

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: The Health Insurance Portability and Accountability Act (HIPAA)
Administrative Simplification: Modification to Medical Data Code Set
Standards to Adopt ICD-10-CM and ICD-10-PCS; Proposed Rule; 73 Fed. Reg.
49,796 (August 22, 2008); CMS-0013-P**

Dear Mr. Secretary:

The undersigned organizations appreciate the opportunity to provide comments on the Department of Health and Human Services' (HHS) proposed rule for adopting the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) for diagnosis coding, and the International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD-10-PCS) for inpatient hospital procedure coding [CMS-0013-P], as the standard code set under the Health Insurance Portability and Accountability Act (HIPAA). These new codes (ICD-10) would replace the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Volumes 1 and 2, and the International Classification of Diseases, Ninth Revision, Clinical Modification (CM) Volume 3 for diagnosis and procedure codes, currently identified under HIPAA.

We are deeply concerned that the October 1, 2011, compliance deadline proposed by HHS will not provide adequate time for a smooth transition from ICD-9 to ICD-10. **We, therefore strongly urge HHS to:**

- 1. Provide at least 36 months to adopt and implement 5010 from the date of publication of the 5010 final rule to accommodate all levels of testing; and**
- 2. Require adoption of ICD-10 no sooner than 60 months following publication of the 5010 final rule and after 5010 industry readiness levels have reached at least 95 percent.**

General Comments

Moving from ICD-9 to ICD-10 is a significant change for the health care community and will require the establishment of a constructive implementation process and timeline that recognizes the challenges and requirements associated with such a transition. ICD-10-CM codes are 3-7 characters in length and total 68,000, while ICD-9-CM diagnosis codes are 3-5 digits in length and number up to 13,000. ICD-10-PCS procedure codes are alphanumeric, 7 characters in length, and total approximately 87,000, while ICD-9-CM procedure codes are only 3-4 numbers in length and total approximately 3,000 codes. Due to the increased number of codes, the change in the number of characters per code, and increased code specificity, this transition will require significant planning, training, software/system upgrades/replacements, as well as other investments for health care payers, clearinghouses, software vendors, physicians and other health care professionals. In addition, prior to moving to ICD-10, another significant transition must

take place; the adoption and implementation of X12 version 5010 Technical Reports Type 3 for HIPAA electronic transactions (5010). The current HIPAA electronic transactions standard (4010) is not compatible with ICD-10. HHS has issued a proposed rule calling for transitioning from 4010 to 5010 by April 1, 2010. We support adoption of the new 5010 HIPAA transaction standards, and organizations, including the AMA, have submitted separate comment letters to HHS on the 5010 proposed rule. However, we are also concerned with the proposed 5010 adoption timeframe given that the proposed deadline does not fully account for the time and resources needed by the health care industry to implement 5010. **Therefore, we urge HHS to support the recommendations and stakeholder input provided by the National Committee on Vital and Health Statistics (NCVHS) on the implementation process and timeline needed for successfully transitioning to 5010 and ICD-10.**

Implementation Process and Timeline

Learning from Previous HIPAA Adoption Experiences

Despite clear input from NCVHS and others, and the overall industry's experience with earlier HIPAA transitions, HHS is proposing an overly aggressive ICD-10 timeline. According to the ICD-10 proposed rule, "ICD-10 code sets would likely represent the most complex of all the HIPAA code sets." Many regard the move to ICD-10 as a more complex undertaking than the adoptions of the first version of HIPAA standards (4010) and of the National Provider Identifier (NPI). As HHS is aware, the transition to the HIPAA electronic transactions and the NPI involved significant investments and workflow changes for all covered entities (i.e., health care providers, payers, and clearinghouses).

In fact, physicians and other health care professionals are still struggling with the transition to the NPI. Although the use of the NPI was required by May 23, 2007, the Centers for Medicare & Medicaid Services (CMS), the agency within HHS charged with the oversight of HIPAA administrative simplification, had to extend the NPI compliance date for an additional year. Yet, ongoing transition glitches, including Medicare's inability to appropriately link a physician's Medicare enrollment information to the new NPI number(s), still persist. Due to continuing problems with the NPI transition, many physicians and other health care professionals have not received Medicare reimbursements since May 23, 2008, which has significantly impacted cash flow, claims processing, and the overall management of their practices. Following an effective NPI implementation process and timeline would have reduced disruptions for physicians and other health care professionals and their patients. HHS underestimated the challenges associated with the NPI transition. We want to avoid repeating mistakes that come with pursuing an overly aggressive compliance deadline.

In addition to the challenges associated with transitioning to the NPI, the transition to 4010 electronic standard transactions also caused significant claims processing interruptions and cash flow concerns. The final 4010 rule was published in 2000 and the compliance deadline was set for 2002. However, the health care industry, including CMS, determined that this deadline was too aggressive and that more time was needed for the industry to comply. Thus, CMS granted HIPAA covered entities additional time to prepare; yet several HIPAA transactions still remain in contingency mode today and many are not being conducted according to required HIPAA standards. The protracted and costly process that the industry and health care system experienced with HIPAA could be avoided with the transition to ICD-10 if an appropriate implementation plan and timeline are developed that recognizes the challenges and complexities associated with transitioning to ICD-10. **We therefore urge HHS to adopt the lessons learned during the**

implementation of 4010 and the NPI in establishing appropriate implementation and adoption deadlines for the transition to 5010 and ICD-10.

NCVHS Recommendations and Industry Input

The ICD-10 proposed rule indicates that the compliance deadline was determined after considering “myriad input from the public, NCVHS, professional organizations, and others.” Yet, HHS’ proposal, which requires covered entities to transition to the use of ICD-10 by October 1, 2011, conflicts with the recommendations made by NCVHS, a federal advisory body comprised of health care industry HIPAA and health information technology (HIT) experts.

NCVHS, in its letter dated September 26, 2007, to Secretary Leavitt, outlined the importance of completing specific activities and setting milestones that all affected organizations must meet in order for the industry to be prepared to successfully migrate to updated HIPAA transactions and codes. Specifically, NCVHS provided two key recommendations:

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 the 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.

The letter also states, “testifiers expressed the need to test and verify Version 5010 before the implementation of ICD-10 code sets.” Therefore, before physicians and other health care professionals can determine whether they are able to send and receive transactions from their trading partners (i.e., payers, clearinghouses, vendors), physicians and other health professionals must first be allowed at least two years to make changes to or replace their software/systems and test them to ensure that they can accurately accommodate the use of 5010. If physician’s trading partners are not ready to accept electronic transactions that use ICD-10 codes, then physicians and other health care professionals will not be able to transition to the use of 5010 or ICD-10 and should not be expected to do so by the proposed compliance deadlines.

HIPAA provides the framework for the adoption of standard electronic health care transactions and codes sets. HIPAA also requires that any standard adopted by the Secretary of HHS be developed, adopted, or modified by a standard setting organization (SSO), except in special cases. Furthermore, HIPAA requires that HHS consult with certain committees (e.g., NCVHS and the Workgroup for Electronic Data Interchange (WEDI)) in the course of the development, adoption, or modification of a standard. HHS must also rely on the recommendations of the NCVHS and consult with appropriate federal and state agencies and private organizations before adopting a standard.

In addition to consulting with NCVHS, HHS is required to consult with the National Uniform Claim Committee (NUCC) and the WEDI on ICD-10. WEDI sent a letter to HHS in May 2006 indicating that the 2009 proposed adoption deadline, under discussion at that time, was not feasible. On March 7, 2008, NUCC issued a letter to CMS reiterating NCVHS’ recommendations on sequencing the implementation of 5010 and ICD-10. Moreover, several

organizations, including the AMA, several medical specialty organizations, the Medical Group Management Association, and the Blue Cross Blue Shield Association also outlined their concerns about a short ICD-10 adoption timeframe to CMS, HHS, and NCVHS through various meetings, letters, and congressional testimonies.

Multiple advisory groups and health care industry stakeholders have alerted HHS of the need for a longer adoption period for both the 5010 and ICD-10 than what HHS has proposed. It is also important to note that CMS' Strategic Action Plan for 2006-2009 stated the following about ICD-10, "Because the codes impact so many parts of CMS, the implementation process is expected to be a 4-5 year effort, starting well before the implementation date and lasting several years after. This will be a significant, agency-wide effort, impacting virtually every part of CMS and all of our patients." It is therefore unclear why HHS proposed the October 1, 2011, adoption deadline—a significantly shorter timeframe than what was recommended by CMS.

Given the proposed compliance dates for 5010 (April 1, 2010) and ICD-10 (October 1, 2011), it is clear that: 1) even if the 5010 rule were finalized tomorrow, the industry would have less than 18 months to adopt and comply with 5010, leaving less than the NCVHS recommended 2-year timeframe for Level 1 testing; 2) the deadlines allow less than the usual 24 months for compliance with HIPAA standards, despite the fact that past experiences point to the need for longer implementation timeframes for standards; and 3) the proposed implementation timeframes for 5010 and ICD-10 will cause these transitions to overlap during the internal Level 1 testing phase, which is contrary to NCVHS' recommendations.

Given HHS' failure to fully consider the nature and extent of the ICD-10 transition, we strongly recommend that HHS support the recommendations and stakeholder input provided by NCVHS and others on the implementation process and timeline needed for transitioning to 5010 and ICD-10. We further recommend the following timeline to ensure a successful transition to 5010 and ICD-10:

- 1) **HHS provide at least 36 months to adopt and implement 5010 from the date of publication of the 5010 final rule so as to accommodate all levels of testing;**
- 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 offices), clearinghouses, and payers are able to successfully send and receive transactions using the 5010 standard and report findings and recommendations, including any adjustments to compliance deadlines, to HHS; and**
- 3) **HHS require adoption of ICD-10 no sooner than 60 months following the publication of the 5010 final rule and after 5010 industry readiness levels have reached at least 95 percent.**

It is also important to note that the Administrative Procedure Act (APA) requires HHS to explain its regulatory proposals and provide the public with notice and opportunity to comment. To ensure compliance with the APA, we caution against the rush to issue a final rule on the ICD-10 prior to fully considering comments on the proposed rule, which are due by October 21, 2008. As noted above, HHS' proposal, that all covered entities transition to ICD-10 by October 1, 2011, contradicts recommendations issued by NCVHS and others. Moreover, HHS' has not provided an adequate explanation for proposing a compliance deadline that conflicts with recommendations from its consultants. The proposed compliance deadline is unrealistic given the costs and complexities associated with such a significant transition. **We believe that HHS has not met the APA requirement to fully explain and justify its regulatory proposal and thus**

urge HHS to adequately assess the impact of ICD-10 implementation, fully consider comments on the proposed rule, and propose an implementation process and timeline consistent with recommendations issued by NCVHS, WEDI, and others.

We are also concerned that CMS did not release the report that it commissioned to study the impact of ICD-10 on the Medicare program prior to the publication of the proposed ICD-10 rule; a study that is intended to help HHS make an informed decision about an appropriate adoption timeframe and the Medicare program's readiness level. In addition, CMS awarded the contract for evaluating the steps needed for Medicare readiness for ICD-10 to the American Health Information Management Association (AHIMA), without allowing other organizations to have an opportunity to bid on the contract, despite AHIMA's obvious conflict of interest. Moreover, as acknowledged by HHS in the proposed rule, other federal agencies have not yet completed their cost estimates for ICD-10, which further suggests the lack of the federal government's readiness for compliance with the proposed ICD-10 implementation deadline.

Other Implementation Concerns

Juggling an Evolving Practice Environment

Physicians and other health care professionals are facing a staggering number of technological requirements, including multiple, overlapping federal mandates, which place significant financial and operational burdens on practices, especially smaller practices. In addition to the previously mentioned challenges that physicians and health care professionals faced with the NPI implementation, in 2007, the new Medicare Physician Quality Reporting Initiative (PQRI) was initiated, which required participating physicians and other health care professionals to modify the way they submit claims so as to capture new CPT Category II or G codes. As with any new program, significant challenges persist, including the use of the NPI and Individual Authorized Access (IACs), the system physicians and other health care professionals are required to utilize to obtain their PQRI bonus. The implementation timeframes for compliance with HIPAA mandates and other HIT-related requirements should be better coordinated to avoid contingency plans and to ensure that physicians and health care professionals and the health care industry as a whole are able to meet these requirements.

For example, while HHS lists April 1, 2009, as the compliance deadline for e-prescribing standards under the Medicare Part D program, there is no mention of the January 1, 2009 start date for the new e-prescribing incentive payment program that was established under the "Medicare Improvements for Patients and Providers Act" (MIPAA) (P.L. 110-275), which became law on July 15, 2008. For many physician practices, upgrading/replacing e-prescribing systems will require significant resources. Physician practices will have to continue to juggle their resources in order to adhere to the e-prescribing mandates on standards, incentives, and avoid penalties for noncompliance, while they transition to the use of 5010 and ICD-10. Furthermore, HHS announced a target compliance date of 2011 for compliance with claims attachments, yet NCVHS recommended that the 5010, ICD-10, and claims attachments implementations be appropriately sequenced in order to avoid an overlap of these extensive transitions. Taken together, all of these changes facing physicians and other health care professionals further speak to the need for an appropriate adoption timetable for 5010 and ICD-10. **We therefore urge HHS: 1) to fully consider the impact that the new Medicare e-prescribing incentive and penalty program will have on physicians and other health care professionals along with the 5010 and ICD-10 implementations; and 2) not to require adoption of the claims attachments standard such that it overlaps with the implementations of 5010 or ICD-10.**

Achieving More Value from HIPAA

Much of the value intended with HIPAA “administrative simplification” is not being fully realized today which could significantly contribute to greater efficiencies for physicians and other health care professionals. For example, many of the HIPAA transactional fields that would provide information on patient 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 and other health care professionals to determine the amount of payment that was made pursuant to the contracted rate. Without this line by line reporting, physicians and other health care professionals 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.

Additionally, many health payers are still not using the transactions standardized by 4010. Informal surveys demonstrate a wide variation in the way standard transactions are being utilized and the level of code set compliance by health care partners. This variation is also evident in the fact that by one estimate there are over 1,200 companion guides in effect today. This adds further challenges for physician practices to comply with HIPAA by creating unique transaction requirements per payer and limits the potential efficiencies intended with HIPAA administrative simplification rules. Problems that physicians and other health care professionals routinely face today include: payers who simply do not provide a response to a request for information using standard transactions; responses provided in non-compliant formats; and imposition of illegal conditions such as requiring physicians and other health care professionals to agree to electronic funds transfer (EFT) as a condition for receiving an electronic remittance advice, all of which are prohibited under HIPAA. While we support the move to 5010, which is expected to solve many physician concerns, there are no assurances given the spotty adherence to the current transactions standard by payers that many of these concerns will improve under the new transaction standards. **We therefore urge CMS to 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.**

Standardized Coding Guidelines

Currently, HIPAA covered entities are only required to follow implementation guides for the ICD-9 code set. HHS has proposed adopting the official guidelines for coding and reporting for ICD-10. It is our understanding that the coding guidelines for the ICD-10 code sets have not yet been finalized. The coding guidelines on the National Center for Health Statistic’s (NCHS) website are dated July 15, 2003 and language in the document states that the guidelines are a “draft.” The lack of finalized coding guidelines will make it difficult for software and systems vendors to develop ICD-10 products and for covered entities to begin training staff and implementing procedures for the ICD-10 code sets. **We urge HHS to appoint a single,**

authoritative source for the ICD-10 coding guidelines to avoid variations in the interpretation and use of the codes.

While CPT was adopted as a standard code set under HIPAA, the CPT coding guidelines and conventions have not been adopted. Without a standard set of guidelines, payers are free to interpret coding rules as they see fit. This significantly undermines administrative simplification and pricing transparency efforts. While Medicare follows the CPT coding guidelines and conventions, payers' coding guidelines vary within and among payers. For example, CPT codes, guidelines, and conventions indicate that a bilateral procedure should be reported with the appropriate CPT code and appended with a modifier 50, indicating that the unilateral procedure was performed bilaterally. Depending upon which claim processing platform the claim used, a payer may report the bilateral procedure according to CPT codes, guidelines, and conventions, or report using a payer-specific guideline with two line reporting (i.e., the CPT unilateral procedure code reported on one line and the CPT unilateral procedure with the modifier 50 on the second line). When a claim reported on two lines enters a claims processing platform that requires one line item reporting for this procedure, the inconsistency results in reduction in payment of approximately 67 percent.

The lack of this single, simple coding guideline and standardization within and among payers causes considerable, unnecessary administrative expenses for the physician and payer. As a result, physicians and other health care professionals see not only a loss of revenue, but, more significantly, an increased administrative cost associated with having to manually audit and appeal these claims to the health care payer for a correction to the inaccurate payments that result from this inconsistency. **We urge HHS to adopt the CPT codes, guidelines, and conventions so as to avert further coding inconsistencies in recognizing and reporting of physician procedures and services.**

Outreach and Education

Along with an appropriate implementation timeframe, we believe that significant physician outreach and education will be critical to ensure a successful transition to ICD-10. WEDI, NCVHS, and others have all recommended pursuing outreach and education throughout the implementation process. The proposed rule only calls for roundtable conference calls with stakeholders, frequently asked questions (FAQs), fact sheets and "other supporting education and outreach materials for partner dissemination." We are concerned that HHS is not adequately planning for the health care provider outreach and education needed to support a transition of this magnitude. Since HHS relies heavily on Medicare for HIPAA education, sufficient resources must be allocated to ensure Medicare contractors have an adequate number of properly trained customer service agents ready to respond to inquiries. Medicare's provider customer service lines are already stretched and physicians and other health care professionals are experiencing significant delays in receiving answers to their Medicare enrollment questions and concerns, on the rollout of the Medicare Administrative Contractors (MACs), and on NPI-related issues. Without dedicating adequate resources to respond to requests for information in a timely and uniform manner, physicians and other health care professionals will undoubtedly experience even greater challenges with the implementation of 5010 and ICD-10.

We strongly recommend that outreach and education activities for the move to 5010 and ICD-10 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 Medicare 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 bimonthly or quarterly basis until at least six months after the 5010 and ICD-10 compliance deadlines; and**
6. **Appoint a point person centrally and in each regional office to guide the 5010 and ICD-10 implementations and to ensure that materials disseminated to industry are consistent and are available to help troubleshoot problems as they arise throughout the implementation process.**

We welcome the opportunity to work with HHS on physician outreach and education initiatives and materials.

Impact on Quality Measurement Development

A move to ICD-10 will also require updating quality measures. Currently, the majority of performance measures are specified using ICD-9 diagnosis codes. Modifying the measures will require considerable time and resources as each measure will need to undergo review and potentially be revised based on changes in the ICD-10 coding specificity and structure. For example, all measures developed by the Physician Consortium for Performance Improvement (PCPI), which make up the majority of measures in the PQRI, will need to be thoroughly reviewed. Each work group must be consulted to determine at a minimum whether the revised coding accurately captures the denominator and may require changes to the measure construction. All of these changes must then be communicated to the PCPI membership and outside organizations such as the National Quality Forum (NQF) and CMS. This review of the measures and specifications cannot be completed all at once and will impact how measures are reviewed and updated by those endorsing or implementing the measures including the NQF, AQA, and CMS. Furthermore, the implications on the implementation and testing of the measures must also be considered. If physicians and other health care professionals will be asked to report on measures in the PQRI that are tied to ICD-9 codes, they will then need to determine how the old codes are being mapped to the new codes and the changes need to be communicated clearly. **We are unclear as to how a change to ICD-10 will impact the ability to measure quality consistently and request that HHS provide clarification.**

ICD-10-CM Diagnosis Codes

HHS states there are 68,000 available ICD-10-CM diagnosis codes, yet prior to the publication of the proposed rule the amount of codes widely cited and even included in HHS' own Justification of Estimates for Appropriations Committees for CMS FY09 has been 120,000. **We urge HHS to clarify why the number of diagnoses codes listed in the proposed rule varies so significantly from previous estimates.**

The proposed rule asserts that the greater detail found in ICD-10-CM code set will facilitate timely electronic processing of claims by reducing requests for additional information and will result in fewer claims being returned. We believe that just the opposite could happen and that payers will actually use this as an opportunity to require additional documentation to support the increased granularity in the new codes further slowing down reimbursement to physicians and

other health care professionals. It is reasonable to assume that given the ICD-10 coding system differs significantly from ICD-9, additional physician documentation will be required not only to support the increased code specificity, but also the resulting payment adjudication flags used by payers for medical necessity given that payers have not yet gained sufficient experience in the use of a specific code. In addition, we expect payers to create new claims payment edits based on ICD-10. Since ICD-10 expands the number of current diagnosis codes, the number of edits that must be managed by a physician practice could increase dramatically.

Of course, an increase in required documentation will create a significant workflow problem for physician practices. The hope of administrative simplification in this area lies with the implementation of the HIPAA standard transaction for claims attachments. **We urge HHS to: 1) remove the assumption that the use of ICD-10-CM will facilitate timely claims processing by reducing additional requests for information; and 2) request that HHS monitor claims rejection rates and requests for additional information and make this data publicly available.**

Mitigating Cash Flow Disruptions

We agree with HHS' assumption that the transition to ICD-10 could cause significant payment interruptions. However, we strongly disagree with HHS' assertion that payers are equipped to handle payment problems. While HHS acknowledges that a "risk of a payment slowdown always exists whenever a new payment system or policy is implemented," we strongly disagree with the statement that "even with major policy changes, plans have learned over time to anticipate these problems and have instituted measures to provide periodic interim payments (PIP)...Most payers have learned through experience the cash flow needs of their providers and can easily set up PIPs and perform reconciliation at the end of the fiscal year." Our recent experience with the NPI and Medicare enrollment problems strongly contradicts the ability of CMS and Medicare contractors to handle such situations.

To date, most physicians and other health care professionals remain unaware of an option for advance payments, despite our requests for HHS to conduct more education and outreach initiatives on this option. This could be attributed in part to an inadequate number of appropriately trained Medicare contractor customer service representatives. Also, it appears Medicare relies at least in part on the volume of claims submitted by physicians and other health care professionals in the immediate past, in order to determine whether a physician qualifies for advance payments. However, the guidelines for advance payments remain unclear. **We strongly urge HHS to work with the Medicare program to ensure that: 1) advance payment guidelines are clear and readily available to physicians and other health care professionals, and flexible enough to accommodate situations such as the ones that arose under the NPI; and 2) customer service representatives working for the contractors inform physicians and other health care professionals of the availability of advance payments.**

Regulatory Impact Analysis (RIA)

Pursuant to the Unfunded Mandates Reform Act of 1995, HHS included a Regulatory Impact Analysis (RIA) in the proposed rule given that the cost of implementing the regulation to the industry is expected to exceed the threshold of \$130 million set in law for one year. HHS estimates that the costs for implementing ICD-10 would be offset by the benefits of transitioning to ICD-10 within four years over a fifteen year period and the benefits would be realized one year after implementation with 100 percent of the benefits being realized by no later than the sixth year. HHS' RIA relied largely on the analysis of two studies (a March 2004 RAND study and an

October 2003 study by Robert E. Nolan), as well as data and input supplied by the American Health Information Management Association (AHIMA), and the American Hospital Association (AHA). Based upon HHS' analysis of the aforementioned studies and data, HHS addressed costs for three main areas: 1) training; 2) productivity losses; and 3) systems changes. HHS did however acknowledge that there is "considerable uncertainty" with the RIA data and assumptions.

We are extremely concerned that HHS has not only underestimated the time needed to transition to ICD-10, but has not analyzed the significant direct and indirect costs for physicians and other health care professionals to implement multiple, overlapping HIPAA and non-HIPAA federal mandates. Although it is hard to quantify the direct and indirect costs for moving to ICD-10, a study conducted by Nachimson Associates released in October 2008 indicates that the "costs [for physicians] will far outweigh any benefits." **Based upon the Nachimson study, the costs to a typical small physician practice (i.e., three physicians and two administrative staff members) for the first year of implementation of ICD-10 could be as much as \$83,290.** The basis for this figure is described in greater depth below.

Adopting each HIPAA standard has been very costly and complex for the entire industry. Because there is a lack of longitudinal data documenting the financial as well as other impacts, we strongly urge HHS to fund a comprehensive study conducted by WEDI or another appropriate independent party to track and analyze the true costs for and benefits to those covered entities, especially small physician practices, that are required to comply with 5010 and ICD-10.

Training

Physicians, other health care professionals and their staff will need substantial training on the increased documentation requirements to support the increased granularity of the ICD-10 codes. For example, ICD-9-CM code E917.0 used to report striking against or struck accidentally in sports without subsequent fall can be translated into 24 different ICD-10-CM detail codes plus 8 higher codes (i.e., W21.00 struck by hit or thrown; ball, unspecified type; W21.31 struck by shoe cleats or stepped on by shoe cleats; W21.32 Struck by skate blades or skated over by skate blades; W21.39 Struck by other sports foot wear; W21.220 struck by ice hockey puck; W21.221 struck by field hockey puck; etc.). Despite HHS' comment that, "the new codes will likely touch every provider who submits diagnosis codes, and every payer that processes health care claims," HHS estimates that only one in ten physicians will need to be trained on how to use the ICD-10 codes. We believe that the vast majority of physicians and health care professionals will need training on ICD-10. According to the American Academy of Professional Coders (AAPC), "every physician will need training on documentation." Furthermore, according to the study published by Nachimson Associates, "Training would therefore involve clinical staff (doctors, nurses, physician assistants, nurse practitioners) that do the treatment and documentation, as well as *nearly every person/department.*" (emphasis added).

Adequate training will have a direct impact on reimbursement. Since payers, particularly Medicare, require physicians and other health care professionals to report specific, relevant codes, physicians and other health care professionals will not be able to simply select "unspecified" as a code. Without precise documentation needed to support selected codes, physicians and other health care professionals will face claims rejections, and cash flow interruptions, or payer requests for additional information. The proposed rule indicates that they will only need four hours of training each at a cost of \$137, however the Nachimson study finds they will need 12 hours of training, coding staff will need 16 hours of training, and other administrative staff will

need 8 hours of ICD-10 training. Moreover, the Nachimson report states that, “this is not a simple substitution of one code for another, the learning curve is expected to be quite steep for both clinicians and their administrative staff... Detailed training would have to be provided to specific staff involved in documentation of patient activities, coding of medical records and administrative records, information technology, health plan relations, and contracts.” **The Nachimson report estimates the training costs for a typical small practice at \$2,405.**

Superbills

HHS asserts that reliance on “superbills” will negate the need for training and minimizes the need for a coder. HHS states, “there will be a minimum number of physicians who will desire such training, leaving it instead to their staff coders, or the use of “superbills” to update their coding information.” We disagree with HHS’ assumption that physicians and other health care professionals will leave the decision about which code to select to their coders. This assumption is unrealistic as the vast majority of physicians and other health care professionals practice in small groups and generally do not have the resources for a “coder,” therefore they select the diagnosis code themselves. An increased code set both in size and scope will certainly change the content of existing superbills which are currently one page sheets used to select an ICD-9 code. In some practices, the expanded code set may necessitate a multi-page superbill, which certainly results in additional cost and less efficiency. Physicians and other health care professionals will likely need to rely on other sources in addition to their superbills to support use of the new codes. Real-time claims processing under these circumstances will become problematic and highly unfeasible in this type of manual workflow in the small physician office.

HHS concludes based upon AHIMA data that the cost to update superbills will only be a one-time, two-hour cost of \$55 per practice. AAPC, however, has reported that they estimate the costs to create additional superbill pages will range between \$2,000-\$5,000, a cost that far exceeds HHS’ estimate. **The Nachimson study reported that the estimated costs for adding an electronic superbill to one practice management software system per user was \$995 and the cost of an electronic superbill, through the use of an Electronic Health Records (EHRs), was \$2,985.**

Documentation

The proposed rule fails to fully assess costs such as increased documentation. The Nachimson report finds that the increased documentation costs associated with use of ICD-10 are estimated to result in a 4 percent increase in provider work time and that this would result in a permanent cost increase. **According to the report, the increased documentation costs to a typical small physician practice could be as high as \$44,000 in the first year.** This report explains that, “While the codes may not be documented until the claim for payment is filed, the documentation for determining the appropriate code starts as soon as the patient visit starts.” The report also indicates that use of an EHR is not expected to remove additional documentation time.

Coding Shortage

A transition from ICD-9 to ICD-10 will require an appropriate supply of coders. Training coders for ICD-10 will require the development of a new curriculum, publication of curriculum materials, and most importantly, adequate workforce training to support the providers and billers under ICD-10. Even AHIMA has acknowledged on their website that, “There is a nationwide shortage of certified medical coders in hospitals, physician practices, and other healthcare facilities. According to the United States Bureau of Labor, employment of medical record and

health information technicians is expected to grow much faster than the average field.” **We therefore urge HHS to incorporate time in the transition process and adoption timeline for the adequate training of coders.**

Productivity Losses

The proposed rule indicates that productivity losses will occur during the move to ICD-10 and rejected claims will need to be resubmitted as coding errors are identified. Given the problems experienced with the transition to the NPI we strongly concur with this assumption. **The Nachimson report has estimated that the cost to a typical small practice for increased claim inquiries and reductions in cash flow during the first year of implementation of the codes will be \$19,500.**

We disagree however with the minimal productivity loss estimates relayed by HHS. HHS first concluded that it would take an additional 1.7 minutes to code an inpatient claim, which is based upon the results of a field test conducted by the AHA and AHIMA using the ICD-10 codes in an ideal inpatient environment with the use of seasoned coders. While the field test did not cover the use of outpatient claims using ICD-10, HHS nonetheless concluded, that it would take outpatient coders one-hundredth of the time they estimated it would take inpatient coders to code a claim using ICD-10. A field test study in a typical outpatient environment should be conducted.

The level of complexity associated with the new codes will slow down the reporting process as physicians and other health care professionals will have to decipher the use of multiple codes. To suggest it will take physicians and other health care professionals .017 minutes or what equates to 1.02 additional seconds to code a claim using ICD-10 is unrealistic. Common sense dictates that one second is approximately the amount of time it would take for a physician to either write or type a diagnosis code, assuming he/she already knew what code to use. **We strongly urge HHS to provide a more reasonable estimate on the time it will take physician practices to decipher and use ICD-10 codes.**

Systems Changes

Vendor System Changes

HHS asserts that larger providers will need to make more extensive coding systems changes whereas smaller practices may only need to upgrade software/systems in order to accommodate longer code lengths. We find the assumptions that there will be no hardware costs and free software upgrades problematic. We expect the dollar cost to physicians and other health care professionals for upgrading to ICD-10 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 and other health care professionals may need to purchase an entirely new software and/or hardware system, if their current system is unable to accommodate ICD-10. Vendors will certainly charge for implementation any of the HIPAA transactions that the practice had not previously implemented. **The Nachimson report estimates the information technology (IT) costs for a typical small physician practice to move to ICD-10 to be approximately \$7,500.** This estimate was based upon an analysis of data from the report, “Examining the Cost of Implementing ICD-10,” which analyzed both the earlier referenced Nolan and RAND studies along with other reports identified by HHS in the proposed rule.

Vendor Readiness

A significant concern for physicians and other health care professionals is the fact that they have to rely upon the readiness of non-covered HIPAA entities (i.e. software vendors) in order to successfully transition to ICD-10. 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. Furthermore, while the lack of vendor readiness will result in the possible need to upgrade systems, physicians and other health care professionals could experience productivity loss and claims denials at least during the initial implementation phase due to the lack of vendor readiness. **As mentioned previously, we strongly recommend that HHS charge NCVHS with monitoring the readiness of the industry, including vendors.**

Mapping

In order to transition from ICD-9 to ICD-10, the codes must be mapped to one another. However, given the significant differences in these two code sets, a number of factors need to be considered that contribute significantly to the conversion process. First, not every ICD-9 code may map directly to an ICD-10 code. One ICD-9 code may have to be mapped to several ICD-10 codes or several ICD-9 codes may have to be mapped to one ICD-10 code. Many codes may not map at all. These challenges are acknowledged even by NCHS, which has recently completed a crosswalk that maps ICD-9-CM Volumes 1 and 2 to ICD-10-CM, confirms these challenges. Mappings between ICD-9-CM and ICD-10-PCS attempt to find corresponding procedure codes between the two code sets, insofar as this is possible,” and in some cases, “translating between them the majority of the time can offer only a series of possible compromises rather than the mirror image of one code in the other code set.” According to industry research, 81 percent of ICD-9-CM codes have a correlating ICD-10-CM code in the ICD-9-CM to ICD-10-CM crosswalk. However, 19 percent of ICD-9-CM codes do not have many correlating ICD-10-CM codes. **We urge HHS to explain how the remaining 19 percent of ICD-9-CM codes should be handled by physicians and other health care professionals in order to accurately code and bill ICD-10-CM codes.**

Moreover, unless the entire industry works from the same crosswalk, there will be significant confusion on which codes are appropriate for use. We would like to emphasize the importance of having correct and complete maps available in order for the industry to successfully implement ICD-10. A thorough analysis of the maps should be done to ensure their completeness and correctness prior to the publication of the final rule. In addition to the creation of maps, consideration needs to be given to whether or not the maps will be maintained going forward. Whether or not the maps will be maintained and continually updated for years to come will greatly impact how organizations handle their historical data during the implementation. If maps will not be maintained in the future, organizations will have to convert all of their data to ICD-10 during their implementation of the code set. This includes all research and warehoused data, in addition to data held by physicians, other health care professionals, other health care providers and organizations, and payers. **We further recommend that HHS: 1) work with key stakeholders, including physicians and other health care professionals, to develop a uniform mapping guideline for guidance as we transition to ICD-10; 2) name a single, authoritative national organization to develop and maintain the maps for each of the ICD-10 code sets; and 3) make the maps freely available in order for the industry to successfully implement the ICD-10 code sets.**

Conclusion

We look forward to working closely with HHS on helping physicians and other health care professionals transition to ICD-10. A transition of this magnitude will require a workable implementation process and timeline for all HIPAA covered entities, and comprehensive outreach and education initiatives to support health care providers, especially small physician practices, throughout this complex move to ICD-10. Should you have any questions regarding these comments, please contact Mari Savickis by phone, 202-789-7414, or by email, mari.savickis@ama-assn.org.

Sincerely,

American Academy of Dermatology Association
American Academy of Facial Plastic and Reconstructive Surgery
American Academy of Hospice and Palliative Medicine
American Academy of Ophthalmology
American Academy of Otolaryngology– Head and Neck Surgery
American Academy of Pain Medicine
American Academy of Physical Medicine and Rehabilitation
American Academy of Sleep Medicine
American Association of Clinical Endocrinologists
American Association of Neurological Surgeons
American Association of Neuromuscular and Electrodiagnostic Medicine
American Chiropractic Association
American Clinical Neurophysiology Society
American College of Cardiology
American College of Chest Physicians
American College of Emergency Physicians
American College of Gastroenterology
American College of Occupational and Environmental Medicine
American College of Osteopathic Internists
American College of Osteopathic Surgeons
American College of Radiation Oncology
American College of Rheumatology
American College of Surgeons
American Gastroenterological Association
American Geriatrics Society
American Medical Association
American Optometric Association
American Osteopathic Academy of Orthopedics
American Physical Therapy Association
American Podiatric Medical Association
American Society for Aesthetic Plastic Surgery
American Society for Gastrointestinal Endoscopy
American Society for Reproductive Medicine
American Society for Therapeutic Radiology and Oncology
American Society of Addiction Medicine
American Society of Anesthesiologists
American Society of Breast Surgeons
American Society of Clinical Oncology
American Society of Colon and Rectal Surgeons

American Society of General Surgeons
American Society of Hematology
American Society of Plastic Surgeons
American Society of Transplant Surgeons
American Speech-Language-Hearing Association
American Thoracic Society
American Urological Association
College of American Pathologists
Congress of Neurological Surgeons
Infectious Diseases Society of America
Heart Rhythm Society
Joint Council of Allergy, Asthma and Immunology
Medical Group Management Association
National Association of Social Workers
Renal Physicians Association
Society for Vascular Surgery
Society of American Gastrointestinal and Endoscopic Surgeons
Society of Gynecologic Oncologists

Medical Association of the State of Alabama
Alaska State Medical Association
Arizona Medical Association
Arkansas Medical Society
California Medical Association
Colorado Medical Society
Connecticut State Medical Society
Medical Society of Delaware
Medical Society of the District of Columbia
Medical Association of Georgia
Idaho Medical Association
Illinois State Medical Society
Indiana State Medical Association
Iowa Medical Society
Kansas Medical Society
Kentucky Medical Association
Maine Medical Association
MedChi, The Maryland State Medical Society
Massachusetts Medical Society
Michigan State Medical Society
Mississippi State Medical Association
Missouri State Medical Association
Montana Medical Association
Nebraska Medical Association
Nevada State Medical Association
New Hampshire Medical Society
Medical Society of New Jersey
New Mexico Medical Society
Medical Society of the State of New York
North Carolina Medical Society
North Dakota Medical Association
Ohio State Medical Association

Oklahoma State Medical Association
Oregon Medical Association
Pennsylvania Medical Society
Rhode Island Medical Society
South Carolina Medical Association
South Dakota State Medical Association
Tennessee Medical Association
Texas Medical Association
Utah Medical Association
Vermont Medical Society
Medical Society of Virginia
Washington State Medical Association
West Virginia State Medical Association
Wisconsin Medical Society
Wyoming Medical Society