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

October 21, 2008

The Honorable Michael O. Leavitt
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards; Proposed Rule; 73 Fed. Reg. 49,742 (August 22, 2008); File Code: CMS-0009-P.

Dear Mr. Secretary:

The American Medical Association (AMA) welcomes the opportunity to provide comments on the proposed rule on modifications to the HIPAA electronic transaction standards published in the *Federal Register* at page 49742, Volume 73, Number 164, on August 22, 2008. The AMA appreciates the Department of Health and Human Services' (HHS) efforts to develop a proposal to update national standards for electronic health care administrative transactions and is committed to working with HHS as well as other key stakeholders to improve the efficiency and effectiveness of the health care system through the implementation of electronic transactions standards. We believe that clear, uniform standards, a constructive implementation process and timeline, and adequate security safeguards to protect patient information transmitted through the electronic transaction process will facilitate the electronic transmission of relevant health information, thus improving quality of care, reducing administrative errors, and enhancing communication between health care payers and physicians.

Implementing a new version of the electronic administrative transactions is a complex and costly undertaking for physicians. Physician practices need time to adequately complete testing of and migration to the updated HIPAA electronic transactions with their trading partners in order to avoid significant disruptions to their practice, patient care, and claims payments. **The AMA is, therefore, deeply concerned with HHS' plan to rapidly mandate the adoption and implementation of X12 version 005010 Technical Reports Type 3 for HIPAA electronic transactions (5010).**

American Medical Association 515 North State Street Chicago Illinois 60610
phone: 312 464 5000 fax: 312 464 4184 www.ama-assn.org

Comments on Specific Provisions of the Proposed Rule

A. Proposed Adoption of X12 Version 5010 Technical Reports Type 3 for HIPAA Transactions

The AMA agrees with the proposed adoption of the X12 version 5010 Technical Reports Type 3 for the named HIPAA electronic transactions (hereinafter referred to as 5010). We recognize that the 5010 transactions are the result of significant collaborative efforts within the health care industry. We are supportive of the changes made in version 5010 as we see that this version will resolve numerous administrative and technical problems that exist under today's current version 004010/004010A1 (hereinafter referred to as 4010). It is also important to note that 4010 is not compatible with the use of ICD-10. We have issued a separate comment letter to HHS on the ICD-10 proposed rule recommending an implementation process and timeline needed to transition to ICD-10. The 5010 transactions help to address evolving business needs. It is our hope that the overall improvements in the 5010 transactions will provide clarifications to the industry that will bring uniformity to their interpretation and implementation, therefore reducing the administrative burden for physicians.

Despite our support of these transactions and commitment to encourage physicians to adopt them, the goal of implementing HIPAA transaction standards, which is to significantly reduce administrative burdens, lower operating costs, and improve data quality through the use of electronic data interchange, has not been fully achieved. For example, many of the HIPAA transactional fields that would provide the physician and patient the financial responsibilities in advance of the service are voluntary and as such are not completed or not completed to the highest specificity necessary, such as the health plan product type, (i.e., Medicare Advantage or one of many commercial products that may be tied to a different contracted fee schedule or patient benefit level). In addition, many fields related to payments received from payers are voluntary as opposed to mandatory. For instance, the "allowed amount" field is voluntary, making it difficult to determine patient responsibility and calculating contractual adjustments. The only requirement of the transactions is that they are syntactically correct (i.e., number in a unit field and letter in an alpha field) and there is no requirement to complete any field on any HIPAA transaction accurately or to the highest specificity. Finally, although payers may pay claims line-by-line, the reimbursement to the physician is presented as a lump sum, making it difficult for physicians to determine the amount of payment that was made pursuant to the contracted rate. Without this line-by-line reporting, physicians must decipher the payments and manually post them to their practice management systems, which adds extra work and costs to their practices to reconcile payments.

In addition, gaps continue to exist in the transactions themselves allowing for variations in implementation by payers. Many situational data elements within the transactions are subject to the discretion of each payer, which has resulted in "companion guides" issued by each payer stating their requirements for the various data elements. Companion guides, estimated to number 1,200, have added a layer of complexity to the system that was meant

to be simplified through uniform standards. It is our understanding that the 5010 transactions will decrease some ambiguity in the transactions, but it is unlikely that companion guides will be eliminated completely with 5010 implementation.

Concerns over the effectiveness of the HIPAA electronic transactions implementation have prompted a number of coalition efforts in the health care industry. The Workgroup for Electronic Data Interchange (WEDI) has established various work groups comprised of industry stakeholders to address issues related to the transactions and provides ongoing education on the implementation of the transactions. The Council for Affordable Quality Healthcare (CAQH) has created the Committee on Operating Rules for Information Exchange (CORE) initiative, which has brought industry stakeholders together to define voluntary standards for using the transactions. In addition, the Centers for Medicare & Medicaid Services (CMS) has evaluated the implementation of HIPAA transactions and issued reports that identify the following primary reasons for HIPAA complaints: 1) standard transactions not being used by trading partners; 2) incorrect application of the implementation guides; and 3) misuse of the HIPAA code sets. Without implementing constructive solutions to existing HIPAA electronic transaction barriers, noncompliance with HIPAA transactions will undoubtedly continue even with the implementation of version 5010.

Another concern we have is the inconsistent manner in which upgraded standards are brought forward to the industry for adoption. Without a predictable schedule, the industry is unable to benefit from the ongoing improvements made to the electronic transactions. It is also challenging for physicians, as well as the rest of the industry, to plan accordingly for these changes. Any cycle for upgrading the transactions needs to consider the existing constraints placed on physicians by HHS, particularly Medicare, given that it is the largest payer and how these other requirements impact a physician's costs and time.

We therefore recommend that HHS increase its enforcement efforts related to the HIPAA transactions to ensure that health care payers are adhering to the requirements of the X12 transactions and reporting data to the highest level of specificity. In addition, we recommend HHS work with the Secretary and the National Committee on Vital and Health Statistics (NCVHS) to develop a predictable cycle for the rollout of upgraded versions of HIPAA transactions.

F. Proposed Compliance and Effective Dates

The AMA has serious concerns about the proposed compliance date of April 1, 2010, for moving to 5010 for the following reasons:

1. Most physician organizations have completed their budgets for 2009 and will be unable to secure the necessary funding to conduct analysis, development, and implementation work until their next budget cycle. Several physician organizations

have indicated that they will be unable to secure funding to work on the updated HIPAA transactions until the transactions are mandated through the publication of a Final Rule. Therefore, the assumption made in the proposed rule that organizations will have ample time to begin transitioning to 5010 now is unrealistic.

2. There is a great dependency of covered entities on the completion of the software and systems development by their vendors, which are not HIPAA-covered entities. In a brief, anonymous, email survey of vendor preparedness for 5010 products, the following comments were received:

    a. "The timeline is too short. HHS does not consider that vendors may be engaged in other work, and the assumption that we can drop everything and begin our work in September 2008, is just not realistic."
    b. "It [the proposed timeline] also does not provide ample time for testing with customers and trading partners, and the implementation process itself is left undefined (as was with version 4010), which leads to industry confusion in that many entities worked to their own goals that were not aligned with other industry participants."
    c. "Some vendors have completed analysis, some are starting based on the NPRM issuance. Many will wait until final rule to begin work, so that they don't expend R&D [research and development] dollars on work that could end up changing."

    At the WEDI Policy Advisory Group (PAG) meeting held on September 9, 2008, several vendors stated that they will be prepared to deploy products to their customers in advance of the April 1, 2010, proposed deadline. Despite these remarks, concerns remain as to whether or not all vendors, specifically the small vendors that support small physician practices, will be able to support their customers so that physician practices can meet the proposed April 1, 2010, compliance deadline. Vendor readiness and the deployment of vendor products well in advance of the compliance deadline are critical steps that must occur so that physician practices are able to prepare and meet the compliance deadline.

3. There is great complexity with implementing such a proposed rule and thus time is needed for physician practices to adequately complete testing of and migration to the updated HIPAA transactions with their trading partners.

4. The cost, especially for small and solo group practices to update software, which in some cases may require entirely new systems, will be burdensome in the current economic climate.

We strongly disagree with the assumption in the proposed rule that a two-year time frame for compliance is not needed because the health care industry has sufficient experience with HIPAA transactions implementation issues. Physicians will need adequate time to conduct their design/build activities and schedule and perform testing. While we recognize that the

base version 5010 transactions are similar to the current version, the volume of business partners is the same or even greater since the initial implementation, so the time and effort for physician practices to transition with their trading partners to version 5010 will be critical. The AMA therefore strongly supports the recommendations and stakeholder input related to the timing of implementation of 5010 from NCVHS in its letter dated September 26, 2007 to Secretary Leavitt.

These recommendations include:

> Recommendation 2.1: HHS should consider establishing two different levels of compliance for the implementation of HIPAA transactions and code sets. Level 1 compliance would mean that a covered entity could demonstrate that it could create and receive compliant transactions. Level 2 compliance would demonstrate that covered entities had completed end-to-end testing with all of their partners.
>
> Recommendation 2.2: The implementation of Version 5010, ICD-10, and claims attachments should be sequenced so that no more than one implementation is in Level 1 at any time. HHS should also take under consideration testifier feedback indicating that for Version 5010, two years will be needed to achieve Level 1 compliance.

We believe that the compliance date for the 5010 transactions must be a specified number of months after the publication of the Final Rule. There are specific activities that must be completed by the covered entities and software/systems vendors throughout the implementation process and timeline. These activities serve as milestones that all organizations must meet in order for the industry to be prepared to successfully migrate to the updated HIPAA transactions. **The following is a recommended timeline of these activities and milestones.**

Time	**Activity**
Day 1	Publication of the Final Rule Organizations begin analysis and development work
Month 12	Software and systems vendors complete product development
Months 12-24	Organizations complete internal programming Software vendors install products for customers Testing begins with trading partners when mutually agreed upon
Month 24-36	Wide-scale end-to-end testing among trading partners Migration of trading partners to 5010 transactions only Dual usage of current and 5010 transactions
Month 36	Compliance with 5010 transactions

The proposed rule discusses the consideration that was given to issuing staggered implementation dates of requiring payers and clearinghouses to be compliant one-year prior to providers. The possibility of staggering the implementation was ruled out because payers and clearinghouses would need robust tracking systems to know which providers were at

what point in the conversion to the updated HIPAA transactions, and staggered dates would affect the coordination of benefits with secondary payers.

Physicians, payers, and clearinghouses will need robust tracking systems for **any** implementation plan and coordination of benefits will undoubtedly be disrupted due to the fact that not all covered entities will be ready on the same date to send and receive the 5010 transactions. In addition, covered entities will have to support the dual use of the current transactions and 5010 transactions until the compliance date. Physicians, payers, and clearinghouses will need to test at different times during the implementation process. A complex process will need to be followed as physicians, payers, and clearinghouses test and migrate to the 5010 transactions at different times. Each organization cannot work internally only until the compliance date and then expect to connect with and transmit to all of their trading partners on one day. The experience of implementing the current transactions and the National Provider Identifier (NPI) demonstrated that a single cut-over date for compliance does not work for the industry. There is a need for the industry to test completely with all trading partners and migrate over a period of time to the new standard.

Given our concerns over the implementation time-frame as outlined above, the AMA strongly recommends that:

1. **HHS provide at least 36 months to adopt and implement 5010 from the date of publication of the final rule so as to accommodate Levels 1 and 2 of compliance;**
2. **NCVHS be charged with monitoring industry readiness through WEDI surveys, Medicare data, and the use of other sources in order to ascertain whether health care providers (especially small physician practices), clearinghouses, and payers are able to successfully send and receive transactions using 5010 and report findings and recommendations, including any adjustments to compliance deadlines, to HHS; and**
3. **HHS allow for a migration period prior to the compliance deadline and specify allowance in the Final Rule.**

<u>Outreach and Education</u>

The proposed rule provides a brief overview and solicits comments on HHS' plans to conduct outreach and education activities related to the 5010 transactions. The AMA believes that appropriate outreach and education to the industry is essential for successfully implementing the 5010 transactions. **We recommend that outreach and education activities for the 5010 transactions require that HHS:**

1. **Develop and make available a detailed provider education and outreach plan, with a special emphasis on small physician practices and software vendors;**
2. **Hire and train an adequate number of customer service representatives;**
3. **Create a separate toll free hotline for questions on 5010 [and ICD-10] similar to what was in place during the transition to 4010;**
4. **Collaborate with the health care industry, especially physician organizations, in order to develop uniform outreach materials;**

5. **Host regional calls (and meetings to the extent possible) with key stakeholders - including national physician organizations and state, specialty, and county medical societies - on a bi-monthly or quarterly basis until at least six months after the 5010 [and ICD-10] compliance deadline;**
6. **Appoint a point person centrally and in each regional office to guide the 5010 [and ICD-10] implementation and to ensure that materials disseminated to industry are consistent and are available to help troubleshoot problems as they arise throughout the implementation process; and**
7. **Clearly identify and separate HHS'/CMS'role as HIPAA overseer (policymaker and enforcer) from its role as a Medicare payer in administering the HIPAA transactions so as to not confuse the industry as to HHS'/CMS' role in this endeavor.**

The AMA welcomes the opportunity to work with HHS on physician outreach and education initiatives and materials.

Comments on V. Regulatory Impact Analysis, C. Anticipated Effects, and 1. Adoption of Version 5010

Costs

The AMA has serious concerns about the assumptions made in the proposed rule about the costs to implement the 5010 transactions. The proposed rule assumes that the move to the 5010 transactions will be less costly because it is an update of existing transactions and the shift to the current transactions was more significant to the industry. We recognize that the base standards for the 5010 transactions may be the same as the current transactions, but the complexity of reformatting existing systems, maintaining dual systems, testing with trading partners, migrating to the updated transactions, and training staff will be costly for covered entities. Other assumptions in the proposed rule with which we disagree include the assertions that: implementation costs for version 5010 will represent 20 to 40 percent of the cost for implementing the current version; there will be no hardware costs for physicians; and all software upgrades will be free under existing vendor contracts.

The estimate that the implementation of the 5010 transactions will cost 20 to 40 percent of the cost for implementing the current version comes from the Gartner report. The report, however, lacks specific details on how these figures were obtained, other than to state that the "slate of interview participants estimated their organizations costs." Based on the fact that there has been no end-to-end piloting of the 5010 transactions, it is unclear how assumptions can be made about the total implementation costs for physicians, or the industry as a whole, and without detailed analysis of the total costs for implementation of 5010 transactions.

We find the assumptions that there will be no hardware costs and free software upgrades problematic. We expect the dollar cost to physicians for upgrading to the 5010 transactions to vary widely. Some vendors will likely pass the costs of the software upgrades on to the physician. Some vendors may recognize that the changes are related to a regulatory

requirement; charges which may be included in their annual maintenance fees. Many physicians may need to purchase an entirely new software and/or hardware system, if their current system is unable to accommodate the 5010 transactions. Vendors will certainly charge physicians to implement any of the HIPAA transactions that the practice had not previously implemented.

The costs of the learning curve and workflow disruptions for implementing the 5010 transactions in the physician practice are difficult to quantify. In general, it has been difficult to gain from the industry a full understanding of what the costs and benefits will be for moving to the 5010 transactions. It is safe to say that any changes that will occur ultimately will be an added cost that a physician must endure either through increased clearinghouse fees, required practice management software upgrades, or other related fees. These changes will negatively affect physician practices' cash flow at least initially during implementation. Keep in mind that over 50 percent of physician practices have five or fewer physicians and account for 80 percent of outpatient visits. Small physician practices have fewer resources to shoulder costly and time consuming changes to their practice management software especially given other mandatory, federal requirements that compete for these limited resources. These cost issues are an additional reason as to why physician practices will need more time than currently proposed to meet the compliance deadline.

In addition, the average physician practice has contracts with at least 20 different health plans and third-party payers, which may all have their own companion guides. Few physician practices have the time or resources to review each contracted insurer's companion guide in the detail necessary to incorporate the requirements into their claims submission activities. Therefore, the physician practices rely on clearinghouses, at an added cost to them, to handle this workload for them. It is our understanding that the need for companion guides is an issue that will persist with the 5010 transactions. Because of this need, it will continue to detract from achieving true administrative simplification. **The AMA, therefore, strongly urges HHS to reassess the total direct and indirect costs to physicians and their practices for transitioning to 5010 transactions.**

Benefits

The proposed rule assumes that the industry will obtain savings through better standards, increased use of the electronic claims transaction, and increased use in the auxiliary transactions. The AMA believes that the 5010 transactions will, because of the improvements in the transactions, streamline various administrative processes, simplify companion guides, remove ambiguity in the current transactions, and resolve technical issues with some of the current transactions.

We also acknowledge the benefits that are achieved through the use of electronic administrative transactions. An analysis done by Milliman in January 2006 demonstrated monetary savings that can be obtained by physician practices conducting electronic

transactions for claims submission, eligibility verification, referral certification, preauthorization for services, claims status verification, and payment posting. The annual cost to perform these functions manually was found to average over $70,000. The cost for performing the same functions electronically averaged less than $28,000, which results in approximately $42,000 in savings per year.

We do have concerns, however, as to whether or not physicians will be able to fully implement all of the auxiliary transactions, as assumed in the proposed rule. The proposed rule bases the total savings amount on all practices implementing all of the auxiliary transactions. Our concern is that, with the proposed expedited compliance dates for implementing the 5010 transactions (April 1, 2010) and the ICD-10 code sets (October 1, 2011), practices will implement the minimum number of 5010 transactions in order to do business and then move onto implementing the ICD-10 codes sets. After implementing the ICD-10 code sets, practices may not have remaining resources to continue the implementation of the other auxiliary transactions. This means that the total assumed cost savings will not be met for the industry. In addition, without end-to-end piloting of the 5010 transactions, it is unclear how assumptions can be made about specific dollars in savings for physicians, or the health care industry as a whole.

Comment on the Code Sets

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, administrative burdens surrounding the coding of health care services within the current system would be eliminated. If payers and physicians are permitted to implement and interpret medical 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. **The AMA urges HHS to adopt as the national standard under HIPAA the Current Procedural Terminology (CPT) coding rules and guidelines to avert further coding inconsistencies in recognizing and reporting physician procedures and services.**

We recently submitted a Change Request to the Designated Standards Maintenance Organizations (DSMO) (CR 1069) recommending to NCVHS to have the CPT coding guidelines named as part of the national standard for implementing CPT codes. The DSMO's disposition of the change request was that further comments were needed from the industry to determine consensus. Concerns were raised during discussions that naming CPT guidelines would impose requirements on the Healthcare Common Procedure Coding System (HCPCS). We disagree with this concern, however, and see the work being done in Minnesota with their electronic data interchange law as a model for the use of guidelines for

medical code sets. To comply with Minnesota's law, companion guides have been developed for the affected transactions. Covered entities will need to comply with these companion guides. Appendix A, Section A.1, number 5 of the guides state the following:

> This appendix does not replace or substitute for standard, national coding resources for HIPAA-adopted code sets (including manuals, online resources, etc.). Consult the corresponding coding resources for descriptions, definitions, and directions for code usage.

This statement was intended to clarify that they are adopting the directions for code usage for the named HIPAA code sets, including CPT. We believe that a simple approach can be taken with the naming of medical code sets' guidelines as national standards. The instructions can be that the applicable code set guidelines are to be used when a code from the code set is being reported. As a result, the administrative burden from various interpretations of codes will be greatly reduced.

Conclusion

We appreciate the opportunity to provide our comments on the implementation process and timeline needed to successfully transition to 5010 transactions and look forward to working further with HHS on this important matter. Should you have any questions regarding these comments, please contact Mari Savickis, Assistant Director, Division of Federal Affairs at 202-789-7414, or by e-mail, Mari.Savickis@ama-assn.org.

Sincerely,

Michael D. Maves, MD, MBA