August 19, 2010

Georgina Verdugo
Director, Office for Civil Rights
U.S. Department of Health and Human Services (HHS)
Attention: HITECH Privacy and Security Rule Modifications
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue, SW
Washington, DC 20201

Dear Director Verdugo:

I am writing on behalf of the American Academy of Family Physicians (AAFP), which represents over 94,700 physicians and medical students nationwide. Specifically, I am writing to share our comments on questions raised in the request for information (RFI) on "Modification to the HIPAA Privacy, Security and Enforcement Rules Under the Health Information Technology for Economic and Clinical Health Act," as published in the *Federal Register* on July 14, 2010. We will focus on those questions that relate most directly to the administrative burden that this places on covered entities, such as family physicians and their practices, as noted in the RIN-0991-Ab57.

We would like to raise the following points in response to the proposed changes:

In the Act under section 13424(b); guidance on de-identification (section 13424(c)); and a study on the Privacy Rule's definition of "psychotherapy notes" at 45 CFR 164.501 refers to the data regarding "direct responses, scores, items, forms, protocols, manuals, or other materials that are part of a mental health evaluation."

> Often in a family practice, physicians care for patients using screening tools for depression, attention deficit disorders, or other conditions that might be considered part of a mental health evaluation. This study raises concerns of how this new ruling may affect the ability of primary care physicians to diagnose, refer, and treat their patients without undue burden of separating these records from the patient's general record and obtaining patient authorization for all disclosures. Should this study result in a proposed change to the definition of psychotherapy notes, clear definition of what constitutes and does not constitute a mental health evaluation (e.g. by CPT code) is imperative.

HHS proposes to amend the definition of ''reasonable cause'' in § 160.401 to clarify the full scope of violations that will come within the reasonable cause category of violations, including those circumstances that would make it unreasonable for the covered entity or business associate, despite the exercise of ordinary business care and prudence, to comply with the

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administrative simplification provisions violated, as well as those circumstances in which a covered entity or business associate has knowledge of a violation but lacks the conscious intent or reckless indifference associated with the willful neglect category of violations.

The AAFP supports this clarification of the rule with the understanding that employees can and sometimes do act in a manner other than described in the training and protocols established by the covered entity (CE). We are encouraged by this recognition that sometimes acts by staff are beyond the control of the employer and the placement of such occurrences into tier two of the four tiers of penalty that may apply under this regulation. We implore the Secretary to use such reasonable considerations in respect to any breech that may occur despite the best efforts of the physician or other covered entity to comply with this complex and broad-reaching legislation.

HHS invites public comment on their proposal to include in § 164.508(a)(4)(ii)(H) a general exception for disclosures made for permissible purposes for which the covered entity received remuneration that was consistent with applicable State law.

The AAFP supports this exception to ensure that the proposed authorization requirement does not deter a covered entity from disclosing protected health information (PHI) for a purpose permitted by the Privacy Rule only because it receives payment of the actual cost of preparing, producing or transmitting the PHI or a fee expressly permitted by law. Physician practices and other covered entities incur costs in disclosing and accounting for disclosures of PHI in accordance with these regulations and should be appropriately reimbursed as provided for by state law.

HHS proposes to implement Section 164.524(c)(2)(ii) using its broader authority under Section 264(c) of HIPAA so that in cases where a covered entity maintains health information in an electronic format but cannot provide the health information in the electronic format requested by a patient, it would require the covered entity to provide the patient with a PDF if both parties agree.

This proposal is untimely given the lack of interoperability between current electronic health record systems and the burden that small practices might experience in producing copies of records in various electronic formats that may be desired by individuals. Section 13405(e) of the HITECH Act does not create the added burden of producing information in the format desired by the individual. Rather, the Act requires only that the individual shall have a right to obtain from such covered entity a copy of such information in an electronic format and, if the individual chooses, to direct the covered entity to transmit such copy directly to an entity or person designated by the individual, provided that any such choice is clear, conspicuous, and specific.

Further, the proposed rule only addresses how a request can be handled if both parties agree and provides no guidance on how this can be addressed if both parties do not agree to a PDF. We request that HHS not include in the rule the proposed requirement to provide records in the form and format requested by the patient. Should HHS include this requirement in the final rule, HHS should, at minimum, include clarification to state that, if the patient's requested form and format cannot be met, that the covered entity may instead provide the information in a PDF format.

Amendment to 164.502(f) to require a covered entity to comply with the protected health information for a period of 50 years following the date of death for a patient.

While we recognize the reasoning behind this proposal, we strongly suggest that, instead of 50 years, the HHS consider a much shorter timeframe consistent with average state record retention requirements of 7-10 years. If a family member or other party is conducting research into the possibility of a disease or death resulting from an inherited disease, it would seem that 50 years is an excessive period to wait. While we respect the privacy of the individual, it would seem to be helpful that the timeframe be reduced to assure that records are available and accessible early enough to be of benefit to surviving immediate family members.

HHS requests comments on the proposal to not change the notification requirement for health care providers with a direct treatment relationship to make the Notice of Privacy Practices (NPP) available upon request on or after the effective date of the revision and must comply with the requirements of § 164.520(c)(2)(iii) to have the NPP available at the delivery site and to post the notice in a clear and prominent location.

We support the current ruling and suggest that no change be made to it**.** Patients often complain already about being asked to sign an acknowledgement that they have received a copy of the NPP. It is unlikely that many would desire more extensive notification requirements for those physicians and health care providers with whom they have a direct treatment relationship. Furthermore, the transient nature of the general population would likely result in wasted expense due to the unavailability of current patient information for those not seen within a short time period.

Section 13405(a) of the HITECH Act makes it clear that an individual has the right to restrict disclosures regarding certain health items or services for which the individual pays for in-full out-of-pocket. HHS requests comments regarding what if any obligation a covered health care provider that knows of a restriction should have to inform other health care providers downstream of such restrictions.

While in theory this seems like a good idea, this portion of the Act will be difficult to put into practice. For example, if a patient is seen by their primary care physician for a back injury that occurred at home and paid out of pocket to avoid their insurance and either current or future employer from knowing of the injury, this could become problematic if the patient is later referred to a surgeon for treatment. Due to the cost, the patient might need to have the surgical care covered by insurance; however, the patient's restriction on the information would prevent both providers from seeking prior authorizations. Therefore, the burden should be upon the patient to understand the use of such restrictions and to request restrictions from each physician or provider at the time of each service. Further, if the patient who paid out-of-pocket at the time a service was rendered later decides that the restriction is no longer desired, this decision should not cause the physician or provider to file a claim and suffer loss due to untimely filing or other payer contractual obligations that could not be met while the restriction was in place.

Thank you for this opportunity to comment on this matter. If you or your staff have any questions or if we may be of further assistance in this regard, please contact Ms. Gail Jones at the AAFP.

Sincerely,

Ted D. Epperly, MD, FAAFP
Board Chair

TDE:gj