Testimony on Behalf of the Association of American Medical Colleges
Before the National Committee on Vital and Health Statistics
Subcommittee on Privacy
November 19, 2003

Introduction

Mr. Chairman and Members of the Committee, thank you for the opportunity to testify today. I am Susan Ehringhaus, J.D., Associate General Counsel for Regulatory Affairs at the Association of American Medical Colleges (AAMC). The AAMC represents the nation's 126 accredited medical schools, over 400 affiliated teaching hospitals, and 94 academic medical societies representing nearly 105,000 faculty members. Our members conduct much of the nation's biomedical and behavioral research, and share a profound interest in protections for research participants, including protections for the privacy of individual volunteers for research and the confidentiality of research data. The AAMC strongly supports measures that will strengthen the capacity of human research protection programs to safeguard privacy and confidentiality while sustaining the vitality of the biomedical and health sciences research enterprise.

We believe, however, that the features of the final Privacy Rule that we will identify today do not preserve essential research activity on which the health and well being of all members of the public depends, nor do they add marginally to protection of privacy and confidentiality of medical information.

Types of Research Significantly Affected

The final Privacy Rule requires changes in well-established, highly regulated research methods and processes. The changes consist of a regulatory apparatus for which there is not a corresponding gain in patient privacy protection. We are concerned about the collective burden on the health research community that is already the locus of extensive regulation and oversight. We question the benefit to cost ratio to the public of the Privacy Rule's research provisions and express our dismay at the new and costly infrastructure for the conduct of research. Turning basic science advancements into clinical application and, ultimately, health outcomes is threatened by dangerously overburdening the research endeavor. Examples of types of research particularly affected by the Privacy Rule's research provisions include the following.

Population-based research, that is epidemiological, health services, environmental and occupational health research, is especially affected in that such research requires broad and unbiased access to medical records of community health care providers as well as of academic medical centers. We are also concerned for long-term medical outcomes

research that is dependent on medical record repositories maintained within or external to academic medical centers, many of which have been accruing patients for decades.

Registry research is commonplace in academic medical center, and it is essential to informed analysis of many disease states. The volume of activity that the Privacy Rule requires of either an institutional review board (IRB) or Privacy Board (PB) with respect to the creation of databases is enormous (authorizations, waivers, limited data sets, data use agreements), yet the gain in subject privacy and confidentiality is virtually non-existent. For those databases maintained within academic medical centers for which IRB approval is required, the IRB process alone should satisfy an appropriately rigorous standard of privacy protection. For other registries not subject to IRB oversight and review, the added requirements of the Privacy Rule confer little in subject protection and greatly impede the activity. Any violations of applicable standards of subject privacy can and should be managed through institutional responses to existing federal and state law and regulatory imperatives, not through an additive but not substantively supplemental Privacy Rule regulatory apparatus.

The Privacy Rule's provisions also especially and negatively affect those engaged in outcomes and public health research. Many common outcomes research techniques have been rendered impossible, without apparent corresponding increase in subject privacy. For these kinds of research, as in the case of the creation of registries, deviations from acceptable privacy standards can and should be dealt with using existing laws, regulations, and institutional requirements.

Genetic longitudinal research has become a labyrinth of Privacy Rule-related questions. There is no doubt that many of the issues implicated can be parsed over time by a bevy of institutional attorneys and privacy experts, but the attendant cost to the researcher and especially to the research activity itself is immense.

Subject recruitment for many types of research under the Privacy Rule has become a thicket of regulatory ambiguity. Researchers and Covered Entities proceed at their peril through bewilderingly complex pathways that appear to double back on themselves in terms of duplicative processes. The resultant drag on researchers, Covered Entities, and the entire research effort is significant.

Summary of Concerns

As we have testified here previously, the obstacles the HIPAA Privacy Rule puts in front of researchers and the medical schools, teaching hospitals, and academic medical centers with which they are affiliated constrict access to essential medical information and impose unwarranted impediments on the process by which research is actually accomplished. Unless modifications are made, the Privacy Rule threatens the viability of research that is already subject to significant oversight and jeopardizes the welfare of the public awaiting biomedical research advances. In fact, several aspects of the rule are already resulting in fundamental alterations to the way in which some research is conducted and even in the ability to carry out some kinds of research on human subjects.

AAMC today presents on behalf of its members concerns in four categories. And today, unlike our previous statements, our concerns are not just informed predictions and projections, but rather they are based on actual experiences with the Privacy Rule's research experience, as revealed in the responses to the AAMC survey that I will describe here. Our concerns are directed at the following provisions of the Privacy Rule, which provisions, according to our initial survey responses, singly and collectively are having a profoundly negative impact on research without enhancing patient privacy: accounting of disclosures, authorizations and waivers, the de-identification standard, and HIPAA's organizational rather than functional focus. Taken together, the experiences of our community that are revealed by the AAMC survey suggest the following negative consequences of the implementation of the Privacy Rule's research requirements.

1. The addition of the authorization requirement to the established informed consent protections has confused the informed consent process for both patients and researchers and has complicated an already intricate and over-burdened set of interactions.
2. Research management and oversight is burdened with expensive (in time, money, and accessibility) HIPAA Privacy Rule requirements that were not designed to apply to research, for which there is no real value added to the public good or private welfare of individuals, and for which there is no funding or other mitigation provided for the huge costs placed on the research enterprise. The progress of some research is slowed or halted, without demonstrable increase in privacy protections.
3. Expensive and confusing disclosure documentation and accounting liabilities regarding release of Protected Health Information (PHI) for research have been placed on Covered Entities, creating research-related burdens that many are unable and/or unwilling to accept, thus diminishing the research subject base, slowing the progress of research, and impeding the access of patients to research participation opportunities.
4. As a consequence of the research requirements of the Privacy Rule, new burdens are placed on the entire process by which biomedical and health sciences research is conducted, adding thereby to the disincentives to undertake such research.

The AAMC Survey

In an effort to monitor and document the effects of HIPAA's Privacy Rule on biomedical and health sciences research, the AAMC undertook in Spring 2003 to create a database of case reports documenting research affected, delayed, hindered, benefited, abandoned, or foregone. The purpose of the survey was to enable the AAMC reliably to report to interested members of the research community and to the government and related bodies, including your Subcommittee, actual experience with the Privacy Rule of researchers and those engaged in managing and overseeing the research process. The survey's Steering Committee includes some of the most distinguished professional organizations in the country: the Academy for Health Sciences Research, the American College of

Epidemiology, the International Society of Pharmaco-Epidemiology, the American Academy of Pediatrics, the American College of Cardiology, the American Society of Clinical Oncology, the American College of Preventive Medicine, the Association of Schools of Public Health, the Society of Behavioral Medicine, the Society of Research Administrators, and RTI Health Solutions. The survey, launched on April 14, targeted investigators, IRB personnel, privacy officials, research administrators, deans, and others involved research. The AAMC sought to discover what research functions were affected, the nature of the problem, and the attempted resolutions.

The resulting data present a troubling picture of the Privacy Rule's bite on the academic medical research community and on a huge portion of the nation's biomedical and health sciences research enterprise. The prospects for the achieving the vision and promise of the NIH Roadmap and indeed even of continuing the present pace of research diminish if these early results are an indication of the impact of the Privacy Rule on research. We believe they are a very good indicator of the depth and scope of the problems we anticipated throughout the gestation of the Rule. We understand that early results can simply reflect unfamiliarity with procedural intricacies, conservative interpretations of requirements, and other phenomena that could lessen or disappear with practice. Though in the interests of time we only provide a snapshot of the survey results to date, we believe that what we report here cannot be dismissed as mere unfamiliarity with the Rule that will abate with time.

Chart 1 presents a disturbing picture of the types of research affected by HIPAA's Privacy Rule, based on a total of 331 responses to date.

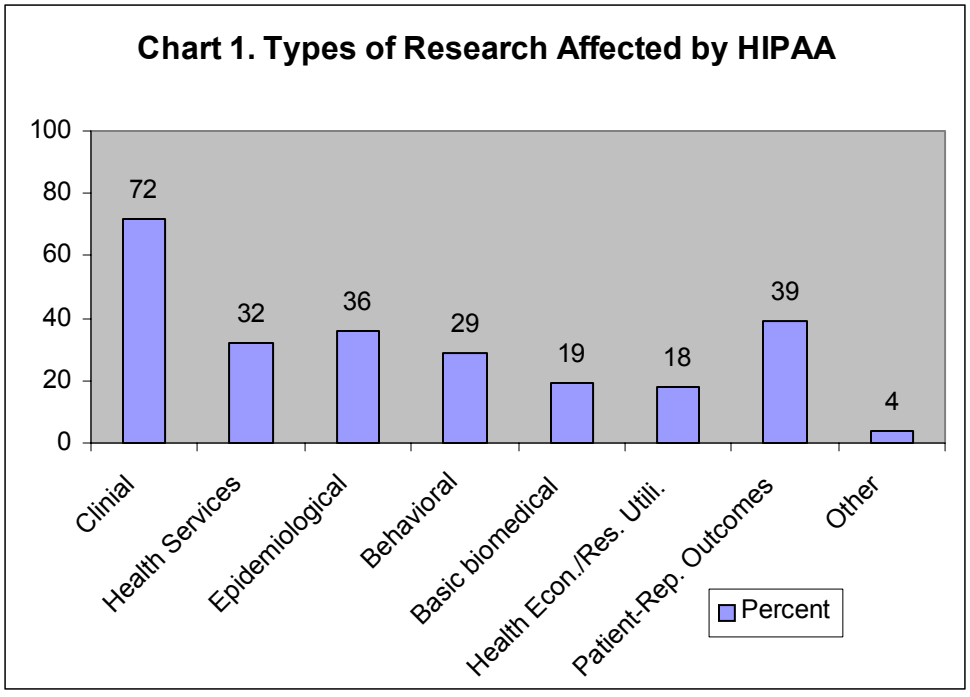
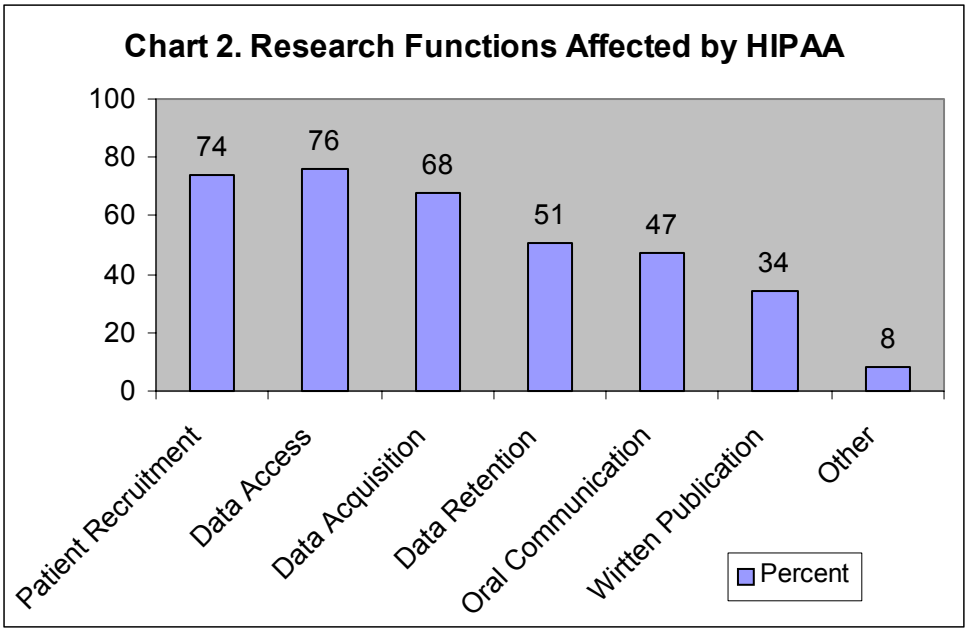


Chart 2 illustrates the research functions affected by HIPAA's research provisions, based on a total of 331 responses to date.



Responses to the AAMC survey question on types of research function affected include the following on the topic of subject recruitment:

> ". . . additional consent form tends to confuse more than inform participant."
>
> ". . . the required HIPAA Authorization is confusing for participants to understand."
>
> "Subjects are overwhelmed by added length to consent form and repetition of several points already made in body of main consent…."

And on the subject of informed consent, the responses include the following:

> "My greatest concern is that the requirement for all these various authorizations to be signed overshadows the importance of the research informed consent document and process."
>
> "I am worried, actually, that subjects are now paying LESS attention to the consent process because they are given so many pages to read and sign."

On the subject of research collaborations, responses include:

> "The major difficulty for us has been establishing multi-site trials and getting everyone to collaborate in the newly derived, fear-of-litigation driven system…."

> "Many health care providers no longer participate/submit data to several observational pregnancy exposure registries as a result of HIPAA."

And on the subject to bias, one respondent observed:

> "The complexity of the authorization form intimidates some potential participants. My concern is that by not including those people in the study, we are not including a 'true' cross-section of the population…. Will this lead to only including college-educated people in studies? . . . 'form comprehension' bias…."

Our data contain literally hundreds of similar examples of profound concerns with the impact of the final Privacy Rule on research. The quoted examples are representative. Despite the use of the available HIPAA-compliant access techniques as suggested by Chart 3 (based on 232 responses to date), such techniques do not appear to be adequate to prevent the problems that the respondents report.

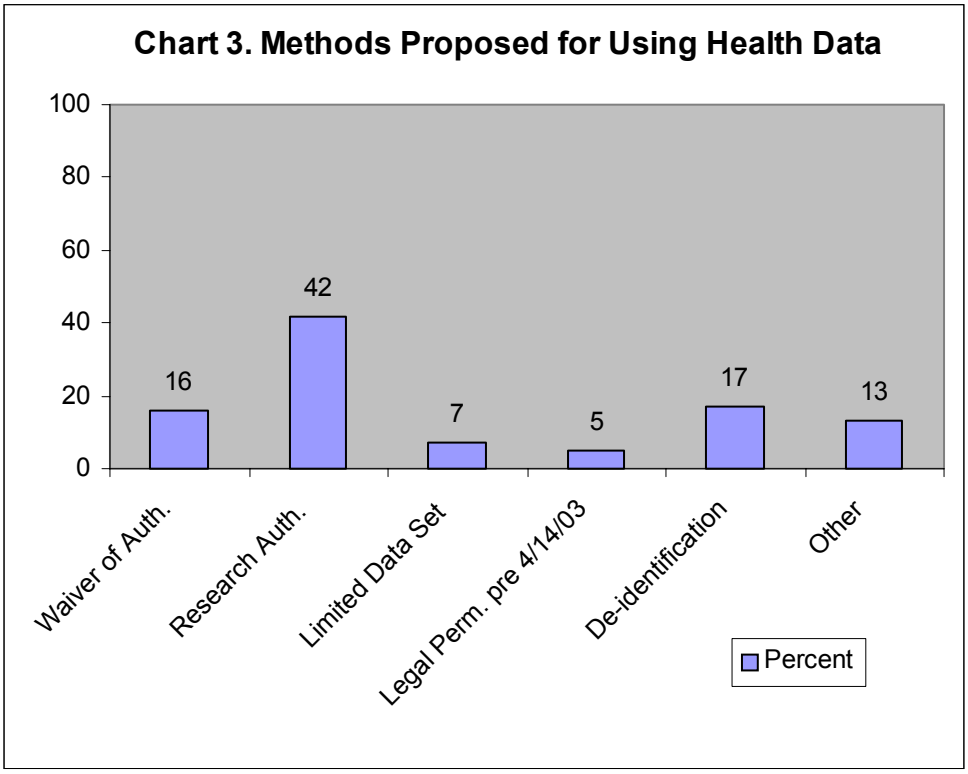


Table 1 provides detail as to the types of respondents to the AAMC survey.

Table 1. Types of Research Affected by HIPAA and Roles of Respondents in Research

Roles in Research

Type	Administrator	HIPAA Official	IRB Member	Investigator	Study Coord/Mgr	Unk	Total Percent
Clinical	8%	3%	2%	43%	22%	22%	100%
Health Services	10%	5%	4%	47%	12%	22%	100%
Epidemiological	9%	4%	3%	51%	9%	24%	100%
Behavioral	12%	5%	4%	47%	11%	21%	100%
Basic biomedical	13%	5%	5%	40%	13%	25%	100%
Health Econ./Res. Utili.	13%	5%	3%	46%	10%	23%	100%
Patient-Rep. Outcomes	9%	3%	3%	48%	17%	20%	100%
Other	15%	8%	8%	31%	23%	15%	100%

In summary, our survey provides clear early signals of the adverse effects of the Privacy Rule on key areas of research activity, as we have long predicted. Significantly, our findings are consistent with those of the National Cancer Advisory Board's Feedback from NCI Cancer Centers, Cooperative Groups, and Specialized Programs of Research Excellence, which project was undertaken to assess the impact of HIPAA on oncology clinical research. Findings consistent across both the AAMC survey and the NCAB survey are the following.

1. Negative impact on informed consent process;
2. Confusion of subjects;
3. Negative impact on subject recruitment;
4. Possible increase in selection bias;
5. Alteration or abandonment of research direction;
6. Inability or impaired ability to collaborate;
7. Additional regulatory burdens on research process already struggling under the weight of extensive regulation;
8. Increased costs;
9. Multiple inconsistent interpretations of HIPAA requirements across institutions, because of its inherent ambiguities.

The promise in the Preamble to the final Privacy Rule has not come to pass. The modifications in the final Rule are said to remove "obstacles that may have interfered with research activities that form the basis of advancements in medical technology and provide greater understanding of disease…." And further, "research is the key to the continued availability of high quality health care. The modifications remove potential barriers to research." (67 F.R. 53259, 53260) There is no doubt that the changes made to the final Rule in August 2002 improved what otherwise would have been experienced by academic medical centers and other providers participating in the research enterprise. Nevertheless, the research provisions that remain in the final Rule represent significant deterrents and impediments to the biomedical and health services research conducted in

this country. Our initial survey results suggest that the following provisions constitute the most problematic barriers to research.

HIPAA Research Burdens

1. Accounting for Disclosures

The Privacy Rule's requirement that individuals are entitled to receive an accounting of disclosures for research involving fewer than 50 subjects made pursuant to a waiver of authorization has imposed and will continue to impose a tremendous regulatory burden on providers and researchers. Our initial data suggest that some community providers and hospitals that do not view research as one of their primary missions are reluctant to assume this burden and unwilling to make patient records available to researchers. This impedes and may prevent much valuable epidemiologic and health services research, to the great detriment of patients whose care is enhanced by new medical knowledge. Though the final Privacy Rule has a carve-out for research involving 50 or more subjects, the provisions remaining are enormous hindrances for researchers and research institutions, without corresponding enhancement to patient privacy.

Accounting of disclosures for research should be eliminated altogether. The requirement is expensive for providers and for their institutions, burdensome for the research enterprise, and is highly unlikely to provide information that is meaningful or relevant to individuals. If inappropriate disclosure is suspected for whatever reason or if curiosity is simply the motivation for a disclosure, the incident can be fully investigated at that point without the elaborate and expensive process of accounting. The major driver for this provision was the assertion of a right to know. If that is the case, we strongly question whether the particular benefit bestowed justifies the costs to other compelling public interests, including the health of the biomedical and health sciences research enterprise.

The accounting requirement is technically and operationally impractical and extremely expensive. Healthcare system records exist in diverse places and diverse formats and are not readily amendable to implementation of accurate tracking and registering of detailed information about every access and then consolidation of such information centrally in formats that are reportable by each individual healthcare consumer's identity. The regulatory burden is unreasonable, and the incremental privacy protection minimal to non-existent.

With respect to disclosures of research access, an individual who requests an accounting of disclosures from a major academic research entity will receive a list of hundreds of protocols for which the medical records of 50 or more individuals may have been reviewed. Such institutions will then be required, if requested, to assist the individual per 45 CFR 164.528 (b)(4)(ii): "*If the covered entity provides an accounting for research disclosures, in accordance with paragraph (b)(4) of this section, and if it is reasonably likely that the protected health information of the individual was disclosed for such research protocol or activity, the covered entity shall, at the request of the individual,*

assist in contacting the entity that sponsored the research and the researcher." The difficulty of determining what is "reasonably likely" relative to an individual, as well as adequate and appropriate "assistance in contacting the researcher", and the unspecified but implicated determination of the adequacy and appropriateness of the ensuing communication between the patient and a researcher so contacted, has the potential to dissuade more institutions from conducting useful research.

2. Authorizations and Waivers

Though the AAMC acknowledges that changes were made during the evolution of the Privacy Rule in the requirements for authorizations and waivers of authorization and associated documentation, the requirements that survived in the final Privacy Rule remain burdensome and discouraging to investigators and to participants in research. In addition to technical and legal ambiguities continuing to appear in the language of the requirements themselves, in practice the impact of these requirements demonstrates their uselessness. It is practically inconceivable that a researcher who presented a good faith justification for a request for a waiver would have the request turned down by an IRB or PB. Hence the rationale for the requirements disappears. Here again the Rule's liability burdens are simply not justified, given that scrutiny of the research proposal would increase only minimally if at all beyond that presumably required under the Common Rule.

The requirement for authorizations and waivers of authorization for disclosure should be eliminated for research uses. The AAMC continues to believe that human subjects who happen to be health care consumers are fully and appropriately covered under current federal regulations governing human subjects research, which includes explicit focus on the protection of personal information. Thus the authorization or waiver of authorization documentation for research does not add to the protections for human subjects that already exist. Furthermore, the requirements add unnecessary complexity, confusion and expense to the Covered Entity's determination of whether PHI may be released to the researcher, both by adding documentation to the required IRB documentation and because the Covered Entity is required to assess whether each new authorization or waiver of authorization form received from another institution includes all HIPAA-required elements.

3. The De-Identification Standard

The Privacy Rule exempts from its requirements any information that a covered entity has successfully "de-identified". The AAMC has enthusiastically supported encouraging the use of de-identified medical information in research. But the standards for de-identification in the final Privacy Rule remain so high as to render the resulting data useless for many epidemiological, health services, and other population-based research purposes. An unrealistically broad list of specific identifiers undermines the basic utility of the de-identification safe harbor and makes it likely that many Covered Entities will decline to de-identify data for research purposes because of the burdens of doing so to the HIPAA standard. This is especially problematic for certain types of research that require the use of data elements that contribute to the understanding of disease associations or

exposures or that uses pedigrees and genotype data for rare diseases. Such data may never be susceptible to de-identification to the Privacy Rule's standards.

The AAMC does not dispute the necessity for addressing the privacy issue and the desirability of using de-identified data whenever possible. The real question is whether or not the Privacy Rule's de-identification standard represents the appropriate mechanism to address the problem. We believe it is not, because the burden on research is disproportionate in terms of the additive privacy protection bestowed and because there are other mechanisms that are less burdensome that will carry the same privacy assurance.

We urge that the de-identification standard be simplified and adapted for biomedical and health sciences research purposes and not tailored as it is to accommodate the most extreme cases of misuse of medical information. Such misuse is in fact addressed and is better addressed through other regulatory mechanisms.

4. Organizational Structure

Continuing with the themes sounded in the immediately preceding section, we believe that the Privacy Rule prevents many academic medical centers from organizing for HIPAA compliance (that is, selecting the Covered Entity status, Hybrid Entity status, or Affiliated Covered Entity status) in a manner that reflects the necessary integration of operations among the medical schools, affiliated practice plans, and teaching hospitals. The HIPAA designation chosen is critical to the question of access to PHI for reviews preparatory to research and subject recruitment, yet the requirements appear to elevate organizational structure over substantive privacy protections and appropriate research access to PHI.

Despite the modifications reflected in the final version, the Privacy Rule continues to pose significant obstacles to many academic medical centers from designating themselves as either Hybrid Entities or Single Affiliated Covered Entities. Even if they are able to take advantage of either status, the remaining barriers to interdepartmental, interdisciplinary, and inter-institutional research, which is what so much research is becoming today, remain almost insurmountable, exceedingly costly, and without redeeming value in privacy protections. **Both text and interpretations of HIPAA's research provisions must shift from organizational form to function served.**

Conclusion

The AAMC's position is that research must be conducted ethically and with scientific integrity and that the protection of human subjects is a paramount obligation of researchers and their institutions. Accordingly, the AAMC strongly supports standards that clarify the responsibility of researchers and institutions to protect the safety, dignity, and privacy of individuals who volunteer to participate in medical and health research. Protecting medical information from harmful use or inappropriate release is crucial to

fulfilling that duty. It is our hope that a method can be found to protect individuals from the real risks associated with intrusions of privacy, while continuing to enable the essential work of the biomedical and health sciences research community to flourish.

We have previously warned that disincentives created by the Privacy Rule summarized here may well cause Covered Entities for whom research is not a core mission to concluded that the cost – and the risks – of disclosing data for research purposes are simply too great. The threat is most severe to research that requires access to large numbers of medical records; for example, public health and epidemiological studies, health services research, post-approval assessment of the safety and efficacy of drugs and medical devices, and the retrospective studies required to understand and eliminate the systemic causes of medical errors.

The AAMC appreciates the willingness of the Department of Health and Human Services to increase the Privacy Rule's "workability" by its attempts to reduce the significant obstacles that earlier versions of the Privacy Rule erected to the conduct of essential biomedical, epidemiological, and health services research and the provision of health care. The AAMC continues to strongly believe that strong protections for the privacy of medical information can be accomplished without jeopardizing either medical care of health research. We emphasize, however, that with respect to the research provisions identified in this testimony and reported in our survey, modifications are essential if the vitality of the research enterprise is to be retained.

On behalf of the AAMC, I would again like to thank the Committee and its Subcommittee for giving us the opportunity to present our serious concerns about the final Privacy Rule's effect on the health of the nation's vital biomedical and health sciences research enterprise.