



Michael D. Maves, MD, MBA, Executive Vice President, CEO

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

Re: *HIPAA Administrative Simplification: Standards for Electronic Health Care Claims Attachments; Proposed Rule; 70 Fed. Reg. 184, 55990 (Sept. 23, 2005; File Code CMS-0050-P)*

The American Medical Association (AMA) appreciates the opportunity to provide its views on the Centers for Medicare and Medicaid Services' (CMS) proposed rule concerning *HIPAA Administrative Simplification: Standards for Electronic Health Care Claims Attachments 70 Fed. Reg. 184, 55990 (Sept. 23, 2005)*.

GENERAL

We appreciate CMS's efforts to develop a proposal to implement national standards for electronic health care claims attachments, and want to reiterate our longstanding interest in working to improve the efficiency and effectiveness of the health care system through implementation of certain health information technology. We believe that the inclusion of clear standards, comprehensive provisions, and strong safeguards, will facilitate the electronic transmission of relevant health information, thus improving quality of care, reducing errors, and improving communication between payers and providers.

As CMS continues to develop national standards for electronic health care claims, the AMA wants to express its long-standing concern regarding the confidentiality, integrity, and security of patient medical record information. The AMA believes that it is critical that any electronic attachment information submitted by physicians to health plans, either directly or indirectly through intermediaries, is protected throughout the transaction process by safeguards designed to limit access to, and use of, patient information.

The AMA also remains concerned about excessive and unnecessary requests for additional information, as well as unexplained delays in processing and payment by third party payers, where a completed standard claim form for reimbursement has been submitted. For this reason, the AMA believes that this rule should provide protection from unnecessary and excessive requests for additional information.

In addition, the AMA is concerned about the lack of specificity as to time frames associated with health plan requests for additional electronic attachment documentation. To date, 49 states and the District of Columbia have state laws requiring the timely payment, and in some cases, processing, of health care claims submitted by physicians, other providers of medical care, and even patients, to health plans and other entities. The AMA feels that clarification is needed regarding how the electronic attachment standards and provisions might impact these state-based patient and provider protections.

MISCELLANEOUS

Pursuant to the Health Insurance Portability and Accountability Act (HIPAA), “[a] health plan that operates as a clearinghouse or requires the use of a clearinghouse may not charge for the clearinghouse service.” The AMA believes that the HIPAA provisions regarding clearinghouses should apply equally to electronic attachments. Where an electronic attachment is required for claims processing, adjudication, and payment, by a health plan that operates as a clearinghouse, or operates its own clearinghouse that must be accessed in order to submit claims and associated information to the health plan for processing, said health plan should be barred from charging for the clearinghouse service.

The AMA believes that more information regarding the result of the pilot study performed by Empire Blue Cross should be shared and assessed. Findings from the study can assist in anticipating and addressing problems that are likely to arise among physicians, transmission entities, and health plans. It will provide insight into important issues such as; the frequency with which documentation is requested both initially, and as follow-up; how easily information is shared; and how difficult it is for physicians and health care entities to implement the process. Although the study was preliminary in many ways, the AMA believes that it can offer some important insights into how the electronic attachment requirements will impact the interoperability of physician practices, as well as connectivity with clearinghouses and health plans.

II. PROVISIONS OF THE PROPOSED REGULATIONS

A. DEFINITIONS

3. CLINICAL REPORTS (pp. 55994)

With respect to the definition of Clinical Reports, the AMA proposes that Clinical Reports be changed to “Clinical Information,” as this terminology is more appropriate given that the physician is generally not required to provide the entire clinical report for the patient

encounter. Rather, the physician is being asked for, and is providing, certain limited clinical information deemed necessary to appropriately adjudicate the claim.

Although not included in the definitions section of the proposed regulations, the AMA believes that in order to encourage transparency in the process of requesting additional documentation, the term “minimum necessary” must be defined through regulation. The AMA is very concerned that absent definition, some health plans may take advantage of the electronic attachment standard to unduly burden physicians with unnecessary and attainable requests for clinical patient information.

Under HIPAA “The health plan must request no more information than it determines necessary for the purpose of the request. The physician may rely on the health plan determination and is not required to make independent determination of what information the health plan needs, unless the request is clearly unreasonable.” HIPAA *does not* require physicians to give the health plan the information it requests. However, HIPAA does not provide a basis for physicians to deny requests for information either. Therefore, the AMA believes that the United States Department of Health and Human Services (DHHS) should provide some guidance to ensure health plans make appropriate requests to physicians.

Consistent with the DHHS Privacy Brief, which states that “the major purpose of the Privacy Rule is to define and limit the circumstances in which an individual’s protected health information may be used or disclosed by covered entities,” and the DHHS Fact Sheet: Protecting the Privacy of Patient’s Health Information, which dictates that “...covered entities may use or share only the minimum amount of protected information needed for a particular purpose,” the AMA believes that an entire medical record should never be requested using the electronic attachment approach and format. A report or specific question regarding a report, however, would be acceptable. Furthermore, the AMA thinks that DHHS should monitor the types, and frequency, of requests for information issued by health plans via the electronic attachment regulation.

Similarly, the AMA feels strongly that the term “one request” should be defined and clarified by regulation. The AMA is concerned that under the current proposed rule, health plans could dispense to participating physicians, via website or other means, information regarding necessary electronic attachments, which would not be considered the “one request,” subjecting physicians to the possibility of a second request upon claim submission. The AMA believes that where health plans have well-documented, well-established policies regarding documentation requirements, these policies should constitute, “one request,” and health plans should be restricted to “one response” to the attachment information originally submitted by the physician; rather than an additional request unrelated to the submitted documentation.

B. EFFECTIVE DATES (pp. 55994)

Under the proposed rule, covered entities, other than small health plans that have 36 months, must comply with the standards for electronic health care claims attachments 24 months from the effective date of the final rule. The AMA believes that these time frames are longer than

necessary and would advocate a shorter implementation period, so long as the approved electronic attachment mediums remain as proposed.

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

6. FORMAT OPTIONS (pp. 55998)

Listed in Table 1 – Human vs. Computer Variants for Electronic Attachments, are three options available to physicians for the transfer of medical information. The options include, scanned images of pages from the medical record, natural language text with captions that match specified questions, and natural language text with captions identified by LOINC® codes and supplemented by coded information. The AMA judges that all of the aforementioned options should remain available to physicians. Solo and small physician group practices may need to rely on the faxed and/or scanned image option indefinitely due to the unavailability, for financial, staffing, or geographic reasons, of sophisticated information technology. The AMA is also concerned with the suggestion that small physician practices will adopt electronic medical records (EMR) in the near future. Decreasing reimbursements and increasing administrative costs are preventing physicians from acquiring the capital needed to invest in EMR technology, notwithstanding the establishment of pay-for-performance incentives by payers. Such flexibility, accompanying standardization, will ensure a smooth transition to the use of electronic attachments.

D. ELECTRONIC HEALTH CARE CLAIMS ATTACHMENT BUSINESS USE (pp. 55998)

The proposed rule states that post-adjudication processes are not part of the electronic attachment requirements process. The AMA agrees with this approach. The AMA also believes that health plans should be prohibited from requesting additional information tied to post-adjudication processes when physicians have submitted additional documentation for the claim in an electronic attachment format. Any request and subsequent provision of information that meets the minimum necessary requirement should prevent a health plan from post-adjudication requests for additional information. Likewise submission of such information should limit a health plan's ability to deny or retract payment based on deficient documentation.

2. SOLICITED vs. UNSOLICITED ATTACHMENTS (pp. 55999)

Pursuant to HIPAA, “[a] health plan may not reject a transaction because it contains data that the health plan does not need.” The AMA believes that this prohibition should apply with equal force to electronic claims transactions. Furthermore, the AMA believes that what has been defined as “unsolicited requests” should be acceptable when a health plan routinely requests additional information for certain claims and/or when a health plan disseminates information regarding required documentation. When physicians know what documentation is required they often submit the necessary documentation in advance of a request. Such efforts

should be encouraged rather than penalized, as they will facilitate the exchange of claim information and expedite the adjudication and payment process. In fact, the AMA believes that health plans should be required to request, in advance, that additional documentation (electronic attachments) accompany certain types of claims and should provide this information initially or whenever a change is made regarding required documentation.

The AMA further believes that requests for additional documentation should be required in only certain limited circumstances and should be narrowly tailored. The AMA is concerned that health plans, under the proposed rule, will fail to be judicious in their requests for additional documentation, causing enormous burdens on physicians. Payers should recognize and respond to all claims and should be permitted to ask for additional information only when such information is deemed necessary based upon the physician's response to the first request. Failure to prohibit payers from continually and repeatedly requesting additional information from a physician for a single claim will undoubtedly result in significant delays in claims adjudication and payment, as well as untoward administrative hassles. Health plans should be permitted one request for information and then a second request if, and only if, the second request is based upon information garnered from the response to the first request. However, the AMA cautions that even this proscription could lead to situations in which an initial request and response generates dozens of follow-up requests and responses. Thus, the AMA feels that there needs to be a definitive point at which no additional information can be requested and/or has to be provided.

Finally, the AMA is concerned by the provision that indicates physicians can send only one attachment per request. In situations where some, but not all, of the information requested is available, physicians should be permitted to submit the accessible information initially in order to commence the adjudication process. Such a procedure has the potential to lesson any unnecessary delays associated with the request for additional information.

3. COORDINATION OF BENEFITS (pp. 55999)

The AMA believes that as suggested above with regard to primary health plans, secondary health plans should be required to inform physicians on its physician Web site or through other means of information dissemination, what its documentation requirements are for certain claims. The AMA does not believe that the primary health plan should receive the secondary health plan's requested information either directly from the physician or indirectly from the secondary health plan. Requested information and the responses to these requests should remain separate when a coordination of benefits issue ensues. The AMA believes that even if the primary health plan and the secondary health plan request the same information be sent via electronic attachment, the physician needs to directly provide each of the plans the requested information in a separate claims transaction.

4. IMPACT OF PRIVACY RULE (pp. 55999)

The AMA strongly believes that physicians own all claims data, transactional data and de-identified data created, established, and maintained by the physician practice, regardless of how and/or where such data is stored. The AMA deems physician ownership of health data to transcend claims data, and to include any data derived from a physician's medical records,

electronic health records, or practice management system. It is the physician, acting as the trusted steward of protected health information, who is required to maintain and safeguard patient health information that is submitted as part of an electronic attachment response to a health plan request for additional documentation. For this reason, the AMA strongly advocates that this rule include prohibitions against using the additional information submitted as a result of electronic attachments, for any purposes other than adjudication and payment. Such prohibitions would protect against third parties establishing and maintaining medical records and/or databases.

Moreover, the AMA thinks that CMS should provide guidance regarding when, and how much, information needs to be blacked out on electronic attachments. While the AMA is cognizant that certain information should not be submitted as part of an electronic attachment, it cautions that blacking out or otherwise trying to extract certain information can often create additional barriers to electronic transactions and further burden physicians.

In addition, under section 1178(a)(2)(B) of the Social Security Act and section 264(c)(2) of HIPAA, provisions of state privacy laws that are contrary to and more stringent than the corresponding federal standard, requirement, or implementation specification are not preempted. The effect of these provisions is to let the law that is most protective of privacy control. To the extent that these conflicts are implicated by implementation of the electronic attachment rule, the AMA would appreciate clarification from CMS on this issue.

The AMA also feels that included in the proposed rule should be a requirement that covered entities turn on their electronic audit trails in their practice management, EMR systems, etc., in order to allow for tracking of individuals access to the clinical record and PHI information. Typically, a vendor can easily comply with this request, as it is usually built into the software application.

Finally, as part of the Impact of Privacy Rule section, the rule states that “[f]or health care physicians who choose to submit attachment information in the form of scanned documents, efforts will need to be made to ensure that those documents do not contain more than the minimum necessary information.” The AMA believes that CMS should clarify that “more than the minimum necessary information,” should not include information that was previously transmitted by the physician.

5. CONNECTION TO SIGNATURES (pp.56000)

The AMA requests that any consideration of how to handle electronic signatures include guidelines and definitions that would ensure that the appropriate person in physician practice has the authority to submit responses to the health plan inquiries. This added security will help physicians monitor information submitted to the health plan. Assistance with monitoring information submitted is of particular importance as physicians will ultimately be liable for any misinformation, violations of minimum necessary requirements, unsolicited requests, and/or other adverse events that can result from submission of an electronic attachment.

G. PROPOSED STANDARDS

1. CODE SET (pp. 56004)

The AMA believes that standard implementation guidelines for code sets are essential for uniform national application of the code sets. If standard guidelines for medical code sets are adopted, many attachments would be eliminated. If health plans and physicians are permitted to implement and interpret medical data code sets as they see fit, the purpose of Administrative Simplification will not be achieved. An important part of Administrative Simplification and reduced regulatory hassle includes the simplification of instructions for the coding of health care services. The overwhelming amount of paperwork to which physicians are subject could be significantly reduced if coding is standardized and electronic transactions are facilitated. Thus, the AMA believes that the CPT guidelines and instructions should be specified as a national standard for implementing CPT codes.

The AMA believes that it is difficult for the industry to submit thoroughly comprehensive comments on the attachment standard, given the number of issues for which the Notice of Proposed Rulemaking (NPRM) is soliciting guidance and assessment. As such, the AMA is of the opinion that HHS should issue an interim final rule (or its equivalent), that includes the comments submitted in response to the NPRM's solicitations. Issuing an interim final rule that includes the submitted comments, and affording a comment period, would provide the industry with an opportunity to react to a more specific set of recommendations

We are pleased that CMS is moving forward with the adoption of standards for certain attachments to electronic health care claims and we support CMS in this effort. We appreciate the opportunity to provide our views on the implementation of the electronic attachment rule and look forward to working further with CMS on this important matter. Should you have any questions regarding these comments, please contact Carolyn Ratner, Washington Counsel, by phone, 202-789-8510, or by email, Carolyn.Ratner@ama-assn.org.

Sincerely,



Michael D. Maves, MD, MBA