

February 20, 2003

MEMORANDUM # 03-06

TO: Council of Deans
Council of Academic Societies
Council of Hospitals and Health Systems

FROM: Jordan J. Cohen, M.D.

SUBJECT: AAMC Initiative to Monitor and Document the Impact of HIPAA on Research

On April 14, 2003, the new federal information privacy regulations will take effect. These regulations, termed the "Privacy Rule", implement new standards for the protection of individually identifiable health information under the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). They will require new practices and policies in all of our institutions.

As you are aware, the AAMC has been deeply concerned about the effect of HIPAA on biomedical and health research from the time of the Privacy Rule's conception. The Association has lobbied vigorously to mitigate the most onerous provisions of HIPAA, and, in fact, the August 2002 modifications to the Privacy Rule are partially responsive to our recommendations and those of others in the research community. Nevertheless, while protecting patient privacy and confidentiality is essential to the integrity of the research process and the protection of individual subjects, we remain concerned that the burdensome and costly regulatory framework imposed by HIPAA poses a substantial threat to medical and health research.

We are especially concerned about population-based research that requires broad and unbiased access to medical records of community health care providers, as well as academic medical centers, i.e., epidemiological, health services, environmental and occupational health research, and post-marketing studies of drugs and medical devices. We are also concerned for long-term medical outcomes research dependent on medical record repositories maintained within or external to academic medical centers, many of which have been accruing patients for decades.

Given the intense lobbying that marked the protracted gestation of the Privacy Rule, and the inability of the Congress to deal with this matter during the preceding decade, we believe that the only reasonable approach to further mitigation, either by regulatory change or legislation, will depend on credible evidence of the adverse effects of HIPAA on ongoing or future research.

Thus, the AAMC has convened a consortium of professional medical and health research organizations to establish a mechanism for collecting evidence demonstrating the effects of HIPAA on research. A broad network that includes participation from the various disciplines in health research is critical to building a robust database that reflects the scope and nature of research being conducted in different health science fields, and provides an effective mechanism for receiving and recording credible data.

Currently, the consortium comprises organizations from the fields of epidemiology, pharmaco-epidemiology, cardiology, oncology, health services research, behavioral research and pediatric

research, all of which share our interest and concern about the new regulations that intend to restrict uses and disclosures of health information. AAMC will serve as the lead organization and coordinating center for this effort. It is especially important that our members participate in this endeavor by establishing their own internal processes for recording specific examples of the detrimental effects of HIPAA, and forwarding them to us for inclusion in the database.

The AAMC is committed to ensuring that credible data are obtained that will provide an accurate picture of the effects of HIPAA on medical and health research and inform further advocacy efforts. To this end, we invite the input of our members and would appreciate receiving information or the names of individuals within your institutions who may wish to contribute to this project. Please contact Dr. David Korn at 202-828-0509 (dkorn@aamc.org) or Rina Hakimian at 202-828-0484 (rhakimian@aamc.org) to discuss your ideas.

cc: Group on Faculty Practice
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