October 16, 2008

Michael Leavitt
Office of the Secretary
Department of Health and Human Services
Attention: CMS-0013-P
Mail Stop C4-26-05
7500 Security Blvd
Baltimore MD

Dear Secretary Leavitt:

The American College of Cardiology (ACC) is pleased to offer our comments on the notice of proposed rulemaking (CMS-0013-P) entitled: "**HIPAA Administrative Simplification: Modification to Medical Data Code Set Standards to Adopt ICD-10-CM and ICD-10-PCS** as published in the *Federal Register* on August 22, 2008.

The ACC is a professional medical society and teaching institution made up of 37,000 cardiovascular professionals from around the world – including 90 percent of practicing cardiologists in the United States and a growing number of registered nurses, clinical nurse specialists, nurse practitioners, physician assistants, and clinical pharmacists. Our goal in commenting on these proposed policy changes is to assure access to quality cardiovascular care for all Americans.

In this proposed rule, the Department of Health and Human Services (HHS) has proposed to mandate the use of the International Classification of Disease Version 10 Clinical Modification (ICD-10-CM) for use in all healthcare transactions covered by the electronic transaction provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) starting on October 1, 2011. While the ACC supports the transition to ICD-10-CM, it believes that the proposed timetable will lead to significant short-term difficulty for the entire healthcare community and will reduce the long term benefits of this switch. The ACC also believes that HHS significantly underestimated the costs to physicians and other healthcare providers in the proposed rule. The ACC does not believe that ICD-10-CM can be successfully implemented before October 1, 2013, and even that extension from HHS's originally proposed date will require significant work in preparation by the healthcare industry.

Under the requirements of HIPAA, electronic healthcare transactions between covered entities such as physicians and insurers must include a common code set. Since the implementation of HIPAA, ICD-9-CM has been the common code set used to report diagnoses by physicians and diagnoses and procedures by hospitals. ICD-9-CM codes are used routinely throughout healthcare business relationships, including healthcare billing, insurance coverage policies, and both public and private payer pay-for-performance programs. Since HHS has not proposed that physicians use ICD-10 for the

reporting of procedures, our analysis primarily concerns the implementation of ICD-10-CM diagnosis codes on the healthcare industry.

In the proposed rule, HHS notes that the ICD-9-CM system has been in use for the past 27 years and may be running out of room to include increasing level of complexity within its existing hierarchy. ICD-10-CM features a different format from ICD-9-CM that would allow the creation of far more diagnosis codes than currently available through the current coding system. There are currently 13,000 diagnosis codes in ICD-9-CM. The version of ICD-10-CM that has been created for the United States includes more than 68,000 diagnosis codes, a five-fold increase, with room for considerable additional growth to accommodate many more diagnosis codes. The ACC acknowledges that ICD-9-CM may be inadequate for future tracking of diseases and injuries. Cardiology's knowledge base has grown considerably since ICD-9-CM was first implemented and can be expected to advance further over time. However, ACC does not believe that the lack of available diagnostic coding detail is so acute as to require the short time frame that is proposed to alleviate it.

In considering this issue, HHS prepared a detailed impact analysis as required by law. This detailed analysis appears to greatly underestimate the impact of such an enormous change on physician practices. HHS first considers the direct impact on physicians themselves and determines that only one in ten physicians will require any training in ICD-10-CM at all, and those that do seek training will only require eight hours of training to achieve proficiency. Such an analysis is based on the HHS assumption that physicians select a diagnosis code from a predetermined list on a document often referred to as a superbill and that such a system precludes the need for knowledge of the system. While superbill use is common practice in the paper-based outpatient office, physicians still must have knowledge of the diagnosis system. In numerous cases, a patient's diagnosis may not be included on a superbill's abridged list. Indeed, with the substantial increase in available diagnosis codes required for ICD-10-CM, it is questionable whether a superbill system could be used at all. A physician lacking any training in ICD-10-CM would be unlikely to understand the hierarchy of the system and the depth of codes included. Without adequate training on ICD-10-CM coding, many physicians would likely select incorrect or unspecified codes when more specific diagnosis codes are available. If only a small percentage of physicians receive training, many of the proposed benefits of ICD-10-CM related to improved public health statistics and better disease tracking will be lost. The ACC believes that all physicians will require training in ICD-10-CM and that this education process will necessarily be more comprehensive than HHS proposed within this ruling. The ACC is very concerned by the HHS assumption that physicians have little to no involvement in the assignment of ICD-10-CM codes when often they are the only ones who are truly qualified to accurately distinguish one diagnosis from another. It is ultimately the physician's responsibility to have the correct and most accurate diagnosis code submitted on bills and such responsibility requires training.

In addition to their own training, physicians must ensure their clinical and administrative staff receive adequate training levels required to understand ICD-10-CM. While the

ACC does not have statistics on the number of administrative employees in a practice that are required to understand coding, the College believes that all clinical staff and the vast majority of administrative staff must have some understanding of the system for it to be used effectively. HHS does acknowledge this training period in the proposed rule, but seems to limit a requirement of knowledge of ICD-10-CM to certain people who either are professional coders or who are responsible for coding. There are many others who need some knowledge of ICD-10-CM to perform their duties, from nurses to file clerks, and to ignore the training requirements for these individuals is to ignore the realities of modern medical practice.

In addition to their own costs, physicians will bear significant costs related to other entities implementing ICD-10-CM. For example, while the cost of rewriting coverage decisions will rest with insurers, the cost of interpreting and navigating these coverage decisions will fall to physicians. If insurers do not have sufficient time to rewrite these coverage decisions to reflect the diagnosis codes, errors likely will occur, resulting in patients who are initially denied services that should be covered. The work of appealing such decisions often rests with physicians. HHS should allow a transition period of sufficient length to allow all covered entities to develop documents and reasonable coverage policies incorporating the ICD-10-CM codes that allow input from the medical community. While HHS's impact analysis addresses the issue of returned claims, it does not differentiate between the costs attributable to various healthcare providers. The administrative burden of a poorly planned ICD-10-CM implementation would rest primarily with physicians, who most often initiate patient care and are closest to the diagnosis sensitivities.

Physician practices generally use practice management software to submit claims to health insurers for payment. The transition to ICD-10-CM will make existing software obsolete, requiring a system upgrade or replacement. While HHS notes in the proposed rule that it believes that an upgrade to ICD-10-CM would be provided at no cost to physician practices as part of a normal upgrade, the ACC does not believe that this reflects the reality of the broad range of physician practices. While many larger groups and practices with more recently purchased software may receive free upgrades, many physicians using older or less common practice management software may not be upgraded at all. These practices would have to purchase new practice management systems at considerable cost. The HHS analysis also does not appear to consider the possibility that practice management software vendors would be unable to complete the transition within the timeframe proposed. We urge HHS to assess the comprehensive impact on physicians and other providers in such a scenario.

Despite all of the short-term and long-term costs physicians will incur, the potential benefits offered by ICD-10-CM are substantial enough to warrant its careful and methodical implementation. That is why the ACC is so concerned about the timetable laid out by HHS in the proposed rule. ICD-10-CM implementation requires adequate time and testing to ensure the transition process is completed smoothly and effectively throughout the healthcare system. HHS notes in its proposed rule that a new HIPAA claims transaction code set known as 5010 must be introduced before the transition to

ICD-10-CM can occur, as the current version known as 4010 cannot accommodate the ICD-10-CM codes. HHS released the proposed rule on 5010 implementation on the same day as the proposed rule on ICD-10-CM implementation and included an implementation schedule in that proposed rule.

While the transition to 5010 will have less direct impact on physicians, this transition does delay work on ICD-10-CM. To date, HHS has experienced substantial delays and contingency periods while implementing HIPAA standards related to privacy and the common identification number for providers. HHS states in the proposed rule that ICD-10-CM implementation will be the most complex and difficult transition of HIPAA transactions, but does not appear to allow the time needed for successful implementation of both 5010 and ICD-10-CM.

In the proposed rule, HHS relies heavily on the recommendations of the National Committee on Vital and Health Statistics (NCVHS). The ACC believes that this is appropriate, as this committee has considerable expertise in this area. However, the ACC does not believe that the NCVHS has recommended a timetable that is as aggressive as that outlined by HHS in the proposed rule. In its September 26, 2007 letter to HHS, NCVHS states that "it is critical that the industry is afforded the opportunity to test and verify Version 5010 up to two years prior to the adoption of ICD-10." Unfortunately, in the proposed rule, HHS does not allow for two years of testing of the 5010 transaction standard before implementation of ICD-10-CM. In its letter, NCVHS notes that it believes that Phase 1 testing of 5010 and ICD-10-CM should be consecutive rather than concurrent and that Phase 1 testing of 5010 will take two years. HHS indicates that it believes the industry experience in implementing HIPAA standards will lead to a speedy implementation and rejects the NCVHS standard in favor of a more accelerated one-year transition. HIPAA transitions have not been smooth in the past and have included numerous delays and contingency periods that make the HHS optimism about its proposed timeline very questionable.

The ACC urges HHS to seriously consider the recommendations of NCVHS and take a reasonable time to implement the 5010 transaction standards and then following that take a reasonable time to implement the ICD-10-CM code sets. The ACC believes that the healthcare industry will require no less than three years to implement the complex and important change of ICD-10-CM implementation. A two-year transition to the 5010 transaction standards, followed by a three year transition to ICD-10-CM, would translate to an integration target date no earlier than October 1, 2013 for healthcare transactions to utilize ICD-10-CM. However, the ACC must stress that this date is contingent on the completion of many steps that must precede it related to the implementation of the 5010 transactions and an assessment of industry's readiness to fully implement this standard.

As HHS implements the ICD-10-CM codes, it should focus on a goal of eventually using clinical data from electronic health records and registries to track public health information. HHS should also examine the clinical modification of ICD-10 created for use in the United States to ensure that the varying levels of description are clinically

relevant and that physicians are likely to be able to use the most specific codes when assigning a diagnosis to their patients.

The ACC's members are committed to providing quality care for their patients. We look forward to the potential advances in healthcare and reduced administrative burdens reflected in adoption of a system that is more descriptive of patient's clinical conditions. However, the ACC is concerned that HHS has not fully considered the implications to physicians and, certainly to the entire healthcare system, related to this massive conversion in multiple systems within a relatively tight interval. A slower but careful transition to ICD-10-CM will benefit everyone. An accelerated but careless transition benefits no one and may result in irreparable harm to the healthcare community.

The ACC appreciates the opportunity to comment on this issue. If you have any questions or wish to discuss the issue further, please contact Brian Whitman, Associate Director of Regulatory Affairs at bwhitman@acc.org or (202) 375-6396.

Sincerely,

W. Douglas Weaver, M.D., F.A.C.C.
President
American College of Cardiology