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April 11, 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 Independence Avenue, SW
Washington, D.C. 20201

Dear Secretary Thompson,

The AAMC welcomes the opportunity to comment on the Secretary's March 27, 2002 proposal to modify the federal medical privacy rule. The AAMC represents the nation's 125 accredited medical schools, nearly 400 major teaching hospitals and health care systems, more than 105,000 faculty in 98 academic and scientific societies, and the nation's 66,000 medical students and 97,000 residents. We submit this formal comment letter in accordance with the requirements of the Notice of Proposed Rulemaking (NPRM).¹

The AAMC deeply appreciates and commends the Secretary's willingness to increase the rule's "workability" by reducing the significant obstacles that the rule erects to the conduct of essential biomedical, epidemiological, and health services research and the provision of healthcare. With this NPRM the Secretary moves substantially toward restoration of the necessary balance between medical privacy and other equally important public interests, including quality healthcare and research-related advances in treatment and prevention. The AAMC offers our strong endorsement of the NPRM while identifying some remaining concerns about the rule and its application. Our comments regarding certain specific proposals in the March 27, 2002 NPRM are listed below.

¹ Standards for Privacy of Individually Identifiable Health Information; Proposed Rule, 67 Fed. Reg. 59, 14776 (March 27, 2002).

Provisions of the Final Rule Affecting Research

Our March 29, 2001 comment letter on the final rule reflected the AAMC's concern that the rule would create substantial impediments to all research involving protected health information.² Although we remain concerned that the modified rule would still impose unwarranted liability and unnecessary procedural burdens upon covered entities who use and disclose health information in federally-regulated research, the AAMC is greatly encouraged that the Secretary proposes to improve the rule's workability for research. We offer the following specific comments on proposed changes to the research provisions:

Authorization and Waiver

The AAMC welcomes the Secretary's proposal to streamline the authorization requirements, to provide one authorization form for all purposes, and to permit all authorization elements to be combined with the consent form for participation in research. We appreciate that the NPRM recognizes the use of an authorization to obtain permission for disclosure of PHI to a repository or database maintained for research purposes. The AAMC also enthusiastically supports the proposal to revise the rule's waiver criteria to focus on the practical need for a waiver of authorization and the adequacy of the researcher's plans to protect patient confidentiality.

The AAMC requests, however, that the Secretary clarify the requirement in proposed §164.508(c)(2)(iii) that authorizations must state "the potential for information disclosed pursuant to the authorization to be subject to redisclosure by the recipient and no longer protected by this rule." The AAMC requests that this criterion be modified as it is not possible for a covered entity even to estimate the risks of disclosure in any particular instance because these risks will be largely unknown to the entity and often outside its control. AAMC requests that DHHS clarify in guidance that when information is disclosed pursuant to an authorization for IRB-approved research, the requirement at §164.508(c)(2)(iii) is met with a statement in the authorization that the researchers are only permitted to use or disclose the protected health information for purposes that have been authorized by the IRB or as required by law or regulation.

De-identification

The AAMC believes that the undeniably strong public interest in furthering epidemiological, public health, and health services research can only be served by a separate, more reasonable standard for the de-identification of protected health information for research purposes.

² Letter from Jordan J. Cohen, M.D., President, Association of American Medical Colleges, to DHHS Secretary Tommy Thompson, regarding the final medical privacy rule (March 29th, 2001).

Covered entities should be permitted to release information that has been de-identified under this research standard if the recipient researcher agrees in writing not to attempt to re-identify or contact the subjects of the information, and not to further disclose the information except as required by law.

The NPRM acknowledges that the research community perceives a pressing need for an alternative de-identification standard, yet the Secretary has not formally proposed to create one.

This issue is of critical importance; the AAMC believes that the "workability" of the rule for research hinges upon adoption of a modified de-identification standard for research uses and disclosures. We have consistently urged the Secretary to adopt the following modification to §164.514:

§164.514(a)(i) Standard: de-identification of protected health information. Health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual is not individually identifiable health information.

(ii) Exception for information disclosed for research purposes. Information that does not directly identify an individual and that conforms to the requirements of §164.514(b)(3) is not individually identifiable health information when disclosed to a researcher or researchers pursuant to each researcher's written agreement that:

(A) The information will be used only for research purposes and will not be further disclosed except as required by law; and

(B) The researcher will not attempt to re-identify or contact individuals who are the subjects of the information.

* * *

§164.514(b)(3). Implementation specifications: requirements for de-identification of protected health information disclosed for research purposes. A covered entity may determine that health information disclosed pursuant to a data use agreement is not individually identifiable health information if:

(i) Under the procedures described in §164.514(b)(1), the covered entity has determined that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by the recipient researcher to identify an individual who is the subject of the information; or

(ii) The following identifiers of the individual or of relatives, employers, or household members of the individual, are removed:

(A) Names;

(B) Street address;

(C) Telephone numbers

(D) Fax numbers;

(E) Electronic mail addresses

(F) Social security numbers

(G) Vehicle identifiers and serial numbers

(H) Photographic images depicting the full face or full profile; and

(iii) The covered entity does not have actual knowledge that the information could be readily used alone or in combination with other reasonably available information to identify an individual who is the subject of the information.

In the preamble to the proposed rule the Secretary describes a possible set of "direct" identifiers that might be removed to create a modified de-identification standard for research. The Secretary's list comprises the elements listed above, with the addition of URLs and IP addresses. We recognize the need to add URLs and IP addresses to the list of direct identifiers and urge that with the addition of these two elements our proposal for a research de-identification standard should be adopted in the final rule.

We note, however, that the preamble discussion of de-identification lists examples of "identifiable information" (e.g., admission dates and five digit zip codes) that a covered entity might be permitted to include in a "limited dataset" to be used or disclosed for research purposes. We assume that the Secretary did not intend that this "limited dataset" be restricted to those data fields described in the NPRM. The AAMC believes that a covered entity should be permitted to include any information in the research or "limited" dataset that is not a direct identifier, as described above, and regarding which the entity does not have actual knowledge that the information could be readily used, alone or in combination with other reasonably available information, to identify an individual who is the subject of the information.

Accounting for Disclosures

Patients who authorize a non-routine disclosure of PHI are plainly aware that the disclosure will occur; therefore, the AAMC agrees with the proposal to eliminate the accounting requirements for disclosures made pursuant to patient authorization.

We remain concerned, however, that continuing to require a specific accounting for all research disclosures made pursuant to a waiver of authorization will impose a tremendous administrative burden upon providers.

We fear in particular that community providers and hospitals that do not view research as their primary mission will be reluctant to assume this burden and thus unwilling make patient records available to researchers. This unfortunate result would impede or even prevent much valuable epidemiologic and health services research, to the great detriment of patients whose care is enhanced by new medical knowledge.

The AAMC urges the Secretary to further modify the accounting for disclosures provision. Covered entities should be permitted to meet this requirement with respect to research disclosures by providing the patient with a list of all protocols (to include researchers' names and contact information) under which the patient's information *may have been disclosed* pursuant to a waiver of authorization. A covered entity could meet this requirement by providing a patient, upon request, a disclosure such as the following: "During the previous six years, this (institution or provider) has disclosed information under a waiver of authorization in support of the research projects listed below."

Public Health Disclosures

The AAMC agrees with the Secretary's proposal to permit covered entities to disclose PHI to sponsor-initiated registries, provided that these registries are created for the purpose of activities related to the quality, safety, or effectiveness of FDA-regulated products. We note, however, that the Secretary does not permit covered entities to make the same disclosures to registries maintained by academic investigators and institutions, or by other non-profit organizations, even when such registries are operated under IRB supervision and do not disclose direct patient identifiers to the researchers who access the registry data. These registries are vitally important to researchers who study epidemiological patterns of disease or track the success of health interventions across broadly dispersed populations. The AAMC sees no justification for the rule's new double standard, under which industry may receive PHI without authorization or waiver to construct registries for legitimate research purposes, but the academic and other non-profit communities may not.

Healthcare Delivery Issues

Consent

The AAMC strongly supports the Secretary's proposal to permit providers to care for patients without first obtaining consent for the use or disclosure of protected health information (PHI). Requiring instead that providers document a good faith effort to obtain patients' acknowledgment of the notice of privacy practices is a reasonable approach that will facilitate timely care.

With this proposed change in the rule, patients will still be apprised of the permitted uses and disclosures of their health information, but they need not fear that their care will be impeded by the final rule's rigid insistence upon prerequisite forms.

This change is also consistent with the intent, as expressed in the initial NPRM, that protected health information be allowed to move efficiently throughout the healthcare system for the core purposes of treatment, payment, and healthcare operations.

Exemption for Incidental Uses and Disclosures

The AAMC supports the rule's proposal to exempt incidental uses and disclosures of patient information that cannot reasonably be prevented, are limited in nature, and occur as a by-product of an otherwise permitted use or disclosure under the privacy rule. This exemption recognizes the importance of communications among caregivers, trainees and patients, and does not penalize covered entities for unavoidable incidents.

Business Associates

The AAMC supports the proposal to provide a one-year grandfathering of existing agreements, and we appreciate the model language that the Department has provided. We urge the Secretary to make the following additional modifications: (1) eliminate the requirement that covered entities enter into business associate contracts with one another; (2) develop a certification program for suppliers that would eliminate the need for many business associate contracts; and (3) create an "incidental disclosure" safe harbor that would clearly eliminate concerns that a business associate contract will be needed with organizations where contact with protected information would result only inadvertently, if at all (e.g., janitorial services).

Definition of a "Hybrid Entity"

The Secretary proposes to revise the definition of a "hybrid entity" by allowing entities to determine whether they will function as single covered entities or as hybrid entities with designated healthcare components. Under the proposal, a hybrid entity may include within its healthcare component(s) any component that engages in covered functions or in activities that would make the component a business associate if it were legally separate. A covered provider must be included in the healthcare component, but a provider who does not engage in standard transactions may be included at the discretion of the covered entity.

The AAMC remains concerned that the privacy regulation prevents many academic medical centers from organizing for HIPAA compliance in a manner that reflects the necessary integration of operations between the medical school and affiliated faculty practice plans and teaching hospitals.

Even as modified, the rule would not permit many academic medical centers to designate themselves as either a hybrid entity or an affiliated entity, since the components of each must belong to a single legal entity or share common ownership or control.

Although the Secretary has provided an alternative means of affiliation, the organized healthcare arrangement (OHCA), for legally separate entities who must share PHI to manage and benefit their common enterprise, it appears that a typical medical school would not be eligible to participate in an OHCA. Such participation would require that the school engage in one of the prerequisite activities (utilization review, quality assessment/improvement activities on behalf of the covered entity, or payment activities where the financial risk of delivering care is shared by participating entities).

As the AAMC noted in our March 29, 2001 comment letter, "the components of an academic medical center have a symbiotic relationship that supports the academic missions of teaching, research and patient care." It is essential that there not be impediments to the flow of information within an academic medical center. The AAMC urges HHS clarify §164.504(a) as follows:

Academic medical center consists of a medical school and all faculty practice plans and teaching hospitals that designate themselves, either formally or informally, as affiliated components of the same academic medical center.

Common control exists if an entity has the power, directly or indirectly, significantly to influence or direct the actions or policies of another entity, and is presumed to exist among the components of a self-designated academic medical center.

Fundraising

Under §164.514(f) of the final rule, a covered entity is allowed to use protected health information for fundraising purposes without an authorization only if the PHI used is limited to "demographic information relating to an individual" and the dates of service. Absent authorization from a patient, institutions are precluded from attempting targeted fundraising efforts. This restriction creates a serious impediment to the fundraising that is essential for academic institutions to sustain their core missions of teaching, research, patient care, and community service.

When patients come to academic institutions, it is sometimes with the expectation that they will be cared for by a specific individual of high repute, but more generally with the expectation that they will be cared for in a particular department or division that has expertise and is renowned for treating the condition from which the patient suffers. It is through these individual physicians and departmental and divisional centers that the excellence of the institution is established and publicized, and critical funds raised to foster future teaching and research.

The AAMC continues to urge DHHS to make the following change in §164.514:

(f)(1) *Standard: Uses and disclosure for fundraising.* A covered entity may use, or disclose to a business associate or to an institutionally related foundation, the following protected health information for the purpose of raising funds for its own benefit, without an authorization meeting the requirements of section 164.508:

- (i) Demographic information relating to an individual; ~~and~~
- (ii) Dates of health care provided to an individual-; and
- (iii) The physician, department, or division of the covered entity from which the individual received treatment.

De-Identification for Quality Comparisons and Benchmarking

The AAMC shares the concern of the American Hospital Association that quality comparisons and benchmarking activities critical to improving the operations of our member hospitals may be severely impeded by the final rule, to the extent that these activities require the exchange of HIPAA identifiers such as full zip codes and dates of service. We urge the Secretary to permit covered entities to use and disclose data stripped of the list of facial identifiers, as discussed earlier and in conjunction with a data use agreement, for specified quality comparison and benchmarking purposes.

* * *

The AAMC recognizes that DHHS never intended that the Privacy Rule unduly burden or prevent vital biomedical and public health research or the provision of healthcare. We are grateful to the Department for its responsiveness to the concerns raised by the scientific community. The AAMC firmly believes that strong protections for the privacy of medical information can be accomplished without jeopardizing either medical care or health research, and that the changes proposed in the NPRM go far to correct the imbalances contained in the Privacy Rule.

Thank you for the opportunity to express our strong support for the important modifications proposed thus far. *We emphasize, however, that with respect to the provisions that we identify in this letter (particularly de-identification and fundraising) further modifications are necessary if the privacy rule is to become a truly workable standard that does not unduly impede patient care and research.*

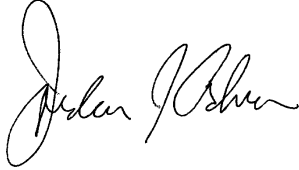
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Should you wish to discuss our comments further, please contact David Korn, M.D., Senior Vice President, Division of Biomedical and Health Sciences Research, or Jennifer Kulynych, J.D., Ph.D., Director, DBHSR, at (202) 828-0484.

Sincerely,

A handwritten signature in black ink, appearing to read "Jordan J. Cohen". The signature is written in a cursive style with a large initial "J" and "C".

Jordan J. Cohen, M.D.