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October 20, 2008

Michael O. Leavitt
Secretary
US Department of Health and Human Services
c/o Centers for Medicare and Medicaid Services
Attn: **CMS-0009-P**
PO Box 8014
Baltimore, Maryland 21244-1850

RE: File Code CMS-0009-P

Dear Secretary Leavitt:

The American Health Information Management Association (AHIMA) congratulates you and the Department of Health and Human Services (HHS) on the Notice of Proposed Rulemaking (NPRM) for the adoption of Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards as published in the August 22 *Federal Register* (CMS-0009-P). AHIMA welcomes the opportunity to provide comments on these proposed regulations.

AHIMA is a professional association representing more than 52,000 health information management (HIM) professionals employed throughout the healthcare industry, and who work with the data transmitted via transaction standards included under the HIPAA standards. The data managed by HIM professionals is necessary for the submission of claims and the processing of an individual's healthcare benefits relative to a disease or procedure (past or future), and to represent additional clinical information necessary to support the claim, benefits, quality measurements, disease management, public health reporting, oversight reporting, and policymaking.

The HIM professional domain also covers diagnosis and procedure classification systems that, among other, uses serve as the foundation for the diagnosis related groups (DRG) discussed in the companion proposed rule related to the adoption of ICD-10-CM and ICD-10-PCS. HIM professionals understand the importance of upgrading the HIPAA-related transaction standards to a newer version so the nation can benefit from more specific, accurate, and contemporary diagnostic and procedural data as you have proposed along with other functional improvements to improve the healthcare industry's administrative processes and lower the administrative costs of healthcare.

Based on the belief that quality information is necessary for quality healthcare (and by extension quality health) AHIMA has long advocated an ongoing, periodic upgrading of the HIPAA transactions standards in line with normal standard development organization (SDO) version upgrades, and for a revision in the process of keeping these standards flexible and updated to serve the needs of the

healthcare industry, similar to the maintenance of commercial software and other industries' use of Accredited Standards Committee X12 (X12) standards. AHIMA has also advocated changes specific to these proposed upgrades to the HIPAA-related standards, because the failure to upgrade over the last eight years has in part kept the United States from adopting contemporary diagnostic and medical procedural classifications on a timely basis.

While we are pleased that adoption of these proposed rules will result in significant upgrades to more current versions of the X12 and the National Council for Prescription Drug Programs (NCPDP) standards, it must be noted that the X12 committee is already working on the X12 5050 level standards, which, when completed, will be adopted for use in a short period of time by other United States industries, except healthcare. The healthcare industry and the federal government agencies using the X12 standards for healthcare should be able to update or upgrade their transaction standards on a regular basis, so that in the future the industry and government will not face as challenging a task as the proposed upgrade from 4010 to 5010.

I. Background (73FR49742)

The NPRM reveals that a number of unresolved issues remain since the last upgrade in the HIPAA-related standards—**AHIMA remains concerned that not only have the HIPAA transactions standards not kept up with contemporary changes, but also that nothing has changed in the process for keeping standards in sync with SDO changes reflecting on-going industry needs for the exchange of electronic data.**

Presently, the process for adopting modifications (upgrades) to the HIPAA designated standards as highlighted in I-C (73FR49744) relies on both the normal modification and maintenance processes within SDOs (under a strict process governed by the American National Standards Institute (ANSI)) and a public consultation process conducted by the Designated Standards Maintenance Organizations (DSMOs) and the National Committee on Vital and Health Statistics (NCVHS). Once these organizations have completed their assigned roles, HHS generally must use the NPRM process for final public comment, which then leads to internal government review and approval before a final rule can be issued. Should the NPRM process raise a significant problem requiring SDO review or revision, the whole process might start from scratch and take an additional year or two. The usual SDO review process usually takes about a year itself.

As noted above, while not proposed in this NPRM, **AHIMA recommends that HHS either consider changes in the HIPAA rules or recommend changes to Congress for revision of HIPAA legislation permitting the healthcare industry to maintain its transaction standards, including those designated by the HIPAA regulations, on a concurrent basis with standards upgraded by the applicable SDO.** Ongoing maintenance of the standards would be better accommodated by users (covered entities) and their vendors, and less expensive to adopt and implement incrementally, rather than the four to six year cycle that now exists. Conceivably, the industry should implement the next upgrade, sooner and smoother so we can find ourselves using the most current versions of the transaction software as in other US and international industries.

Alternatives suggested by AHIMA and many other organizations and included in the 109th Congress' HR 4157 *health Information Technology Promotion Act of 2005* would have allowed for considerable informed public input into the SDO process of developing and modifying standards at the same time as

permitting necessary government involvement. The entire process proposed in this bill would have resulted in a modification process that would take approximately two years rather than the current process, which has taken much longer. **AHIMA and other industry organizations involved in the HR 4157 proposal are pleased to work with HHS to see this revision in process brought about in the near future.** We must also point out that at this juncture the process of modifying and upgrading the HIPAA transactions standards must be reviewed in light of the changing environment of new industry players including the Health Information Technology Standards Panel (HITSPP), the Certification Commission for Health Information Technology (CCHIT), and the newly formed AHIC Successor.

AHIMA believes that the healthcare industry's lack of understanding of the technical nature of electronic data interchange (EDI) standards (such as those developed and approved by the X12 or NCPDP operating under the auspices ANSI), along with the other technical aspects of the upgrades proposed has caused fear among many users and HIPAA entities. This fear in turn has raised concerns that the proposed upgrade will assume many of the characteristics of the original HIPAA transaction standards adoption and implementation, and further concerns related to the recent NPI implementation experience. Accordingly, we believe the push back on the implementation period set by these proposed rules is a direct result of limited understanding of the standards, the implementation steps needed to make the proposed upgrade changes, and the role of testing the standards at the user level.

Considerable discussion on this proposed rule in the healthcare industry has taken place. It is clear the general healthcare community does not understand the nature of EDI standards and their modification design. The proposed changes in this NPRM are perceived by many as new standards rather than as upgrades to existing standards already in use or being used by a clearinghouse or subcontractor. This lack of understanding is further exacerbated by the fact that in the case of the ASC X12 standards, most laymen do not understand exactly what is being changed (standards, guides, and so forth) and the role of "technical reports" in the standards. The proposed rule falls short in this explanation and education is needed.

II. Provisions of the Proposed Rule (73FR49745)

The proposed rule provides a good description of the impetus for the proposed changes and the important benefits to simplify complex administrative processes.

ASC X12 Version 5010 TR3 Reports (beginning 73FR49746)

AHIMA shares HHS' concerns related to the gaps that exist in Version 4010/4010A. The ASC X12 standards were designed to be upgraded on a regular basis, which is the case in most industries outside of healthcare. **AHIMA again urges HHS to consider changes to the HIPAA rules to accommodate regular updates to the HIPAA standards, in line with changes made on a regular basis by the SDOs. We urge HHS to take immediate steps to streamline these procedures so upgrading the X12 standard in the future will not require the time and resources identified in the proposed rule and for future changes.**

AHIMA agrees with HHS that the use or misuse of companion guides occurring since the adoption of the HIPAA standards has resulted in less conformity rather than the uniformity and consistency

envisioned in HIPAA. As a result, the return on investment, especially for providers, has not been at the level anticipated and experienced in other industries. Disappointment in the results of HIPAA implementation to date, has led many providers not to adopt and use HIPAA standards, beyond the Health Care Claims or Equivalent Encounter Information Transaction (837) and the Health Care Payment and Remittance Advice Transaction (835). AHIMA anticipates that with the adoption and implementation of these proposed rules, more organizations will have the opportunity to make use of the (improved) X12 standards beyond claims (837) and remittance (835) and experience the demonstrated value that EDI has provided other industries. AHIMA is a member of the Healthcare Administrative Simplification Coalition (HASC), and as a group we certainly want to work with HHS to improve healthcare administration with appropriate use of the transaction standards. **AHIMA urges HHS to work with groups such as HASC to increase the understanding of the HIPAA standards and the value they can create, and to insure that with this new modification all health plans will adhere to the uniform user guides and rules anticipated for the HIPAA standards when they were first conceived. It is only through uniform adoption, use, and adherence to the standard and guides that administrative simplification will take place.**

AHIMA agrees that updating the Institutional Health Care Claim (837I) will provide a better means for hospitals to comply with the "Present on Admissions" (POA) requirement. **AHIMA suggests that HHS and CMS further agree to accept and utilize all diagnoses codes associated with an admission or encounter, not just those easily accommodated within the limits first set by paper forms decades ago.** Currently, many providers accumulate more than the limited number of codes (nine diagnoses and six procedures) permitted for submission even though documentation exists in the health records that support such codes and the industry uses transaction standards that accommodate more codes than the current maximum. Even with the proposed changes, facilities cannot properly meet the POA and similar requirements when diagnoses and procedures are truncated to a number equal to what was accommodated on a paper claim. Since most claims are now electronic, the additional information, especially after ICD-10-CM is in place, will provide significantly better and more detailed data.

AHIMA welcomes version 5010's ability to provide clear definitions and precise rules for consistent reporting of information with the same position and meaning throughout the transaction. This will promote a cleaner claim and make for less rework and the additional costs that rework entails. AHIMA notes that throughout the descriptions of the transactions it appears that version 5010 will permit better uniformity and consistency in the presentation and meaning of data.

AHIMA also appreciates the improvement in the Referral Certification and Authorization (278) transaction. Improving the demographic and clinical data in these transactions begins to allow users to build appropriate links between these reports and electronic health records. This is a prime example of where consistent data definitions, uniform use, and other administrative simplification can create cost savings and a more efficient system.

AHIMA is pleased to note the elimination of a number of requirements to report sensitive personal health information on the Health Care Claim Status (X12 276/277) transactions. This proposed change will significantly assist healthcare providers to honor the privacy requests of their patients and build consumer trust in the healthcare claims process and system.

NCPDP D.0

AHIMA is pleased that among the enhancements associated with the Telecommunication Standard Implementation Guide D.0 are changes that better accommodate the HIPAA privacy rule. Any improvements enhancing the industry's ability to safeguard patient information are welcome, and can only increase public trust in the electronic exchange of healthcare data.

Finally, with regard to all the proposed transaction upgrades, we note that the changes made to the ASC X12 and NCPDP versions and standard transactions also support the adoption and use of the ICD-10-CM and ICD-10-PCS classification standards proposed in the companion NPRM. Implementation and use of the improved HIPAA transaction standards will, in turn, streamline the administrative process and permit use of the ICD-10-CM and ICD-10-PCS. This, in turn, will increase our medical knowledge and improve the care and support of patients or consumers and the overall health of our population.

Proposed Compliance and Effective Dates (begins page 73FR49754)

In commenting on the proposed dates, we have taken note of testimony from healthcare and information industry technologists, vendors, and systems experts over the last six years, as have the NCVHS and HHS. **AHIMA anticipates that an upgrade in the ASC X12 and NCPDP standards that make up the HIPAA transaction standards should not be as difficult to install and test as the initial adoption and implementation of the standards several years ago.** We also recognize that the changes associated with the adoption of these improved versions apply to a variety of applications residing among HIPAA-covered entities. Accordingly, **AHIMA agrees that:**

- **There is no reason for an additional year for small health plans or others to comply with the proposed changes given the experience from the past and the need for consistency among all trading partners in this 21st century environment.**
- **The NCPDP and ASC X12 standards have been available for some time, therefore there is no reason that HIPAA entities and vendors should not already be making the necessary changes to upgrade the appropriate transaction software, just as they would upgrade other software programming as a vendor or client.**
- **Testing is a significant part of successfully upgrading of these transactions standards. We recommend that HHS, and its Medicare and Medicaid programs (which make up a considerable volume of all transactions with providers), along with various state healthcare trade and professional associations work together to organize, facilitate, and accommodate appropriate testing in line with the implementation finally proposed by HHS.**

The proposed compliance date for the transaction standards upgrade acknowledges previous industry input and the need to accommodate the ICD-10-CM and PCS implementation. **AHIMA urges HHS to recognize the deadline for the 5010 and D.0 conversion is dependent on HHS meeting its timetable for a final rule and providing the assistance CMS and HHS have promised the industry for implementation.**

The healthcare industry will require HHS' education, leadership, and assistance for a smooth transition. As previously noted, there is a significant lack of understanding regarding the HIPAA

transaction standards updates and the process necessary to accommodate these updates. Likewise, there is concern regarding the process of testing standards and testing the transmission of standards among trading partners. For this reason, some sectors of the healthcare industry are taking a conservative approach to determine the time that will be involved in completing implementation and testing, and the implications of other changes that might also be demanded of them by HHS during the same period. **If adoption is going to occur in a period similar to that proposed, AHIMA recommends that:**

- **In the absence of a designated facilitator or coordinator over HIPAA-related transaction standards modification and testing, HHS must provide such coordination and facilitation.**
- **HHS should educate all affected entities and vendors as to the nature of the actual system audits, changes, and testing necessary. Such education will not only assist in understanding the steps needed in implementation, but also lower fears that this project could result in a process well beyond the proposed implementation period.**
- **Early coordinated education will also help HIPAA entities to work better with their vendors and trading partners in laying out their timelines toward testing and compliance.**
- **HHS should establish a set of steps or milestones for stakeholders to ensure the upgraded standards are in place and ready for use by the final compliance date.** It is suggested that if the industry and its vendors do not meet certain milestones, then the deadlines for compliance should be extended. **We believe assumptions of extensions gives stakeholders negative incentives not to move forward at a reasonable pace and significantly raises the costs to those entities that engage in early steps toward compliance.** Local training partners, including federal related health plans and providers, should keep each other apprised of their progress so entities falling behind can receive appropriate assistance to maintain forward progress.
- **HHS should share its knowledge and know-how with regard to the process of upgrading the HIPAA related standards so other stakeholders will have better information to guide their implementation strategies toward compliance.**
- **HHS and its regional offices and agencies, along with its contractors and state Medicaid programs supported by HHS, should be required to be intimately involved with other stakeholders on a local basis, so that implementation progresses in an orderly fashion and testing is coordinated among all trading partners. To this end, HHS should facilitate, and expedite the provided funding needed by state Medicaid programs to ensure these programs not only meet the required milestones for compliance, but also modify their systems to be in continued compliance with the HIPAA transaction standards requirements. Likewise, HHS should take a leadership position among all federal healthcare programs, across all federal departments so that all federal health programs will also be in a position to test their transactions and meet all compliance transactions.**
- **HHS should petition the Certification Commission for Healthcare Information Technology (CCHIT) to include version 5010 or D.0 in all products expected to carry the upgraded standard to facilitate compliance with the final rule. We believe this will be especially important for small covered entities in the process of purchasing software between now and the compliance date.** We recognize a period between the effective date of the rule and the possible certification by CCHIT exists, but if purchasers are aware of the

need to request products that meet the incoming HIPAA requirements, conversion will be smoother and less expensive.

The upgrading of the HIPAA standards as proposed takes place in a different environment than that earlier in this decade. As these comments are written, the HHS Office of the Coordinator for Health Information Technology (ONC), the American Health Information Community (AHIC) and its successor the AHIC Successor, Inc., and Congress are in a position to either facilitate or delay implementation of these HIPAA-related standards upgrades or the companion ICD-10 adoption and implementation. **AHIMA suggests that HHS join with us in urging all these bodies to recognize the efforts needed to implement the proposed modifications and adoptions and to work with the industry and HHS to ensure other proposals coming forward from these groups won't endanger the industry's ability to meet the final rule compliance date and requirements.**

The implementation of HIPAA standards involves thousands of individual entities and groups. With such large numbers, there must be leadership and coordination. While the positive results of upgrading the HIPAA standards should be an incentive for quick development and change, it cannot occur across without guidance, involvement, and leadership. Associations and groups seeking improvement in our healthcare transactions and achievement of administrative simplification stand ready to work with their members and the industry and would welcome the opportunity to work with HHS to see the proposed transition take place as smoothly and efficiently as possible.

Regulatory Impact Analysis (73FR49757)

Every HIPAA-covered entity will be affected by these proposed rules, but the analysis provided in the NPRM represents an average, not what any one organization might actually experience. Impact depends in part on vendor's foresight, planning, and expertise. The provider, health plan, or clearinghouses' internal capabilities, knowledge, and expertise are also factors, as is the need to schedule and oversee testing among trading partners including Medicare and Medicaid programs and intermediaries and the need to accommodate any other HHS proposed changes to the industry that influence the resources of the industry.

As noted above, AHIMA agrees with HHS that staggering implementation is not a feasible approach. Both health plans and providers need to complete the testing of the HIPAA transaction standards upgrades and the proposed classification systems. Staggering an implementation would stand as a barrier to a smooth implementation.

AHIMA also agrees that waiting for a future standard, say conversion to the X12 5050, does not resolve the current problems with the transaction standards or the need to implement the ICD-10-CM and ICD-10-PCS classification systems. Upgrading to X12 5010, now, will increase use of HIPAA transactions beyond the claim and remittance advice that can result in more efficient service to consumers and administrative savings for users. Further delaying the proposed implementation will make future standards upgrades more challenging and costly. If the healthcare industry can implement the upgrade to version 5010 and D.0, HHS can concurrently take steps to allow an incrementally smaller upgrade to a higher version over the course of the next several years after the ICD-10-CM and PCS standards are in place.

The changes to upgrade the transaction standards are long overdue and highly desirable. Since HHS has considerable influence on the industry's electronic health data projects, **AHIMA again recommends that consideration be given to provide access to the resources HHS created to implement and test these standards to affected vendors and HIPAA entities..**

CMS and its Office of Electronic Standards and Security have raised the specter of finalizing the proposed HIPAA Claims Attachment Transaction Standard. AHIMA notes that HHS did not include this standard in the impact discussion of the upgrade to the standards covered in this NPRM. or in the ICD-10-related NPRM. **AHIMA recommends that HHS not release the Claims Attachment Transaction Standard in final rule until compliance with this rule and the ICD-10-CM and –PCS rule has occurred. AHIMA believes implementation of upgrades to the existing standards, along with the use of ICD-10-CM and ICD-10-PCS, will relieve the necessity for the claims attachment. HHS will also see significant benefit if it expands the number of codes accepted as part of the electronic claims process.** AHIMA is also concerned that the most recently (2005) presented claims attachment standard no longer reflects the advancements made in the standards for the electronic health records and concerns for confidentiality, privacy, and security.

It is clear that the proposed upgrades to the HIPAA Transaction Standards are occurring at the same time HHS is proposing the adoption of ICD-10-CM and ICD-10-PCS. **AHIMA agrees with HHS' assessment that these two projects are needed, cannot wait, and can occur concurrently.** As HHS and CMS have noted, the standards involved are now and have been available. All stakeholders should instigate the planning and tasks needed to accomplish compliance immediately. This is not an easy or inexpensive task, and resources are limited for most of the stakeholders. **AHIMA urges HHS to work with the industry and Congress to limit the burden of adding even more tasks (such as major changes to prospective payments systems or adding additional HIPAA transaction standards) during this period of implementation.** It is important that the healthcare industry and the government focus on getting these transaction standards upgraded and classifications adopted in as efficiently and effectively possible. No one wants to see a slowdown of this nation's progress on healthcare information technology adoption, but placing additional burdens on the same resources will slow progress on all fronts.

Finally, there is considerable concern among some in the industry regarding the cost of implementation, the ability of vendors and clearinghouses to accommodate the change, and the potential impact on an office or practice's day-to-day workflow during and immediately after these changes are made. We have alluded to the fact that some concerns come from limited experience using the full complement of HIPAA transactions, which in turn has meant that the promised administrative simplification has not yet been recognized. Some concern also comes from long-term ongoing issues associated with Medicare reimbursement limitations that threaten the viability of smaller physician practices and providers. While we believe the impact on such providers is significantly less than for larger entities with greater resources, it is important that all entities achieve a smooth and workable transition. AHIMA recommends that Congress and HHS consider the plight of these smaller practitioners and provide any education, resources, and assistance possible. The only way the healthcare industry will achieve all the benefits of EDI, EHRs, and HIE is if all the components of the industry can be brought on board efficiently and effectively together.

Conclusion

AHIMA appreciates the opportunity to comment on the NPRM for the modification and upgrades to the HIPAA Electronic Transaction Standards. AHIMA stands ready to work with HHS and the healthcare industry to ensure an appropriate and timely implementation. If AHIMA can provide any further information, or if there are any questions or concerns in regard to this letter and its recommendations, please contact Allison Viola, MBA, RHIA, AHIMA's director of federal relations at (202) 659-9440 or allison.viola@ahima.org, or me at (202) 659-9440 or dan.rode@ahima.org.

Sincerely,

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CC: Allison Viola, MBA, RHIA
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