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April 25, 2002

The Honorable Tommy G. Thompson
Secretary, U.S. Department of Health and Human Services
Office of Civil Rights
Attention: Privacy 2
Hubert H. Humphrey Building
Room 425A,
200 West Independence Avenue, SW
Washington, DC 20201

Dear Secretary Thompson:

The members of the American College of Epidemiology are engaged in epidemiology and health services research across a wide spectrum of patient diseases and conditions under the sponsorship of federal and state government and private foundations. The field of epidemiology is vital to the health of the nation. In an era of newly emerging infectious diseases and the growing importance to chronic diseases, hardly a day goes by without a report in the lay press about epidemiological contributions to the fight against disease. The proposed restrictions will compromise our ability to do the research that directly affects public health. We offer several comments on the proposed Standards for Privacy of Individual Identifiable Information issued on March 27, 2002.

First, our researchers are increasingly denied access to patient information from hospitals, even when an Institutional Review Board has approved the research, owing to the fear, however unfounded, that release of patient data will generate a lawsuit against the “covered entity.” Although your Department has reiterated the importance of health services and epidemiologic research, liability concerns continue to control decision-making on the access to data for research. Epidemiology, by its very nature, entails the study of large populations across multiple institutions. Widespread denial of access to patient data, either to identify patients from whom to obtain consent, or to create de-identified datasets, will ultimately lead to uncontrollable bias in that research. The investigation of both established and emerging health issues, such as antibiotic resistance or bioterrorism, should not be jeopardized by institutional liability concerns that ignore public health and overlook individual patients’ rights to participate in worthwhile research. For that reason, we recommend that the Department monitor the impact of the regulations on the conduct of research and access to patients. Covered entities should be required to record, and to report upon request, the disapproved as well as the approved requests for access to patient information for research. Disapprovals should state the reasons for the denial.

Second, under the proposed regulations (section 165.152(i)(2)(ii)(A)((2)), researchers must present, and Institutional Review Boards must document, an adequate plan for the destruction of patient identifiers at the earliest opportunity, when waiver of the requirement for individual consent is indicated. This requirement, while appropriate and reasonable, raises a practical problem. Reputable research organizations must ensure the integrity of computer databases through backups to archival tapes at regular intervals. Tapes are securely stored in locked file cabinets, accessible only to computer professionals. When patient identifiers are “destroyed”, those files are deleted from the computer disks, but cannot be selectively erased from system backup tapes. Identifiers could still, in theory, be restored through access to an archival tape created before destruction. Old tapes are eventually reused, destroyed, or erased after many years. A literal interpretation of the proposed regulations would entail a substantial change in standard requirements and procedures for computer integrity and security. We recommend that local IRBs have broad the discretion to permit standard computer backup procedures for research computers that contain patient identifiers.

Lastly, we would like to express our support and agreement with the comments sent to you on this matter from the American Association of Medical Colleges.

We appreciate your consideration of these issues.

Sincerely,

Brian L. Strom, M.D., M.P.H.
Chair,
American College of Epidemiology
Policy Committee

BLS/jss

CC: Richard A. Kaslow, M.D., M.P.H.
ACE Policy Committee