TEXAS MEDICAL ASSOCIATION

Physicians Caring for Texans

August 1, 2011

Secretary Kathleen Sebelius
U.S. Department of Health and Human Services
Office for Civil Rights
Attention: HIPAA Privacy Rule Accounting of Disclosures
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue, SW
Washington, DC 20201

Re: RIN 0991-AB62; HIPAA Privacy Rule Accounting of Disclosures Under the Health Information Technology for Economic and Clinical Health Act; as published in the Federal Register on May 31, 2011.

Dear Secretary Sebelius:

The Texas Medical Association (TMA) appreciates this opportunity to comment on the Department of Health and Human Services' notice of proposed rulemaking as published on May 31, 2011, which proposes modifications to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule's standard for accounting of disclosures of protected health information (PHI).

TMA is a private voluntary, nonprofit association of Texas physicians and medical students. TMA was founded in 1853 to serve the people of Texas in matters of medical care, prevention and cure of disease, and improvement of public health. Today, its mission is to "Improve the health of all Texans." Its almost 46,000 members practice in all fields of medical specialization. It is located in Austin and has 119 component county medical societies around the state.

TMA has long supported laws and regulations that enable physicians to both effectively and efficiently protect the privacy and security of their patients' health information. As trusted custodians of PHI, Texas physicians have a keen interest in the Department's proposed rules regarding accounting of disclosures.

TMA, therefore, appreciates the Department's efforts in drafting its notice of proposed rulemaking and in appropriately seeking and considering stakeholder responses on this important issue. TMA respectfully offers the following comments on the proposed rules, as published in the Federal Register at 76 Fed. Reg. 31426.

I. **Right to an Accounting of Disclosures of PHI (Proposed 45 CFR §164.528(a)(1)(i))**

First, TMA strongly supports the Department's proposed modifications to the scope of the individual's right to an accounting of disclosures under proposed 45 CFR §164.528(a)(1)(i). TMA contends that this revised provision provides individuals with a more limited, yet equally meaningful right to an accounting of disclosures. Specifically, the provision grants an individual the right to a written accounting of *certain* disclosures of PHI (located in a designated record set) made by a covered entity or a business associate in the three years prior to the date on which the accounting is requested.

TMA notes that the newly-proposed language narrows the scope of the individual's right to an accounting of disclosures from the current regulations in three important respects (i.e., location of PHI disclosed, time frame of disclosures, and types of disclosures). First, the proposed language limits an individual's right to an accounting of disclosures to that information which is located in a designated record set (as opposed to the current requirement that applies *regardless* of where the information is located). TMA strongly supports adoption of the proposed designated record set limitation in order to: (1) align the requirements with other provisions of the HIPAA privacy rules and (2) facilitate covered entity/business associate compliance with the accounting requirement.

TMA agrees with the Department's assertion that designated record sets (i.e., medical and health care payment records maintained by or for a covered entity, and other records used by or for the covered entity to make decisions about individuals) contain the information that is of the most interest to the individual. Thus, limiting the accounting to designated record set information will not sacrifice the usefulness of the accounting to the individual. However, limiting the accounting requirement to the designated record set will significantly benefit covered entities by aligning the accounting requirement with the individual's rights to access and amend protected PHI at 45 CFR §§164.524 and 164.526, respectively, which are both limited to PHI about an individual in a designated record set.[1] As the Department notes in the preamble, covered entities should already have documentation of which systems qualify as designated record sets under 45 CFR §164.524. Thus, "covered entities and business associates are likely able to track those disclosures of protected health information within defined and established record sets and systems more easily."[2]

Next, TMA strongly supports the Department's proposed reduction of the timeframe for accounting of disclosures to three years prior to the date on which the accounting is requested. TMA appreciates the Department's efforts in aligning the *general* accounting period in paragraph (a)(1)(i) (which is currently six years) with that which is required under Section 13405(c)(1)(B) of the Health Information Technology for Clinical Health (HITECH) Act for accounting of treatment, payment, and health care operation disclosures through an electronic health record (which is three years). TMA contends

[1] 76 Fed. Reg. 31430.
[2] *Id*.

that consistency in the application of the accounting period among *all* disclosures will aid covered entities/business associates in appropriately applying and complying with the requirement. Additionally, reducing the accounting period to three years for *all* disclosures (not merely those covered by HITECH) will relieve covered entities and business associates of the significant burden of maintaining information on six years of disclosures, as opposed to three years. TMA agrees with the Department's assertion that the reduction of the accounting period to three years will not act to the detriment of requesting individuals, because those who request an accounting of disclosures are generally interested in learning of more recent disclosures ("e.g., an individual is seeking information on why she has recently begun to receive information related to her health condition from a third party").[3]

Next, TMA strongly supports the Department's proposed modification of paragraph (a)(1)(i) to expressly list the types of disclosures subject to the accounting requirement. Under the current regulations, the Department generally requires *all* disclosures to be subject to the accounting requirement, then provides a series of exceptions. The current framework (requiring covered entities to navigate a complicated series of exceptions) fails to provide adequate guidance for covered entities seeking to comply with the requirements of the regulation. The Department's newly-proposed language will provide much-needed clarity to this requirement and essentially serve as a check-list for providers when responding to a request for an accounting. TMA, therefore, strongly supports the Department's new approach of explicitly listing those disclosures subject to the accounting rule.

Finally, TMA supports the Department's narrowing of the scope of the accounting in paragraph (a)(1)(i) to exclude from the accounting those impermissible disclosures for which the covered entity has already provided notice under the Breach Notification Rule. TMA contends that providing an accounting for such disclosures that have already been addressed in a much more rigorous fashion under the Breach Notification rule would be duplicative and unduly burdensome from an administrative perspective. TMA appreciates the newly-proposed rules' acknowledgement of this fact.

In summary, TMA agrees with the Department's assertion in the rule preamble that all of the above-referenced modifications to 45 CFR §164.528(a)(1)(i) will serve "to improve the workability of the requirements and to better focus the requirements on providing the individual with information about those disclosures that are most likely to impact the individual's legal and personal interests, while taking into account the administrative burdens on covered entities and business associates."[4] TMA applauds the Department for generally taking a balanced approach in modifying the scope of paragraph (a)(1)(i).

II. **Right to an Access Report (Proposed 45 CFR §164.528(b))**

Next, in 45 CFR §164.528(b), the Department proposes providing individuals with a new right to receive an "access report" that indicates who has accessed their electronic

[3] *Id*.
[4] 76 Fed. Reg. 31429.

designated record set information. As the Department notes, this new right (which is *in addition* to the right to an accounting of disclosures) was designed "to implement Section 13405(c) of the HITECH Act by providing individuals with information about disclosures through an electronic health record (EHR) for treatment, payment, and health care operations."[5] However, as drafted, the new right is much broader than that which is required by HITECH. Notably, the right to receive an access report (as currently drafted) includes the right to information regarding both uses *and* disclosures of electronic PHI (not merely disclosures) located in a designated record set (not merely through an EHR).

Further, proposed 45 CFR §164.528(b)(2)(i) specifies the contents of the access report, which must include the following:

(A) Date of access;
(B) Time of access;
(C) Name of natural person, if available, otherwise name of entity accessing the electronic designated record set;[6]
(D) Description of what information was accessed, if available; and
(E) Description of action by the user if available, e.g., "create," "modify," "access," or "delete."

In the preamble to the rule, the Department asserts that the aforementioned requirements regarding the scope and contents of the access report are reasonable, "since all such covered entities and business associates are required by the Security Rule to maintain access logs and, therefore, should be able to provide this information to individuals in response to requests."[7]

TMA, however, contends that the proposed rule significantly underestimates the burden associated with producing access reports, especially with regard to small physician practices. Specifically, TMA challenges the assumption that limiting the content of the access report to that which is already required to be collected under the Security Rule will enable a more automated report and, therefore, ease the burden on covered entities.

As set forth in the proposed rule, the access report must meet certain specifications,[8] must consolidate content from multiple systems if they exist,[9] must allow individuals to limit

[5] 76 Fed. Reg. 31436.
[6] TMA recommends that the Department consider requiring the report to include the role (e.g., physician, nurse, accounting, etc.) of the person accessing the electronic designated record set, rather than merely the name of the natural person. Inclusion of the role of the person accessing the designated record set may alleviate the burden of follow-up calls from patients seeking further information on the propriety of the individual's access to the electronic designated record set.
[7] See 76 Fed. Reg. 31437; see also reference on this page to Section 164.312(b) of the Security Rule (Standard: Audit Controls) and Section 164.308(a)(1)(ii)(D)(Implementation specification: information system activity review).
[8] Proposed 45 CFR §164.528(b)(2).
[9] 76 Fed. Reg. 31436.

their requests to specific time periods or persons,[10] and must be made available in an electronic format as requested by the individual, if possible.[11]

Although the information in the access report is limited to content already required to be collected, EHR vendor products are *not* required to provide an automated process to produce an electronic report that meets the proposed rule's requirements. Consequently, production of an access report will not typically be a simple, automated process (as is seemingly contemplated by the proposed rules). Rather, the covered entity will have to produce the report through a manual process in which some technical skills are needed to design and configure the report to meet the proposed rule's specifications, to consolidate content from multiple systems, to customize the report to meet requested limitations and/or to re-format the report.

For example, programming skills will be needed to create an access report from a typical EHR that produces an automated audit log that only shows the User's ID when a record is accessed, but not the individual's name (as is required for the access report under proposed 45 CFR §164.528(b)(2)(i)(C), if available). In that case, the report must be re-configured to map the actual name of the individual in place of the recorded User ID. When one change is made in an electronic report, other changes may be necessary in order to accommodate the change. In this example, mapping content from the NAME field to the USER ID field might also require the report writer to increase a character limit in the USER ID field in order to prevent cutting off long names. This second change could cause the report to extend beyond the set margins of the report's design, which would then require the report writer to change the design of the report. Thus, formatting a report and configuring a report may be much more complicated than it would appear at first blush.

Based upon the above example, complying with the proposed rule's access report requirements may necessitate the use of additional resources to engage someone with the technical expertise needed to properly configure and/or format the report. The availability of technical expertise to configure and/or format the report (which involves manual work) will vary widely depending upon the size of the provider. Most large healthcare systems and some large physician practices have an IT Department or employ IT personnel who have the expertise and skills needed to design, configure and format reports. For large entities, the access report may not create a significant new burden, because the entities may tap existing IT resources. However, very few small physician practices have the resources necessary to comply with the proposed rule. In order to produce an access report, a small practice may have to hire outside resources to design, configure and format the report at a variable cost. The cost will obviously be dependent on the complexity of each report and the IT consultant's hourly rates. However, even a fairly small cost may represent a large burden to a small physician practice, especially when the proposed rule prevents such costs from being shared or incurred by the requesting

[10] Proposed 45 CFR §164.528(b)(2)(ii).
[11] Proposed 45 CFR §164.528(b)(3)(ii).

individual (at least in the context of an individual's first access report request in a 12-month period).[12]

Based upon the foregoing concerns regarding the undue burden that the proposed access report rule places on physicians and small practices in particular, TMA recommends that the proposed rule be modified to require small practices to provide the system's automated audit log, as configured by the vendor, if available, from any of their systems that store PHI. TMA contends that the Department should place the burden on the vendors to configure their products to produce automated reports that meet the specifications and requirements of the proposed rule, rather than on the small physician practice. TMA further recommends that vendors configure their products to utilize a standard format for the aforementioned automated audit reports. Such nationally-standardized format should be developed with the input of patient representatives for ease of understanding. Standardization in formatting (in addition to content) is advisable in order to facilitate industry implementation, provider rule compliance, and patient understanding. The final version of this standardized report should be piloted before being released to the vendor community to program. The use of a web services approach in order to avoid hundreds of EMR vendors coding the same report should also be considered.

Finally, if a small practice is required to hire IT consultants to design and configure or modify an access report, TMA urges the Department to permit the practice to impose a reasonable, cost-based fee on the requesting individual for each access report provided (i.e., even for the first access report requested by an individual in a 12-month period).

III. **Conclusion**

Once again, TMA thanks you for the opportunity to provide these comments. If you should have any questions or need any additional information, please do not hesitate to contact me at TMA's main number 512-370-1300.

Sincerely,

Joseph H. Schneider, MD, MBA
Chair, *ad hoc* Committee on Health Information Technology
Texas Medical Association

[12] Proposed 45 CFR §164.528(b)(3)(iii)(A).