

# Alliance of Medical Societies

A Coalition of 12 Medical Societies Representing Over 150,000  
Physicians in the United States



Written Statement of  
Members of the Alliance of Medical Societies  
Health, Education, Labor, and Pensions Committee  
United States Senate  
Hearing on  
Medical Privacy  
April 16, 2002

As you are aware, on March 27, 2002, the Department of Health and Human Services (HHS) issued a proposed rule to modify the "Standards for Privacy of Individually Identifiable Health Information." We, the undersigned members of the Alliance of Medical Societies, strongly support the proposed modifications that HHS is considering with respect to prior consent and research and would also like to comment on the business associates provision.

The Alliance of Medical Societies comprises 12 national medical societies representing more than 150,000 specialty-care physicians. Its mission is to promote sound federal health care policies that will enhance the ability of specialty-care physicians to provide the best possible health care to their patients.

## **Prior Consent**

The proposed modifications to the prior consent portion of the rule represents a workable compromise between the original proposed regulation issued in 1999 that would have prohibited providers from obtaining consent and the final privacy regulation issued in 2000 that mandated prior consent requirements. These modifications maintain the patient privacy protections required by Congress without disrupting patient access to quality health care.

The Alliance supports meaningful privacy protections for patients' medical records and believes that it is important for patients to be notified of their rights. The proposal for regulatory permission as opposed to mandatory written consent would not change the ethical and professional practice of physicians and most health care providers to obtain patient consent. Not only would the prior consent requirement add yet another mandatory form to the already unmanageable paperwork burden that physicians and practitioners face on a daily basis, it could pose serious problems for patient care. HHS outlined many of the potential problems in the proposed rule. We strongly believe that HHS chose wisely in proposing to make prior consent discretionary, and we oppose any efforts to change it.

**Medical Research**

We also thank the Administration for improving the provisions governing medical research. The proposed modifications alleviate the burdens placed on medical researchers and removes obstacles that would impede important public health research. In particular, the Alliance supports the Administration’s proposal to simplify the authorization process and to eliminate the inconsistent privacy review criteria for Institutional Review Boards. Without these critical changes, health care studies may be abandoned or avoided altogether as the burdens and liability associated with compliance would deter many medical researchers.

In addition, although HHS did not propose to modify the de-identification standard, we appreciate their call for additional comments on this provision. We urge the Department to reconsider the Final Rule’s current standard, which requires the removal of 18 characteristics from data in order to render it “de-identified.” Some of the data that must be removed – specifically, dates of admission or service and device serial numbers – are often needed when evaluating medical records for epidemiological and other health related research.

We believe the regulation could be improved significantly by modifying the de-identification standard to require that information instead be stripped of direct identifiers that would facially identify an individual. Direct identifiers would be defined as name, address, electronic mail address, telephone number, fax number, social security number, health benefits number, financial account numbers, drivers license number or other vehicle numbers that are in the public records system.

**Business Associates**

While the Administration proposes to provide a one-year window for covered entities to revise their contracts with business associates, these same covered entities will be required to comply with the new rule regardless of whether or not a new contract has been secured. Hence, the one-year window provides a false sense of flexibility. We are further concerned that HHS will require business associate contracts between two covered entities. This seems to defy reason since each covered entity will be required to comply with the regulation independently.

To conclude, we strongly support meaningful and workable privacy protections for patients’ medical records and appreciate this opportunity to express our views on the modifications to the privacy regulations proposed by HHS.

Sincerely,

American Academy of Dermatology Association  
American Assoc. of Neurological Surgeons/Congress of Neurological Surgeons  
American Association of Orthopaedic Surgeons  
American College of Cardiology  
American College of Radiology  
American Society of Cataract & Refractive Surgery