ACP
AMERICAN COLLEGE OF PHYSICIANS
INTERNAL MEDICINE | *Doctors for Adults*

January 10, 2006

Office of the Secretary
Department of Health and Human Services
Attention: CMS-0050-P
Room 445-G, Hubert Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: HIPAA Administrative Simplification: Standards for Electronic Health Care Claims Attachments; Proposed Rule, 45 CFR Part 162, CMS-0050-P, (September 23, 2005)

To Whom It May Concern:

The American College of Physicians (ACP), representing over 119,000 doctors of internal medicine and medical students, appreciates the opportunity to submit comments on the proposed rule: *HIPAA Administrative Simplification: Standards for Electronic Health Care Claims Attachments; Proposed Rule*, published in the Federal Register dated September 23, 2005. This proposed rule would establish new standards for electronically requesting and sending additional health care information to support submitted health care claims data. In addition, we recognize the importance of this rule as it helps to simplify and expedite the health care claims adjudication process when additional documentation is requested to support the original claim.

We appreciate this opportunity to provide comments about the adoption of this rule as it will allow our members to reap the rewards from the standardization of the claims adjudication process. In this proposal we recognize the Centers for Medicare & Medicaid Services' (CMS) attempt to increase the adoption of information technology, however those who use the technology the least but stand to benefit the most, will face significant obstacles in attempting to comply with this proposal without some modification and additional consideration. Further, the College recognizes the potential to facilitate the auto-adjudication of claims for those who possess Electronic Medical Records (EMRs) will significantly reduce their administrative costs but the process of electronic claims attachments may present an onerous burden on providers with small offices (a significant number of our members) and therefore defeat the intention of accelerating the adoption of health care information technology and the development of the national electronic health information system.

SUMMARY OF RECOMMENDATIONS

- We propose a pilot or the publication of the results of any previous pilots to fully evaluate the implications to health care providers, health plans, and clearinghouses as they attempt to comply at the *practical* level.

- We further recommend that when and if physician compliance is required, it may be prudent to implement the rule in a graduated manner i.e. larger practices implement prior to smaller practices.

- We propose as part of the rule that CMS consider establishing an expedited procedure for the adoption of other claims types for industry use.

- We also recommend that large imaged or scanned documents be imbedded in the X12 transaction as compressed or zipped file format. This will ultimately reduce the size of the file that will be stored on servers and computers, and in addition, facilitate the reduction of upload, transmission, and download times of the files

- In addition, we request the exemption of computerized faxes used in response to a request for additional information, as a form of electronic transmission.

- We recommend that plans be required to be more transparent about situations that routinely require additional documentation and that this documentation should be accepted as part of the initial claim.

- We propose that health plans be specific about documentation needed for prior authorization of visits, procedures, and medications and if physicians requested and received prior authorization they should send the pre-specified documentation in the original claim. Prior authorization should be sufficient to adjudicate a claim and physicians should not be required to send additional information to adjudicate the claim further.

- We request (as a practical consideration) that physicians who respond electronically to the request for additional information be afforded a well defined, practical safe harbor regarding the "minimum necessary" provision.

- We recommend that there should be a standard field/code that will allow the physician to indicate that he does not have the documentation and/appeal the request.

GENERAL COMMENTS

We believe the standardization of the electronic claims attachment process will speed up the adjudication of claims. This will be beneficial to health plans, clearinghouses, and healthcare providers. We are concerned however, that certain aspects of this proposal will be burdensome for many providers and will act as a deterrent to its use and ultimately the adoption of EMRs.

It is our contention that those who will reap the greatest benefit from this rule are those who have invested or plan to invest in EMRs and benefit from auto-adjudication. For these physicians the implementation of this rule will result in significant administrative savings and expedited reimbursement. However, for a significant number of our members, who do not have EMRs and choose to comply, there are aspects of this proposal that will pose significant challenges.

The ACP offers the following comments on the proposed rule:

SPECIFIC COMMENTS & RECOMMENDATIONS

EFFECTIVE DATES (p. 55994)

Though we recognize the need to standardize the claims attachment process and although this rule proposes to take effect in two years for large health plans and three years for smaller ones, we think that prior to full implementation there should be some attempt to pilot the application of this proposal to ensure that all aspects of this process effectively interact and to clarify the necessary processes for providers --- both those in large and small practices, and those using and not using EMRs --- to implement realistically these claim attachment procedures. It would also be helpful if CMS would include in the final rule the results of any pilots that have been previously conducted. Further, when and if physician compliance is required, it may be prudent to implement the rule in a graduated manner i.e. larger practices implement prior to smaller practices.

Recommendations:

- We propose a pilot or the publication of the results of any previous pilots to fully evaluate the implications to health care providers, health plans, and clearinghouses as they attempt to comply at the *practical* level.

- We further recommend that when and if physician compliance is required, it may be prudent to implement the rule in a graduated manner i.e. larger practices implement prior to smaller practices.

ELECTRONIC CLAIMS ATTACHMENT TYPES (p. 55996)

We agree that covered entities need to gain experience with implementing and using an initial proposed set of claims attachment types for the initial rollout of this rule. In addition, we agree that there is a subset of information that will be common to most claims attachments. We propose that CMS should identify a standardized methodology to facilitate the adoption of other claims attachment types at a later date. We think that leaving the adoption of other types to ad hoc voluntary agreements between covered entities will negate the benefits of adopting standardized claims types and the standardization of the electronic claims attachment process. We think that there should be an expedited methodology to facilitate the development and adoption of new claims types; for example HL7 or an

appointed group of industry and provider representatives who would vet, approve, and disseminate new claims types for universal adoption.

Recommendation:

- We propose as part of the rule that CMS consider establishing an expedited procedure for the adoption of other claims types for industry use.

FORMAT OPTIONS (p 55997)

The *human decision variant* allows the health care provider to send electronic claims attachments to the payer as imaged or scanned documents or as narrative text for human review. You propose that this will be a benefit to small practices that do not have EMRs. We think that for many of our members this method will predominate and while this will encourage some to use the standard there are still significant hurdles to overcome: the size of files, the bandwidth for transmission, and the size/storage capacity servers etc.

For example, if large sections of the medical record need to be scanned or imaged, there will be a substantial burden on the provider to have available additional server and computer storage capacity. In addition, the upload and transmission of these large data files can be slow and inefficient if the practice does not have sufficient bandwidth. One solution to these problems is to reduce the size of the files by compressing them. The benefits of compressed or zipped files include faster upload and transmission, less storage space on servers and desktops. For this reason, the X12 transaction should facilitate the use of compressed files.

We also request that to the extent that providers transmit claims attachments using computerized faxes that these faxes should be exempted from the electronic claims attachment rule. This will be consistent and in keeping with other rules (e.g. e-prescribing rule) that have exempted computerized faxes as electronics formats.

Recommendations:

- We also recommend that large imaged or scanned documents be imbedded in the X12 transaction as compressed or zipped file format. This will ultimately reduce the size of the file that will be stored on servers and computers, and in addition, facilitate the reduction of upload, transmission, and download times of the files

- In addition, we request the exemption of computerized faxes used in response to a request for additional information, as a form of electronic transmission.

SOLICITED vs. UNSOLICITED ATTACHMENTS (p. 55999)

The College is in agreement with the proposal to require health plans to submit only one electronic request for additional claims information. We also agree that this requisition should contain all the questions that are minimally necessary or the health plan to adjudicate the claim. In addition, we agree that there should be an attempt to limit "unsolicited" claims attachments. However, there are certain, specific, service claims for

which health plans routinely request additional information. Nonetheless, the plans will not accept "unsolicited" claims attachments submitted with the original claims. This causes an unnecessary delay in the billing process. We recommend that plans be required to be more transparent about situations that routinely require additional documentation and that this documentation should be accepted as part of the initial claim.

As a special circumstance we request that those instances where the provider requested and obtained prior authorization for a procedure, visit, or medication from a health plan that on submission of that claim, the health plan should not be permitted to ask for additional information to adjudicate the claim. In this instance, the physician will be required to attach all the necessary documentation used for the approval with the original claim.

We also agree that it is important for providers to comply with the minimum necessary standard, however it maybe impossible or impractical for medical practices to comply as shown in the following practical example:

A physician refers a patient to an orthopedist for a back problem. In theory, the physician should send the patient with a referral (if required) and the minimum necessary information for effective continuity of care. Then the patient follows up with his physician for review of his hypertension, diabetes mellitus, obstructive lung disease, and back pain. All information pertinent to the visit is recorded in the note for that day. The medical note represents a summary of all the issues related to the visit in this instance all four diagnoses. For this visit and all others the medical note represents a single integrated note, which touches on multiple issues. The managed care company sends an electronic claims attachment request, which specifies, "...please send all notes pertaining to back pain."

What is considered the minimum necessary information to comply with this request - the entire note, or just the parts of the note that are relevant to back pain? We seek further clarification considering the practical considerations and implications. For the average physician it is not often possible or practical to separate from the medical note that information only specific for back pain. If the physician complies using *Provider Scenario 1* (see page 56007 of proposed rule) all the notes, results etc that contain back pain would have to be copied, and checked for compliance with the minimum necessary provision and all information not pertinent to the request would then have to be blacked out. The final document(s) would then have to be scanned, and finally uploaded into the system as an image or Portable Document File (PDF) to be sent electronically to the health plan. In this scenario compliance with the "minimum necessary" provision would require that physicians hire additional medical records staff to function as chart redactors. If the ultimate aim is to encourage physicians to adopt electronic transmission of claims and claims attachment, we think this will represent a significant obstacle to adoption. As a possible solution, we request that physicians who respond electronically to the request for additional information with scanned or imaged documents be afforded a well defined, practical safe harbor regarding the "minimum necessary" provision

In *Provider Scenario 4* (page 56008), the provider uses an EMR to respond electronically to the request for additional information. To an extent EMRs may make it relatively easy for physicians to separate visit notes by diagnosis, but they may not be able redact notes according to the minimum necessary standard. In other words, it may not be possible to take that note and only extract information pertinent to back pain. Again, we request that

physicians with EMRs who respond electronically to the request for additional information be afforded a well defined, practical safe harbor regarding the "minimum necessary" provision

Recommendations:

- We recommend that plans be required to be more transparent about situations that routinely require additional documentation and that this documentation should be accepted as part of the initial claim.

- We propose that health plans be specific about documentation needed for prior authorization of visits, procedures, and medications and if physicians requested and received prior authorization they should send the pre-specified documentation in the original claim. Prior authorization should be sufficient to adjudicate a claim and physicians should not be required to send additional information to adjudicate the claim further.

- We request (as a practical consideration) that physicians who respond electronically to the request for additional information be afforded a well defined, practical safe harbor regarding the "minimum necessary" provision.

PROVIDER vs. PLAN PERSPECTIVE (p. 56001)

There are instances where the health plan will request additional documentation to adjudicate a claim; however, there is no provision in the proposed rule to allow the physician to indicate that he does not have the required documentation and to appeal the request.

Recommendation:

- We recommend that there should be a standard field/code that will allow the physician to indicate that he does not have the documentation and/appeal the request.

ATTACHMENT CONTENT AND STRUCTURE (p. 56001)

To reduce the size of files facilitate the incorporation of compressed data files (see *FORMAT OPTIONS* above)

MODIFICATIONS TO STANDARDS AND NEW ATTACHMENTS (p. 56013)

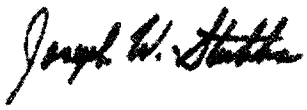
There should be an expedited process to facilitate modifications and new attachments especially if they conform to previous standards. There should be a clear roadmap to guide the modification of existing types and the introduction of new claims attachment types. If they go through a SDO such as HL7 and are consistent with previous standards then their adoption as standards should be expedited. Also see *ELECTRONIC CLAIMS ATTACHMENT TYPES* above.

CONCLUSION

The College applauds any attempt to encourage healthcare providers, clearinghouses, and health plans to adopt health technology and ultimately build the healthcare information technology infrastructure. The electronic claims attachment proposal is one element that will help our members to implement technology in their clinical practice. However as outlined about there are many considerations that we think CMS should take into account.

Again, the ACP greatly appreciates this opportunity to comment on the proposed standards. Please do not hesitate to contact Dr. Mureen Allen., Senior Associate, at (202) 261-4539 or mallen@acponline.org if you have any questions regarding these submitted comments.

Sincerely,



Joseph W. Stubbs, MD, FACP
Chair, Medical Service Committee

Date: January 5, 2006

RE: Official Solicitation to participate in responding to public comments related to the Notice of Proposed Rulemaking (NPRM) for the electronic claims attachments standard. Specifically, HL7 is seeking your support in replying to comments related to the claims attachment for Ambulance Services, Emergency Department (ED) Services and or Rehabilitative (rehab) Services. These claims attachments were designed by industry experts working with HL7 for use with the ASC X12N 837 Health Care Claim or Encounter.

Dear Ambulance / ED / Rehab Services Attachment Stakeholder:

Several years ago HL7 convened a group of interested industry stakeholders to define the appropriate content for use in each of these three claims attachment types. These attachments were developed along with three others, and were offered to the Department of Health and Human Services (HHS) as the standard electronic attachments for consideration as the HIPAA standard. These standard attachments, once named in a Final Rule by HHS, will be available for use by all health care entities that utilize additional information to support a health care claim for ambulance, ED and rehab services.

The NPRM for the electronic standard for claims attachments under HIPAA has been published in the Federal Register and the public comment period associated with it will conclude January 23, 2006. As comments are received by HHS they will be reviewed and those that are deemed appropriate for HL7 to assist in responding to will be forwarded to HL7. It is in this endeavor that we seek your assistance.

If HL7 receives comments **related to the appropriateness of data in the Ambulance, ED or rehab Services Attachment** (e.g. whether certain data are necessary for claims adjudication, whether they should be required in all cases, whether the data can only be reported once versus multiple times) it is our hope that individuals with these specific areas of expertise will support us in responding to those comments. Ultimately we will be responding to comments that will shape the national standard, and that will be required under law for use when exchanging ambulance, ED and rehab Services attachment information

electronically from provider to payer. For these reasons we believe that your subject matter expertise is critical to the success of this initiative.

Because we will have a limited timeframe in which to return our responses to HHS, we are attempting to organize our subject - matter– specific teams now, and ask those who volunteer to stand by until you are notified shortly before we begin convening the meetings to review comments. Our best guess at the time of this writing is that we could start convening these teams to respond to comments anywhere from January to February of 2006. Please understand that HL7 has no way of knowing with certainty how many comments will be forwarded to us, or when this will start.

Those individuals who volunteer to help will be added to a list and contacted once we are ready to review and respond to comments. We will likely be able to provide some advance notice, but it may only be a week to 10-days or so. Once we have formulated HL7 responses to the comments we will forward that information to HHS for consideration in preparing the Final Rule.

The attached information describes our work group protocols, past accomplishments, current objectives, and desired time frames.

Contact **Karen Van Hentenryck** via email at **HL7NPRM@hl7.org** by **January 23, 2006** to become a participant in the HL7 Ambulance, ED or rehab Services Attachment NPRM comment response team. When you contact Karen, please indicate which attachment type (ambulance, ED, rehab) you will be assisting us with. **We ask that you also forward this request to your constituents, particularly if you are involved in an "association" or "committee" type of organization.**

Sincerely,

HL7 Attachment Special Interest Group (ASIG) Co Chairs:

Maria Ward, PricewaterhouseCoopers, LLP
Wes Rishel, Gartner
Penny Sanchez, EDS
Mike Cassidy, Siemens

Date: January 5, 2006

Dear Ambulance/ Emergency Department (ED) / Rehabilitation Services Attachment Stakeholder,

For several years now, two American National Standards Institute (ANSI) accredited Standards Developing Organizations (SDOs) have been collaborating to develop a standard electronic claims Attachment transaction. Health Level Seven (HL7) and Accredited Standards Committee (ASC) X12 Insurance Subcommittee (X12N) have been working together since 1997 to develop the transaction, as well as standardize the content of various attachment types.

Our goal is to create clear and unambiguous questions for payers to ask when requesting additional information from a provider about a healthcare claim. By doing this we will help to eliminate the practice that currently exists, with each payer requesting additional information to support a claim and creating their own questions, leaving providers to respond to hundreds of variations of the same question.

To date we have standardized six attachment types **for claims**: Ambulance, Emergency Department, Rehabilitative Services, Lab results, Clinical notes, and Medications. These claims attachments were named in an NPRM for HIPAA on September 23, 2005 and the public comment period will close on January 23, 2006. Once the public provides comments on that NPRM HL7 will need to review and respond to some comments (comments sent to HL7 for response will be determined by HHS). For more information on the current six standardized claims attachments consult www.HL7.org and go to Special Interest Groups – Attachments.

The effort of standardizing questions asked by payers or healthcare organizations requires participation from all entities involved in the exchange of healthcare data, particularly providers, payers, associations (if applicable) and technical solution partners (vendors, clearinghouses etc.) Convening these industry stakeholders is how we developed the attachments named above, and it is how we believe HL7 can best respond to comments about the attachments. This is where you come in. The HL7 Attachment Special Interest Group (ASIG) will be convening individuals with subject matter expertise in the area of ambulance, ED and rehabilitation services to respond to NPRM comments and we are requesting your participation in this endeavor.

The Details:

Task:

- In an effort to support HHS, review and respond to public comments submitted to HHS in response to the claims attachment NPRM. Specifically, this group will review and respond to comments about the Ambulance, ED and rehabilitation Services Attachments.

Commitment and Timeframe:

- Analysis of the comments will begin shortly after HL7 receives them from HHS. We are not able to forecast how long this activity will take, as that will vary depending on the number and complexity of comments we have to review. It is anticipated that at the most this exercise should not last longer than 2-3 months once it has begun. Again, this is an estimate and is subject to change once we actually receive the comments.

Recommended Resources Needed:

- *Provider Staff*:
  Business Office / Billing staff, Billing Office Supervisor, individuals with expertise in ambulance, ED or rehabilitation services billing and receivables, Information Systems Staff,

- *Payer Staff*:
  Medical Directors, Nurse Reviewers, Medical Review and utilization management staff; Information Systems staff (particularly people who implement health care services request/response systems and electronic data interchange)

- *Technology partners (Vendors, Clearinghouses, Billing Services, etc)*
  Individuals involved in the design, support, training etc. of systems and services tailored specifically to ambulance, ED and or rehabilitation services billing and payment.

How to Participate:

Provide your facility / organization name as well as contact person information including:

- Contact person name
- title (or role in the organization)
- phone number and fax number
- e-mail address
- Attachment type you are have subject –matter expertise in (ambulance, ED, rehabilitation services)

Please send the information above to **Karen VanHentenryk** at **HL7NPRM@HL7.org**. You can also contact Karen if you have questions. Please include your telephone number with your request and we will get back to you.

We expect that each volunteer will be responsible for any expenses incurred by participation in this project. Experience has shown us, and we continue to believe that the only costs will be those associated with the volunteer's time, both on teleconference calls and working independently. At this time there is no expectation that we will need to convene in-person meetings.

Please contact **Karen VanHentenryk** by **January 23, 2006** if representatives from your organization will participate in this important healthcare industry initiative. Upon receipt of the contact person's information we will add the name(s) to our Ambulance, ED or Rehabilitation Services team list, and contact individuals prior to convening the first conference call. **We also ask that you forward this invitation to any person or organization that you feel would be able to contribute to the development of responses to the NPRM comments for the these Attachments.**

Sincerely,

HL7 Attachment Special Interest Group (ASIG) Co Chairs:

Maria Ward, PricewaterhouseCoopers. LLP
Wes Rishel, Gartner
Penny Sanchez, EDS,
Mike Cassidy, Siemens

Cc: George Arges, Chair, National Uniform Billing Committee
Jean Narcisi, Chair, National Uniform Claim Committee
Alix Goss, Co Chair, ASC X12N TG2
Frank Pokorny, Dental Content Committee
Lynne Gilbertson, National Council for Prescription Drug Programs
Lorraine Doo, Centers for Medicare and Medicaid Services
Mark McLaughlin, Chair, Workgroup for Electronic Data Interchange

34

American
Clinical Laboratory
Association

January 23, 2006

VIA HAND DELIVERY

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: Comments on the Proposed Rule Regarding HIPAA Administrative Simplification: Standards for Electronic Health Care Claims Attachments – File Code CMS–0050–P

2006 JAN 24 AM 11:32

Dear Sir or Madam:

Enclosed please find the comments of the American Clinical Laboratory Association on the Centers for Medicare and Medicaid Services' proposed rule regarding HIPAA administrative simplification standards for electronic health care claims attachments. 70 Fed. Reg. 55990 (Sept. 23, 2005).

If you have any questions or comments, please feel free to contact me.

Sincerely yours,

Alan Mertz/cej

Alan Mertz
President

1250 H Street, N.W. • Suite 880 • Washington, DC 20005 • (202) 637-9466 • Fax: (202) 637-2050

Comments of the American Clinical Laboratory Association on the HIPAA Standards for Electronic Health Care Claims Attachments CMS-0050-P

American Clinical Laboratory Association

The American Clinical Laboratory Association ("ACLA") is pleased to submit these comments on the proposed rule regarding "HIPAA Administrative Simplification: Standards for Electronic Health Care Claims Attachments" (the "Proposed Rule"). 70 Fed. Reg. 55990 (Sept. 23, 2005). ACLA is an association representing independent clinical laboratories throughout the United States including local, regional, and national laboratories. In the United States alone, clinical laboratories perform millions of tests each year for physicians and other health care professionals. Virtually all of the billing for this testing is done electronically. Thus, ACLA members will be significantly affected by the Proposed Rule.

While ACLA supports the efforts of the Office of the Secretary (the "Secretary") to propose standards for electronically requesting and submitting health care claims attachments to support health care claims data, ACLA members have several concerns regarding the implementation of these proposed standards, which are addressed below.

Cost and Benefits

The impact analysis in the Proposed Rule does not adequately or accurately evaluate all the costs and benefits associated with implementation of the proposed standards. ACLA is particularly concerned that there is minimal evidence to support any return on providers' investment in implementing and complying with the proposed standards. In fact, the cost and benefit analysis is primarily based on data from a 1993 Workgroup for Electronic Data Interchange ("WEDI") study, which is too dated to extrapolate to present circumstances. 70 Fed. Reg. at 56017. ACLA urges the Secretary to request a study from the Government Accountability Office ("GAO") or the Office of Management and Budget ("OMB") to determine the actual costs and benefits associated with this Proposed Rule before it is finalized.

In addition, the benefits discussed in the analysis seem only to inure to health plans. Meanwhile, providers such as clinical laboratories will be forced to bear the costs of the proposed standards. Although most of the recent electronic health initiatives (*e.g.*, the National Provider Identifier, ICD-10, and the HIPAA standard transactions) are intended to increase efficiency and therefore reduce health care costs, payors seem to be the only participants realizing these benefits, while providers are forced to expend significant, precious resources to comply with the regulatory requirements. This is a fundamentally unfair public policy. The Proposed Rule appears to provide no benefit to clinical laboratories, and therefore, there is no economic incentive for laboratories to adopt and use the standard. We urge the Secretary to remain cognizant of other unfunded regulatory mandates being simultaneously imposed on health care providers and to coordinate its HIPAA Administrative Simplification rulemaking and other electronic health initiatives in a manner that more fairly allocates the burdens and benefits

1250 H Street, N.W. • Suite 880 • Washington, DC 20005 • (202) 637-9466 • Fax: (202) 637-2050

of such rules among all of the affected stakeholders, rather than merely benefiting health plans at the expense of providers, such as clinical laboratories.

Further, the Proposed Rule references a Medicare pilot program to test the X12 request and response transactions, the Logical Observation Identifiers Names and Codes ("LOINC®"), and at least two of the attachment types, using the HL7 Additional Information Specifications ("AIS"). 70 Fed. Reg. at 55996. It is expected that the pilot will be able to demonstrate the capability of sending the X12 request transaction from a health plan to a health care provider and then for the health care provider to respond to the health care plan with an X12 response. However, ACLA is unclear as to whether the pilot has demonstrated any significant positive progress thus far. In fact, it is our understanding based on the Empire Medicare Services ("EMS") Report that the pilot has shown minimal progress and produced limited results, due to a number of technical issues, including the file size requirements for transmitting data. Thus, ACLA urges the Secretary not to rely solely on the pilot program in crafting the final claims attachment standards, but to pursue publication of an interim report on the current status of the pilot to inform all affected stakeholders of the implementation issues being faced by the participants. Most importantly, ACLA strongly encourages the Secretary to postpone further drafting and implementation of claims attachments standards until such interim report on the pilot study is made available to the public.

Finally, the Proposed Rule states that the proposed standards for electronic health care claims attachments set forth will "facilitate the electronic exchange of clinical and administrative data to further improve the claims adjudication process when additional information ... is *required*." 70 Fed. Reg. at 55991 (emphasis added). This statement misconstrues the provision of additional information by providers because such information is not required of providers, but is instead *requested* by health plans. In fact, the request for additional information should only occur when clinical information necessary to adjudicate a claim for purposes of payment is not contained within the claim itself, and not for every instance in which a health plan "requires" additional information of providers. We discuss these issues in more detail below in response to specific requirements of the Proposed Rule.

Effective Dates

According to the Proposed Rule, most covered entities would be required to comply with the proposed standards two (2) years from the effective date of the Final Rule. 70 Fed. Reg. at 55994. Development and implementation of the claims attachment transaction at the provider level is a complicated, labor-intensive process. ACLA strongly believes that more time is needed before covered entities must comply with the standard. The underlying technical requirements and the integration of different standards will be especially difficult for laboratories because they have separate clinical and billing systems, which will have to be combined and assimilated. The 24-month time frame is simply not sufficient for covered entities to become familiar with the complexities of the proposed standards and operationalize all of the requirements. Thus, ACLA recommends that the effective date be extended beyond two years for all covered entities, not just small health plans. Covered entities, irrespective of size, will require at least three (3) years to become fully compliant with the rule as proposed.

Overview of Extensible Markup Language (XML)

The Proposed Rule states that XML is widely adopted by most major companies in information technology for the purpose of interoperability. 70 Fed. Reg. at 55995. It also provides that XML is more beneficial than Hypertext Markup Language ("HTML") because of its ability to both preserve the content and semantics for a document, as well as format the document attractively (similar to HTML). Id.

Although ACLA appreciates the benefits of XML, we do not agree that it is a technology that has been widely used by the health care industry. In fact, for providers, the use of XML is not a standard practice. Although XML is often discussed by vendors, it is the experience of ACLA members that in practice, vendors and providers have not made significant use of the new technology, which is a step above the current HL7 industry standards. Thus, ACLA encourages the Secretary to realistically consider the resources and time that will be required to adopt this new technology throughout the health care industry.

Overview of Clinical Document Architecture

According to the Proposed Rule, Health Level 7 ("HL7") Clinical Document Architecture ("CDA") Release 1.0 is the currently approved document markup standard encoded in XML that specifies format and content for clinical documents for the purpose of information exchange. 70 Fed. Reg. at 55995. The Proposed Rule also provides that HL7 continues to improve its standards and that CDA Release 2.0 may be approved prior to the Final Rule. In response to the request for comments regarding the adoption of CDA Release 1.0 or CDA Release 2.0, ACLA supports the use of CDA Release 2.0 for the Final Rule. ACLA recommends the adoption of CDA Release 2.0, provided that it has undergone a successful pilot study. In addition, ACLA members strongly encourage the Secretary to make the results of the pilot study available to the public before its adoption into the Final Rule.

Transactions for Transmitting Electronic Claims Attachments

The Proposed Rule provides that version 4050 of the X12N 277 request transaction and version 4050 of the X12N 275 response transaction will be used for the attachment related questions and the corresponding responses or questions. 70 Fed. Reg. at 55996. However, ACLA recommends adopting version 5010 for X12N 277 and X12N 275 instead. The 5010 version of these standards will likely replace the 4050 version before the Final Rule is published. Therefore, to promote uniformity across the standards, the 5010 version should be adopted in the Final Rule.

Electronic Claims Attachment Types

The Secretary proposes six specific electronic attachment types: (1) ambulance services; (2) emergency department; (3) rehabilitation services; (4) clinical reports (which can include laboratory results); (5) laboratory reports; and (6) medications. 70 Fed. Reg. at 55997. Unlike some providers, clinical laboratories would have the opportunity to use two of the electronic

attachment types – clinical reports and laboratory reports. However, the Proposed Rule does not provide guidance on when it would be more appropriate to use one attachment versus the other. Accordingly, ACLA is requesting clarification on this issue.

Format Options

The Proposed Rule includes three possible formats for the electronic health care claims attachment: (1) Human Decision Variant (scanned); (2) Human Decision Variant (narrative text); and (3) Computer Decision Variant (automated processing). Id. ACLA supports the Secretary's goal of minimizing costs by allowing covered entities to slowly transition (through the use of these three different options) to an electronic format for claims attachments. This will allow clinical laboratories, and other providers, the flexibility necessary to comply with the claims attachment standard. To maintain this flexibility, ACLA also urges the Secretary to clarify in the Final Rule that payors are required to accept any and all of the three proposed formats submitted by providers.

Electronic Health Care Claims Attachment Business Use

According to the Proposed Rule, the purpose of health care claims attachments is to request and/or provide supplemental information regarding a claim before it is paid. 70 Fed. Reg. at 55998. The attachment may include information such as clinical data, hospital discharge notes, and laboratory results. Id. Attachments may be requested or submitted "when the supplemental medical information is directly related to the determination of benefits under the subscriber's contract, or when directly related to providing medical justification of health care services provided to the individual when that medical justification can affect the adjudication of the payment for services billed by the provider..." Id.

However, additional clinical or administrative information may also be requested following adjudication of a claim, for purposes such as quality control, pay for performance, or fraud and abuse review. The Proposed Rule provides that these types of requests would not be part of the claims payment process, and therefore, would not be subject to the Proposed Rule. Id. Covered entities may voluntarily comply with the standard transaction format when submitting claims under the post-adjudication process, but would not be required to do so under the Proposed Rule. However, providers are often subject to additional requirements by payors as a condition of doing business. ACLA is concerned that payors may either demand that providers "voluntarily" comply with the claims attachment standard for post adjudication processes, or may subject providers to multiple, proprietary, non-standard methods of requesting and submitting such data electronically, at the option of the payor.

The Proposed Rule should clarify that a health plan cannot demand that a health care provider comply with the claims attachment standard for post-adjudication processes as a condition of doing business, but that if a health care provider requests that a health plan conduct attachment requests and submissions pursuant to the standard for post-adjudication processes, the health plan must do so. Further, health plans should not be permitted to circumvent the intent of the Proposed Rule by amending their claims adjudication policies and procedures to require, as a

condition of claims adjudication, the submission of attachments related solely to post-adjudication matters.

Solicited vs. Unsolicited Attachments

The Proposed Rule would allow payors to submit only one electronic attachment request transaction and providers would be allowed to respond using only one response transaction. Id. Although the goal of this requirement would be to avoid inefficient, redundant processes, the result could be a significant delay in the claims adjudication process because laboratories would be forced to wait until all of the requested information was acquired before sending a response to the payor. Further, the Proposed Rule fails to address how this limitation on the number of attachments would be enforced. It seems likely that the restriction would disadvantage providers more frequently than health plans.

In addition, under the Proposed Rule, providers would be prohibited from submitting unsolicited electronic attachments with a claim, unless the provider has received specific advance instructions pertaining to that type of claim or service from a health plan. 70 Fed. Reg. at 55999. The Proposed Rule cites a number of reasons underlying this decision, including compliance with the Privacy Rule's "minimum necessary" requirements. ACLA notes that even in situations where the plan has provided advance instructions for the unsolicited claims attachment, clinical laboratories and other health care providers would still need to satisfy the requirements of the minimum necessary standard before sending the attachment.

Moreover, ACLA encourages the Secretary to expand this provision in the Final Rule to permit unsolicited attachments sent in response to the denial of a claim for payment, even if the provider has not received specific advance instructions pertaining to this situation. Such a clarification would make the Final Rule consistent with current industry practice whereby providers often submit additional explanations for claims when they initially receive a denial, regardless of whether the health plan has provided instructions for doing so in advance.

Provider vs. Plan Perspective

The Proposed Rule addresses the differences in perspective between providers and health plans regarding claims attachments, noting that while providers prefer to minimize the number of attachments and consider requests for additional information as unnecessarily extending the payment cycle, health plans consider attachments to be a necessary tool to ensure appropriate payment decisions. 70 Fed. Reg. at 56001. The Proposed Rule also provides that claims attachment standards do not include requirements for the appropriateness of requests for additional information. Rather, the proposal is intended to reduce miscommunication and multiple requests for information by providing specificity to the request and the response, and establishing limits on the content of the attachment. Id.

ACLA believes that the Final Rule should impose limitations on the type of requests for additional information that payors can make, as part of the business rules surrounding the use of the transaction. The Proposed Rule seems to assume that requests will only be made for information that is necessary to process the claim, but from past experience, we know that this is

not always the case. Clinical laboratories, and other providers, should not be required to comply with additional information requests that are unnecessary and serve only to delay the payment process. Similarly, clinical laboratories should not be required to provide payors with additional information, which may be valuable for business purposes, but which is not integral to the claim adjudication process. This has also been an issue with other HIPAA standard transactions. Thus, ACLA strongly encourages the Secretary to consider a limitation on the substance of requests as part of the Final Rule.

Connection to Signatures (Hard Copy and Electronic)

Requirements for electronic signatures ("e-signatures") are not included in the Proposed Rule. 70 Fed. Reg. at 56000. According to the Secretary, there is no consensus standard for e-signatures, nor is there authority to require the private sector to comply with e-signature rules that apply only to Federal agencies. Under the Proposed Rule, however, there would be an accommodation for a signature within the standard, but this would not be specific to HIPAA. Id.

ACLA members support this policy of not requiring an e-signature under certain situations. When using the natural language human decision variant format (not the scanned image format), it will be difficult to represent the signature, unless clinical laboratories are permitted to say "signature on file" as part of the typed response. Nonetheless, an established policy on e-signatures could enhance the efficiency of the standard transaction significantly. Thus, we recommend that the Secretary clarify these issues surrounding e-signatures in the Final Rule.

Attachment Content and Structure

There are two separate transactions associated with electronic claims attachment – the health plan's request for health care claims attachment information and the health care provider's response, which includes the attachment information. 70 Fed. Reg. at 56001. The file size for the X12 275 response transaction allows up to 64 megabytes of data in a single transaction. Id. Pursuant to the Proposed Rule's request for comments on file size, ACLA recommends that 64 megabytes be the default file size for the Binary Data ("BIN") segment to store attachment information. However, ACLA strongly believes that trading partners should be afforded the discretion and flexibility to determine the number of BIN segments that could be permitted in a single file. Different payors will have different capabilities and systems requirements in this regard; therefore, ACLA recommends that the Final Rule permit trading partners to negotiate the number of BIN segments that can be included within each attachment file, so long as each BIN segment does not exceed the 64 megabyte limit.

Alternatives Considered: Candidate Standards for Transaction Types and Code Sets

LOINC® provides sets of universal names and identification codes for identifying laboratory and clinical test results in addition to other units of information that would be useful in electronic claims attachments. 70 Fed. Reg. at 56003. The Proposed Rule adopts LOINC® as the code set that would be used with the X12 transaction standards and HL7 specifications. Id. However, it is important to note that there is no implementation guide for LOINC®. As a result,

different covered entities may apply the codes in different ways, which does not achieve the purpose of standardization as intended by the Proposed Rule. In addition, there is often a delay of several months before the codes are updated to accommodate new laboratory tests. Consequently, there are no LOINC® codes to support necessary laboratory services, which will only delay the submission of electronic claims attachments. Thus, until the pilot study has proven that the LOINC® codes can support the attachment information that is requested and submitted, ACLA recommends that these codes not be implemented. If the LOINC® codes satisfy this pilot measure, ACLA encourages the Secretary to include implementation guidelines in the Final Rule and to ensure that such guidelines are developed for all providers and payors to promote consistent utilization of the codes. Otherwise, providers are faced with separate, distinct implementation guides for each payor to which they submit claims – a result that is contrary to the underlying principles of administrative simplification and standardization.

Proposed Standards

The Proposed Rule provides that Additional Information Specification 0005: Laboratory Results Attachment permits health care providers to report a "wide variety" of laboratory results. 70 Fed. Reg. at 56006. According to the Proposed Rule, data elements of this specification may include individual identifiers, reasons for the study, actual laboratory results, and abnormality indicators. Id. Although ACLA supports the broad scope of the Laboratory Results AIS, ACLA members are concerned that health plans may request information that clinical laboratories are unable to provide. As a result, it is important that limits are placed on the additional information that is requested and that laboratories are not required to expend resources on providing information that is not within their possession.

Requirements (Health Plans, Covered Health Care Providers and Health Care Clearinghouses)

The Proposed Rule states that health care providers would have the option of using paper as their mode of communication, and not submitting attachments electronically. 70 Fed. Reg. at 56012. However, from a practical perspective, health plans will likely include such a requirement in their private contracts with providers; therefore, providers will essentially be required to submit attachments electronically for all claims for which attachments are requested. The Secretary should take this into consideration when determining how long covered entities will have to implement these changes before compliance is required. In addition, the Secretary should clarify in the Final Rule that if a provider chooses to respond electronically to an attachment request, the health plan is required to *receive, accept* and *utilize* the information sent in the standard format. Currently, the Proposed Rule is silent on this point and we strongly encourage the Secretary to clarify this requirement.

Modifications to Standards and New Attachments

The Proposed Rule includes a discussion of the proposed process for making modifications to existing standards and developing new claims attachments. 70 Fed. Reg. at 56013. The processes for and ability to make timely revisions to the standard transactions has been an issue in the past for health care providers of all types. ACLA remains concerned that

there is no effective, efficient process for adopting new claims attachment types or amending the rules for existing attachment types, as may become necessary in the future. Thus, we recommend that the Secretary take advantage of this opportunity to create a clear and efficient process for improving and modifying the claims attachment transaction standards, which provides an equal opportunity for all relevant stakeholders to participate and affect change.

Further, the Proposed Rule provides that the Secretary must permit all affected entities at least 180 days for the implementation of an adopted modification to a standard before compliance with the modified standard would be required. Id. ACLA recommends that clinical laboratories and other providers be permitted at least 12 months in which to implement any proposed modifications. This represents a more realistic assessment of the time and resources that are necessary to make any required changes in compliance with new standards.

Conclusion

ACLA appreciates the opportunity comment on the Proposed Rule. We look forward to working with the Office of the Secretary to finalize and implement standards for electronic health claims attachments. Please do not hesitate to contact us should you have any questions about this information or need any further information.

WDC01/221673v7

AHIMA
American Health Information Management Association®

2006 JAN 24 AM 11: 32

January 20, 2006

Honorable Michael O. Leavitt
Secretary
Department of Health and Human Services
CMS-0050-P
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

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

Dear Secretary Leavitt:

This letter is to offer comments and recommendations on behalf of the members of the American Health Information Management Association (AHIMA) to the Department of Health and Human Services' (HHS or Department) proposed rule, published on September 23, 2005, establishing an additional Health Insurance Portability and Accountability Act (HIPAA) Administrative Simplification standard for electronic healthcare claims attachment.

AHIMA's 50,000 members are professionals educated, trained, and certified in various aspects of health information management (HIM). A sizeable number of these professionals work in hospitals, health systems, large clinics and health plans, and are directly affected by the requests and responses that take the form of the "attachment" information, which is the focus of the September notice of proposed rule making (NPRM). HIM professionals are also deeply involved in activities now underway to achieve a standard electronic health record (EHR) and other projects to achieve electronic interoperability and harmonization in all healthcare standards and data. To this end AHIMA members and staff play an active part in the Health Level Seven (HL7) standard data organization and its work, including work toward securing appropriate attachment standards. Additionally, HIM professionals have also been involved in the security and confidentiality of health records since the 1920's including the process known as "release of information." All of these HIM functions and experiences are touched in the proposed rule.

EHR, NHIN, and Interoperability v Timing and Implementation of this Proposal

As AHIMA reviewed the proposed rules, overarching concerns were raised that bear addressing up front. This NPRM, pending for almost a decade, comes at a time when the industry is actively addressing various aspects of obtaining, storing, exchanging and reporting complete, relevant, standard clinical healthcare data. Emphasis in the last three years on the development and adoption of a standard EHR and an interoperative nationwide health information exchange (NHIN) have been at the

1730 M Street, NW, Suite 409, Washington, DC 20036
phone (202) 659-9440 • *fax* (202) 659-9422 • www.ahima.org

top of the Department's agenda and our profession's as well. Current activity and priorities raise concern that some aspects of this proposed HIPAA standard, based on information collected in, and from, the environment of the 1990s, does not fit in today's environment and priorities. Any action taken on implementing this standard and adopting a final rule must consider the environment of 2006 as our industry addresses a variety of aspects related to how clinical information should be provided by the health record in a standardized process.

The attachment process is important, and there is a place for the work of the Accredited Standards Committee X12 (X12) and HL7 that will result in a transaction standard with which to report standardized clinical data necessary for claims adjudication. But, these transaction standards must be flexible and must be built on the basis of the definitions and data sets of the standard EHR now under development and not a record from an era when clinical information was non-uniform, paper-based, and used mainly for reimbursement purposes. To proceed with adoption of the standards proposed and not recognize the need for flexibility, uniformity or consistency, and interoperability will hinder the goals that have now been raised by the President and the healthcare industry. Likewise, adoption and implementation of these standards must be done in light of the goals, objectives, resources and timetables of today's healthcare environment and not that of standards regulations initiated ten years ago.

Attachments are a Secondary Use of the EHR

If the transactions represented by these proposed rules, strictly related to administrative data associated with electronic claims, there might be less concern. Unfortunately, the data is transferred in these attachments comes from the health record and thus becomes part of the clinical data and other factors under consideration in the adoption of the EHR, or in other words, attachment data and data sets must be viewed as a secondary use of the EHR more than an extension of the claim. AHIMA, therefore, questions adopting final regulations until further adoption of the EHR standards necessary to ensure a means of uniform consistent information that can be used not only for clinical care, but also for the secondary uses of the record, including claims attachments.

Given the fact that attachments are one form of a secondary use of the EHR, AHIMA must also note that while the LOINC® code set is identified in the proposed standard, it is without reference to supporting or related terminologies and code sets and their relationship. Clinical content contained within a claims attachment must be based on a robust clinical vocabulary – which LOINC is not. Knowing how well LOINC relates to SNOMED and maps to other pertinent code sets and vocabularies is crucial as the nation moves into the adoption of a standard EHR.

Contemporary Classifications and Standards Could Lessen the Need for Attachments

While the development and adoption of the EHR is extremely important, AHIMA does not deny the need to respond to requests for information in a form often defined as an "attachment." Generally, it is AHIMA members who manage health information management departments that respond to such requests (sent via the institutions billing or claims department). It is important to note, however, that both the development of EHR standards as well as work done in the past by HHS on classification systems could alleviate the need for many of these attachments if allowed to progress. AHIMA has testified on several occasions, as has the Centers for Medicare and Medicaid Services (CMS), the American Hospital Association (AHA), and others, that if HHS would proceed with the adoption and

implementation of ICD-10-CM and ICD-10-PCS, classifications (developed by CMS) to replace the 30-year old ICD-9-CM classification, there would be less need to request additional information since much more detail is integrated into these contemporary classification systems.

In advocating for adoption of these HHS-developed classifications, AHIMA and others have also discovered barriers created by HIPAA, the NPRM rules, and the implementation process itself, that now produce a situation where any change could take up to four or five years to complete – an intolerable situation in the early 21st century. If the ICD classifications were adopted in 2006, and the problems with the HIPAA transactions processes ignored, it could take another 5 or six years before the actual use of these classification or standards could occur. In addition, the proposed transaction relies on several data sets that could likewise meet the same fate because of the inflexibility of the current HIPAA law and regulation, leaving the healthcare industry mired in bureaucracy and short-sited rules. This situation must be changed.

Process for Standards Adoption, Upgrading, and Implementation – HIPAA v Current Environment

Before HHS proceeds any further with modification or implementation of the proposed standard for electronic health care claims attachments, please consider the impact of such on the projects and goals mentioned above and the processes and user implementation that must occur. If this standard is considered without also considering of the existing environment, the need for a standard EHR, and recognition of the primary and secondary uses of data from a standard EHR, then users could be placed in a dilemma of what agenda and adoption activities must be addressed first with limited resources. Should the attachment be completed before the record from which it takes its information? While AHIMA supports a process to provide "attachment" data the context in which this NPRM is proposed presents a challenge and possibly a barrier to the goals of interoperability and flexibility also underway at this time. In the next few years, the healthcare industry will address many secondary uses for EHR data including quality measurement, injury prevention, biosurveillance, chronic disease management, research and so on. We recommend that the secondary use for claims attachments should be considered in this context as well and integrated.

As noted the process of adopting and modifying HIPAA standards must also be reviewed. This NPRM identifies the problems created by the numerous delays built into the current HIPAA approval system that prevent modifications to standards on a timely basis. While implementation can be as short as 180 days, the standard development organization (SDO) and regulation procedures expand the entire process by years. This cannot be tolerated in 2006 and must be addressed by HHS and possibly the Congress. This NRPM also has not addressed how the e-attachment standard, that includes significant clinical data, will be addressed by the Health Information Technology Standards Panel (HITSP) and the Commission on Certification of Health Information Technology (CCHIT) recently created by the Office of the National Coordinator for Health Information Technology (ONC). The data included in the NRPM e-attachment standard must be reviewed by these bodies to ensure harmonization and coordination with new HIT products. HHS, therefore, must address how standards and data sets, including those covered by HIPAA, will be coordinated with these process in the future so as to not negatively impact the data content and standards enveloped in the standard EHR, and other NHIN transactions and processes.

Implementation of the e-Attachment Standard

The changes in the healthcare industry environment also affect healthcare providers' approach to this possible HIPAA standard. The push for implementation of EHRs, certified by CCHIT has not entertained how such a certification would apply to attachment software and may create confusion as providers consider purchasing systems. While AHIMA welcomes the approach to phasing in the attachment standard, we anticipate that given all the changes in the environment, many providers and we suspect health plans will maintain manual systems, or at a minimum the human variant proposed. Such reluctance might be appropriate, but it will impact on any potential savings initially perceived in the advent of this regulation

Implementation Guides

The discussion of implementation guides (70FR55993) raises two concerns:

- The text addresses guides developed by the Accredited Standard Committee X12 (ASC X12 or X12) and HL7, and it references use of certain guides under the NPRM. However, as noted above the proposed rule appears to ignore the need to have standards and the guides that are up-to-date. For instance, it is noted that the X12 4050 version will be used in the standard, yet we know that version X12 5010 version is scheduled to be finished in 2006 and would be more current by the potential compliance date of 2008. In fact a good standard should have an even more current version if implementation is some 2 or more years off. AHIMA recommends that HHS work with the SDOs, other appropriate bodies, such as the National Committee on Vital and Health Statistics (NCVHS), ONC and its contractors, and the industry to target X12 or HL7 versions that would be current at the time of compliance and provide users with the knowledge of how to work with these organizations during the interim for a guide that represents actual needs and expectations.

- In testimony to the NCVHS in January of 2005, the Workgroup for EDI (WEDI) noted that there were now well over 1000 supplemental guides to the X12-837, providing additional instruction from health plans to covered providers. Multiple supplemental guides or this type are not appropriate in AHIMA's understanding of the intent of HIPAA or in the interest of administrative simplification. AHIMA suggests that this e-attachment rule should place limits on the variance or supplemental requirements for a transaction that can be develop and required by health plans. The final rule should also address who will be responsible for the guidelines covering the standards related to e-attachment and their harmonization.

DEFINITIONS

AHIMA recommends that any definitions determined in the final rule be compatible with those throughout the healthcare industry and should be in the rule itself or identify the section where such a standard definition exists and adhered to in the industry. To this end we note that several services listed under "rehabilitation services" (70FR55994) are used in other segments of the industry and are not exclusive to this area.

EFFECTIVE DATES

Given the current environment discussed above, AHIMA believe the implementation time specified, stand-alone, is adequate, however, AHIMA again suggests that HHS consider the effective dates in this rule, in recognition of other HHS and industry requirements and the impact of such requirements on each other and all affected entities.

Overview of Clinical Document Architecture

In line with AHIMA's concerns noted at the beginning of this letter, we must point out that in the discussion on page 70FR55995, work being done by the HL7 on the Clinical Document Architecture (CDA) toward a second release is described. The NPRM notes that CDA Release 2.0 may be completed before any compliance date for e-attachment rules. It is also noted, however, that HHS will not consider using a more up to date release until some time after compliance (2008?). This potentially means that Release 2.0, completed in 2006, could not be implemented until 2010. To make the standards functional for the industry, AHIMA recommends that the final rule either require use of the CDA release 2.0, or the most current balloted HL7 CDA standard, and urges HHS work with the Congress, the SDOs, HITSP, and the industry to reexamine the process for approved standards modifications and upgrades so the health care industry can move forward in its use of all healthcare transaction standards, similar to other industries ability to use electronic standards.

Transactions for Transmitting Electronic Attachments

The comments regarding the transaction standards, considered on page 70FR55996, identify using the standard version X12 4010 but also reference the X12 4050 version. The discussion ignores the fact that by the time compliance is required for a final rule, the versioning of the X12 then current will likely be at a higher version than either standard. Such a decision does not reflect the "current" needs of the healthcare industry. AHIMA recommends that the processes associated with HIPAA, be revised to allow the industry to use current versions of approved standards, accordingly HHS, or if necessary Congress, should revise HIPAA law or regulation to permit the use of contemporary transaction standards or data sets.

ELECTRONIC CLAIMS ATTACHMENT TYPES

The introduction on page 70FR55996 discusses a demonstration on attachments for Medicare claims that began in July of 2004. A report on this demonstration was published in late December of 2005, and it appears that the demonstration fell short in the testing of all aspects of the proposed transactions and data sets, and was limited to only one health plan. While AHIMA welcomes CMS' work toward testing these standards, we are concerned that the pilot and its results do not provide crucial information needed to evaluate the proposed rule as to the structure, elements, and outcomes especially related to the use of the LOINC® codes and other computerized data not commonly used today. We also must note that Medicare claims processing is significantly different than the myriad of process used by other health plans.

On page 70FR55997, you request information as to whether the six proposed attachment types are still the most frequently requested by health plans. AHIMA has encouraged its members to participate in a survey being conducted by the American Hospital Association and the National Uniform Billing

Committee, and looks forward to seeing these results of this study. Never the less, as noted above, claims attachment information is only one secondary use of the health record. HHS must consider the need for attachments – what it takes for a provider to produce the data for such an attachment, and the relationship of this secondary data to the standard EHR – before finalizing this regulation. AHIMA also recommends that HHS consider the impact of implementing an update to the ICD-9-CM classification system as a means to provide additional information on the claim itself, thus negating the need for an attachment.

In recent months, the NUBC has recommend that HHS consider requiring health plans and payers accept all applicable and relevant ICD-9-CM (or in the future ICD-10-CM and ICD-10-PCS) and CPT® codes that can be transmitted with an electronic claim (X12-837), so that a full picture of the diagnoses and procedures related to the patient and episode of care can be had by the health plan or provider. This additional information should eliminate the need for many attachments and can also provide considerable information for health plan programs such as quality measurement.

Further comments on page 70FR55997 suggest that in the future, as other attachment standards could be developed by SDOs, providers and health plans and could be used on a voluntary basis (not as HIPAA standards). Such an idea has merit, but we must point out:

- The industry could then find itself in a versioning dilemma, since newer standards would most likely be in a higher version than those approved under HIPAA;
- That different health plans could the request different versions and have different guidelines which would discourage moving to such a practice; and
- Vendors have indicated to us that they will not begin to spend resources to incorporate standards into their products until the standard has a "force of law" or significant industry demand.

HIM professionals agree that all standards' users should be involved in the development of new standards and modifications and other changes to existing standards. It is not clear, however, how this will occur with proprietary standards such as the LONIC codes. Will there be a public process for LONIC, as is required for other HIPAA transaction and code set standards? What will the process be? AHIMA recommends that the final rule address these questions to maximize public participation in this SDO.

AHIMA is concerned that the rule, as proposed, is vague as to which provider setting is covered for which attachment types. Is the rule meant for all provider organizations or just hospitals and clinics as implied? Although the claims attachment types specified could apply to a variety of provider settings, the discussion of additional new attachments for DME and home care call the question of whether these settings are to be using the proposed attachments or if they should wait for specific attachments unique to their setting?

AHIMA is also concerned that there appears to be a lumping of skilled nursing services under rehabilitation services. Although some skilled nursing services are rehabilitation, others are not. The intent of HHS should be more specified for provider compliance.

FORMAT OPTIONS

The NPRM notes that many healthcare providers are not fully automated. AHIMA agrees and also notes that at the present time a standard EHR or harmonization of standards – ventures that HHS-ONC

and the industry have recently undertaken, are but in their infancy. It is important to point out that most health plans have also not upgraded their legacy systems to permit the auto-adjudication as suggested in this section. At this point in time, therefore, any transmission, no matter what variant, cannot be handled automatically by most health plans. Before health plans are forced to accept either the second "human decision variant" or the "computer decision variant" there are other changes that could be made in the healthcare data system that could provide much richer data for adjudication without the need for some attachments. Such changes would include the adoption and implementation of ICD-10-CM and ICD-10-PCS that have significant detail that provide some of the information commonly asked by health plans.

Human Decision Variant - 1

This variant alternative (first described on 70FR55997) essentially changes the attachment process of healthcare providers from copying and mailing claims attachments to electronic scanning and electronic transmission of these same documents. Since the majority of healthcare providers are not using a standard medical record, this means that a significant human intervention – to copy or scan the appropriate parts of the record in response to the request – remains. Standardizing what data must be in a standard attachment will assist the process over time, especially as the provider also migrates to an EHR, but the amount of human intervention will essentially be the same once the attachment request is received for quite some time. At this time, until the standard EHR is adopted and implemented, it is our judgment that most providers will continue to use this variant, which then in turn might keep health plans from investing in auto-adjudication processes.

Human Decision Variant – 2

This alternative provides a means to reply to questions with text and LOINC codes. It appears that it would work well for solicited situations where the amount of information could be less than the maximum data set. It must be noted however, that HIM departments can only report on information that is in the health record. If not questions must be transmitted to the healthcare provider/clinician. Variant 2 also is a new process that will need significant training and testing. Since there are limited guidelines in the use of the LONIC codes, additional steps will need to be taken by HHS to ensure proper and consistent use and understanding of the LONIC code set.

Computer Decision Variant

The computer decision variant alternative provides for an electronically extracted response to the request, with the computer reading the request and responding to the answer. It also suggests that the response will then be read by a health plan computer that will perform computer-based adjudication. AHIMA agrees that this is an optimum solution, however, we question if this solution is not a bit premature until the industry agrees on its direction use of a standard EHR, otherwise, providers will have to have systems that convert current electronic information into the standard either when a request comes in, or in anticipation of such a request. From our current work with auto-assisted coding, we are aware that such a system approach has a significant potential for error, and will require some type of monitoring or auditing, especially until the industry adopts and fully implements a standard EHR and deals with the question of "minimum necessary," in an automated environment.

Combined Use..Collaboration

AHIMA applauds the concept of using combined standards as highlighted in this rule, we must however comment on the statement on page 70FR55998 where it is noted that standardizing attachments "allows health care providers to anticipate requirements from health plans regarding additional documentation." We are concerned about this statement for a several reasons:

- First we are not sure if HHS intended this to suggest that clinicians are falling short of providing ample information in their charting, or if you were suggesting that items are not being reported adequately from the record. If it is the former, then there may be a question if such items have been agreed to by the affected clinical profession, otherwise, it becomes an issue for HIM professionals to get such data if not charted as guidelines would suggest.
- If there is on-going information needed, by consensus, about a particular type of service or services rendered in response to a particular patient type, diagnosis, and so forth, then perhaps a non-solicited approach should be considered in more cases as institutions implement electronic records and administrative programs. (This is stated with the knowledge that privacy minimum necessary rules must be adhered to.) To build additional software applications programs for attachments is expensive and while standards help the process, applications program architectures are not standard.
- Much of the data requested in an attachment is clinical, AHIMA is recommends that any attachment standard be harmonized with the clinical standards and EHR standards currently under development and in line with the goals of uniformity, consistency, and interoperability. ONC recently initiated the HITSP harmonization process, and this regulation should reflect this process. The healthcare industry cannot afford to have the HIPAA standards out of sync with those developed in our nation's quest for a standard EHR.

Electronic Health Care Claims Attachment vs. Health Care Claims Data

In the introduction of the proposed rule and on page 70FR55999, the NPRM states the difference between data that should be in the claim itself, with data that is to be considered for a claims attachment. There is no discussion or description put forth as to how, where, or when such a consideration should be made. It appears that for some services claims, attachments will always be needed and therefore are essentially an ongoing addendum to the claim. Such demands do have some variation, but in the interest of administrative simplification AHIMA believes that HHS should have an identified, transparent, on-going process for the healthcare industry to determine what data is necessary in a standard claim (X12-837), versus an ongoing attachment, versus a non-standard request.

SOLICITED v UNSOLICITED ATTACHMENTS

Based on our comments immediately above, AHIMA agrees with HHS that attachments should not be submitted in a unsolicited manner, however, some of the attachments suggested by HHS could easily become "routine" once standards are enacted – raising a concern that they in fact become a automatic claim addendum requiring additional work for some providers. Since it will be some time until the majority of healthcare providers will have a system allowing for complete computerization of the requests and responses covered under this proposed rule, the handing of attachments as an exception becomes a additional administrative expense, whether or not the attachment in question is a standard. AHIMA suggests that HHS work with the industry to monitor the claims process and provide and designate situations (claims types) where an unsolicited attachment will be provided to all health plans, for example an ambulance attachment for all ambulance claims.

HHS proposes that for each specific claim, health plans may solicit only one electronic attachment request transaction. This does not prevent additional solicitation, outside of this attachment process, and that reimbursement for claims are often held until all responses to all questions are accepted, even if the original request is met.

Impact of Privacy Rule

AHIMA members have been the administrators of individuals' health records since before AHIMA's beginnings in 1928. Over the years HIM professionals have administered this trust by exercising professionalism over the release of healthcare information and have continued to do so under the HIPAA privacy rule through training and even additional certification. As the industry moves forward, HIM professionals will continue to exercise the rights given to protect individuals/patients under the HIPAA privacy rule's "minimum necessary" sections with respect to the content in each of the approved attachment standards, whether information is requested or sent electronically or on paper.

Problems have arisen with regard to the minimum necessary standard, as HIPAA transaction standards have been implemented. AHIMA expects that the same will hold true for the electronic attachment standard depending on the request for additional information and the particular situation of the patient. According to AHIMA's annual privacy and security survey, over 50 percent of states have some sort of consent law that must be adhered to in addition to the HIPAA standard so each request for information must be review on a situational basis against prevailing laws. In addition, HIM professionals are concerned about the ability to establish an audit trail for the release of such information in case privacy becomes a concern at the receiver end. (See signatures below.)

While AHIMA agrees that only the minimum necessary should be provided, we are concerned that electronic attachments (either scanned or computer variant) will contain information that is over and above the minimum necessary standard. It is impractical and extremely labor intensive and error prone to redact scanned documents so that they only contain minimum necessary. The requirements for minimum necessary should be clarified for scanned and text documents.

Impact of the Security Rule

AHIMA agrees with HHS that the security rule itself should not hamper the use of standard attachments. Concern has been raised however, concerning the need for non-repudiation agreements and the ability to maintain data integrity is systems involving scanning and transmission of LOINC codes. The impact in this case will be related more as to how information is transmitted and received. Some HIM professionals also noted that HHS has not yet addressed the ability to use the Internet for claims or for claims attachments. Given the current environment in healthcare, addressing this issue and allowing for secure Internet transactions would greatly enhance the administrative process for many small providers. (See signatures below.)

Connection to Signatures - Authentication

The issue of signatures has been outstanding since the passage of HIPAA. Signatures and the issue of authentication must be addressed, or there will be problems not only for this proposal, but any exchange of healthcare data that includes personal health information (PHI). While the use of "signature on file"

has served the industry for many years, these proposed regulations ignore the fact that the solicitor of additional data must also be properly identified. There is no mention in this regulation of how the requestor will – in a standard manner – identify themselves and their relationship to the health plan. The proposed regulation also does not address the process for sending a response. Should it always be sent to the same address as the claim, if not what security process should be utilized to ensure privacy is met?

AHIMA is also concerned with the language in the NPRM related to electronic signatures that permits health plans to request a paper copy of the signature plan without limitation. We are concerned that plans will use this practice for a routine audit of claims – a practice that would be to the detriment of providers. Request for paper copy of a signature is used in some cases to delay the claims adjudication process by requiring a manual document be copied and submitted. AHIMA recommends that this practice be constrained and invoked only where there is a specific concern. In the absence of a national standard, we also recommend that health plans accept the provider's policy for use of electronic signature to authenticate electronic documents and not impose their own standard or policy for what is or what is not an electronic signature.

Connection to Consolidate Health Informatics (CHI) Initiative

AHIMA agrees with HHS' comments regarding CHI, however, we would also note that the standards under CHI were not adopted under HIPAA and have not been harmonized under HITSP. We believe this identifies the need to ensure harmonization of HIPAA and CHI standards and appropriate mapping so that true data interoperability exists in the future.

ATTACHMENT CONTENT AND STRUCTURE

While the NPRM mentions the amount of time attachment standards have been under consideration by the SDOs, you also note that significant changes are occurring in the healthcare industry and your concern for the impact of these changes on these standards and the processes and workflow that surrounds them. Among the changes in the industry is the quest for the standard EHR and an interoperable healthcare data exchange. Inherent in this approach is the potential that healthcare data could reside in more than one location for a patient – meaning that potentially to complete all the information being requested in an attachment might require a different approach than that which is currently being considered in stand-alone organizations. This should be studied and accounted for in any final rule, and AHIMA offers its resources for such a review.

AHIMA and its members are deeply involved in the various activities related to achieving interoperability and the EHR. We are concerned that as HHS is attempting to put in to place a process (and tangential work process) for "attachment" data to be exchanged between providers and payers, it should consider today's environment and goals, and not those identified in 1993 and 1998 -- the last time any serious consideration was given to the need for attachments. This is not a question of if we address the need for attachments, but rather of "how." The work flow associated with the attachment process is significant for healthcare providers and health plans. The proposed rule has not addressed the current situation for attachments beyond those identified several years ago. We see the direction the Department is leading the industry for the EHR, NHIN, and harmonization and we believe the rule should reflect more coordination with the goals of the President, Secretary, and ONC, and describe how this rule will be harmonized with these goals and current needs.

AHIMA and many other healthcare providers, professionals, population health organizations, vendors, health technology groups, and some health plans have been actively seeking adoption and implementation of an upgrade to the ICD-9-CM classification system for diagnoses and inpatient procedure and technology, since 1993. In 2003, both the NCVHS and the Congress made similar recommendations to the Secretary, but no action has yet occurred toward adoption. We have argued that if the ICD-9-CM system were replaced with HHS-developed ICD-10-CM and ICD-10-PCS classification systems; significant detail would be present for adjudication that could eliminate some of the details often sought out in the request for attachments. The Centers for Medicare and Medicaid Services (CMS) has made a similar argument in testimony to the NCVHS, and other government agencies have likewise recommended such an upgrade. Those that have argued against a more refined and detail set of classification systems, have noted that health plans can ill afford to change adjudication systems to accept more detail, this appears contrary to the rational proposed in this September 23, 2005 NPRM.

On a similar note, the National Uniform Billing Committee (NUBC) has also called on CMS and the industry to begin using all of the potential diagnoses and procedure codes that are available on the X12-837 claims transaction and not limit them to just those that can be identified on the paper claims. Again, this is additional detail that can often eliminate the need for attachments.

Besides questioning the information and approach to attachments, given today's environment, we are also concerned about the approach to the standard's versions expressed in this proposed rule. Recently in our work to secure adoption of an upgrade to ICD-9-CM, it came to the attention of many that the X12 and NCPDP standards and guidelines also need upgrading, for a variety of reasons including the ability to accommodate the ICD-9-CM upgrade appropriately. It was further discovered that any modification under current HIPAA regulations and law could take well over 4 years because of the required activities of the SDO, DSMO, and the Department. Four years in today's environment is intolerable, and AHIMA and many others are seeking a means to change such a process, and yet allow the necessary role of the SDO and the industry to ensure our standards are up-to-date and not a barrier to our healthcare system and the services we render our patients. For this reason AHIMA recommends that HHS consider some alternative to locking the proposed standards into what could be antiquated versions by the time the final standards are compulsorily.

ALTERNATIVES CONSIDERED....

As noted elsewhere, AHIMA agrees with the approach that HHS took to arrive at a process that uses more than one standard. However, as just noted we are concerned that the standards selected might not be up-to-date when a compliance date is met and therefore be detrimental to the industry.

AHIMA members have worked with the X12 and HL7 for several years and understand their approach and how the public can work with these SDOs for a consensus standard. While AHIMA members are familiar with LOINC, especially in the area of laboratory reporting codes, we are less familiar with the codes being recommending for messaging and beyond laboratory reporting. Likewise, since LOINC is a proprietary coding system, we are not aware of how the public/industry will be given access to the coding change or modification process similar to some of the other codes utilized in standards under HIPAA. HHS should consider

- identifying the public's role in LOINC and its codes and guidelines once the standard is accepted,
- identifying any guidelines for the use of LOINC under the HIPAA standard, and

- work with the industry to ensure education is available on the use of LOINC and its guidelines.

Examples

AHIMA reviewed the examples and flowcharts provided, and has the following comments:

The flow charts for providers do not indicate the request for an attachment (solicited). It is presumed that such a request might be in the standard suggested by the rule, but not necessarily. Some providers may not be able to accept such a request, especially smaller entities that use clearinghouses for claims, but do the rest of their work by paper, phone, and Internet.

Figure 1: Our review of this flow chart raised the point that scanning documents is often more complicated than the current process of copying. Members and vendors we queried were not aware of industry-wide billing application software that would move the scanned image into the billing application and capture a record of the transaction. It was noted that currently some providers request a receipt from the health plan that accepts the transaction. This proves that the attachment was sent and accepted by an appropriate party. Currently HIPAA does not have a receipt process – perhaps, since there are X12 transactions that would accomplish this transaction, one or more transaction standard could be added to the HIPAA standards.

Figures 2/3: AHIMA's review noted that these flows add additional manual steps and could result in more errors. In larger organizations only HIM personnel would be involved in responses that simply record additional information from the record, however, there are times when the response must come from a clinician. Again, there are the issues of appropriate application software, a copy of what was sent, and an acknowledgement.

Figure 4: We viewed this scenario as future, since it would work more economically with a standard EHR than today's proprietary systems. Since most of the electronic records systems, today, do not permit outside query, concerns were raised about how the request gets into the system to generate a response and how manual that effort might be. Concern was also raised about the ability to place privacy walls in order to ensure that the provider's minimum necessary requirements are met.

Figure 5. This figure suggests that the electronic attachment will either be reviewed on a screen or printed and reviewed. Our reviewers were concerned about health plan issues with the integrity of the data of the data and the ability to have a non-repudiation process. Any conversion of data could create a problem, and both parties to a transmission should understand any problems that could occur as transmitted data is opened and processes in this figure or any of those following.

Figures 6-8: These figures identify additional abilities that health plans might add to automate the adjudication of attachments. Given the status of the industry we do not see the ability or the desire to implement such systems, and would note that health plans should pay special attention to the standard being developed for the EHR. Those developing the EHR and the architecture in which it will reside must be aware of data that will commonly be requested and reported. Such data may be in a classification process that combines data elements in the EHR, or the reporting of specific data out of the EHR. Close work at this stage of development should improve information flow for a variety of uses including claims processing and these attachments.

Requirements – Maximum Data Set

On page 70FR56013, the NPRM discusses the maximum data set. AHIMA agrees with the concept described, but the restriction recommended does not preclude a health plan for asking for additional information outside of the electronic claims process. When the original HIPAA claims transactions were being considered there was also a thought concerning a maximum data set, with the idea that health plans and respective partner health providers could agree on transmitting less than the full data set (to reduce redundancy), however in practice the full maximum data set has become the standard forcing the transmission of data that is not needed in all cases. While use of the human variant-2 and the computer variant, might be able to address a concept of less than total data, we are not sure this will happen.

AHIMA agrees that covered entities need to review the AIS and provide comments regarding applicability to today's environment, but we must point out that a process should be in place to do this on an ongoing basis, with appropriate upgrades to the standard. Failure to have a process that allows for change in a rapidly changing industry will not resolve its administrative costs and information concerns.

MODIFICATIONS TO STANDARDS AND NEW ATTACHMENTS

Our comments above noted that a survey has only recently been undertaken by the NUBC on the types of attachments needed. AHIMA is aware that the HL7 has reviewed the recommended attachment types and raised questions regarding the emergency department attachment. In the meantime, the AHIC has undertaken a "breakthrough" task associated with information also coming from emergency departments. Given the breath of AHIMA's membership and the current environment, we have no recommendation for or against the attachment types proposed in the NPRM, but recommend that they be reviewed in light of other activity occurring in projects associated with AHIC, ONC, and CMS pay for performance efforts.

Currently the ICD-9-CM volume 3 procedure and technology codes are in danger of reaching a point, in the near future, where new codes cannot be generated or granted unless out of appropriate sequence. If this occurs, additional attachment information will likely be needed to identify new technologies and procedures. This may be an area that needs consideration for such an attachment, however, at the same time, development and implementation of new attachments many not be able to keep up with the need as pointed out above.

AHIMA strongly recommends that there be an efficient process for adding new claims attachments that recognizes the primary purpose of the standard EHR, the need for uniform, consistent data, and accommodates the industry need for secondary claims data on a timely basis. It appears that current HIPAA regulations and possibly law will need modification to permit this to happen. AHIMA looks forward to working with HHS to see such a process develop.

Modification to Standards

AHIMA has noted several times concern with the current HIPAA modification process and requests the Department address these problems. We have also noted our concern that the NPRM does not address public participation, schedules, and the processes in the establishment and maintenance of LOINC codes and guidelines, other than submission of requests for new codes. It is our belief that, under HIPAA, coding maintainers should have a process for not only requests, but also for public comment regarding

changes that might be made to codes and code sets. To do this requires a transparent process so that the industry/public can be so involved in the process.

Issues identified in sections B and C have been addressed above.

COSTS and BENEFITS

AHIMA must note our concern that the NPRM uses studies undertaken in 1993 and refers to pilots and studies that have just been reported and are limited. While we share HHS' goals for standardization and privacy, we do not see relevant information that provides data to determine cost and benefits in today's environment. Implementation will vary by organization and the demand for attachment information. Costs will also be affected by other demands and projects that will occur during the implementation phase. We have noted elsewhere in these comments, that the attachment is but one secondary use of health record data. Adoption and implementation of this transaction must we done in relation to other changes anticipated by HHS and the industry.

Conclusion

It has been clear for many years that standardization of health claims attachments had the potential to improve the administration of the claims process for providers and health plans. As the HIPAA standards were conceived, claims attachments became one of the prime standards identified, but over the course of the 10 years since HIPAA legislation came into being many other changes have occurred in the healthcare industry that while not changing the need for standard attachment data, have changed the perspective as to how we approach developing such standards. At the same time, the priorities and projects undertaken by the healthcare industry toward a standard EHR, interoperability, and an NHIN have also accelerated immensely.

AHIMA's comments have take both of these changes into account in addressing the NPRM released in September 2005. We have also recognized and urge others to recognize that claims attachments are a secondary use of the data contained in the health record. As the industry moves to standardized both of these collections of data, it must do so in a reliable and reasonable fashion. AHIMA, and the 50,000 professionals it represents, professionals who task is to report data from the record, stand ready to work with the industry to accomplish a reasonable and timely implementation of the standard EHR and claims attachment, as well as ensure that data in both is harmonized, consistent, uniform, and reliable. AHIMA members also stand ready to work with providers, health plans, and HHS to ensure that administrative simplification can be achieved, and when possible eliminate the need for some data exchange now needed to process claims.

Our thanks for your review and your consideration of this letter. If you have any questions or concerns, or would like additional AHIMA involvement as the development of standards move forward, please let me know at 202/659-9440 or at dan.rode@ahima.org.

Sincerely,

Dan Rode, MBA, FHFMA

HBMA
Healthcare
BILLING & MANAGEMENT
Association

January 23, 2006

The Honorable Michael Leavitt
Secretary
Department of Health and Human Services
Attention: CMS-0050-P
Mail Stop C4-26-05
Baltimore, MD 21244-1850

HBMA Comment to CMS on the Proposed Standards for Electronic Health Care Claims Attachments CMS–0050–P NPRM (45 CFR Part 162)

Secretary Leavitt:

The Healthcare Billing & Management Association (HBMA) is pleased to offer comments and recommendations on the Department of Health and Human Services Notice of Proposed Rule Making (NPRM) of September 23, 2005, that proposes standards for electronically requesting and supplying additional health care information in the form of an electronic attachment to support submitted health care claims data.

Founded in 1993, the (HBMA) is the only trade association representing third-party medical billers. HBMA members process physician and other provider claims integral to the health care delivery system. They not only bill for medical services, but frequently perform all of the physician's administrative functions. Three out of four HBMA members are expanding their business to include accounts receivable management, consulting and practice management services.

HBMA members typically provide services to specialty physician groups and primary care practices and process Medicare, Medicaid, and private health insurance claims. A typical HBMA member processes approximately 20,000 claims per month, totaling $20 million per year; some do much more.

HBMA member companies are largely involved in the administrative and management functions of a medical practice. While some of our members possess technical knowledge and have developed computerized billing software, this is not where the bulk of our expertise resides.

In developing these comments, HBMA members worked closely with other industry representatives, particularly the Association for Electronic Health Care Transactions

(877)640-4262 PHONE • (949)376-3456 FAX • www.hbma.com
1540 S. COAST HWY, SUITE 203 • LAGUNA BEACH, CA 92651

(AFEHCT). We urge the Department to review and consider carefully the comments submitted by AFEHCT as they have considerable expertise in this area.

1. General Observations

HBMA would like to express its disappointment that the Health Insurance Portability and Accountability Act (HIPAA) was adopted in the mid-'90s and we have yet to realize the benefits promised when this legislation was adopted. While most providers and billing companies have made major investments in purchasing and utilizing the technology necessary to submit electronic claims, we have not seen a similar commitment on the part of many commercial third party payers to remitting claims payments and data in an electronically efficient manner. Consequently, while third party payers have met the letter of the law in terms of remittance of electronic claims information, the remittance information is often so inconsistent that it's impractical to process electronically. We have billing companies that are less automated today, than they were 10 years ago.

The goal of HIPAA remains laudable and appropriate. Unfortunately, there remain significant failures of standardization that prevent efficient and smooth electronic transactions. As a result of these failures, we believe there is significant skepticism on the part of the provider community to making any more investment in technology and the human resources necessary to make electronic transactions fully operational.

Companion guides are a mechanism through which a third party payer is able to require special formatting or information from a provider that effectively negate the value of electronic transactions. HIPAA established standardization with regard to the data fields but the content of those fields remains within the purview of the individual plan. This has led to significant differences from plan to plan as to what are acceptable characters or content within those standardized fields. Rather than have a consistent, uniform electronic claims processing mechanism, the provider community continues to deal with multiple requirements and individualized requests for information that prevent the provider community from realizing the efficiencies HIPAA promised.

We STRONGLY urge the Department to go back and review the whole concept of companion guides, their value to the industry and whether they should continue to be permissible. Furthermore, we recommend that HHS go the next step and direct uniform content standards for the data fields.

2. Electronic Claims Attachment Types Reference: "Electronic Claims Attachment Types" NPRM II.C.5. – page 55997, column 1;

CMS Proposed Policy

In this proposed rule, CMS proposes six specific electronic attachment types, each with data content requirements related to treatment or services provided. These six

attachments are: (1) Ambulance services, (2) emergency department, (3) rehabilitation services, (4) clinical reports, (5) laboratory results, and (6) medications.

HBMA Recommendation

At the present time, the 6 electronic claims attachment types identified in the proposed rule are common attachment requests; however, they are not the only information that could be requested as an attachment. It is not uncommon for third party payers to request a copy of the surgical notes as part of a payment determination for a surgical procedure. It is also not uncommon for a plan to request an invoice as an attachment. Consequently, we recommend the addition of a category (7) surgical notes and a category (8) other.

3. SOLICITED vs. UNSOLICITED ATTACHMENTS

In general, health care providers will submit their electronic health care claims attachment information to the health plan for certain claim types, upon request, after the health plan has received and reviewed the claim. This follows the course of claims adjudication today. Health plans may also request, in advance, that additional documentation (the attachment) accompany a certain type of claim for a specific health care provider, procedure, or service.

A. Modify Prohibition Against Sending Attachments without a specific Plan request: SOLICITED vs. UNSOLICITED ATTACHMENTS -. NPRM II.D.2, page 55999, 56024

Many in the billing industry believe that third party payers will use this solicited vs. unsolicited option as a means for delaying payment either through delays in processing a claim when an unsolicited attachment is provided or, through delays in requesting an attachment, even though the provider knows that the third party payer typically requests additional information on a particular claim.

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

HBMA Recommendation:

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

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

- If a plan receives an unsolicited attachment, it may not later request the same attachment.

B. Electronic Health Care Claims Attachment vs. Health Care Claims Data: Solicited vs. Unsolicited Attachments, NRPM, page 55999

CMS Proposal

"We are proposing such a restriction around ``unsolicited" electronic attachments, because we believe that there are legal, business, and technical implications for health care providers, health plans, and their business associates for handling and processing unsolicited attachments without prior direction."

HBMA Recommendation

While HBMA appreciates the "legal, business and technical implications" surrounding solicited vs. unsolicited claims attachments, we believe the rule is overly cautious. It is important to keep in mind that those submitting the claim are either covered entities or business associates. The principle concern on the part of the government appears to be adherence to the requirement that the payer only solicit and the provider only provide, the minimum necessary to properly adjudicate the claim.

What a provider deems the "minimum necessary" and what the plan deems the "minimum necessary" may vary greatly. In our view, allowing the individual provider to use his or her professional judgment and experience does not violate the "minimum necessary" requirements of HIPAA.

We believe, as noted below, that when a provider has, based upon past experience, a belief that a third party payer will request additional information, the provider be permitted to submit that information without a formal request from the plan. If the plan does not need the information, they are not obligated to open the attachment and if it is necessary, it is available for review.

C. Permit Multiple Requests for Additional Information Reference: "SOLICITED vs. UNSOLICITED ATTACHMENTS" NPRM p55999

The prohibition against multiple requests contains an inaccurate premise that the entire need for additional information can be determined by examining the claim. But it is possible that for some cases, the need for a second request is not knowable until a first

request has been satisfied. If a second request is not permitted, the result would be for a plan to load up the first request to obtain, at the provider's expense, contingent information that is generally not needed.
A health plan will ask for more information than it needs on average in order to obtain what it needs for low frequency cases. Request for unneeded information increases the burden on providers and unnecessarily delays payment.

What happens if a plan finds it did not request sufficient information? Does the plan deny the claim and require resubmission? That detracts significantly from efficiency for both the plan and provider. Or must the plan pay the claim with insufficient information? Perhaps that raises health care costs.

HBMA Recommendation:

Permit multiple requests provided that a subsequent request is based on information obtained in an earlier attachment and is not duplicative of earlier information received from the provider.

D. How to Apply 'Minimum Necessary' Standard to Attachments Reference: "SOLICITED vs. UNSOLICITED ATTACHMENTS" NPRM II.D.4.

HBMA Recommendation

In our view, the Privacy Rule already restrains a plan from asking for more information than it needs. It also restrains a provider from sending more information than requested. But there is a reasonableness issue here as well; a provider should make an assessment of what is being requested if it seems to exceed what is necessary for the purpose required, as required by Privacy rule section 164.514. We think the Privacy Rule is fully applicable and this rule should not contain more privacy language. As we said previously, rely upon the professional judgment of the providers and plans.

E. Method for Signatures on Claims Attachments Reference: "SOLICITED vs. UNSOLICITED ATTACHMENTS" NPRM II.D.6. p56000

HBMA believes that most health plans, including Medicare and Medicaid programs require signatures certifying certain types of services, such as sterilization, certain rehabilitation plans, and authorization for certain types of equipment. Health plans may request a paper copy of the signature page, or they may accept the response code indicating that the signature is on file.

HBMA Recommendation:

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

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

Will this allow us to realize needed changes quickly enough to be responsive to industry needs?

HBMA Recommendation:

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

5. **Implementation Compliance Date Reference: "EFFECTIVE DATES" NPRM pp55994, 56025**

HBMA Recommendation:

HBMA recommends that the final rule be published as soon as possible. Again, as noted earlier, HIPAA has been on the books for nearly a decade and under the current timetable, it could be another 3 – 5 years before claims attachments are implemented – presuming some 3rd party payer group does not seek further delay.

Because much of the technology exists for the transmission and acceptance of attachments and the technical requirements already exist, we see no reason why it should take 3 – 5 years for health plans to be able to accept attachments. We would note that all commenters were able to submit their comments as attachments and we were provided multiple formats (although one was preferable) in which to submit those comments.

Conclusion

On behalf of the Healthcare Billing and Management Association, I want to thank you for the opportunity to provide these comments. Please do not hesitate to contact us if you need any additional information. Our contact is:

Bill Finerfrock
202-544-1880
bf@capitolassociates.com

Sincerely,

Randal Roat, CHBME
Chair
Government Relations Committee
Healthcare Billing and Management Association

JAN 24 2006

STATE OF WASHINGTON

DEPARTMENT OF SOCIAL AND HEALTH SERVICES
HEALTH AND RECOVERY SERVICES ADMINISTRATION
DIVISION OF AUDIT AND INFORMATION SYSTEMS
623 8TH AVE. S.E. · P.O. BOX 45511
Olympia, Washington 98504

January 10, 2006

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

Thank you for the opportunity to review the HIPAA Administrative Simplification Standards for Electronic Health Care Claims Attachment. The State of Washington's review indicates that the proposed changes for the first release of the Electronic Claims Attachment Transaction will not significantly impact current business processes. This is due to the fact that none of Washington Medicaid's high-volume paper attachments are included in the first release. For that reason, we have noted and submit the following comments and questions for consideration.

- Please consider a clarification in the final rule that clearly excludes Prior Authorization attachments from this regulation.
- **Proposed Standards – 56006** The proposed rule does not include insurance backup in its initial release. Since a large proportion of Washington Medicaid's paper attachments are insurance backup documents, Washington requests that electronic insurance backup be added to the initial release for the 275 transaction. The addition of this claims attachment to the initial release of the 275 transaction would have a significant positive impact on Washington Medicaid's claims processing functions.
- **Proposed Standards – 56006** The proposed rule does not consider consent forms in the initial release of the 275 transaction. Although it is noted for future consideration, Washington Medicaid requests consideration of adoption as soon as possible. Consent forms are widely utilized as claims attachments and a mechanism for electronic receipt of consent forms would have a significant positive impact on our claims processing functions.
- **Proposed Standards – 56006** Washington Medicaid requests that claims attachments supporting eligibility verification or confirming a client's eligibility be considered as a valid attachment type to be included in the 275 transaction. Health care providers are frequently required to send documentation to verify a member's eligibility status at the time a service was provided; copies of Medicare or Medicaid identification cards or Medical Eligibility Verification receipts are examples of this documentation. In addition, Washington Medicaid requires proof of eligibility for a number of psychiatric services. These are provided by entities such as our county-operated Regional Support Networks which provide community-based mental health services and could include attachments such as the Involuntary Treatment Agreement form or Certification for Inpatient Psychiatric Stay. The ability to receive these documents electronically would be extremely valuable to our claims processing functions related to these services.
- **Solicited vs. Unsolicited Attachments – 55999** Washington does not believe that a limitation of one request per response if feasible. The determination of need for additional backup is often based on the processing of the first requested attachments.

For example, the health plan may require medical records to authorize a procedure before they know that an invoice will be required to price the supplies used in conjunction with that procedure. In addition, the health care provider may not be aware of or sufficiently comply with the initial request, prompting additional requests.

The Washington State Department of Social and Health Services submits these comments and questions to the Department of Health and Human Services, Office of the Secretary for review. I would be happy to discuss these items in more detail if you have questions.

Thank you for your consideration of this matter.

Bob Covington, Director
State of Washington Department of Social and Health Services
Health and Recovery Services Administration
Division of Audit and Information Systems

Cc: Cathie Ott
Christopher Nguyen

38

MGMA Center for Research
American College of Medical Practice Executives
Medical Group Management Association

MGMA

January 23, 2006

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

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

Dear Dr. McClellan:

The Medical Group Management Association (MGMA) appreciates the opportunity to comment on the proposed rule for electronic claims attachments. MGMA is the nation's principal voice for medical group practice. MGMA's almost 20,000 members manage and lead more than 12,000 organizations in which more than 242,000 physicians practice. Our individual members, who include practice managers, clinic administrators and physician executives, work on a daily basis to ensure that the financial and administrative mechanisms within group practices operate efficiently so physician time and resources can be focused on patient care.

We are a strong proponent of administrative simplification and believe that, once properly implemented, e-claims attachments can streamline an important billing transaction for medical group practices. We encourage CMS to move forward expeditiously in the development of the final rule and continue to solicit provider feedback during this process.

General Comments

As the federal government and the health care industry move toward adoption of standards for electronic claims attachments, the following issues should be considered:

- Standards Should be Flexible and Scalable – From the physician perspective, standards for electronic claims attachments must take into account the wide variety of clinical settings and specialties. The final standard must be both flexible and scalable to encourage adoption by both small and large health care organizations and physician specialties processing both low and high volumes of claims attachments. The standards should also provide for the needs of larger, more complex group practices and health systems. This flexibility will allow physicians to consider critical factors such as clinical quality, safety, efficiency and integration with existing practice management software and electronic health record systems when making an investment.

- No Undue Burdens on Providers – In these challenging economic times, with decreasing reimbursement and increasing practice expenses, it is critical that CMS craft a final rule that does impose undue financial burdens on physician practices. Furthermore, e-claims attachments systems should be designed in such a way that clinicians are able to utilize this technology in a time-efficient manner.

HEADQUARTERS
104 Inverness Terrace East
Englewood, CO 80112-5306
phone:303.799.1111
fax:303.643.4439

GOVERNMENT AFFAIRS
1717 Pennsylvania Avenue
North West, Suite 600
Washington, DC 20006
phone:202.293.3450
fax:202.293.2787

www.mgma.com

- Promote the Security and Privacy of Patient Data – Patients are more concerned than ever about maintaining the security and privacy of their health information. At the same time, providers are embracing the new standards in these areas as mandated by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Electronic claims attachments must maintain these HIPAA standards as part of its core operating features. CMS should provide guidance on the critical issues surrounding the minimum necessary provision of the Privacy regulation and its impact on e-claims attachments.

- Incentives for Providers – While medical practices typically absorb the cost of purchasing the health information technology necessary for e-health technologies, many of the benefits accrue to others in the system. MGMA believes there should be a "realigning" of these incentives by promoting appropriate public and commercial reimbursement programs. MGMA has supported the concept of a federal program of tax credits for physician investments in health technology that could serve as a significant incentive. Additionally, a federally guaranteed loan fund for physician health technology investments, coupled with loan forgiveness for service to medically underserved populations, could also serve as a stimulus to e-health adoption.

- Technology Savings Accounts – The federal government should also explore innovative methods to assist medical practices in the acquisition of health information technology. Technology Savings Accounts (TSAs) would provide a reduced level of taxation for funds designated for practice health information technology (HIT). A TSA would be a special account owned by a group practice where contributions to the account pay for current and future qualified health information technology expenses including e-claims attachments software and hardware. A TSA is a savings product that would offer a different way for group practices to pay for their health information technology expenses. TSAs could enable group practices to pay for current expenses and save for future qualified health information technology expenses on a tax-free basis. Unspent account balances would accumulate and accrue interest.

- Stark Regulation Safe Harbor – There are clear legal barriers to the adoption of health technology solutions in medical groups. Anti-kickback and self-referral concerns prevent some health care organizations from offering free or discounted technology to medical practices. MGMA has advocated for government approval of legal protections, such as safe harbors and regulatory exceptions, to facilitate health technology implementation. We congratulate CMS for their important step in this direction through its creation of a health technology safe harbor in the physician self-referral phase II interim final rule (CMS-1810-IFC; 59 Fed Reg 16054).

- Development of Clinical and Administrative Crosswalks—To assist the industry in fully realizing the administrative savings potential of e-claims attachments, CMS should develop and freely make available crosswalks between ICD, CPT, and LOINC code sets. It is expected that the 277RFI transaction will encompass ICD and CPT codes (in addition to other requests) and a robust and publicly available crosswalk would assist software developers, standardize products, and potentially lower costs for purchasers.

- Staggered Compliance Dates – The protracted nature of the HIPAA implementation process suggests that the federal government's e-health regulatory process must be modified. MGMA calls on the government to stagger implementation dates, thus providing clearinghouses and health plans time to upgrade and test systems before provider implementation takes effect. While piloting is not needed to establish the applicability of the core function standards, piloting of the e-claims attachments standard should be completed prior to full national implementation in

order to identify and correct problems. The proposed rule (p. 56001) states that "It would be helpful if health care clearinghouses were among the first of all entity types to come into compliance with these standards so that testing between trading partners - health care providers and health plans - could be executed in a timely fashion." We agree with this assertion but believe this testing phase should be mandated as part of the implementation process.

- Development of a National Rollout Plan - HIPAA regulations typically call for implementation 26 months after the final rule. This timeline may not be feasible for e-claims attachments. CMS should initiate a national rollout plan that would take into account the requirements of each impacted sector of the industry. MGMA recommends that providers be given an additional 12 months to come into compliance. CMS should institute piloting to ensure that implementation of the final rule will be as efficient and costs-effective as possible. In addition, Medicare and state Medicaid programs should develop the capability to send and receive e-claims attachments as quickly as possible after the final rule is released. This will facilitate a more rapid adoption of these transactions.

- Continued Consultation with the Physician Practice Community – Physician practices must play an integral role in the development and deployment of any standardized e-claims attachments system. Since the vast majority of all health care is delivered in these practices, the success or failure of these initiatives will depend heavily upon physician acceptance of this new technology. MGMA encourages CMS to continue its outreach to this community to ensure that the requirements and concerns of physicians are addressed.

- Industry Outreach – The successful adoption of e-claims attachments will depend, in part, on the ability of the federal government and the industry to encourage all covered entities understand and support the system. Providers in particular will be most challenged by this new regulation. Physician practices typically are not well versed in HL7 and LOINC and will require substantial education before they are fully aware and comfortable with this transaction. CMS should also communicate with the software vendor community, through town hall meetings and open door forums, etc., Vendors must be encouraged to move forward with the development of products as quickly as possible. In addition, MGMA recommends that CMS work with the appropriate industry associations to deliver a consistent message on this important change in the health care system.

Specific Comments on the Notice of Proposed Rule Making

Summary

Citation (P. 55991) "And finally, this rule proposes the adoption of the Logical Observation Identifiers Names and Codes, or LOINC for specific identification of the additional information being requested, and the coded answers which respond to the requests."

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

Comment: Providers will be significantly challenged by LOINC. The HL7 "languages" are not commonly used by physician practices, especially smaller ones. CMS needs to identify a process to educate providers on how to access and utilize LOINC codes. In addition, providers will need to be appraised of how the maintenance and updating to LOINC will occur. We understand that

educating the provider community on claims attachments will be a significant undertaking for CMS. Accordingly, we recommend that CMS partner with provider associations and industry coalitions to develop consistent outreach materials and programs to ensure that the transition to these new transactions is as rapid and effective as possible.

Effective Dates

Citation: (P, 55994) "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."

Issue: Is the proposed time implementation time frame sufficient for the industry to come into full compliance?

Comment: MGMA believes that the timeframe outlined is not adequate for the implementation of the claims attachment standard. In order to transition to this new standard, like the other HIPAA transaction and code set standards, providers will be forced to rely on their software vendor partners, the majority of which are not covered entities. The extraordinary delay in the promulgation of this rule may have delayed development of software products. It is our understanding that few software vendors are currently offering "compliant" e-claims attachments products. These will have to be designed and marketed and we expect that many of the vendors will wait until after the final rule is released before initiating the development process. This will greatly shorten the time available for providers and others to come into compliance within the 24-month period allocated. Providers, and other covered entities, will require time for budgeting, adoption, training, and testing. In addition, there are numerous other e-health activities that will be competing for scarce resources, including electronic health records, electronic prescribing, and other HIPAA regulations including updates to the transactions and code sets standards and implementation of national identifier standards. We recommend that providers be given 36 months to come into compliance. This affords a designated 12-month testing period between clearinghouses/health plans and their provider partners.

In addition, MGMA recommends that Medicare and state Medicaid programs develop the capability to send and receive e-claims attachments as quickly as possible after the final rule is released. By exhibiting this leadership and adopting these standards, Medicare and Medicaid programs can immediately begin experiencing administrative savings while jumpstarting the industry and facilitating the widespread implementation of these transactions.

Overview of Clinical Document Architecture

Citation (P. 55995) "We invite comment on the pros and cons of each CDA release."

Issue: The NPRM is seeking comment on whether to name HL7's CDA Release 1 versus Release 2 as part of the clinical document architecture.

Comment: CMS should consider moving to CDA Release 2. Release 2 adds the improvement of technical consistency among all new HL7 standards including some of the following: Genomic Reporting; Adverse Event Reporting; and the Care Record Summary used for Continuity of Care Record. Release 2 facilitates the use of off the shelf software to a greater degree than Release 1. It increases the compatibility of electronic health records for standards and other applications based on CDA. In addition, Release 2 offers improved technology for validating computer-

decision variant instances of attachments (when this is required) and complies with the recommendations offered by the U.S. Federal Consolidated Healthcare Informatics initiative. At the same time though, MGMA recommends that CMS initiate and complete a pilot prior to the identification of Release 2 as the national standard.

Electronic Claims Attachment Types

Citation (P. 55997) "In this proposed rule, we propose six specific attachment types, each with data content requirements related to treatment or services provided. 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"

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

Comment : While we agree that the six attachment types named in the proposed rule are still relevant and important for claims adjudication, we contend that there are numerous other types that should be incorporated into the final rule. These may include such types as durable medical equipment, medical necessity, sterilization consent forms, Medicaid spend-down, secondary payer questionnaire, and home health. We encourage CMS to partner with the industry to establishment a process to explore which additional types should be prioritized and proposed to HL7 for implementation guide development.

Electronic Claims Attachment Types

Citation (P. 55996) "Based on industry feedback following implementation of the Transactions Rule, it became clear that pilot programs and early testing of new standards and processes were vital to the standards adoption process."

Issue: The use of pilot programs to facilitate adoption of e-claims attachments.

Comment: For many group practices, the economics of investing in e-claims attachments and other health information technology is simply not evident. In an environment of scheduled Medicare reimbursement cuts, sharply rising malpractice premiums and ever-increasing administrative expenses, many practices are concerned that moving to an electronic information systems will not be financially beneficial. MGMA recommends that CMS develop educational programs that utilize the lessons learned from the claims attachment pilot completed in New York State. Establishing and widely disseminating the fact that provider and health plans both observed a replicable quantifiable return on investment (ROI) is an excellent method of encouraging the industry to more quickly adopt this electronic transaction. We also encourage CMS to initiate additional pilots to help identify the ROI for this transaction.

Solicited vs Unsolicited Attachments

Citation: (p. 55999) "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."

Issue: The proposed rule indicates that unsolicited attachments could continue if "instructions" between health plan and provider exist.

Comment: MGMA asserts that providers should be permitted to send unsolicited attachments if, based on prior arrangement and/or experience with a health plan, they have been asked to send them previously. If the health plan does not wish to receive these unsolicited attachments, they should inform the provider and make other arrangements to collect the necessary data. In addition, should the plan instruct the provider that an attachment is not required but resumes requesting the attachment, CMS should permit the provider to resume sending unsolicited attachments. CMS should also take a leadership role in coordinating industry efforts to adopt "operating rules" pertaining to these "specific advance instructions." It would be extremely beneficial for providers to receive these instructions in a common format. In addition, CMS should prohibit health plans from refusing to offer specific advance instructions to providers when requested.

MGMA recommends that the term "instructions" (in Sec. 162.1910 and 162.1920) be changed to "prior arrangement." This would allow the sending of unsolicited attachments between providers and health plans where a trading partner agreement already exists. If possible, CMS should design the final rule so that current trading partner agreements permitting unsolicited attachments would not have to be rewritten.

MGMA also has concerns that health plans may send unnecessary attachment requests, which would have the effect of delaying the payment cycle. In order to avoid this, MGMA recommends that CMS not permit the requesting of information in a claims attachment that is already contained in a compliant 837 transaction.

Issue: Should the attachment transactions allow a separately submitted unsolicited attachment (separately submitted from the claim)?

Comment: MGMA believes that CMS should allow an unsolicited attachment to move separately from the 837. We do not believe CMS should place a time limit on when a provider is permitted to send an attachment in support of an 837. Trading partner agreements between providers and health plans will determine the appropriate time limits.

Citation: (p. 55999) "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: Should health plans be permitted to request an attachment to the same claim more than once?

Comment: MGMA believes that the CMS objective here is laudable—namely, to further the goal of administrative simplification by not permitting health plans to request an attachment on more than one occasion for the same claim. On one hand, providers would like to avoid the situation where they respond to an attachment request with the appropriate response only to find later that the plan has additional attachment requests. It is clear that multiple requests slow the adjudication process. On the other hand, we recognize that there may be situations where the health plan legitimately requires more information than they anticipated in the initial attachment request. We have concerns that health plans, having not received the information they feel is necessary to adjudicate, would simply deny the claim. We recognize that the appeals process adds administrative burden to both providers and health plans and would like to avoid any potential situation that could cause an increase in this occurrence. Should CMS decide to include the "one

attachment only" provision in the final rule, we recommend a provision that would prohibit the health plan from denying the claim solely for the reason that they failed to ask the appropriate questions in the initial attachment request.

Issue: Are health plans that utilize the unsolicited attachment business model required to send the 277 transaction when asked by providers?

Comment: If a health plan does not have a business model that sends a 277 transaction for additional information, but rather relies on an unsolicited attachment business model, MGMA contends that they still must support the 277 transaction when requested to by providers. In a practical sense, specific advance instructions and trading partner agreements should eliminate the need for a 277, but MGMA believes providers must have the opportunity to utilize this transaction if they request it.

Electronic Health Care Claims Attachment Business Use

Citation: (P. 55998) "Although additional clinical or administrative information may be required following adjudication of claims, such as for post-adjudication review to support quality control, fraud and abuse, or other post-adjudication reviews and reporting requirements, we do not consider these post-adjudication requests for claims-related data to be part of the claims payment process. Therefore, post-adjudication processes are not covered by this proposal."

Issue: Should e-claims attachments be utilized in non-claim payment situations?

Comment: MGMA agrees with the CMS proposal not to specifically permit e-claims attachments to be used in, for example, post-adjudication processes. However, it is important to recognize the potential for the e-claims attachment to transmit clinical and administrative data from the provider (or other entity) to an authorized recipient. These other uses (i.e., public health data reporting, pay-for-performance) should not be prohibited, but rather should be permitted so long as the appropriate trading partner agreements are adopted. MGMA recommends that CMS work with the industry to examine the issue of additional (non-claims) usage of e-claims attachments and develop industry consensus on how best to leverage this transaction.

Coordination of Benefits

Citation: (P.55999) "However, 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 (X12N 277) transaction sent directly to the health care provider. In health plan-to-health plan (also known as payer-to-payer) COB transactions, the primary health plan may not know the secondary health plan's business rules, and therefore would not be expected or required to request an attachment on behalf of the secondary health plan."

Issue: The NPRM indicates that when multiple health plans are involved in the adjudication of a patient's claim (coordination of benefits process) that each health plan would submit their own

claim attachment request for information. Should the primary health plan should forward the responses they receive to the secondary or tertiary health plan?

Comment: MGMA agrees with the CMS assertion that the primary payer cannot be responsible for forwarding additional claim information onto secondary payers. Marketplace practices make it unlikely that the primary payer will know the business rules and claims requirements for other payers. In addition, the primary payer may be disinclined to forward information that was not specifically asked for by the secondary payer due to concerns regarding the minimum necessary provision of the HIPAA Privacy regulation. It should be left up to secondary and other payers to request additional information via an e-claims attachment from the provider.

Requirements: Health Plans, Covered Health Care Providers and Health Care Clearinghouses

Citation: (P. 56012) "The use of the standard electronic health care claims attachments would not preclude the health plan from using other processes or procedures to verify the information reported in the attachment documentation."

Issue: Once the rule is implemented, will a health plan be permitted to deny a claim due to insufficient clinical information?

Comment: It is our understanding that some health plans use a business process that will deny a claim for a reason of "needing additional clinical information." Once the rule is implemented, this "clinical information" would be available in an e-claims attachment. If this process can continue, how would the provider know what additional information to submit? We recommend that CMS not permit health plans to deny a claim when they have the ability to request that information through a 277 transaction.

MGMA appreciates your consideration of these comments. If you have any questions, please contact Robert Tennant in the MGMA Government Affairs Department at 202. 293.3450.

Sincerely,

William F. Jessee, MD, FACPME
President and Chief Executive Officer