED CT has received these favorable recommendations, we have worked to make it as accessible and usable as possible. We have encouraged collaboration with other medical specialty groups, and have also encouraged comments from the health care provider community. To facilitate this, we have established an Internet based request submission system where any SNOMED user can provide comments regarding current or future content.

The CAP is supportive of the efforts that the Centers for Medicare and Medicaid Services (CMS) is trying to establish by this proposed rule to facilitate the transfer of electronic health information, and we offer the following comments for your consideration.

Code Sets

With respect to the code set standard for use in the claims attachment rule, we question the limitation of the identified code set to Clinical LOINC, which would be appropriate for some segments of the claims attachments, but not exclusively, and particularly not for clinical data that would be coded with SNOMED under the NCVHS and CHI recommendations. While it is understood this proposed regulation was developed over a period of eight years or more, legislation and government recommendations for terminology standards have evolved tremendously in the most recent two or three years, and the proposed regulation should be updated to reflect current reality in this area, in particular with respect to SNOMED CT. As noted above, SNOMED CT has consistently been recognized as a valuable and important component of the federal government's initiatives for clinical terminology standards.

As a terminology standard, SNOMED CT is recommended for use beyond laboratory investigations. SNOMED CT is recommended as the terminology standard of choice for the clinical representation of interventions and procedures, anatomy, diagnosis and problems, and nursing data. We believe that the proposed regulation is inconsistent with current practice and both the CHI and NCVHS recommendations. In fact, the US Department of Veterans Affairs is taking a leadership position as it incorporates the CHI standards into its new computer system that will support the electronic medical record throughout the 170+ national hospital network.

The CAP recommends an approach in which claims attachments requiring coded clinical data are limited to a set of well-defined claims attachment templates utilizing a standardized coded clinical terminology that can clearly capture any clinical information contained in the medical records. Specifically, the use of SNOMED CT would be most effective as a source for clinical codes, which can be formatted according to the coding system in HL7 message standards specification, and which can be formatted and transmitted using the X12 standard.

It is important to note that both the NCVHS and CHI have recommended SNOMED CT and the *laboratory subset* of LOINC for use in electronic health records. In contrast, the terminology proposal within the HIPPA Standards for Electronic Health Care Claims Attachments recommend Clinical LOINC codes even where SNOMED CT codes are available. A major implication of this recommendation for those organizations using SNOMED CT within their electronic health records is the inability to automatically populate fields needed for claims settlement as well as the aggregation of clinical data from a variety of sources.

In the interest of providing some specific examples regarding the ability to use SNOMED CT within the various claims attachments, please see the following examples where SNOMED CT is appropriate for the coded data elements found within:

Ambulance Service Attachment

- Reasons for scheduled and unscheduled trips
- Disorders/findings, events, diagnostic tests

Clinical Reports Attachment

- Provider history and physical notes
- History of present illness
- Hospital discharge diagnosis/findings, procedures, summary and follow/up
- Hospital course

Emergency Department Attachment

- Emergency Department clinical findings
  - Including but not limited to physical as well as social/environmental findings

Medications Attachment

- Usage scenarios:
  - Current medications, medications administered and discharge medications

Rehabilitation Services Attachment

- Psychiatric, Skilled Nursing, Respiratory Therapy, Occupational Therapy, Physical Therapy, Speech Therapy, Cardiac Rehabilitation, Alcohol/Substance Abuse Rehabilitation specific codes
- **Plan Data:** Diagnoses, medical history, initial assessment, functional goals, plan of treatment, medications, symptoms and behavior

While the CAP recognizes that no single code system captures all clinical concepts, SNOMED CT is recognized to be the most comprehensive healthcare terminology available today for use within a variety of clinical and research environments. It is designed to encompass all of the content necessary to document the total healthcare experience. As previously noted, SNOMED CT is used in many healthcare applications, including electronic health records, disease surveillance, public health reporting, and cancer reporting, to name just a few.

An additional advantage of SNOMED CT is its ability to adapt to multi-purpose vocabularies, datasets, and classifications. The CAP has long recognized the value of collaboration with other standards developers. As a result, SNOMED CT is currently cross-referenced with ICD-9CM, ICD-10, NIC, NOC, NANDA, PNDS, CCC, and the Omaha System. We have also been working with the National Library of Medicine to support their efforts to offer a comprehensive set of standards via the UMLS. Most of these efforts have involved mapping between vocabularies. We support the NLM's approach that no single standard can satisfy all needs, but that this goal will more readily be achieved through offering an array of standards. The CAP proposes that the wording of this regulation be such that it supports this goal, and in particular does not exclude the use of SNOMED CT where it is appropriate.

To move forward now, after so much time has elapsed since the initial development of the regulation over eight years ago, without the appropriate inclusion of SNOMED CT as a code set standard for claims attachments may place an undue burden on the required covered entities under HIPAA. In that period of time, SNOMED CT has been recognized as an essential foundation for the electronic health record by the actions of the NLM and CHI initiative as well as many others among the user and vendor communities. For the regulation to exclude this option is in conflict with these other initiatives. We are confident that CMS recognizes the importance of the electronic health record and its relationships to claim attachments and we encourage you to also recognize the value of SNOMED CT for its role in current and future claims attachments standards.

The CAP appreciates the opportunity to comment on this proposed regulation. Should you have questions please contact Lynn Boyd, Director of Federal Affairs for SNOMED at lboyd@cap.org or at (202) 354-7136.

Sincerely,

Thomas Sodeman MD FCAP

Thomas Sodeman, MD, FCAP
President

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Rec'd 11/22/05

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Andrew Morrison
Senior Vice President, Public Affairs

November 21, 2005

Submitted via Federal Express

The Honorable Mark McClellan, MD, Ph.D.
Administrator
The Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8014
Baltimore, MD 21244-8014

Re: **File Code CMS 0050-P**
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:

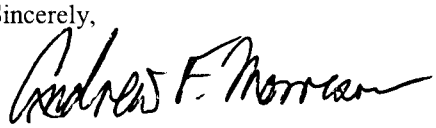
WellPoint, Inc. is pleased to have the opportunity to comment upon the impact of the Department of Health and Human Services (DHHS) proposed HIPAA Administrative Simplification Standards for Electronic Health Care Claims Attachments that appeared in the *Federal Register*, Volume 70, No. 184, on Friday, September 23, 2005.

WellPoint, Inc. is the largest publicly traded commercial health benefits company that, through its subsidiary companies, provides health care benefits to approximately 28.8 million people. WellPoint is an independent licensee of the Blue Cross and Blue Shield Association. WellPoint is the Blue Cross licensee in California and a Blue Cross and Blue Shield licensee in 12 other states: Colorado, Connecticut, Georgia, Indiana, Kentucky, Maine, Missouri (excluding 30 counties in the Kansas City area), Nevada, New Hampshire, Ohio, Virginia (excluding the immediate suburbs of Washington, D.C.), and Wisconsin. WellPoint also serves customers throughout various parts of the country as HealthLink and UniCare.

WellPoint strongly supports the Centers for Medicare & Medicaid Services (CMS) decision to limit unsolicited electronic attachments to situations where the health plan and provider have a prior agreement that would define when a provider could or should submit an attachment without a prior electronic request. Of particular concern is the timing of other current and upcoming HIPAA projects on issuance of this final rule. These projects include the National Provider Identifier, upgrade to the 5010 for other transactions, the National Payer Identifier, and updates to major code lists, like ICD-9 to ICD-10. We respectfully request that CMS coordinate the effective and implementation dates of the final HIPAA Claims Attachment Rule in light of these other significant HIPAA projects, such that covered entities do not simultaneously shoulder major HIPAA compliance burdens.

WellPoint submits the following attached comments and recommendations concerning the Claims Attachment Standards. We appreciate the chance to offer these comments, which we believe will help make HIPAA electronic claims attachments useful to the health care industry.

Sincerely,



Andrew F. Morrison
Senior Vice President, Public Affairs

Attachments

November 22, 2005

WellPoint, Inc. 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

Implementation Guides in HIPAA Regulations (Page 55993)

Proposed Rule: 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.

Issues: Compatibility of different versions of the Implementation Guides.

WellPoint Comment: It is not entirely clear that if a provider needs to submit its 837 claim transaction in the 4050 version in order to avail itself of its practice management system's ability to generate 275 claims attachment response transactions in 4050, whether the payer must accept the 837 claim transaction in the 4050 version.

Effective Dates (Page 55994)

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

Issues: Other HIPAA requirements such as implementation of the national provider identifier, upgrade to the 5010 for other transactions, national payer identifier, and migration from ICD-9 to ICD-10 may be being implemented concurrently to the Claims Attachment Standards.

WellPoint Comment: We suggest that the issuance of the final Claims Attachment Standards rule be coordinated with the above HIPAA initiatives in order to ensure that health plans and healthcare providers are able to implement these standards in a coordinated fashion without conflict with other major HIPAA compliance initiatives.

Overview of Clinical Document Architecture (CDA) (Page 55995)

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

Issues: CDA Release 1.0 was approved in November, 2000, while Release 2.0 is still in the process of being adopted by HL7. The Release 2.0 requires modification to the identified Additional Information Specifications (AIS) included in this proposed rule and subsequent AIS currently in development.

WellPoint Comment: There is insufficient clarity currently over which CDA version is being proposed in this rule, and we request that this be clarified in the final rule. Additionally, because CDA Release 2.0 is still actively in the process of being formalized, and it is unclear to us what

will be the impact of adopting Release 2.0 on the requirements of this final rule and the Additional Information Specifications. CMS should seek additional recommendations from stakeholders on how to assess CDA version 1 versus version 2 to determine which has the greatest chance of success during the initial implementation. If not used at initial implementation, we would recommend consideration of CDA version 2 as part of the 5010 upgrade whenever that occurs.

Electronic Claims Attachment Types (Page 55996)

Proposed Rule: CMS invites comments as to whether the six proposed attachment types are still the most frequently requested by health plans.

Issues: Whether there are other types of attachments frequently requested by health plans in addition to or in lieu of the six proposed attachment types.

WellPoint Comment: We suggest that CMS strongly consider adding the following additional attachment types to the final rule: durable medical equipment (DME); home health and infusion

Industry Standards Acknowledgements (Page 55996)

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

Issue: There are no requirements for the use of standard acknowledgements such as the ANSI X12N 997, 998, TA1 and 824. While none of the other HIPAA transactions require the use of standard acknowledgements, they are critical to the control and management of electronic transactions. Because of a lack of required standards health plans have incorporated instructions concerning acknowledgements into their respective companion guides. Also we have noted a lack of standard reports being used by the clearinghouse community. We also note reference to a 102 transaction in the 275 transaction implementation guide that would not be useful to this endeavor. By adding such a requirement we believe industry process flow will be improved by eliminating many duplicate claim submissions, reduce claim inquiries and subsequently reduce administrative cost to the industry. We believe improvements such as this are consistent with WellPoint's commitments to make business processes work more efficiently.

WellPoint Recommendation: CMS should work with X12N to establish requirements for the use of standard electronic acknowledgements and to eliminate the reference to the 102 transaction.

Format Options (Page 55997)

Proposed Rule: The rule permits healthcare providers to choose one of three formats for sending electronic claims attachments: Human Decision Variant (scanned), Human Decision Variant (natural language text) and Computer Decision Variant.

Issues: Health plans will need to be ready to receive all three format options from healthcare providers on the compliance date as established by the final rule.

WellPoint Comment: We are concerned that the majority of providers that choose to conduct electronic claims attachment transactions will likely initially use the Human Decision Variant (scanned) as being the technologically simplest. Health plans will not be able to build out auto-adjudication of the Computer Variant efficiently until sufficient volume of data is being received from a diverse group of providers, so as to scope proper workflow processes. It will be expensive

and impractical for health plans to modify their systems to accept the Computer Variant format without sufficient trading partners to work with to ensure interoperability. Thus, we suggest a staggered approach for both health plans and health care providers of the format options: implement first the Human Decision Variant (scanned); then after 12-18 months of experience, implement the Human Decision Variant (natural language text); then finally implement the Computer Decision Variant after 12-18 months of additional experience.

Industry Standards LOINC Codes (Page 55997)

Proposed Rule: Under the proposed rule the finite list of LOINC Codes documented within 4 of the 6 Hl7 AIS workbooks would require rulemaking to either add or delete codes from the lists.

Issue: WellPoint believes the potential for code changes for the workbooks is relatively high and the need for code changes will occur frequently. If such additions and deletions are subject to the agency rulemaking process, it will generally take three years to get changes implemented. We believe that the combination of LOINC maintenance by the Regenstrief Institute and the HL7 ballot and approval process for the workbook content are sufficient in terms of LOINC code list maintenance.

WellPoint Recommendation: WellPoint requests that CMS modify the final rule to designate the LOINC code workbook list as external code sets that are not subject to the administrative rulemaking process.

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

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

WellPoint Recommendation: The final rule should clarify this issue.

Combined Use of Different Standards (Page 55998)

Proposed Rule: CMS invites comments on the strategy of using different standards.

Issues: Using the HL7 and X12N standards together works well. It would be more difficult and costly to implement the electronic claims attachments if they were sent only using HL7 standards.

WellPoint Comment: We support the dual maintenance strategy adopted by CMS.

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 or documentation needs relevant to that specific claim. Healthcare providers must respond completely to that request, using one response transaction.

Issues: Whether the "one 277 request, one 275 response" is practicable in the real world.

WellPoint Comment: When requesting additional information to process claims, it is not uncommon for health plans to need to contact providers for further clarification or information.

We believe this may continue to be the case with electronic claims attachments, and we suggest that the final rule state that health plans should make efforts to include all requested or desired questions in the electronic claims transaction, but that health plans be afforded the chance to follow up electronically if the provider's response is incomplete or generates more questions. Otherwise, the need to follow up with the provider via phone or U.S. Mail will subtract from the efficiencies inherent in electronic transactions.

Proposed Rule: Healthcare providers may only submit an unsolicited electronic attachment with a claim only when a health plan has given the provider specific advance instructions pertaining to that type of claim or service.

Issues: There are challenges in linking unsolicited 275s back to their associated 837s.

WellPoint Comment: We request that the final rule reflect that a provider's unsolicited 275 should not obviate the payer's possible need to generate a 277 for additional information, because the claim and/or the 275 itself may generate further questions from the payer. Additionally, if the incoming 837 fails business edits and is returned, it is not clear in this proposed rule how the health plan is to handle the accompanying 275.

Impact to Privacy Rule (Page 56000)

Proposed Rule: CMS invites 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.

Issues: Whether application of "minimum necessary" will require health plans to generate more than one 277 in order to receive adequate additional information.

WellPoint Comment: The proposed rule preamble correctly notes that under the Privacy Rule the provider may rely, if such reliance is reasonable, upon the health plan's request for PHI as being the minimum necessary. Our experience under the Privacy Rule has been that healthcare providers often do not rely upon the plan's request, but make their own minimum necessary determination, which is typically less than the information the plan requests. When the provider has the unilateral right to determine the minimum necessary protected health information it will include in its 275 response to the health plan's request, the "one 277 request, one 275 response" will negatively affect the plan's right to obtain additional information to process the claim. This is an additional reason why it is reasonable to permit health plans to have the ability to send more than one 277 transaction per claim. CMS should apply a reasonable approach to minimum necessary. If the data in a document is related to a request but not specifically requested it should be allowed. Both parties are covered entities, both parties are obligated to protect the information and there should be minimal risk to the person whose protected health information is being exchanged.

Connection to Signatures (Hard Copy and Electronic) (Page 56000)

Proposed Rule: CMS invites industry input on how signatures should be handled when an attachment is requested and submitted electronically.

Issues: The issue is whether there is sufficient electronic authentication inherent or built into the 275 response transaction, such that an additional electronic signature is not necessary.

WellPoint Comment: In most circumstances, there should be adequate security in the connection between plan and provider trading partners, for each party to trust that the transaction is truly coming from the trading partner, as opposed to an unknown third party. There should thus be adequate authentication for information security purposes such that an additional electronic signature would not be necessary. However, we believe that plans should have the option to require electronic signatures from their trading partners, if there is any question about the information security level of their partners, to ensure an appropriate level of authentication. This situation may occur, for example, where a healthcare provider directs a health plan to send any 277s to the provider's business associate.

Provider vs. Plan Perspective (Page 56001)

Proposed Rule: Health plans may not reject any electronic claims attachment transaction from a healthcare provider simply because it is being conducted as a standard transaction.

Issues: Under the proposed rule, the provider has the option whether to use the electronic claims attachment transaction, and to require the health plan to send 277s rather than paper requests for additional information.

WellPoint Comment: As drafted, the rule will require health plans simultaneously to maintain both non-electronic and electronic methods of requesting additional information from providers, and to keep records of which providers have requested only information requests. The proposed rule does not limit a provider from requesting 277s from a plan for certain types of information (and paper for other information types), nor does it preclude a provider from switching back and forth from electronic to paper. The cost to health plans of maintaining two types of information-request procedures and systems, as well as creating a control system to accurately record provider choice, does not appear to have been factored into the ROI equations for this rule.

Proposed Rule: The implementation guide for the 275 response transaction permits up to 64 megabytes of data in a single transaction. CMS solicits comments on this limit and on file size.

Issues: Whether health plans have adequate server storage capacity to store massive 275 files.

WellPoint Comment: We are very concerned about the sizing implications for image processing. Sizing of transactions and their contained BIN data will have a direct, and perhaps significant, impact on transmission duration, processing through-put, and storage assessments/allocations. A multi-fold increase in the 837-275 combined file size may impact the health plan's translation layer system's ability to process 837s in a timely manner. Because the 837 is the most used EDI transaction in health care, successful timely processing of large 837 volumes is a significant core competency to maintain. It is not clear whether adequate benchmarking tests have been executed that can provide data on the metrics measured. There is also the reality of having to increase space in health plans' clearinghouses to accommodate these file sizes, with associated costs.

Alternatives Considered: Candidate Standards (Page 56002)

Proposed Rule: The 4050 versions of the 277 and 275 are proposed for adoption.

Issues: Whether the 4050 version is the appropriate version for the 277 and 275 transactions.

WellPoint Comment: We recommend that CMS adopt the 5010 version of the 277 and 275, that 5010 CICA be allowed, and that CMS permit using X12 syntactical structures (versus X12 CICA XML) to be driven by the parties' trading partner agreement. X12's version 5010 includes CICA

(X12's XML implementation), which would allow the X12 portion and the HL7 portion of the 275 to be all XML instead of being a "mixed mode" transaction. We realize that the X12 CICA XML and HL7 CDA1/CDA2XML may have subtle differences. This eases the burden on the provider's vendors and software translators. A "mixed mode" transaction is poor design methodology, requiring a dual layer transaction – in other words, it would require opening one envelope to get to a second envelope needing to be opened. Adopting the 5010 version would also allow trading partners to use an all-XML transaction (including embedded images, if the human variant is used), which is gaining general industry momentum as the long-term vision for EDI.

Proposed Rule: CMS invites all segments of the industry to comment on the proposed attachment content, the attachment criteria and the procedures, so that the standards can be validated, and any appropriate revisions to those standards made and approved in time for the final rule.

Issues: Whether LOINC® codes are adequate for communicating detailed or specific clinical information to supplement a claim.

WellPoint Comment: LOINC® codes are needed specific to a request for pre-operative photographs. For example, for procedure code 15823 (blepharoplasty), pre-operative photos are requested in order to document the upper eyelid margin, per coverage criteria.

Proposed Rule: Uses the term "electronic envelope" applied to the 277 as convening the LOINC® code or codes appropriate to that electronic attachment request.

Issues: The term "electronic envelope" can be subject to misinterpretation.

WellPoint Comment: We would urge caution in referencing the term "electronic envelope" when it is not directly related to a discussion point dealing with interchange (ISA/IEA) and functional group (GS/GE) groupings. As a result of operations and support around 837 and 835 transactions, "envelopes" are now generally understood to be associated at the ISA and GS levels. If this reference to "electronic envelope" is meant to refer to the transaction grouping within ST/SE, then it would make sense but is still somewhat misleading. If it specifically refers to the BIN segment alone, then the term "envelope" should not be used. A more appropriate term might be "container."

Proposed Rule: On medication and rehabilitation, additional implementation guides cite the NDC codes.

Issues: Clarify industry understanding of when NDC codes are allowed.

WellPoint Comment: We recommend that the final rule clarify that NDC codes are allowed in the relevant attachment types.

Modifications to Standards and New Attachments (Page 56013)

Proposed Rule: The proposed rule set forth 6 types of electronic attachments (AIS) that can be used in claims attachments, and LOINC codes associated with those attachment types.

Issues: Whether industry business needs require development of additional LOINC codes.

WellPoint Recommendation: WellPoint believes that additional LOINC codes should be developed, prior to promulgation of this final rule, for the additional AIS we suggest that CMS adopt, as set forth in the attached chart.

Costs and Benefits (Page 56016)

Proposed Rule: CMS solicits industry comments on cost and benefit analysis in adopting the electronic claims attachments rule.

Issues: CMS views health plans' implementation of the electronic claims attachments as a minor incremental cost compared to implementation of the HIPA Transactions Standards and Code Sets rule, because covered entities have readied their systems for the other X12 transactions and will have ample experience with X12 by the time the final electronic claims attachments rule is effective.

WellPoint Comment: We wish to comment that our current day processing expertise and strength is firmly in the area of ANSI X12 processing. Our HL7 experience is very limited. Therefore, CMS' assumption that plans will only incur minor incremental costs in implementing the 277/275 transactions is unwarranted.

WellPoint Recommendations to the Additional Information Specifications

AIS0001 -- Ambulance

File Code	NPRM Page	Issue Identifier	Current Text	Suggestions/Comments
CMS-0050-P	56001	**ATTACHMENT CONTENT AND STRUCTURE** -- Invites comments on the implementation guide for the attachment content, and format, and the transaction's function. **Ambulance Service Attachment AIS**	Page 7-9, Allowable LOINC codes for Ambulance Service Attachment	Remove duplication in comparison to 837. Duplication as follows (LOINC code vs 837 2300 Loop Segment and Element): 18584-3=CR103 (Kg allowed in LOINC), 15517-6=CR103, 15509-3=CR104 (3 more values in LOINC code set), 15510-1=CR106, 18588-4=CR110, 18591-8=CRC03, 18592-6=CRC03. Reason: Per 837P HIPAA Implementation Guide, all of these elements are required per the situation where the claim is an ambulance claim. Claim will be an ambulance claim when the case is that Ambulance attachment has been requested. Implication is that either provider did not submit a HIPAA compliant claim or provider must provide duplicate ambulance data to Health Plan.

AIS0002 -- Emergency Department

AIS Page	Section	Current Text	Suggestions/Comments	Reason
6	2.3	No pain severity assessment	Include Pain severity assessment score data point, either mild, moderate, severe or 1/10 to 10/10 scale.	This is an important assessment that is seen currently on the large majority of our ER records in Virginia.

WellPoint Recommendations to the Additional Information Specifications

AIS0003 -- Rehabilitation

AIS Page	Section		Current Text	Suggestions/Comments	Reason
No Comments					

AIS0004 -- Clinical Reports

AIS Page	Section		Current Text	Suggestions/Comments	Reason
N/A	N/A	N/A		Need LOINC codes specific to a request for pre-op photographs. For example: 1. For procedure code 15823 blepharoplasty, pre-operative photos are requested in order to document the upper eyelid margin per coverage criteria. 2. For procedure code 15831 abdominoplasty, pre-operatives photos are requested in order to determine if the panniculus hangs below the level of the pubis per coverage criteria.	Medical Review requests photos in situations mentioned in suggestions/comments.
Page 3	1.4	Fee text		Typo - "free" text	Looks like "f" and "r" are overlaid
Page 1	1	N/A		General (positive) Comment: LOINC at component level - Med Review sees as a benefit because we can be more specific with requests	Saves time - easier to locate pertinent information

WellPoint Recommendations to the Additional Information Specifications

Page 1	1	N/A	General (positive) Comment: LOINC modifiers - Med Review sees as a benefit we can be more specific with requests.	Reduces volume of irrelevant documentation - saves time and storage costs
Page 1	1	N/A	General (concern) Comment: LOINC Codes - Med Review not familiar with codes; therefore, training will be required	May be difficult to extract a "working set" of codes from RELMA for incorporation into a user interface
N/A	N/A	N/A	Not found in document. Need LOINC code for Service Date/Onset Date of Accident/Injury. Possible fit in document for code might be section 11492-6.	Information required by Processors in certain circumstances in order to process a claim
N/A	N/A	N/A	Not found in document. Need LOINC code for Amount charges for each service. Possible fit in document for code might be section 11492-6.	Information required by Processors in certain circumstances in order to process a claim
N/A	N/A	N/A	Not found in document. Need LOINC code for Documentation of Medical Necessity. Possible fit in document for code might be section 11492-6.	Information required by Processors in certain circumstances in order to process a claim
N/A	N/A	N/A	Not found in document. Need LOINC code for Dates services were rendered. Possible fit in document for code might be section 11492-6.	Information required by Processors in certain circumstances in order to process a claim
N/A	N/A	N/A	Not found in document. Need LOINC code for Explanation of Medicare, Blue on Blue, or other Carrier Benefits. Possible fit in document for code might be section 11492-6.	Information required by Processors in certain circumstances in order to process a claim

N/A	N/A	N/A	Not found in document. Need LOINC code for Itemized Bills/Breakdown of charges. Possible fit in document for code might be section 11492-6.	Information required by Processors in certain circumstances in order to process a claim
N/A	N/A	N/A	Not found in document. Need LOINC code for Cardiac Ablation. Possible fit in document for code might be section 11492-6.	Information required by Processors in certain circumstances in order to process a claim
N/A	N/A	N/A	Not found in document. Need LOINC code for Description of code used. Possible fit in document for code might be section 11492-6.	Information required by Processors in certain circumstances in order to process a claim
N/A	N/A	N/A	Not found in document. Need LOINC code for Prescription for Durable Medical Equipment. Possible fit in document for code might be section 11492-6.	Information required by Processors in certain circumstances in order to process a claim
N/A	N/A	N/A	Not found in document. Need LOINC code for Purchase Price for Durable Medical Equipment. Possible fit in document for code might be section 11492-6.	Information required by Processors in certain circumstances in order to process a claim
N/A	N/A	N/A	Not found in document. Need LOINC code for Referring Physicians Name and Address. Possible fit in document for code might be section 11492-6.	Information required by Processors in certain circumstances in order to process a claim
N/A	N/A	N/A	Not found in document. Need LOINC code for Study Models. Possible fit in document for code might be section 11492-6.	Information required by Processors in certain circumstances in order to process a claim
N/A	N/A	N/A	Not found in document. Need LOINC code for Tracings. Possible fit in document for code might be section 11492-6.	Information required by Processors in certain circumstances in order to process a claim

N/A	N/A	N/A	Not found in document. Need LOINC code for Valid CPT for Services Rendered. Possible fit in document for code might be section 11492-6.	Information required by Processors in certain circumstances in order to process a claim
N/A	N/A	N/A	Not found in document. Need LOINC code for Tilt Table Study. Possible fit in document for code might be section 11492-6.	Information required by Processors in certain circumstances in order to process a claim
N/A	N/A	N/A	Not found in document. Need LOINC code for Neuropsychological Evaluation. Possible fit in document for code might be section 11492-6.	Information required by Processors in certain circumstances in order to process a claim
N/A	N/A	N/A	Not found in document. Need LOINC code for Skilled Nursing Facility records from (specify dates). Possible fit in document for code might be section 28563-5.	Information required by Processors in certain circumstances in order to process a claim
N/A	N/A	N/A	Not found in document. Need LOINC code for MRA Report. Possible fit in document for code might be section 18726-0.	Information required by Processors in certain circumstances in order to process a claim
N/A	N/A	N/A	Not found in document. Need LOINC code to be able to Request a span of dates for a questionable pre-existing claim. Possible fit in document for code might be section 11492-6.	Information required by Processors in certain circumstances in order to process a claim
Page 7	Table 2.5 LOINC report subject identifier codes	Anesthesia records	Suggest moving to Structure type of Specific or add additional LOINC codes to request 1) Anesthesia start/stop time 2) request the name of the supervising Physician	Duration of Anesthesia is need for claim processing but we don't always need the entire record. When a CRNA is providing the anesthesia the name of the supervising physician may be required.

WellPoint Recommendations to the Additional Information Specifications

Page 7	Table 2.5 LOINC report subject identifier codes	Dialysis Records	Need to add LOINC to request the onset/first date of dialysis	This is needed to determine order of benefits for claims processing and is not always in the dialysis records
Page 7	Table 2.5 LOINC report subject identifier codes	Dental Operative Notes	(LOINC code needed) This is a specific Structure type but there is not a LOINC code that allows the request of dental x-rays	This may be needed in determination of benefits for claims processing
Page 8	Table 2.5 LOINC report subject identifier codes	Provider Operative Notes	(LOINC code needed) This is a specific Structure type but there is not a LOINC code that allows the request of pre op photos	This may be required when determining medical necessity for a surgical procedure
N/A	N/A	N/A	A LOINC code is needed for Implants to request a copy of the purchase invoice.	This is needed when an Implant is billed on an Inpatient Bill and negotiated rates needs to be determined.
N/A	N/A	N/A	A LOINC code is needed for Ophthalmology/Optometry to request the date of Cataract surgery.	For Claims processing this is needed to determine if this is a covered benefits when glasses are purchased post surgery
N/A	N/A	N/A	A LOINC code is needed for DME(durable medical equipment) that would allow the request of purchase price and duration of time the equipment is needed. The ordering Physician name and address would also be required	Information is needed in Claims processing to determine benefits
N/A	N/A	N/A	A LOINC code is needed for Accident Information to request the date/onset of injury and accident details.	This is needed by claims processing to determine benefits and third party liability.
N/A	N/A	N/A	Within table 3.4.1 Cervical Spine X-Ray, need LOINC code for Date and Time of X-ray	Possible need date/time of current test so can compare from when last one was done and know the time frame
N/A	N/A	N/A	Within Table 3.4.2 CT Head Study, need LOINC code for Date and Time of CT Scan	Possible need date/time of current test so can compare from when last one was done and know the time frame

N/A	N/A	N/A	Within table 3.4.3 CT Extremity Study, need LOINC code for Date and Time of CT scan	Possible need date/time of current test so can compare from when last one was done and know the time frame
N/A	N/A	N/A	Within table 3.4.4 MRI Study Head, need LOINC code for Date and Time of MRI	Possible need date/time of current test so can compare from when last one was done and know the time frame
N/A	N/A	N/A	Within table 3.4.7 CT Guidance for Aspiration Study, need LOINC code for Date and Time of Aspiration Study	Possible need date/time of current test so can compare from when last one was done and know the time frame
N/A	N/A	N/A	Within table 3.4.8 Ultrasound Study of Neck, need LOINC code for date and time of Ultrasound	Possible need date/time of current test so can compare from when last one was done and know the time frame
N/A	N/A	N/A	Within table 3.4.5 Mammogram Screening Study, need to add LOINC code for History of Previous Cancer	This would be an important piece of information when review a mammogram
N/A	N/A	N/A	Within Table 2.5 of Care Provider Notes, need to add the following LOINC note sets: Parent LOINC code 19004-1 LOINC code 27574-3 (Skilled Nursing Tx Plan, Progress Notes and Attainment of Goal)	This appears to be SNF or Home care services records. May be needed if home care or SNF stay is reviewed
N/A	N/A	N/A	Within Table 2.5 of Care Provider Notes, need to add the following LOINC note sets: Parent LOINC code 19004-1 LOINC code 27573-5 (skilled nursing tx plan, plan of treatment [narrative])	This appears to be SNF care and would include the reason for admission. This would be needed for UM activities
N/A	N/A	N/A	Within Table 2.5 of Care Provider Notes, need to add the following note sets: Parent LOINC code 27572-7 LOINC code 27572-7 (skilled nursing tx plan, initial assessment)	This appears to be SNF care and would include the initial eval. This would be needed for UM activities

N/A	N/A	N/A	Within Table 2.5 of Care Provider Notes, need to add the following note sets: Parent LOINC code 19003-3 LOINC code 27726-9 (respiratory therapy)	This is a respiratory therapy report and would contain info necessary for UM activities
N/A	N/A	N/A	Within 18726-0 Radiology Study Reports, need to add the following note sets: Parent LOINC code 18726-0 LOINC code 24905-2 (MRI of Shoulder)	Almost all other MRI's of specific body parts are listed. Why not this one?
N/A	N/A	N/A	Within set 266441-6 Cardiology Studies, need to add the following note sets: Non-exercise stress test. Unable to locate LOINC code	Also known as Thallium stress test or possibly Persantine stress test. May be used in evaluation for candidacy of Heart transplant
N/A	N/A	N/A	Within set 28563-5 Care Provider Notes, need additional note set for Wound Care Management Notes. We couldn't find a LOINC code for this set.	Frequently used in SNF and Home care. Gives good indication of wound management
N/A	N/A	N/A	Within set 28563-5 Care Provider Notes, need additional note set for Case Management Notes.	Used in Hospital and Home care settings. Frequently gives overview of plans for discharge
N/A	N/A	N/A	Within set 28563-5 Care Provider Notes, need additional note set for Medication record.	Used in Hospital and SNF settings. Frequently gives overview of medications given
N/A	N/A	N/A	Within set 28563-5 Care Provider Notes, need an additional note set for MD orders.	Used in Hospital, Home care and SNF settings to verify what physician has ordered.
N/A	N/A	N/A	In Table 2.5, within section 28650-0 (Clinical Notes & Chart), need LOINC code added for Nurses Notes	Daily clinical status of the patient's condition is documented

6	2.3	"Certain clinical reports include LOINC codes for the name and identifier of the signing practitioner....."	Comment: I am concerned over need for an electronic signature for documents that are adhoc and not a specific report.	Past history has demonstrated that billers complete info and clinical info is not always correct when not communicated via a clinical person. Have seen where things are communicated because it is what the payer wants vs the actual clinical condition of t
N/A	N/A	N/A	Comment/Concern: Have not read specifically but have been told that this format will not allow an NDC be submitted to the payer. Even if the billing provider submits an NOC or NOS code.	NDC codes are critical to our business. For NOC or NODSS pharmaceuticals- it helps us identify the drug and dosage so we pay fair market value - all info driven by the NDC code.

AIS0005 – Lab Results

AIS Page	Section	Current Text	Suggestions/Comments	Reason
			There does not appear to be anywhere for the payer to free text on the 277 for the AIS0005. The provider has the capability but in reviewing the attachment information I do not see anywhere for the payer to free text in the 277. Many times when requesting a Lab Report from a provider it is because they are submitting unlisted laboratory procedures. We cannot utilize LOINC's when we do not know the test being performed.	

WellPoint Recommendations to the Additional Information Specifications

AIS0006 -- Medications

AIS Page	Section	Current Text	Suggestions/Comments	Reason
AIS 0006	Table 3.3	LOINC Codes	This AIS contains a list of all valid LOINC codes for this attachments	There are situations when the weight of the patient is pertinent to the Medical Review process.
AIS 0006	Page 6	Human-decision variant with textual information		There is some concern that allowing the ability to "free format" this information could lead to erroneous data being provided.

DELTA DENTAL

www.deltadental.com

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.

Delta Dental Plans Association
1515 W. 22nd Street, Suite 450
Oak Brook, IL 60523

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

Comment on Claims Attachment Types

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

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

Future Periodontal Care Rule

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

Combined Clinical and Administrative Data

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

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

Initial Types of Claims Attachments

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

Dental Benefits Attachments

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

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

Timely Process for Standards Adoption

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

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

Effective Date of Final Standards

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

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

Comments on Standards for Claim Attachments

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

LOINC Code Usage

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

AIS Books Technical

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

X12 and HL7 Standards

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

Maintenance of LOINC

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

Comments on Definitions and Scope of the Proposed Rule

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

Definition of Claims Attachment

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

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

Definition of a Claim

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

Definition of Adjudication of a Claim

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

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

Definition of Solicited and Unsolicited Information

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

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

Definition of Adjudication and Post-Adjudication

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

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

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

Other Definitional Issues

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

Comments on Voluntary Implementation

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

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

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

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

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

Comments on Cost Impact

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

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

Cost Information Related to Claims Attachments

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

Frequent Claims Attachment Types

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

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

Comments on Privacy and Security Rules

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

Exercise of Discretion

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

Comment Period Extension

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

* * * * * * * * *

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

Sincerely,

Kim E. Volk

Kim Volk

President and Chief Executive Officer

Delta Dental Plans Association

Chart Attachment

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

C C R	162.1002 (LOINC) 162.1915 162.1925	RT RT RT	Standards	Yes	**Is there agreement with the proposed X12 and HL7 standards, including versions and 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 Variant 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.
R	II, C, 2 Overview of Clinical Document Architecture	P	Standards	Yes	Comment #1: Recommend to move to CDA release 2 assuming that there is a pilot 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.
C	II.C.5 Electronic Claims Attachment Types	P	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.

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

	Reg is 162.1910 –C	RT			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.
R	II, E Attachment Content and Structure	P	Standards	No	Comment #1: Recommend that the 64 MB be left as a recommendation and not be a standard or maximum.
R	II, A Definitions	P RT	Standards	Yes	Included in text letter
R	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

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

C	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, clearinghouse, payers, billing offices. d. Recommend that testing be done with the Human Variant. Phase in the Computer variant 2 years after the HDV is in place.
C	II, D, 9 HC Clearinghouse perspective	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-workgroup on claims attachments.
N/A	N/A	N/A	Implementation		
C	II.D.2 Solicited vs. Unsolicited Attachments Reg is 162.1910 –C	P RT	Business Process	Yes	**Completeness/Single iteration process that only allows a single 277 request and a single 275 reponse.** Comment #1: Payers should endeavor for completeness of the request by asking all known questions at the initial request with the understanding that further questions may be asked based on information contained in the initial response. Payors 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.

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

C	II.D.2 Solicited vs. Unsolicited Attachments 162.1910 (a)(3)	P RT	Business Process	No	**Unsolicited 275 using payer instructions method.** Comment #1: A provider, based on prior arrangement or experience with a plan, may send unsolicited attachments until a 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	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 the 837 claim i.e. not required to be bundled in the same interchange or transmission file (ISA/ISE), as long as they are sent in the same daily cycle.
R	II, D Electronic Claims Attachment Types Business Use	P	Business Process	No	**Discussion of the post adjudication and the current definition of what is an attachment. Is it permissible but not required to used attachments for purposes other than adjudication.** Comment 1: The regulation should not be interpreted to disallow health plans from collecting information via the claims 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 standards in all other situations where they meet business needs for information exchange, prior authorization, post adjudication, public health reporting, etc.
R	II, D, 3 Coordination of Benefits	P	Business Process	No	**Is the method proposed for use of attachments with COB appropriate?** Comment #1: Add to the COB section language that will specifically state that if a payer receives

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

					attachment information, they are not required to send this information to the subsequent payer.
C	II , D.6 Connection to Sugnatures	P	Business Process		No comment
L	II, H Requirements (HP, CH, Providers)	P	Business Process		No comment
N/A	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 additional information (electronic or hardcopy), does the health plan have to use the 277 if a provider requests it to be used. Example, 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 of "needing additional clinical information," i.e. needing information that would be in a claim attachment. Can that process continue? Or does the request for that information now have to come through a 277 RFI? If this process can continue, how does the provider know what additional information to submit? 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?

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

L	162.1910 (a)(2) Electronic health care claims attachment request transaction	RT	Clarification	No	Comment #1 Please clarify the workflow is being described here at (2) "(a) The health care claims attachment request transaction is the transmission, from a health plan to a health care provider, of a request for attachment information to support the adjudication of a specific health care claim. A health plan may make such a request ... (2) In advance of submission of the health care claim" –
R L	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 just 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.
N/A	VI	P	Impact		**Comments on the Impact Analysis section. Are the citations related to the cost & benefits findings**

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

	Regulatory Impact Analysis		Analysis	Yes No	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. This 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 consistently 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

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

					the named attachments in order to accomplish payment.

America's Health
Insurance Plans

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Suite Five Hundred
Washington, DC 20004

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NOV 22

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

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.

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BlueCross BlueShield
of Illinois

NOV 22

November 30, 2005

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

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)

Health Care Service Corporation, a Mutual Legal Reserve Company (HCSC), doing business as Blue Cross Blue Shield of Illinois, Blue Cross Blue Shield of Texas and Blue Cross Blue Shield of New Mexico appreciates the opportunity to comment on the Proposed Rule to adopt standards for an electronic claims attachments under Title XI of the Social Security Act subpart C Administrative Simplification.

I would like to state that HCSC supports the adoption of standardized electronic transactions, including the electronic claims attachments transaction, to improve the cost and effectiveness of healthcare delivery.

Please find enclosed, HCSC's detailed comments.

Sincerely,

Donald W. Donahue

Donald W. Donahue
Vice President, Corporate Subscriber Services

Enclosure

BlueCross BlueShield of Illinois

Comments on Proposed Rule NPRM CMS-0050-P

Page #	Section #	Proposed Rule Section	Proposed HCSC Comment
55994	Section B - Effective Dates	Covered entities must comply with the standards for electronic health care claims attachments 24 months from the effective date of the final rule unless they are small health plans. Small health plans will have 36 months from the effective date of the final rule to come into compliance.	We do not support the 24 month time frame between the effective date of the final rule and compliance / enforcement. Past experience with implementation of HIPAA mandates has shown that clearing houses and small third party vendors typically do not release supporting software until near the compliance date. That will not give the industry sufficient time to test the process. We are suggesting an additional 180 days be added after the compliance date, and prior to the enforcement date. This 180 days is to allow trading partners (such as clearing houses, third party vendors, providers and health care payers) time to correct inconsistencies and potential differences in interpretations.
55995	Section C - Overview of Key Information for Electronic Health Care Claims Attachments - #2 - Overview of Clinical Document Architecture	We invite comments on the pros and cons of each CDA release, the issues related to the use of a style sheet to permit use of either CDA release, and the costs and timing associated with implementing one release version over the other.	We support adopting CDA Release 2.0 because of its compatibility with vendor applications and clinical systems. CDA Release 2.0 is more compatible with applications currently used by Government entities (such as Veterans Administration and the Department of Defense). CDA Release 2.0 is downward compatible, while CDA Release 1.0 is not upward compatible. That lack of interoperability would place a financial burden on users who would be required to maintain and utilize two Release versions.
55997	Section C - Overview of Key Information for Electronic Health Care Claims Attachments - #5 - Electronic Claims Attachment Types	Comments are invited as to whether the six proposed attachment types are still the most frequently requested by health plans, and if there are others that are equally or more pressing for the industry.	We agree that the six proposed attachment types are most commonly requested. We do not see enough volume of requests for other attachment types to justify inclusion of additional booklets in the regulation. However, the regulation should not exclude the use of additional attachments between two trading partners when mutually agreed to by the partners. Additionally, there is duplication between the 837 Claim transaction information and that contained on the Ambulatory AIS. This duplication needs to be addressed and the appropriate use clarified in the final regulation. We also believe that the regulation needs to clarify that if a provider chooses to utilize one electronic Claim Attachment transaction type, then all Claim Attachment types must be done electronically.

A Division of Health Care Service Corporation
An Independent Licensee of the Blue Cross and Blue Shield Association
300 East Randolph Street
Chicago, Illinois 60601-5099

Comments on Proposed Rule NPRM CMS-0050-P

Page #	Section #	Proposed Rule Section	Proposed HCSC Comment
55997	Section C - Overview of Key Information for Electronic Health Care Claims Attachments - #6 - Format Options (Human vs. Computer Variants) for Electronic Claim Attachments	Under this proposal, the electronic health care claims attachments may be sent in one of three formats. Two of the formats are in the category of Human Decision Variant, and the third format is a Computer Decision Variant.	We support using both Human Decision Variant and Computer Decision Variant as viable options for transmitting information. This approach allows the flexability for both the payer and provider to develop and implement processes at their own pace and according to their business needs.
55998	Section C - Overview of Key Information for Electronic Health Care Claims Attachments - #7 - Combined Use of Two Different Standards Through Standard Development Organization Collaboration	The purpose of proposing the combined use of both ASC X12N and HL7 standards is to address both the administrative and clinical aspects of the attachment transactions from a format and content perspective. However, because these two standards have not been used together before, we solicit industry feedback regarding this strategy.	We support combining the two standards. Using both standards will serve as a bridge between clinical services (HL7) and administrative standards (ASC X12N), enhancing interoperability for health information exchange.
55999	Section D - Electronic Health Care Claims Attachment Business Use - #2 Solicited vs Unsolicited Electronic Health Care Claims Attachments	We are proposing that health care providers may submit an unsolicited electronic attachment with a claim only when a health plan has given them specific advance instructions pertaining to that type of claim or service.	We support this for all the reasons stated in the proposed rules. Using this approach we retain the ability, through our Trade Partner Agreements (TPA), to allow unsolicited attachments for specified types of claims or services as defined by our business requirements. A provider, when submitting a Claim Attachment transaction unsolicited (per prior arrangement), must bundle the Claim Attachment transaction with the Claim transaction to make it a complete claim.

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Chicago, Illinois 60601-5099

Comments on Proposed Rule NPRM CMS-0050-P

Page #	Section #	Proposed Rule Section	Proposed HCSC Comment
55999	Section D - Electronic Health Care Claims Attachment Business Use - #2 Solicited vs Unsolicited Electronic Health Care Claims Attachments	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 believe a payer should be allowed to request a claims attachment more than one time. Often a claim will be reviewed because it was submitted with a miscellaneous code. Additional information is needed to determine the service and pricing. Once the information is received, it could be determined that the claim also needs to be reviewed for medical necessity. This requires the medical reviewer to ask for additional information. This same scenario could happen with any claim that is being reviewed, where the information received leads to additional questions. If we are required to make a determination with the information we have, then the claim will most likely be denied. This will merely move the workload to the Appeals Unit where they will request the additional information to be submitted on paper. This "one-time" requirement is counter to the "minimum necessary" requirement since we would need to request information we conceivably "might" need in order to adjudicate the claim. Payers should endeavor for completeness of the request by asking all known questions with the initial request, with the understanding that further questions may be asked based on the information contained in the initial response. We have concerns over the limitations of having only one electronic request transaction per claim.
55999	Section D - Electronic Health Care Claims Attachment Business Use - #3 - Coordination of Benefits	With respect to electronic attachment requests and responses in a COB scenario, we assume that the primary health plan will request only the attachments it needs to adjudicate its portion of the claim. The secondary health plan would request its own attachments in a separate transaction send directly to the health care provider.	We support the decision to allow the secondary payer to request information separate from the primary payer. The secondary payer may require additional or different information that the primary payer.

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Comments on Proposed Rule NPRM CMS-0050-P

Page #	Section #	Proposed Rule Section	Proposed HCSC Comment
56000	Section D - Electronic Health Care Claims Attachment Business Use - #6 Connection to Signatures (Hard Copy and Electronic)	We solicit impact from the industry on how signatures should be handled when an attachment is requested and submitted electronically.	In today's world if the provider has a signature on file, an indicator is placed on the claim and the indicator is accepted as the electronic signature. We believe that today's business practices are sufficient and that a scanned image of a signature is not required.
56001	Section D - Electronic Health Care Claims Attachment Business Use - #9 - Clearinghouse Perspective	Must be able to accept and transmit a standard transaction when asked by a health care provider or health plan for which they serve as a business associate for those functions. Since both health care providers and health plans have dependencies on the health care clearinghouses, it is imperative that the health care clearinghouse industry participates actively in the rulemaking process, standards review, and implementation assessment as well.	Based on experience from past HIPAA implementation transactions, we suggest that the entities would need to show that they are compliant by the compliance date but would be given another 180 days until the effective date. Refer back to comments on Section B - Effective Dates.
56001	Section E - Attachment Content and Structure	The implementation guide for the X12-275 response transaction permits up to 64 megabytes of data in a single transaction. Industry comment on file size is also welcome.	No Comment on the size of 64 megabytes since there is not enough industry data to develop an opinion at this time. However, the regulation sets 64 megabytes as a limitation, where as the implementation guide sets 64 megabytes as a recommendation. We believe it should be a recommendation.

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Page #	Section #	Proposed Rule Section	Proposed HCSC Comment
56013	Section H - Requirements - #3 Maximum Data Set	Four of the attachment specifications have a finite set of LOINC® codes that can be used to ask the questions for those services. The specifications for Lab results and Clinical reports do contain pre-defined lists of codes because clinical developments in those two areas necessitate the ability to use and request information about new tests and reports. Thus, we ask that during the comment period health plans and health care providers engage fully in the process of evaluating this maximum data set and the required, situational, and optional elements, and provide us with comments on these issues.	We suggest making Additional Information Specifications (AIS) booklets maintained by HL7 "external" to the regulatory process. If the data sets are maintained by HL7 they would not go through the regulatory process. Having AIS booklets maintained by HL7 will allow a more efficient, timely response to industry needs when adding new LOINC codes. While we realize we would no longer have the opportunity to comment via an NPRM, we would be able to voice our comments through participation in HL7.
56018	Section VI - Impact Analysis - Costs and Benefits - Cost and Benefit Analysis for Health Plans	We solicit industry input as to the anticipated implementation costs for technical, business and operational changes that may be required, as well as any anticipated savings.	We are not able to comment specifically on additional costs or savings at this time; however we expect significant costs because of changes to the infrastructure and the number of systems involved in the implementation. We encourage CMS sponsored industry pilots be conducted to assist in identifying costs and savings.
56024	Section 162.1920 d - Electronic Health Care Claims Attachment Response Transaction	Response information may be free text, scanned documents or embedded document within the BIN segment of the response.	Recommend that the content of the BIN not be validated for data not being used.

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Comments on Proposed Rule NPRM CMS-0050-P

Page #	Section #	Proposed Rule Section	Proposed HCSC Comment
56024	Section 162.1925 (1915) - Standards and implementation specifications	This implementation guide is based on the October 2001 ASC X12 standards, referred to as Version 4, Release 5 (004050)	A new version of the ASC X12 standards (5010) is awaiting approval from that workgroup. We propose that HHS share comments from this NPRM with ANSI. The comments would then be incorporated by ANSI into the 5010. The final rule could be reissued, adopting the 5010 version, giving the industry time to review and comment on the 5010.
275 Implementation Guide	Section 2.3.4 Associated Data (102)	The Associated Data (102) will be used to provide HL7 syntax validation. It can be requested by one of the trading partners. This transaction set is used to acknowledge (accept/reject) the HL7 standard in the 275 BIN segment. This transaction is based on mutual agreement between trading partners, unless mandated under HIPAA. If not mandated the authors strongly suggest the use of the 102 Transaction.	Since acknowledgements are not mandated, we recommend the use of the 824 transaction as acknowledgement of receipt of a 275 transaction. The 824 allows for error codes that address both ASC X12 and HL7 when acknowledging the 275 transaction.

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a2

NUCC

National Uniform Claim Committee

DEC 12 2005

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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)

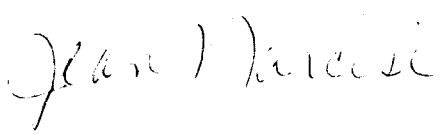
We would like clarification of the language in Section 162.1910 (a) (2) that indicates that an attachment can be sent in advance of a health care claim. The process being allowed by this language is not a workflow that was considered in the development of the standard.

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

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WORLD **PRIVACY** FORUM

2033 San Elijo Avenue #402
Cardiff by the Sea, CA 92007

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]

Dear Sir or Ms.:

Attached please find one original and two copies of 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) on HIPAA Administrative Simplification: Standards for Electronic Health Care Claims Attachment, Proposed Rule. [45 CFR Part 162] [CMS-0050-P].

If you have any questions about our submission or need to talk to anyone about this submission, please do not hesitate to contact me, Pam Dixon, at 760-436-2489 or at info2005@worldprivacyforum.org.

Kind regards,

Pam Dixon
Executive director,
World Privacy Forum

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,

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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.

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.

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.

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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.

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.

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 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.

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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>.

(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

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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.

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 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

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

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,

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November 22, 2005

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RE: [CMS-0050-P] HIPAA Administrative Simplification: Standards for Electronic Health Care Claims Attachments; Proposed Rule (70 Federal Register 55990) September 23, 2005.

Dear Dr. McClellan:

On behalf of our 4,800 member hospitals, health care systems, and other health care organizations, and our 33,000 individual members, the American Hospital Association (AHA) appreciates this opportunity to comment on the proposed rule on standards for electronic health care claims attachments as mandated by the Health Insurance Portability and Accountability Act (HIPAA).

We welcome many of the recommendations in the proposed rule but wish to emphasize the importance of having an attachment standard that also imposes specific limitations on its use. Without strict limits, we will see inappropriate use of the attachment standard. The practice of requesting an attachment should be rare and never become a routine item that would accompany all claims for a specific type of service. Health plans and others that require routine reporting of a particular piece of data have opportunities to present their requests to the appropriate data content committees. Misuse of the attachment standard will increase not only the administrative burden and costs for providers, but more importantly, the potential for privacy violations.

The proposed standards introduce several elements that are not widely used in today's billing process. As such, they will require new methods for capturing and handling clinical information at significant costs for providers. In fact, we believe the attachment standards will yield a zero net return on investment for hospitals. Moreover, the attachment standard will be far costlier to implement than the previous HIPAA claims standards.

Hospitals will need time to meet these requirements. We recommend a contingency period of at least three years after the final rule is issued to allow hospitals adequate time to prepare budgets, train staff and conduct testing with their trading partners.

We offer detailed comments to specific sections of the proposed rule in our attachment. However, one area not directly mentioned in the proposed rule, but of significant concern to providers, involves the establishment of a formal communication process between providers and health plans.

Today, many claims are delayed pending additional information from the provider. However, hospitals are often unaware that the health plan has submitted a request for additional information and are left wondering about the status of their claims. The health plan's request is often lost as it moves from the health plan to the clearinghouse and sometimes even to an unspecified location within the provider's operations. The communication flow is unpredictable.

Clearinghouses usually do not know how to handle such requests, and consequently, they are unable to direct the request to the responsible person at the provider's operation. We would welcome a set of comprehensive business rules that would improve how covered entities would formally communicate with one another to handle such requests on a timely basis. While the "request" transaction standard (the 277) includes specific contact information about the contact at the health plan, there is no comparable segment for the provider to indicate the contact person within its operations. It is unfortunate that the claim standard (the 837) does not have a similar segment that would allow providers to designate contact persons within their organizations to handle specific types of attachment requests. We recommend the Centers for Medicare & Medicaid Services (CMS) establish a technical group to explore options for creating better communications between providers and health plans.

Finally, the AHA suggests that CMS issue the rules for ICD-10 adoption prior to finalizing the rule for claim attachments. ICD-10 provides greater clinical specificity and has the ability to reduce or eliminate the reliance on claim attachments. Since resources are limited for handling new system changes, it is important to weigh carefully the derived benefits. While the claim attachment standard is estimated to benefit less than 2 percent of all claims, the adoption of ICD-10 benefits all claims and allows for a more refined reimbursement approach. It also improves public health's disease surveillance abilities and provides hospitals with better information to improve the quality of care.

The AHA appreciates this opportunity to comment on the proposed rule for adopting standards for electronic claims attachments. If you have any questions or concerns about the comments presented here or in our attachment, please contact George Arges, AHA senior director of policy, at (312) 422 -3398 or garges@aha.org.

Sincerely,

Rick Pollack
Executive Vice President

Attachment

American Hospital Association
Detailed Comments on the Proposed Rule for HIPAA Claims Attachments

Definitions (pg 55993-4)
Generally, we agree with the definitions as stated in the proposed rule.

Effective Dates (pg 55994)
The proposed rule calls for implementation to begin two years after the final rule for all covered entities except small health plans, which have an additional year.

We recommend a three-year implementation period to allow providers sufficient time to budget, train and test these standards. We further suggest CMS consider a staggered implementation schedule with specific sequencing of the attachment standards mentioned in the proposed rule. Hospitals have indicated that an orderly progression for each of the attachment standards would also be best for all parties.

Overview of Clinical Document Architecture (CDA) (pg 55995)
Proposed language includes a discussion and overview of the merits of using XML-based standards to simplify data exchange and database connectivity. CDA of HL7's "style-sheet" is available (it could be CDA release 1 or CDA release 2); or, organizations may choose to create their own style-sheet.

We recommend CMS adopt CDA release 2, but only if it has undergone satisfactory pilot testing prior to the issuance of the final rule. There are benefits associated with release 2 that warrant serious consideration for adoption as the CDA style-sheet standard. We urge immediate pilot testing of CDA release 2 so evaluations are available prior to the final rule. If results are satisfactory, release 2 should be adopted.

Transactions for Transmitting Electronic Attachments (pg 55996)
This section calls for the adoption of Version 4050 of the X12N 277 Attachment Request and the X12N 275 Attachment Response, and solicits comments on implementing this version of the attachment standard.

The AHA recommends adopting Version 5010 for these standards. By the time the final rule is issued, it is likely that 5010 will have replaced the existing named standards. Using the same version across standards would be best, especially since the intent is to supplement the information contained in the claim standard.

Electronic Claims Attachment Types (pg 55996-7)
This section seeks comments on whether the six attachment types mentioned are still the most frequently requested by health plans. It also asks if there are other attachments for adoption and, if so, should these be allowed on a voluntary basis.

Of the six attachment types mentioned in the proposed rule, the one pertaining to emergency services appears troublesome. According to several large hospitals and health systems, a request by health plans for emergency room notes rarely occurs. This may be due to data elements introduced to the claim standard in recent years. For instance, the Balanced Budget Act of 1997 introduced language pertaining to emergency room services and the prudent layperson. The National Uniform Billing Committee (NUBC), which has responsibility for the data content to the institutional claim, added the "patient's reason for visit" to the claim in 1999. This code uses the ICD-9-CM codes to describe the basis for the patient's visit to the emergency room. Many health plans indicated this information would alleviate the need for asking for emergency room notes. We suggest CMS conduct a national survey of providers and health plans to gauge the frequency of use of the different attachment types.

The ambulance and rehabilitation therapies attachment types also include many data elements that are on the institutional claim. For instance, institutional-based ambulances report miles traveled as a revenue code within the UB-92 data set and in the SV2 segment of the 837 (institutional) claim transaction. Similar reporting occurs for plan of treatment dates and visits. Typically, these items are occurrence codes or value codes contained in the HI segment in the 837. We recommend reporting these data items within the institutional claim standard rather than in an attachment transaction.

The claim attachment should be used only as a supplement to the claim. If information is part of the institutional claim, a health plan should not request the same information in a claim attachment. Health plans must be prepared to handle the entire range of data elements that comprise the claim standard. Failure to do so would be a compliance violation on two fronts: they are unprepared to use the information reported in the claim standard; and they are misusing the attachment standard by asking for information contained in the claim.

Hospitals recommend several other types of attachments for future adoption. These include DME – Medical Necessity; Secondary Payer Questionnaire; Sterilization Consent Forms; and Medicaid Spend-down forms. These supplemental documents would alleviate delays in claims processing. We encourage the adoption of a formal process that involves the data content committees and the standard developing organizations. The data content committees, the NUBC, National Uniform Claim Committee and Dental Content Committee, already have a special consultative role as mentioned in the HIPAA legislation. Since their focus is on reviewing the data needs for a claim, they should be the first to review any new proposals to supplement the claim. Once these national committees approve a new type of attachment, they could work with the X12 and HL7 groups to ensure that the 275 and 277 standards and the corresponding implementation guides handle these new types of attachments.

Format Options -- Human vs. Computer Variants (pg 55997)

The proposed rule would allow sending claim attachments in one of three formats:

1. Human variant – scanned image of document;
2. Human variant – narrative text along with original LOINC request code; or
3. Computer variant – narrative text along with LOINC response code.

The AHA recommends that the final rule clearly states that a hospital may use any one of the three variants and that a health plan cannot force a hospital to use one variant over another. A health plan that is not ready to use the computer decision variant can still convert this format to a human decision variant.

Electronic Health Care Claims Attachment Business Use (pg 55998-9)
The proposed rule indicates that the attachment standards should not convey information that is already in the claim, but instead provide supplemental information to the claim. Supplemental information gives the medical justification for health care services provided to the individual when this is necessary for a health plan to adjudicate the claim.

We support the proposed rule's view that the electronic claim attachment process is not appropriate for post-adjudication reviews. Additionally, requests for attachments should not interfere with any state's prompt payment laws. Further, only the services in question should be subject to a delay in payment. Services not in question should be adjudicated expeditiously.

As mentioned earlier, the AHA opposes expanding the attachment standard to include post-adjudication reviews without an analysis of the merits. In 1993, a voluntary collaboration of health care organizations came together to develop a set of post-adjudication guidelines. This came at the request of Sen. William Roth of Delaware who was interested in establishing a post-adjudication review process that was fair to providers and health plans. The organizations that participated included the Health Insurance Association of America, Blue Cross Blue Shield Association, AHA, Healthcare Financial Management Association, and the Association of Internal Auditors. The group published The National Billing Audit Guidelines. We recommend reconvening this group, expanded to include a few more organizations such as government health plans (e.g. Medicare and Medicaid and others), to examine whether post-adjudication procedures could benefit from the use of attachment standards. There are numerous issues to explore before deciding to utilize the claim attachment standards in post-adjudication reviews.

Electronic Health Care Claims Attachment vs. Health Care Claims (pg 55999)
This section indicates that attachments not convey information that is already required on every claim; the purpose of the attachment is to convey supplemental information.

We agree that the attachment standards should be limited to providing supplemental information only. When the claim standard includes specific codes to describe a particular event or situation then providers should use the claim standard to report this information; health plans must be able to process this information. Health plans must stay current with billing codes and build the necessary logic in their processing systems to recognize this information.

Many health plans appear weak in handling the diagnosis and procedure codes reported in claims. The claim standard allows the provider to report up to 25 diagnoses and 25 procedure codes; however, many health plans, including Medicare, recognize and process only a small number of these codes. Some health plans have indicated that their claim

adjudication systems only handle the first three codes. This is extremely problematic since a patient with multiple co-morbidities or complications could easily require more than nine diagnosis or nine procedure codes to explain services provided for an episode of care. Health plans must have the ability to process and evaluate the entire number of clinical codes allowed on the claim standard. Otherwise, providers will receive requests for attachments that seek justification for the services that could have been derived if the health plans had the ability to process all of the clinical codes reported.

Coordination of Benefits (pg 55999)

The proposed rule indicates that each health plan (primary, secondary or tertiary) should file a separate request for attachments if they need information to help them adjudicate their portion of the claim. The health plans should not forward their attachment information to subsequent payers.

We concur with the proposed language supporting the minimum necessary concept. We support the proposal to require health plans to submit their own requests for attachments only if they need this information to adjudicate their portion of the claim.

Impact of Privacy Rule (pg 55999)

Covered entities must make reasonable efforts to limit requests for, or disclosures of, protected health information to the minimum necessary to accomplish the intended purpose of the request for disclosure. The proposed rule seeks comments as to whether the proposed attachment standards will facilitate the application of the minimum necessary.

We would appreciate further clarification around the term "reasonable efforts," especially when a provider receives a request for information and the relevant document contains unrelated information. It would be burdensome for a provider that adopts the human decision variant of a scanned image to edit the document to remove sections not requested. It would be "reasonable" for the provider to scan and send the entire page of the document as long as it contains the information requested by the health plan.

Connection to Signatures (hard copy and electronic) (pg 56000)

The proposed rule suggests that electronic signatures not be part of the standard. However, some health plans and/or regulations require a signature for services such as sterilization or for the issuance of specialized equipment.

We agree that electronic signatures should not be part of the electronic attachment standard. If in the future, a document, such as sterilization consent form, becomes a standard, the field should evaluate the merits of a digital signature. In this case, it might be best to scan the entire document that includes the patient's signature.