Health IT Policy Committee

A Public Advisory Body on Health Information Technology to the National Coordinator for Health IT

Public Comment
Virtual Hearing on Accounting for Disclosures

September 30, 2013

American
Clinical Laboratory
Association

August 1, 2011

Secretary Kathleen Sebelius
U.S. Department of Health and Human Services
Office for Civil Rights
Attn: HIPAA Privacy Rule Accounting of Disclosures; RIN 0991-AB62
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue SW
Washington, DC 20201

RE: RIN 0991-AB62; Comments on HIPAA Privacy Rule Accounting of Disclosures under the Health Information Technology for Economic and Clinical Health Act ("HITECH Act")

Dear Secretary Sebelius:

The American Clinical Laboratory Association ("ACLA") thanks the Office for Civil Rights ("OCR") for the opportunity to submit comments on the Notice of Proposed Rulemaking for the HIPAA Privacy Rule Accounting of Disclosures under the HITECH Act.[1] ACLA is a not-for-profit association representing the nation's leading national and regional clinical laboratories on key issues of common concern, including federal and state government reimbursement and regulatory policies. Virtually all of ACLA's members are "covered entities" and may also be "business associates," as those terms are defined in 45 C.F.R. § 160.103. ACLA members also work with business associates who would be impacted by the proposed rule just as ACLA members will be. Because ACLA's members would be affected directly by the proposed rule, the association responded to the OCR's May 3, 2010 Request for Information on this topic and now submits these comments. (Please see ACLA's response to the Request for Information, attached.)

While ACLA supports some of the provisions of the proposed rule that would amend the existing accounting of disclosures requirement, it strongly opposes the establishment of a new requirement for covered entities to provide individuals an "access report" covering all instances of access to protected health information ("PHI") in an electronic designated record set, regardless of the purpose of the access or whether it was disclosed outside the covered entity. Such a requirement would contradict the will of Congress as expressed in the HITECH Act, ignore HHS's own prior interpretation of the HIPAA Security Rule, and fail to properly weigh the tremendous administrative cost and burden on covered entities and business associates, without significantly advancing individuals' legitimate privacy interests.

ACLA urges OCR to: 1) modify the portion of the proposed rule relating to an accounting of disclosures to track the requirements of Sec. 13405(c) of the HITECH Act,

[1] HIPAA Privacy Rule Accounting of Disclosures Under the Health Information Technology for Economic and Clinical Health Act, 76 Fed. Reg. 31426 (May 31, 2011).

expanding the right to an accounting of disclosures to include a disclosure of PHI for treatment, payment, and health care operations ("TPO") purposes specifically and only when made through an electronic health record, while maintaining the Privacy Rule's existing definition of "disclosure"; 2) clarify that Laboratory Information Systems ("LIS") are not electronic health records and therefore are not subject to the requirement to account for disclosures of PHI for TPO purposes; 3) withdraw altogether the portion of the proposed rule relating to an "access report;" and 4) relieve covered entities of the burden of having to provide accountings and access reports not only for themselves but also for their business associates.

Following are ACLA's general comments on the proposed rule in the context of its authorizing legislation, as well as comments on the specific provisions of the proposed rule.

A. The proposed rule does not implement Congress's intent in enacting the HITECH Act because the proposed rule attempts to impose regulatory requirements on far more than *disclosures* through an *electronic health record.*

1. OCR overstepped its authority in proposing the creation of the right to an access report, which includes far more than *disclosures*.

OCR overstepped its authority in proposing the creation of a right to an access report. In the HITECH Act, Congress expanded the right to an accounting of disclosures by requiring covered entities to account for disclosures of PHI for TPO purposes, but only when such PHI is *disclosed* through an *electronic health record.* Nowhere in the text of the HITECH Act or in its legislative history is there evidence that Congress contemplated the creation of a separate and distinct "access report" relating to PHI contained in an "electronic designated record set."

The text of the relevant portion of the authorizing statute, the HITECH Act of 2009, says:

> "In applying section 164.528 of title 45, Code of Federal Regulations, in the case that a covered entity uses or maintains an electronic health record with respect to protected health information, (A) the exception under paragraph (a)(1)(i) of such section [referring to disclosures made for treatment, payment, and operations] shall not apply to disclosures through an electronic health record made by such entity of such information, and (B) an individual shall have a right to receive an accounting of disclosures described in such paragraph of such information made by such covered

entity during only the three years prior to the date on which the accounting is requested."[2]

We must presume that Congress meant what it enacted into law when it referred specifically to "disclosures," particularly given the fact that it referenced the existing accounting of disclosures rule and noted that this new requirement to account for disclosures of PHI for TPO purposes was to be carried out in applying that particular rule. For purposes of the existing accounting of disclosures rule, the term "disclosure" is defined as "the release, transfer, provision of access to, or divulging in any other manner of information *outside the entity holding the information.*"[3] Therefore, it is clear from the unambiguous language itself that Congress did not intend to create a new obligation related to access to PHI that occurs within a covered entity holding PHI. Yet the proposed regulatory requirement to provide an access report would apply not only to disclosures of PHI outside the covered entity, but also to access to PHI within the covered entity itself, contrary to the clearly expressed intent of Congress.

OCR's general authority under HIPAA does not allow it to disregard Congress's clear direction. In the preamble to the proposed rule, OCR states that the accounting and access portions of the proposed rule are based on its "general authority under HIPAA" and that the access rule is based in part on "the requirement of 13405(c) of the HITECH Act to provide individuals with information about disclosures through an [electronic health record] for treatment, payment, and operations." While OCR may have general rulemaking authority under HIPAA in the absence of contrary legislation subsequently enacted by Congress, here, OCR is proposing to use its general authority under HIPAA in a way that directly contradicts Congress's intent in subsequent legislation and goes beyond what Congress called for. This proposed action by OCR is inconsistent with the canons of statutory interpretation that the terms of a more specific statute override the terms of a more general statute.[4]

2. OCR overstepped its authority in expanding beyond disclosures through an *electronic health record.*

OCR went too far when it proposed that an accounting of disclosures must include disclosures of information in a "designated record set," rather those disclosures made through an electronic health record, as the statute sets forth. When defining the parameters of the expanded right associated with an accounting, Congress specifically referred to covered entities that use or maintain *electronic health records*, not to any covered entity that may use or maintain PHI in electronic form. Indeed, the title of the section of the HITECH Act is "Accounting of Certain Protected Health Information Disclosures Required *if Covered Entity Uses Electronic Health Record*" (emphasis added). Also, the House and Senate committee reports and conference agreement refer to

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[2] Health Information Technology for Economic and Clinical Health (HITECH) Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 , Pub. L. 111-5, Sec. 13405(c)(1).

[3] 45 C.F.R. § 164.501 (emphasis added).

[4] *See, e.g., United States v. Estate of Romani*, 523 U.S. 517, 532 (1998) (a later, more specific statute governs).

PHI for TPO purposes contained in and disclosed through *electronic health records*, not to information in an "electronic designated record set," as called for in the access portion of the proposed rule.[5] If Congress had intended to apply the requirement to all covered entities, as OCR is proposing, it easily could have done so. But instead, Congress carefully limited the scope of the right, conditioning its application to a covered entity only *if* it uses electronic health records. This leads one logically to the conclusion that Congress meant to apply the scope of the right only to those disclosures made by *covered entities using electronic health records*, not to any covered entity with an "electronic designated record set."[6]

The fact that Congress intended to limit the right to an accounting of disclosures of PHI for TPO purposes to that contained in and disclosed by a covered entity using an electronic health record is supported further by the section that sets forth the legislation's effective dates. The effective date of the law is determined based on *when a covered entity acquired an electronic health record.*[7] Congress gave the Secretary the authority to set a later effective date if necessary, but it did not authorize the Secretary to apply the law to the subset of covered entities who do not use or maintain electronic health records at all. As clinical laboratories do not use or maintain electronic health records systems, they do not "acquire" electronic health records and should be excluded from the scope of the rule.

The HITECH Act did not leave it to the discretion of OCR to disregard the statutory definition of "electronic health record" or to define "electronic health record" in a way that is inconsistent with the statutory definition. An "electronic health record" is an "electronic record of health-related information on an individual that is created, gathered, managed, and consulted by authorized health care clinicians and staff."[8] While the terms "clinician" and "health care clinician" are not defined in the applicable statutes or regulations, the Merriam Webster Medical Dictionary defines a "clinician" as "an individual qualified in the clinical practice of medicine, psychiatry, or psychology, as distinguished from one specializing in laboratory or research techniques or theory."[9] Notwithstanding the clear definition of the term "electronic health record" that focuses on creation, management, and consultation by a clinician, the proposed rule disregards the statutory definition of an electronic health record and substitutes a far more expansive concept of an "electronic designated record set," which thereby would apply to every covered entity that uses or maintains PHI in electronic form, whether or not the covered entity is a clinician or an "electronic health record" is involved.

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[5] *See* H.R. Rep. No. 111-007 (2009); H.R. Rep. No. 111-016 (2009); S. Rep. No. 111-003 (2009).

[6] We note, also, that OCR uses a variety of terms to describe the scope of the regulation, from "designated record set" to "electronic designated record set" to "designated record set information" to "designated record set systems." We disagree with OCR's arbitrary extension of the right beyond information in an electronic health record; nevertheless, if the rule is implemented as proposed, OCR must make clear that the access report obligation encompasses only a single designated record set and that only the electronic systems that contain the actual designated record set must be tracked for purposes of this regulation.

[7] Pub. L. 111-5, Sec. 13405(c)(4).

[8] 42 U.S.C. § 17921(5).

[9] Merriam Webster Medical Dictionary (2007).

3. Clinical laboratories do not use electronic health records – they use Laboratory Information Systems.

a. The difference between an "electronic health record" and an "electronic designated record set" is of great consequence to clinical laboratories.

The distinction between an electronic health record and an "electronic designated record set" is critical. Clinical laboratories do not use electronic health records – they use Laboratory Information Systems, described in detail below. Applying the accounting of disclosures (or access report) requirement to electronic health records would not include an LIS, while applying the requirements to an "electronic designated record set" could include an LIS. The latter result is inconsistent with the intent of Congress in enacting the relevant provision of the HITECH Act.

As a general matter, most clinical laboratories develop, control, maintain, and use an electronic LIS to facilitate the performance of clinical laboratory services ordered by a patient's direct treatment providers, generally physicians. The LIS is an integral part of the laboratory's infrastructure and is connected to various data entry points within the laboratory, i.e., directly from automated instruments or personal computers, where data is entered manually by laboratory technicians performing the testing services. However, and most importantly, the LIS is not consulted by a patient's health care clinicians or his or her staff. Indeed, the LIS and ordering provider's electronic health record system are entirely two separate systems that may communicate in a limited capacity, specifically with respect to ordering laboratory services and transmitting test results. However, the clinician consults paper records or records managed in a separate electronic health record system, typically stand-alone in the clinician's office, for patient care purposes.

Some information, such as orders or billing demographic information needed by the laboratory to perform its services, may come into the LIS from outside. However, the LIS is not consulted by outside clinicians. Laboratory test orders that contain diagnosis codes, a narrative or coded description of the requested test, and other individually identifiable patient demographic information are in some cases electronically transmitted to the LIS by health care providers and their staffs who are authorized to order laboratory tests, receive test results, and administer treatment to their patients under applicable laws. In other instances, laboratory test orders are entered manually into the LIS by laboratory personnel, such as phlebotomists and specimen processors, from paper scripts received from ordering providers. Other laboratory personnel who are licensed or otherwise authorized to perform ordered tests may refer to and make further entries into the LIS in the course of performing testing services, which may include consultations with the ordering provider. However, the information is gathered for laboratory purposes, and the laboratory does not use the information to make health care decisions regarding the treatment of a patient, which is the clinician's role.

As a result, it should be clear that an LIS is not an "electronic health record" as that term is defined under the HITECH Act. Unlike an electronic health record, an LIS is a separate electronic system at the laboratory for receiving, processing, and storing

information used solely by the clinical laboratory in the performance of laboratory testing, for reimbursement purposes, and for other informatics purposes. We do not believe Congress intended the definition of an "electronic health record" to include an LIS based on the most critical component of its definition. Specifically, an LIS is *not* "created, gathered, managed, and consulted by *authorized health care clinicians and staff*." It is clear from the definition of an "electronic health record" that Congress could not have intended an electronic health record to mean a system, such as an LIS, which is *not* managed, and consulted by the clinicians (*e.g.*, ordering physicians) and their staffs. Thus, because an LIS is used and maintained solely by the clinical laboratory, and not by clinicians and their staff, an LIS does not constitute an "electronic health record," as defined in the HITECH Act.

b. Unlike an electronic health record, an LIS is not a patient's complete medical record.

Although not expressly stated in the HITECH Act definition, an "electronic health record" is generally understood to describe an individual's *complete* medical record, which an LIS does not. This understanding is well-recognized in the vendor and laboratory industries and is consistent with the Healthcare Information and Management Systems Society's (HIMSS's) definition of an electronic health record. HIMSS defines an "electronic health record" as a "longitudinal electronic record of patient health information generated by one or more encounters in any care delivery setting."[10] In other words, an electronic health record is a compilation of health-related information across multiple care delivery settings and dates of service that is used and maintained by the treating practitioner. According to HIMSS, an electronic health record includes information, such as patient demographics, progress notes, problems, medication, vital signs, past medical history, immunizations, laboratory data, and radiology reports. Importantly, as noted by HIMSS in its definition, an electronic health record has the ability to generate a *complete* record of a clinical patient encounter, which may include evidence-based decision support, quality management, and outcomes reporting, as well as supporting other care-related activities directly or indirectly via an interface.[11]

By contrast, an LIS maintains an electronic record of only that patient health information necessary to facilitate the provision of clinical laboratory services for individuals. This information essentially is limited to the information needed to perform the testing ordered for that patient for that encounter, such as the name of the patient and the ordering physician, the test to be ordered, and the results of the test performed. Additionally, information is not captured or aggregated in an LIS in the format of a medical folder or record for each patient, and testing for each patient over a period of time is not aggregated or linked within the LIS. Instead, each time a test is performed on a patient, the results are stored in a separate, distinct record and are not connected with other records of that patient, contrary to the way a patient's medical record would be maintained, stored, and accessed in an electronic health record. Finally, as noted above,

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[10] *See* definition of an "EHR" on the HIMSS website, *available at* http://www.himss.org/ASP/topics_ehr.asp.

[11] *Id.*

an LIS is used and maintained by the laboratory itself, and not by health care clinicians or their staffs. As such, an LIS is clearly not the type of system that should be considered to be an "electronic health record."

In summary, OCR would not be implementing the relevant section of the HITECH Act as Congress intended if it were to apply the rights to an accounting and to an access report to *all* covered entities and business associates, or if it applied those rights to all electronic PHI in an "electronic designated record set," as opposed to the subset of covered entities who are clinicians and who maintain and consult electronic health records. Congress's intent was made clear in the text of the statute and in the legislative history: the provisions affect only covered entities that use electronic health records and information contained in and disclosed through an electronic health record. Clinical laboratories do not use electronic health records and should not be included in the application of the accounting portion of the rule.

B. OCR misinterpreted the HIPAA Security Rule, and the proposed rule fails to account for the significant administrative burden associated with the proposed access report.

1. OCR has misinterpreted both the text of the HIPAA Security Rule and its own prior interpretations of the rule.

OCR's assumption that the establishment of an access report requirement would require minimal changes to existing information systems is based on new interpretation of the HIPAA Security Rule. OCR now presumes that the HIPAA Security Rule requires a covered entity to collect and maintain exactly the same information that an access report would include and that compliance with one leads invariably to the ability to comply with the other. Even as OCR acknowledges that the capabilities to gather the relevant information do not exist in the context of "meaningful use" of electronic health records or for Health Information Exchanges, it assumes that covered entities *do* have those capabilities if they are in compliance with the Security Rule. In fact, the Security Rule contains very little discussion of "audit trails," on which OCR bases this assumption.[12] And in the Department of Health and Human Services' ("HHS's") own educational materials, it states that "the Security Rule does not identify data that must be gathered by the audit controls or how often the audit reports should be reviewed. A covered entity must consider its risk analysis and organizational factors, such as current technical infrastructure, hardware and software security capabilities, to determine reasonable and appropriate audit controls for information systems that contain or use [electronic PHI]."[13] It is confounding that OCR now asserts that compliance with the Security Rule automatically puts a covered entity in a position to comply with the proposed access report, when in the past OCR has not interpreted the Security Rule as "one size fits all." As the agency knows – indeed, as it has stated in the past – not all covered entities automatically have the capabilities, software, hardware, and technical

[12] *See* 45 C.F.R. § 164.312(b), *see also* 76 Fed. Reg. 31,436.
[13] HIPAA Security Series, #4, "Security Standards; Technological Safeguards."

support to compile all of the information that would be required for an access report, as proposed.

OCR appears to be misinterpreting its own prior statements about the Security Rule in rejecting its inherent flexibility. From the inception of the rule, HHS has taken a flexible approach to compliance with the HIPAA Security rule by making the requirements scalable based on the specific operations and activities of the organization, developing a rule that was technology-neutral, and making clear that "covered entities may use any security measures that allow the covered entity to reasonably and appropriately implement the standards and implementation specifications as specified in this subpart."[14] For years, covered entities have relied upon that approach in implementing the requirements of the HIPAA Security Rule, and as a result, the manner in which particular security requirements have been implemented vary accordingly among covered entities and even within covered entities. The proposed rule takes a new and very different approach, suggesting that covered entities and business associates must track all access and make the information available in a particular way. This drastic change in HHS policy to implement a proposal that Congress never intended is unjustified, impractical, unfair, and unwise.

2. OCR has failed to account for the significant administrative burden associated with the proposed access report.

OCR has ignored the significant administrative burden associated with the proposed access report. Furthermore, if implemented as proposed, covered entities already could be violating the rule because the three year "look back" period envisioned in the proposed rule could include the present day, but no provider today is tracking, or able to track, the information required by the proposed rule.

In creating a new right to an "access report," OCR fails to heed Congress's direction that regulations implementing the relevant portion of the HITECH Act "shall only require such information to be collected through an electronic health record in a manner that...*takes into account the administrative burden of accounting for such disclosures*" (emphasis added).[15] The burden of producing an access report is significant for covered entities, and the burden is multiplied many times because OCR proposes that covered entities provide access reports that also include information from their business associates, which is not the case today and would be extremely burdensome to implement. ACLA believes that OCR should withdraw the access portion of the rule. However, if OCR retains that portion, it must make substantial changes to avoid information overload.

Despite evidence to the contrary in public comments, OCR appears not to have given any consideration to the burden on covered entities and business associates who will have to comply with the access report requirement, and it has made faulty assumptions about the burdens imposed upon them. It seems to have disregarded what it

[14] 45 C.F.R. § 164.306(b).
[15] Pub. L. 111-5, Sec. 13405(c)(2).

learned from its May 3, 2010 Request for Information, which was that many systems do not and cannot do what OCR is contemplating and that there is a wide range of capabilities in electronic data systems used by health care providers.[16] Moreover, it is not the case, as OCR assumes, that "the proposed right to an access report will require minimal, if any, changes to existing information systems," and it is a fatally erroneous assumption that "covered entities and business associates who are compliant with the Security Rule or their business associate agreements should already be logging the information necessary for an access report and should be able to generate an access report."[17] Especially for clinical laboratories, which organize data in an LIS, it would require significant changes and a tremendous administrative burden to comply with the proposed right to an access report. (One of our members has identified as many as 248 separate laboratory systems that would be impacted by the proposed rule.)

Further, the volume of uses and disclosures of PHI by clinical laboratories for TPO is staggering. For example, our ACLA member laboratories perform well over *one billion* tests each year. Each of these tests produces a test result, which becomes a disclosure of PHI to the ordering provider for treatment purposes, but there are many uses of PHI to produce that result. Each of these tests also produces a request for payment, which typically involves many uses and disclosures of PHI for payment purposes. As a result, each patient encounter generates multiple uses and disclosures of PHI for treatment, payment, and health care operations purposes on a daily basis. Countless instances of access to PHI are necessary and routinely occur within the laboratory for perfectly legitimate purposes.

Within a clinical laboratory, numerous individuals are required to process a single laboratory order and access PHI. For example, a phlebotomist with an electronic order needs to access the order to determine for which tests he or she needs to draw blood and to identify the correct patient. A lab courier picking up specimens (and electronically logging receipt) may review all test order forms and specimen types to ensure specimen integrity and to verify that he or she has picked up the correct specimen. Laboratory personnel processing a specimen must verify the date of birth, last name, specimen quantity and/or temperature, gender, and other demographic information as a pre-condition to performing tests. Billing personnel must review a test order to ensure appropriate diagnosis, insurance, and other information is obtained from the patient. Customer service personnel may need to review an order or final test result to clarify an ambiguous order or report test results and critical values to physicians. In addition, lab personnel may have to perform general system inquiries using common identifiers (i.e., the last name "Smith"), which could result in a brief review of several patient records to identify that correct patient. Does OCR really expect that access to a patient record as part of such a general inquiry be tracked and made part of the proposed access report?

For ACLA member laboratories, the scenarios we have illustrated above translate into multiple billions of instances of access to and disclosures of PHI every year that would have to be tracked and stored and that would be subject to aggregation and

[16] *See* 76 Fed. Reg. 31,428.
[17] *Id.* at 31,439.

reporting if their LIS systems were determined to be subject to an access report requirement or even a requirement to account for disclosures of PHI for TPO purposes. Due to the sheer volume of transactions in which clinical laboratories are engaged, the complexity of their systems, and the ongoing efforts to achieve other major compliance initiatives mandated by HHS during the same timeframe (*e.g.*, implementation of ICD-10), the burden of complying with this requirement for clinical laboratories would be severe and excessive, considering the routine nature of these uses and disclosures. Laboratories would have to buy new hardware, reprogram existing system applications in all systems maintaining PHI, retrain tens of thousands of employees, and reorganize their business processes in providing laboratory services to individuals and their health care providers. Because of the requirement to include the uses and disclosures by numerous business associates, this burden would be increased significantly – well beyond the ability of any responsible covered entity to comply.

Most covered entities would be out of compliance as soon as the rule became effective. This is because OCR has determined that a covered entity must begin to comply with the access report portion of the proposed rule on January 1, 2013 (if it acquired a "designated record set system" after January 1, 2009) or on January 1, 2014 (if it acquired a "designated record set system" before January 1, 2009).[18] Given the requirement that an access report must cover the three years prior to the date on which the report was requested, a covered entity must be able to collect, aggregate, and organize all of the required information going back to either January 1, 2010 or January 1, 2011 – long before the rule was proposed. As we explained above, and as OCR learned in its Request for Information, many systems used by covered entities do not and cannot do what the proposed rule contemplates. Even if a covered entity today acquires entirely new systems to meet the requirements of the proposed rule, it could not comply with the rule for the period of time between January 1, 2010 or 2011 and the date of that acquisition. ACLA strongly urges OCR to withdraw the access report portion of the proposed rule, but at the very least it must postpone the rule's effective date.

C. OCR must give covered entities a choice whether to include business associates' disclosures and access, as permitted by the HITECH Act.

In Sec. 13405(c)(3) of the HITECH Act, Congress provided covered entities a choice whether to include business associates' disclosures in an accounting, and OCR must do the same to implement Congress' intent. The text of the relevant section of the legislation says:

> "In response to a request for an individual for an accounting, a covered entity shall elect to provide either an –
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> > (A) accounting...for disclosures of protected health information that are made by such covered entity and by a business associate acting on behalf of the covered entity; or

[18] Please see ACLA's specific comment on the elusive definition of "designated record set system," below.

> (B) accounting...for disclosures that are made by such covered entity and provide a list of all business associates acting on behalf of the covered entity, including contact information for such associates (such as mailing address, phone, and email address.)
>
> A business associate included on a list under subparagraph (B) shall provide an accounting of disclosures (as required under paragraph (1) for a covered entity) made by the business associate upon request made by an individual directly to the business associate for such accounting."

Nowhere in the "accounting of disclosures" portion of the proposed regulation does OCR give a covered entity the option of providing information about its disclosures of PHI, along with contact information for business associates acting on its behalf. OCR dismisses out of hand the legislative text that gives a covered entity a choice of how to respond to a request, saying that it "places an undue burden on the individual," and it asserts once again that it is relying on its "general authority under the HIPAA statute" when eliminating that choice.[19] OCR may not use its general authority under the HIPAA statute to contradict the will of Congress (as set forth in a later, more specific statute, the HITECH Act) and ignore Congress's clear direction that covered entities be given a choice about how to respond to requests from individuals for access reports.[20]

Considering the significant burden of complying with the "access report" portion of the rule, as proposed, the rule must be modified and the OCR should not require a covered entity to provide information about access to information contained in electronic designated record sets held by business associates. The overwhelming burden on clinical laboratories of complying would be multiplied many times over if OCR were to retain that requirement. As explained above, some clinical laboratories have many separate systems of their own that would be impacted by the proposed rule and that would have to be modified or changed altogether to comply with OCR's proposal. When access reports from those internal systems are combined with reports from all business associates' systems, the administrative burden of compiling an access report is disproportionate to the marginal benefit an individual would derive from such a report. It would be nearly impossible for a covered entity to comply with the unrealistic time frame OCR has proposed for a covered entity to produce an access report as proposed, considering the number of business associates that may be involved, as well. Because the regulation flouts the will of Congress, and because of the crippling administrative burden imposed upon covered entities, OCR must not require in all cases that covered entities provide accountings and access reports both for themselves and for their business associates.

D. ACLA's specific comments on the "accounting" portion and the "access report" portion of the proposed rule

ACLA does not believe that Congress intended that the proposed rule apply to clinical laboratories or other health care providers and suppliers who do not use,

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[19] *Id.* at 31,437.
[20] *See* 523 U.S. 517.

maintain, or disclose PHI through electronic health records, and it strongly opposes the creation of the right to an "access report." Nonetheless, it offers the below comments about both the "accounting" portion and the "access report" portion of the proposed rule.

Accounting

OCR proposes to modify the existing requirements for accountings of disclosures, and ACLA offers the following comment on those proposed modifications.

OCR should clarify that disclosures of PHI for TPO do not need to be included in an accounting (45 C.F.R. § 164.528(a)(1)): It appears that OCR proposes that an individual's right to an *access report* under 45 C.F.R. § 164.528(b) would include information related to access of PHI for TPO, but OCR should clarify that an *accounting of disclosures* under 45 C.F.R. § 164.528(a) does not have to include disclosures of PHI related to TPO, as we believe OCR intended.

In the proposed rule, OCR lists the types of disclosures that must be included in an accounting. The first type of disclosure that OCR proposes must be included in an accounting is "disclosures not permitted by this subpart..." We note that 45 C.F.R. § 164.506 specifically permits the disclosures of PHI for TPO without an individual's authorization. Moreover, none of the other types of disclosures for which an accounting would be required implicate TPO. Accordingly, it appears that disclosures of PHI for TPO purposes, not being explicitly stated, would *not* be included in the enhanced right to an accounting of disclosures, as proposed.

However, one of OCR's statements in the preamble is ambiguous in this regard and creates confusion. It is not clear from the following statement whether, despite OCR's comments to the contrary, OCR might consider a disclosure of PHI for TPO purposes in an electronic designated record set to be part of what must be included in an accounting:

> "Disclosures to carry out treatment, payment, and health care operations as provided in § 164.506 would continue to be exempt for paper records. However, in accordance with section 13405(c) of the HITECH Act, an individual would be able to obtain information (such as the name of the person accessing the information) for all access to electronic protected health information stored in a designated record set for purposes of treatment, payment, and health care operations."[21]

Confusion about OCR's intent is created because this statement is included in the section of the preamble about the right to an accounting, not the right to an access report. However, we believe that, given the language and context of the statement, OCR merely was referencing the ability of an individual, through the right to an access report, to obtain information for all access to electronic PHI in a designated record set for purposes of TPO. The statement uses the term "*access*," which is the language that OCR typically

[21] 76 Fed. Reg. 31,432.

uses with respect to the right to an access report, while the right to an accounting of disclosures provides an individual with information concerning *disclosures* of PHI outside of the entity holding the PHI, which is only a small subset of "all access to electronic PHI stored in a designated record set for purposes of treatment, payment and health care operations." If OCR proceeds to finalize the rule as proposed (which ACLA strongly opposes), OCR should make explicit that disclosures of PHI for TPO are not included in the accounting of disclosures portion of the proposed rule for paper or electronic records, as it has made clear that access to PHI for TPO purposes is included in the access report portion of the proposed rule.[22] To be clear, it is our primary and fundamental position that OCR should instead withdraw the access report proposal and modify the accounting of disclosures requirement to track section 13405(c) of the HITECH Act, while maintaining the Privacy Rule's existing definition of "disclosure," and clarify that an LIS is not an electronic health record to which the rule applies.

ACLA supports shortening the accounting time frame (45 C.F.R. § 164.528(a)(1)): ACLA supports OCR's proposal that covered entities and business associates would have to account for disclosures over the previous three years, instead of the six year period currently specified in regulations.[23] This would implement Congress's clear intent that the time frame for an accounting be decreased to three years. Given the complexity of the HIPAA regulations in general, and the vast amount of PHI with which some of ACLA's members deal day-to-day, it makes sense to simplify this portion of the Privacy Rule by aligning the time period with other requirements, and it reduces the burden on covered entities and business associates alike who must maintain information on disclosures. ACLA also supports the reduction in the time frame for which a covered entity or business associate must maintain documentation in order to provide an accounting of disclosures, from six years to three years.[24]

ACLA supports exempting disclosures contained in a breach notification (45 C.F.R. § 164.528(a)(1)): We support OCR's proposal to exempt from the accounting requirement those impermissible disclosures about which a covered entity, either directly or through a business associate, already has provided a breach notice to an individual.[25] It is administratively burdensome for a covered entity or a business associate to have to respond to accounting requests if it already has taken the affirmative step of providing a breach notice, because the breach notification generally serves the same purpose as the accounting.

ACLA supports changes to the content of an accounting (45 C.F.R. § 164.528(a)(2)): ACLA supports the proposal to expand the ways for describing the date of a disclosure or the time period in which a disclosure occurred.[26] Occasionally, it is not possible to know the exact date of a disclosure or multiple disclosures. Accordingly, it is helpful to be able to state a date, a date range, or a description of a date of a disclosure in relationship to other events. The purpose of providing the date to the individual seeking

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[22] *Id.*
[23] *Id.* at 31,430.
[24] *Id.* at 31,436.
[25] *Id.* at 31,431.
[26] *Id.* at 31,434.

the accounting still will be met: learning when an individual or entity obtained PHI about the individual.

ACLA also supports standardizing the practice of covered entities providing an individual with an option to limit the accounting to a particular time period, type of disclosure, recipient, or organization disclosing the PHI, as in proposed 45 C.F.R. § 164.528(a)(2)(ii), because it reduces the administrative burden on both covered entities and business associates, and it permits an individual to receive only the information that matters most to him or her.

ACLA opposes shortening the time to respond to an accounting request (45 C.F.R. § 164.528(a)(2)): ACLA strongly opposes shortening the time frame for responding to an accounting request to 30 days from the currently allowable 60 days.[27] While our members endeavor to respond to accounting requests as quickly as possible, it oftentimes is not feasible to collect and organize this information in such a short time, especially where a covered entity has a complex business and/or has many business associates. This is especially true when an individual has not accepted the suggestion to limit an accounting request to a particular period of time or organization, for instance. The marginal benefit to individuals of a shorter 30-day time frame is outweighed significantly by the burden to covered entities and business associates.

Access Report

In addition to the right to an accounting of disclosures, OCR proposes to provide individuals with a separate right to receive an access report that indicates who has accessed the individual's electronic designated record set information. ACLA strongly opposes the creation of an access report and believes OCR should withdraw this new requirement. In addition, ACLA offers the following comments on OCR's proposals.

The rule should not apply to all electronic PHI in an "electronic designated record set" (45 C.F.R. § 164.528(b)(1)): For the reasons set forth above in Section A of this letter, ACLA strongly disagrees with OCR's proposal to establish an access report requirement that would apply to any access, for whatever purpose, whether by a person within or outside of a covered entity, to PHI contained in an "electronic designated record set."[28] This is contrary to Congress's intent, which was to limit the right to an accounting of PHI for TPO purposes to that included in, and disclosed through, an electronic health record.

The access report provision should be withdrawn; if it is not, OCR should considerably limit its scope (45 C.F.R. § 164.528(b)(3)): ACLA opposes the proposed access report requirement and urges that it be withdrawn; however, if it is not withdrawn, ACLA supports the proposal to provide an individual with an option to limit an access report to a particular time period, individual, or organization accessing the PHI, as in proposed 45 C.F.R. § 164.528(b)(2)(ii), because it would reduce the administrative burden on both covered entities and business associates that otherwise would be incurred,

[27] *Id.* at 31,435.
[28] *Id.* at 31,437.

and it would permit an individual to receive only the information that matters most to him or her.

"Designated record set system" is an undefined term, and such a system does not exist as OCR contemplates (76 Fed. Reg. 31,442, Effective and Compliance Dates): OCR decided to base the compliance date upon when a covered entity acquires a "particular designated record set system." While the term "designated record set" has an established meaning that is well understood by covered entities, ACLA is unaware of what a "designated record set system" is, as this term is not defined in this proposed rule or elsewhere in statutes, regulations, or guidance. We believe this demonstrates a fundamental misunderstanding on the part of the agency about how information that is part of a designated record set is held and by whom. A covered entity does not acquire a "designated record set system" in the same way as it would acquire an electronic health record system, and it is not possible for a covered entity to determine when the proposed rule would apply to it. OCR should withdraw the "access report" portion of the proposed rule altogether; if it does not withdraw that portion, it should base the compliance date, as Congress did, on the acquisition of an electronic health record, but it should at the very least clarify what it means by "designated record set system."

Responding to the access report request is administratively burdensome and unreasonable, and the benefits do not outweigh the regulatory burden (45 C.F.R. § 164.528(b)(2-3)): ACLA disagrees that its members and other covered entities already are required to perform the actions called for in the proposed access rule and that the additional burden would be negligible. OCR claims that the administrative burden on covered entities and business associates of complying with the proposed access rule will be reasonable, given existing requirements under the Security Rule, 45 C.F.R. § 164.302 et seq., to "log access to electronic protected health information" and to "record and examine activity in information systems that contain or use electronic protected health information."[29] However, as discussed above, this interpretation is totally inconsistent with the flexible interpretation of the HIPAA Security Rule that HHS has stated, and on which covered entities have relied, since the rule's inception. Further, what OCR proposes goes far beyond merely logging and examining such information and far beyond what is required currently, even if OCR's new interpretation of the Security Rule is correct. For instance, OCR proposes that a covered entity or business associate must include the name of the person or entity accessing the information, yet OCR learned in its Request for Information that not all information systems automatically retain the name of the person who accesses information – acquiring this information or translating a unique ID into a name may require additional steps on the part of the covered entity and business associates. Those steps would be multiplied when a covered entity has decentralized information systems and responding to the request for an access report would require the collection and collation of data from multiple information systems.[30]

Additionally, the proposed rule requires a covered entity to provide the information in a "form and format requested by the individual, if it is readily producible

[29] *Id.* at 31,437.
[30] *See id.* at 31,428.

in such form and format; or, if not, in a readable electronic form and format as agreed to by the covered entity and the individual." It would be a tremendous administrative burden to tailor access reports to the desires of each requesting individual or to negotiate an agreeable format with each individual, especially when that requirement is combined with other changes contemplated in the proposed rule. A hard copy option in the form and format determined by the covered entity must be the fall-back provision so that covered entities are not overwhelmed by customized format demands.

Even OCR recognizes in the preamble that "a covered entity will usually have electronic designated record set information in multiple systems which each maintain separate access logs" and that "data from each access log will be gathered and aggregated to generate a single access report (including data from business associates' systems)."[31] It is not realistic to expect a covered entity to be able to aggregate and construct an access report from multiple systems and potentially multiple organizations' systems within that time frame. For the reasons set forth above in the section on accounting, ACLA recommends that OCR withdraw its proposal to require a covered entity to respond to a request for an access report and to produce such an access report within 30 days of the request.[32]

D. Conclusion

OCR should rescind its overly broad interpretation of "electronic health records" and make clear that entities such as clinical laboratories that do not use or maintain electronic health records are exempted from the application of the proposed rule with respect to accounting for disclosures of electronic PHI for TPO purposes. Additionally, OCR should withdraw altogether the "access report" portion of the proposed rule, because it would be extremely administratively burdensome to covered entities and business associates and because Congress contemplated only an amendment to the right to an accounting of disclosures, not the creation of a separate right to an access report.

ACLA appreciates the opportunity to comment on the Proposed Rule and hopes that OCR will incorporate ACLA's suggestions in the final rule. Thank you for your consideration of our recommendations.

Sincerely,

Alan Mertz, President
American Clinical Laboratory Association

Attachment: ACLA's Response to the OCR's May 3, 2010 Request for Information

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[31] *Id.* at 31,436.
[32] *Id.* at 31,440.

ACLA

American
Clinical Laboratory
Association

May 18, 2010

Director Georgina Verdugo
Office for Civil Rights
Attention: HITECH Accounting of Disclosures
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue, S.W.
Washington, DC 20201

5/18/2010

RE: HITECH Accounting of Disclosures (RIN 0991-AB62)

Dear Director Verdugo:

The American Clinical Laboratory Association (ACLA) is pleased to have this opportunity to submit our response to the *HIPAA Privacy Rule Accounting of Disclosures Under the Health Information Technology for Economic and Clinical Health Act; Request for Information ("Request for Information")* issued by the Office for Civil Rights (OCR).[1] ACLA is an association representing clinical laboratories throughout the country, including local, regional, and national laboratories. As covered entities under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), clinical laboratories will be directly affected by the forthcoming regulations on the accounting of disclosures to carry out treatment, payment, and health care operations, as mandated by the Health Information Technology for Economic and Clinical Health Act (the "HITECH Act").

While ACLA and its member companies appreciate the importance of individuals having the right to request an accounting of disclosures of their protected health information (PHI), we are concerned that any possible benefits associated with the new accounting of disclosures could be outweighed by the administrative burdens that will be placed on covered entities having to comply with this requirement. As such, our response will focus first on the reasons the new accounting of disclosures requirement should not apply to clinical laboratories and then turns to the specific questions that have been outlined in the Request for Information.

INTRODUCTION

Currently, the HIPAA Privacy Rule requires covered entities make available to an individual upon request an accounting of certain disclosures of the individual's PHI over the past six years.[2] The HIPAA Privacy Rule excludes from this requirement disclosures made by covered entities relating to treatment, payment, and health care operations. Under the HITECH Act, however, this exemption no longer applies to disclosures through an "electronic health record" or "EHR." As such, individuals will be permitted to request an accounting of disclosures of their PHI relating to treatment, payment, and health care operations so long as the covered entity uses or maintains such

1 *75 Fed. Reg.* 23214 (May 3, 2010).
2 45 CFR § 164.528.

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PHI in an EHR. The threshold question regarding whether this requirement is applicable to a covered entity, therefore, is whether the covered entity discloses PHI through an "EHR" as defined under the HITECH Act. As discussed in greater detail below, we strongly believe that is not the case for disclosures from a clinical laboratory's information system (LIS). To illustrate this point, we have provided a description of a typical LIS and set forth the reasons why an LIS does not constitute an EHR.

Overview of Laboratory Information Systems

As a general matter, most clinical laboratories develop, control, maintain, and use an electronic LIS to facilitate the performance of clinical laboratory services ordered by a patient's direct treatment providers, generally a physician. The LIS is an integral part of the laboratory's infrastructure and is connected to various data entry points within the laboratory – whether they are directly from automated instruments or personal computers – where data is manually entered by laboratory technicians performing the testing services, but is not intended to be consulted by a patient's health care clinicians or his or her staff. Indeed, the LIS and ordering provider's EHR system are entirely two separate systems.

Laboratory test orders that contain diagnosis codes, a narrative or coded description of the requested test, and other individually identifiable patient demographic information, are in some cases electronically transmitted to the LIS by health care providers and their staffs who are authorized to order laboratory tests, receive test results, and administer treatment to their patients under applicable laws. In other instances, laboratory test orders are manually entered by laboratory personnel, such as phlebotomists, specimen processors, and accessioners into the LIS from paper scripts received from ordering providers. Other laboratory personnel, who are licensed or otherwise authorized to perform the clinical laboratory tests ordered, may refer to and make further entries into the LIS in the course of performing testing services. However, the LIS is not used by the laboratory to make health care decisions regarding the treatment of a patient.

Laboratory Information Systems are not "Electronic Health Records"

An LIS is not an "EHR" as that term is defined under the HITECH Act. Section 13400(5) of the HITECH Act defines an "electronic health record" as "an electronic record of health-related information on an individual that is created, gathered, managed, and consulted by authorized health care clinicians and staff." By this definition, alone, an LIS is not an EHR. First, unlike an EHR, an LIS is an electronic solution for receiving, processing, and storing information used solely by the clinical laboratory in the performance of laboratory testing, for billing purposes, and for other information gathering activities as required by our customers. While the definition of an "EHR" is seemingly broad in its inclusion of an "electronic record of health-related information," we do not believe Congress intended the definition of an "EHR" to include an LIS based on the most critical component of its definition. Specifically, an LIS is <u>not</u> "created, gathered, managed, and consulted by *authorized health care clinicians and staff.*" It is clear from the definition of an "EHR" that Congress could not have intended an EHR to mean a system, such as an LIS, which is not managed, and consulted by the clinicians (*e.g.*, ordering physicians) and their staffs. Thus, because an LIS is used and maintained solely by the clinical laboratory, and not by clinicians and their staff, an LIS does not constitute an "EHR," as defined in the HITECH Act.

Second, although not expressly stated in the HITECH Act definition, an "EHR" is intended to describe an individual's *complete* medical record, which an LIS does not. This understanding is well-recognized in the vendor and laboratory industries and is consistent with the Healthcare Information and Management Systems Society's (HIMSS's) definition of an EHR. HIMSS defines an "EHR" as a "longitudinal electronic record of patient health information generated by one or more encounters in any care delivery setting."[3] In other words, an EHR is a compilation of health-related information across multiple care delivery settings that is ultimately used and maintained by the treating practitioner. According to HIMSS, an EHR includes information, such as patient demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data, and radiology reports. The EHR permits the clinician to automate and streamline his or her workflow. Importantly, as noted by HIMSS in its definition, an EHR has the ability to generate a *complete* record of a clinical patient encounter, which may include evidence-based decision support, quality management, and outcomes reporting, as well as supporting other care-related activities directly or indirectly via an interface.[4]

By contrast, LIS systems maintain only an electronic record of patient health information necessary to facilitate the provision of clinical laboratory services for individuals. This information is essentially limited to the name of the patient and the ordering physician, the test to be ordered, and the results of the test performed. Additionally, information is not captured in an LIS in the format of a medical folder or record for a patient and testing over a period of time for each patient is not linked within the LIS. Instead, each time a test is performed on a patient the results are stored in a separate, distinct record and are not connected with other records of that patient, contrary to the way a patient's medical record would occur in an EHR. Finally, as noted above, an LIS is used and maintained by the laboratory itself, and not by health care clinicians or their staffs. As such, an LIS is clearly not the type of system that should be considered to be an "EHR."

Accordingly, we ask that OCR make a clear distinction between LIS systems and EHRs in its forthcoming regulations on the new requirement to account for disclosures relating to treatment, payment, and health care operations. Further, we strongly encourage OCR to exclude LIS systems from the definition of an EHR.

RESPONSE TO QUESTIONS

While it is our position that an LIS is not an EHR, we have responded to the Request for Information based on our member companies' use and maintenance of their existing LIS systems.

1. What are the benefits to the individual of an accounting of disclosures, particularly of disclosures made for treatment, payment, and health care operations purposes?

The accounting of disclosures requirement for treatment, payment, and health care operations will be of little benefit to individuals requesting these disclosures. With respect to disclosures relating to treatment and payment, most of these disclosures are already either known by the individual or assumed by the individual as part of the regular course of business in health care.

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3 *See* definition of an "EHR" on the HIMSS website, *available at* http://www.himss.org/ASP/topics_ehr.asp.

4 *Id.*

For example, when an individual visits his or her physician's office and has blood drawn for a cholesterol test, the individual either knows or assumes that certain PHI will be transmitted by the physician to the laboratory, and that the laboratory will then report the test result, including associated PHI, back to the ordering physician. The individual also either knows or assumes that the laboratory will use certain PHI to bill the individual's insurance carrier for the test if insurance coverage exists. Accordingly, an accounting of disclosures for treatment and payment purposes provides no meaningful information that the individual either did not already have or could not readily obtain by other means.

As to disclosures of PHI for health care operations purposes, covered entities are currently required to provide in their notices of privacy practices a description, including at least one example, of the types of uses and disclosures of PHI that the covered entity is permitted to make for treatment, payment, and health care operations.[5] Individuals are, therefore, already aware that covered entities are permitted to make disclosures of PHI for health care operations purposes, and have at least a general idea of the nature of those disclosures and, therefore, would derive little benefit from such an accounting. Learning of specific disclosures of PHI for health care operations purposes through an accounting would not create any tangible benefit to the individual. Such disclosures are permitted, and expected, by virtue of notices of privacy practices.

In summary, whatever may be the benefits to individuals for an accounting of disclosures of PHI for treatment, payment, and health care operations purposes, those benefits are significantly outweighed by the burden imposed on covered entities – particularly those that have an indirect treatment relationship with the individual, such as clinical laboratories. As we discuss throughout our response, ACLA member laboratories perform a substantial number of tests – well over 1 billion – a year and each of these tests results in a disclosure related to treatment, payment, and/or health care operations.

2. ***Are individuals aware of their current right to receive an accounting of disclosures? On what do you base this assessment?***

All individuals are either aware of their current right to receive an accounting of disclosures or should be aware of their right to receive an accounting of disclosures because it is a required element of a covered entity's notice of privacy practices, which covered entities are required to make available to individuals.[6] The HIPAA Privacy Rule requires that any individual who has received health care services in a direct treatment relationship from a covered entity receives a notice of the covered entity's privacy practices and is able to view the notice on the covered entity's website.[7] In turn, covered entities that have direct treatment relationships with patients are required to make a good faith effort to obtain written acknowledgements from individuals to ensure that individuals have received the covered entity's notice of privacy practices.[8] Further, the HIPAA Privacy Rule requires that any covered entity with an indirect treatment relationship (*e.g.*, a laboratory) with an individual must make available to the individual its notice of privacy practices

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5 45 CFR § 164.520(b).
6 45 CFR § 164.520(b)(iv)(E).
7 45 CFR § 164.520(c).
8 *Id.*

upon request and also post such notice on its website.[9] As such, there should be no instance in which an individual is not aware of their right to receive an accounting of disclosures.

3. ***If you are a covered entity, how do you make clear to individuals their right to receive an accounting of disclosures? How many requests for an accounting have you received from individuals?***

As discussed in response to Question #2, the HIPAA Privacy Rule requires that covered entities make individuals aware of their right to an accounting of disclosures through the covered entity's notice of its privacy practices.[10] As indirect treatment providers, clinical laboratories are required to post notices of privacy practices on their websites and make such notices available to individuals upon request. In compliance with this requirement, our member laboratories have notices of privacy practices that clearly state an individual's right to receive an accounting of certain disclosures of PHI under current law.

ACLA member laboratories have received few or no requests (depending on the laboratory) for accountings of disclosures under current law. It is the view of our member companies that there has been limited interest in requesting accounting of disclosures. As discussed in greater detail in our response to Question #9, to the extent that clinical laboratories would be required to comply with this new requirement, this change would be particularly burdensome for clinical laboratories given the enormous number of tests performed by clinical laboratories each day and, thus, the number of disclosures for which an accounting could be requested.

4. ***For individuals that have received an accounting of disclosures, did the accounting provide the individual with the information he or she was seeking? Are you aware of how individuals use this information once obtained?***

ACLA's member laboratories that receive requests for accountings of disclosures provide to individuals making such requests the information that is currently permitted under the HIPAA Privacy Rule. ACLA member laboratories are not aware of how individuals use this information once it is obtained.

5. ***With respect to treatment, payment, and health care operations disclosures, 45 CFR 170.210(e) currently provides the standard that an electronic health record system record the date, time, patient identification, user identification, and a description of the disclosure. In response to its interim final rule, the Office of the National Coordinator for Health Information Technology received comments on this standard and the corresponding certification criterion suggesting that the standard also include to whom a disclosure was made (i.e., recipient) and the reason or purpose for the disclosure. Should an accounting for treatment, payment, and health care operations disclosures include these or other elements and, if so, why? How important is it to individuals to know the specific purpose of a disclosure— i.e., would it be sufficient to describe the purpose generally (e.g., for "for treatment," "for payment," or "for health care operations***

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9 *Id.*

10 45 CFR § 164.520(b)(iv)(E).

purposes"), or is more detail necessary for the accounting to be of value? To what extent are individuals familiar with the different activities that may constitute "health care operations?" On what do you base this assessment?

An accounting for treatment, payment, and health care operations disclosures should not include any mandatory elements beyond those identified in 45 CFR § 170.219(e). The "description of the disclosure" element that is currently part of the standard could reasonably be interpreted to include the recipient and the purpose of the disclosure. As such, there is no reason to specify that the recipient of the disclosure and the purpose of the disclosure be required elements of the standard. Additionally, the specificity of the purpose of the disclosure should be limited to the general categories of treatment, payment, and health care operations. Any greater specificity would likely be technologically and operationally infeasible, as well as costly to the covered entity. To the extent that accountings for disclosures of PHI for treatment, payment, and health care operations purposes have any value to the individual, a general description of the purpose of the disclosure should be sufficient for the accounting to be of value to the requesting individual.

With respect to disclosures of PHI for health care operations purposes, as discussed previously, covered entities are currently required to provide in their notices of privacy practices a description, including at least one example, of the types of permitted uses and disclosures of PHI.[11] Individuals are, therefore, aware that covered entities are permitted to make disclosures of PHI for health care operations purposes, and have at least a general idea of the nature of those disclosures. However, the definition of "health care operations" covers a number of specific topics that notices of privacy practices are not currently required to cover in detail.[12] For that reason, individuals would likely benefit from more specific explanations of the health care operations for which PHI can be disclosed than is typically provided in notices of privacy practices. However, such additional information could be provided through amended notices of privacy practices in the form of a general description as to what constitutes a "health care operation" under the HIPAA Privacy Rule. If there is a concern that individuals should be made more aware of disclosures of their PHI relating to health care operations, this would be a far less burdensome way in which to accomplish this goal. Given the choice between providing an accounting of disclosures relating to health care operations and amending notices of privacy practices to include a better description of what constitutes a "health care operation," an amended notice of privacy practices would also be of greater benefit to the individual with respect to the information that is typically provided in notices of privacy practices.

As such, while we do not believe that an LIS is an EHR, rather than imposing an accounting of disclosures requirement, we would encourage OCR to consider this less burdensome alternative. We encourage OCR to replace this requirement with a requirement that covered entities amend their notices of privacy practices in such a way that would allow individuals to better understand the activities that are considered to be "health care operations," as defined under the HIPAA Privacy Rule.

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11 45 CFR § 164.520(b).

12 The definition of "health care operations" includes a number of covered entity activities, such as conducting quality assessment and improvement activities, conducting or arranging for medical reviews, and business planning and development. 45 CFR § 164.501.

6. For existing electronic health record systems:

(a) Is the system able to distinguish between "uses" and "disclosures" as those terms are defined under the HIPAA Privacy Rule? Note that the term "disclosure" includes the sharing of information between a hospital and physicians who are on the hospital's medical staff but who are not members of its workforce.

As we have discussed, ACLA does not consider an LIS to be an "EHR" as defined under the HITECH Act. However, it is the experience or our member laboratories that there is variability with respect to whether an LIS is able to distinguish between "uses" and "disclosures" as defined in the HIPAA Privacy Rule. To the extent that the LIS is able to make such a distinction, it does so by identifying whether the recipient is within or outside the laboratory.

(b) If the system is limited to only recording access to information without regard to whether it is a use or disclosure, such as certain audit logs, what information is recorded? How long is such information retained? What would be the burden to retain the information for three years?

As we have discussed, ACLA does not consider an LIS to be an "EHR" as defined under the HITECH Act. However, it is the experience of our member laboratories that if the LIS only records access to information without regard to whether it is a "use" or "disclosure" (*e.g.*, an audit log) it would be extremely burdensome to comply with the new accounting of disclosures requirement. For example, one of the issues with an accounting from an LIS is that the laboratory would have to manually review the laboratory records as it would not be customary for a laboratory to store test result information and disclosures online for the period of time for which an accounting would be requested. As such, it would be particularly difficult to comply with the new accounting of disclosures requirement, particularly if the LIS is not capable of distinguishing between "uses" and "disclosures."

The information that is recorded and the duration of time for which the information is retained would vary by the capabilities of the individual LIS.

(c) If the system is able to distinguish between uses and disclosures of information, what data elements are automatically collected by the system for disclosures (i.e., collected without requiring any additional manual input by the person making the disclosure)? What information, if any, is manually entered by the person making the disclosure?

As we have discussed, ACLA does not consider an LIS to be an "EHR" as defined under the HITECH Act. However, it is the experience of our member laboratories that some LIS systems may be able to automatically capture the date and time of a disclosure, the User ID of the individual making the disclosure, the record disclosed, and the recipient of the disclosure. Manual entries are typically not made by the person making the disclosure unless the disclosure is made under unusual circumstances that might prompt such an entry.

When an accounting of disclosures is requested, the response is manually generated based on data captured by the LIS and such additional manual research as may be necessary to prepare the response. Given the variability of requests from individuals that will result from the new accounting of disclosures requirement, the extent to which laboratories will need to manually generate such reports will increase significantly. That is, in response to each individual's request the laboratory would need to manually generate an accounting for any disclosures relating to treatment, payment, and health care operations for the three years prior to such request. This will not only be extremely administratively burdensome for laboratories, but financially burdensome as well.

(d) If the system is able to distinguish between uses and disclosures of information, does it record a description of disclosures in a standardized manner (for example, does the system offer or require a user to select from a limited list of types of disclosures)? If yes, is such a feature being utilized and what are its benefits and drawbacks?

As we have discussed, ACLA does not consider an LIS to be an "EHR" as defined under the HITECH Act. However, it is the experience of our member laboratories that most LIS systems do not record a description of disclosures in a standardized manner. Descriptions of disclosures would have to be entered manually in designated fields if they were to be captured at the time of the disclosure. To the extent that descriptions of disclosures are not manually entered at the time of the disclosure, manual research would be required to determine the purpose of each disclosure upon a request for an accounting.

(e) Is there a single, centralized electronic health record system? Or is it a decentralized system (e.g., different departments maintain different electronic health record systems and an accounting of disclosures for treatment, payment, and health care operations would need to be tracked for each system)?

As we have discussed, ACLA does not consider an LIS to be an "EHR" as defined under the HITECH Act. However, it is the experience of our member laboratories that some laboratories may have a single LIS, but many have a decentralized LIS for which separate accountings of disclosures would need to be tracked for each system.

(f) Does the system automatically generate an accounting for disclosures under the current HIPAA Privacy Rule (i.e., does the system account for disclosures other than to carry out treatment, payment, and health care operations)?

As we have discussed, ACLA does not consider an LIS to be an "EHR" as defined under the HITECH Act. However, it is the experience of our member laboratories that an LIS cannot automatically generate an accounting of disclosures under the current HIPAA Privacy Rule. As mentioned in response to (c) of this question, a response to a request for an accounting of disclosures is generated manually.

i. If yes, what would be the additional burden to also account for disclosures to carry out treatment, payment, and health care operations? Would there be additional

hardware requirements (e.g., to store such accounting information)? Would such an accounting feature impact system performance?

N/A

ii. If not, is there a different automated system for accounting for disclosures, and does it interface with the electronic health record system?

As we have discussed, ACLA does not consider an LIS to be an "EHR" as defined under the HITECH Act. However, it is the experience of our member laboratories that there is no other automated system for accounting of disclosures.

7. The HITECH Act provides that a covered entity that has acquired an electronic health record after January 1, 2009 must comply with the new accounting requirement beginning January 1, 2011 (or anytime after that date when it acquires an electronic health record), unless we extend this compliance deadline to no later than 2013. Will covered entities be able to begin accounting for disclosures through an electronic health record to carry out treatment, payment, and health care operations by January 1, 2011? If not, how much time would it take vendors of electronic health record systems to design and implement such a feature? Once such a feature is available, how much time would it take for a covered entity to install an updated electronic health record system with this feature?

Again, as we have discussed, ACLA does not consider an LIS to be an "EHR" as defined under the HITECH Act. However, in response to this question, we urge OCR to extend the deadline for compliance with the new accounting of disclosures requirement to the extent permitted under the HITECH Act. If an LIS constitutes an "EHR" as defined in the HITECH Act, and the LIS was acquired by the laboratory after January 1, 2009 and currently lacks the capability to account for disclosures automatically, it is highly unlikely that a laboratory with such an LIS would be capable of beginning to account for disclosures for treatment, payment, and health care operations by January 1, 2011. We believe it would take vendors of LIS systems at least two years to design and implement such a feature, and that it would take a laboratory at least a year to install an updated LIS system with this feature. Therefore, we urge OCR to delay the compliance date for covered entities that acquire an EHR after January 1, 2009 from January 1, 2011 to December 31, 2013.

Additionally, the HITECH Act also provides that a covered entity that has acquired an electronic health record as of January 1, 2009 must begin accounting for disclosures for treatment, payment, and health care operations on January 1, 2014, unless HHS extends the deadline to no later than 2016. Again, if an LIS constitutes an "EHR" as defined in the HITECH Act, it will be more difficult to convert older LIS systems than newer LIS systems to comply with the new accounting for disclosures requirement, and Congress has recognized this distinction by granting OCR the discretion to delay the compliance date for older systems even later than it can delay the compliance date for newer systems. Moreover, it may be technically impossible to covert some older LIS systems to comply with the new requirement, which will necessitate an entirely new, compliant LIS and impose a significant increase in time and expense for the laboratory to implement the new system. We, therefore, urge OCR to delay the compliance date for covered

entities that acquired an EHR on or before January 1, 2009 from January 1, 2014 to December 31, 2016.

8. ***What is the feasibility of an electronic health record module that is exclusively dedicated to accounting for disclosures (both disclosures that must be tracked for the purpose of accounting under the current HIPAA Privacy Rule and disclosures to carry out treatment, payment, and health care operations)? Would such a module work with covered entities that maintain decentralized electronic health record systems?***

The feasibility of an EHR module that is exclusively dedicated to accounting for disclosures is questionable, at least in the context of LIS systems. Most LIS systems are extremely complex systems that are either entirely, or partially, internally developed. As a result, each one is unique, and any EHR module designed exclusively for the purpose of accounting for disclosures would likely have to be modified and reprogrammed to accommodate the particular features of any given LIS.

9. ***Is there any other information that would be helpful to the Department regarding accounting for disclosures through an electronic health record to carry out treatment, payment, and health care operations?***

As we have reiterated throughout our response, ACLA does not consider an LIS to be an "EHR" as defined under the HITECH Act and, therefore, clinical laboratories that use and maintain an LIS should not be required to account for disclosures to carry out treatment, payment, and health care operations, which is a requirement specific to EHRs. However, we feel it is important to note here the significant burden that would be placed on clinical laboratories should an LIS be considered an EHR. That is, the volume of disclosures of PHI by clinical laboratories for treatment, payment, and health care operations is staggering. For example, our ACLA member laboratories perform well over 1 billion tests each year. Each of these tests produces a test result, which becomes a disclosure of PHI to the ordering provider for treatment purposes. Each of these tests also produces a request for payment, which typically involves a disclosure of PHI for payment purposes. Moreover, other covered entities are increasingly demanding test results or related PHI for their own legitimate health care operations purposes. As a result, each patient encounter generates multiple disclosures of PHI for treatment, payment, and health care operations purposes on a daily basis.

For ACLA member laboratories, that translates into multiple billions of disclosures of PHI every year that will be subject to an accounting if their LIS systems are determined to be "EHRs" as defined in the HITECH Act. Due to the sheer volume of transactions in which clinical laboratories are engaged, the complexity of their systems, and the ongoing efforts to achieve other major compliance initiatives mandated by the Department of Health and Human Services (HHS) during the same timeframe (*e.g.*, implementation of ICD-10), the burden of complying with this requirement for clinical laboratories would be severe. Laboratories would have to buy new hardware, reprogram existing system applications in all systems maintaining PHI, retrain tens of thousands of employees, and reorganize their business processes in providing laboratory services to individuals and their health care providers. In short, we do not believe Congress intended to apply

these requirements to indirect treatment providers, such as clinical laboratories, and we urge OCR to clarify that they are exempt from the requirement.

However, in the event that clinical laboratories are subject to the new requirement, we believe that the following recommendations could be adopted by OCR to minimize its impact. First, as we pointed out earlier in our response, OCR should use its discretion to delay the compliance dates to the latest dates permitted by the HITECH Act. Therefore, covered entities that acquire an EHR after January 1, 2009 should have until December 31, 2013 to comply with the new requirement and covered entities that acquired an EHR on or before January 1, 2009 should have until December 31, 2016. Second, the HIPAA Privacy Rule should be amended to permit covered entities to charge a reasonable fee for *each* request for an accounting of disclosures of an individual's PHI. The HIPAA Privacy Rule currently requires a covered entity to provide the first accounting to an individual in any 12-month period without charge, and only permits a reasonable, cost-based fee for each subsequent request for an accounting by the same individual within the 12-month period, provided that certain requirements are satisfied.[13] As amended, a covered entity could charge an individual a reasonable fee *each* time a request is made to account for the inherent costs attributed to complying with the individual's request. Third, OCR should consider replacing the accounting of disclosures requirement with a requirement that covered entities amend their notices of privacy practices, which would provide individuals with greater detail with respect to the types of permitted disclosures made by covered entities. The alternative of providing amended notices of privacy practices would inform individuals as to the types of disclosures that are made on their behalf without unduly burdening the covered entity.

CONCLUSION

In closing, we appreciate the opportunity to respond to the Request for Information. If you have any questions or need any further information in connection with the agency's forthcoming regulations on accounting of disclosures for treatment, payment, and health care operations, please do not hesitate to contact us.

Sincerely,

Alan Mertz
President

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13 C.F.R. § 164.528(c)(2).

MGMA Center for Research
American College of Medical Practice Executives
Medical Group Management Association

August 1, 2011

Georgina C. Verdugo
Director
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RIN 0991–AB62

Re: HIPAA Privacy Rule Accounting of Disclosures Under the Health Information Technology for Economic and Clinical Health Act

Dear Ms. Verdugo:

The Medical Group Management Association (MGMA) is pleased to submit the following comments in response to the Notice of Proposed Rulemaking (NPRM) entitled, "HIPAA Privacy Rule Accounting of Disclosures Under the Health Information Technology for Economic and Clinical Health (HITECH) Act," as published in the May 31, 2011 *Federal Register*.

MGMA is the premier membership association for professional administrators and leaders of medical group practices. Since 1926, MGMA has delivered networking, professional education and resources, and political advocacy for medical practice management. Today, MGMA's 21,500 members lead 13,700 organizations nationwide in which some 275,000 physicians provide more than 40 percent of the healthcare services delivered in the United States.

MGMA strongly recommends that the Department of Health and Human Services (HHS) Office for Civil Rights (OCR) withdraw the current proposed rule and significantly reevaluate its approach to meeting the HITECH accounting of disclosures provision. In addition, we urge the agency to fully engage impacted stakeholders, including medical groups, patient advocates, electronic health record (EHR) software vendors, and other critical stakeholders, in a formal outreach process prior to release of the next iteration of the regulation. The goal of this outreach should be to ensure that the regulation appropriately balances the patient's interest in protected health information (PHI) disclosures in a manner that leverages readily available EHR technology while not overly burdening covered entities and their business associates.

To better respond to this NPRM, MGMA conducted a Legislative and Executive Advocacy Response Network (LEARN) online questionnaire for MGMA members on July 6-22, 2011. The results of this research questionnaire are provided below.

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The research was completed by more than 1,400 participants representing groups where approximately 30,000 physicians practice. Note that only those research participants who indicated that their organization currently utilized an EHR were asked to respond to questions directly related to EHR capabilities.

Summary of Key Recommendation and Concerns

MGMA recommends withdrawing the rule. We also recommend OCR convene a formal process of outreach to physician practices and other critical stakeholders in an effort to develop a consensus-based solution to the HITECH requirements. We believe the rule must be withdrawn because of the following fundamental concerns:

- **Failure to adhere to the statutory requirements** – HITECH is clear that the regulation must balance the needs of the individual to receive information about disclosures of their PHI with the administrative burden on the provider. The statute also stipulates that this regulation only applies to disclosures made through an EHR. The proposed rule fails to adhere to either of these statutory requirements.

- **Significant administrative burden on physician practices** - The new access report right proposed by OCR will impose significant burdens on physician practices. There will be a substantial cost to collect and store information related to every time a patient's PHI is accessed, including for treatment, payment and healthcare operations (TPO), for up to three years and then provide a report of this information to the individual. This administrative burden is exacerbated in many practices because clinical and administrative data, including payment and healthcare operations information, are commonly collected and stored in separate computer systems. This proposed rule also conflicts with the President's Jan. 18, 2011 Executive Order aimed at reducing administrative burden.

- **Access report functionality requirement –** The proposed rule requires functionality that is not currently available or widely used in the EHR environment. Further, information systems other than EHRs that store or transmit health information typically do not have access report functionality.

- **Low volume of current patient requests for accounting reports** – Requiring physician practices to provide the patient with information at the level of detail proposed in the regulation is unreasonable because very few patients have requested an accounting of disclosures since the HIPAA Privacy Rule went into effect in 2003.

- **Erroneous reliance on HIPAA Security Rule requirements** – In creating the new access report right for individuals, the proposed rule relies heavily on its interpretation that the HIPAA Security Rule currently requires this action and that practices already perform these access tracking tasks as part of their compliance efforts. We assert that OCR's interpretation of the Security Rule's requirements is incorrect and that practices typically do not capture and store access data, nor are they required to do so under the Security Rule.

- **Discouragement for physician practice adoption of EHRs** – The burden and cost of providing the proposed access report will be such a significant challenge for physician practices that the requirement acts as a deterrent to adoption of EHR technology. HITECH also includes significant financial incentives through the meaningful use program to assist practices in adopting this important new technology to both enhance clinical performance and improve efficiency. It would be unfortunate if OCR promulgates a regulation whose result was to undermine the efforts of this landmark incentive program.

- **Challenging time for new healthcare costs** – We encourage OCR to develop regulations that recognize that physician practices are facing a difficult financial environment due to a weak economy, the looming threat of substantial cuts in Medicare reimbursement, and compliance with the myriad of new HIPAA, HITECH and Affordable Care Act requirements.

- **Pilot test –** Prior to finalizing a rule on this issue, we recommend that OCR pilot test any report requirement. This pilot could assess the value to the individual of the information contained in the report, the format and structure of the report, the burden on providers of producing the report, and the technical ability of the EHR to meet the regulatory requirements. Through this process, OCR could truly balance the interests of the patient and the burden on the provider, as required by HITECH.

- **Alternative approaches** – Rather than create a new right that is both unnecessary for patients and impractical for practices to provide, we encourage OCR to examine alternative approaches to addressing patient privacy interests. These alternative approaches could include augmenting the ability of practices to investigate potential inappropriate disclosures, improved covered entity training, enhanced privacy notices, and patient education regarding their ability to restrict access.

Issue: Statutorily required balancing test and the administrative burden on providers

Discussion: Under the HIPAA Privacy Rule, each individual has the right to receive an accounting of disclosures of PHI made by a covered entity in the six years prior to the date of the individual's request. Prior to passage of HITECH, that right did not extend to several types of disclosures, including disclosures for treatment, payment, and healthcare operations (TPO). The primary reasons for excluding disclosures for TPO were that patients "understand that information about them will be used and disclosed in order to provide treatment or obtain payment;" such an accounting "could be extremely long and detailed… far too detailed to adequately inform the individual;" and would "place a tremendous burden on the covered entities." 64 Fed. Reg. 59,918, 59,985 (Nov. 3, 1999).

HITECH changes the accounting of disclosures requirement to include even disclosures for TPO. Under HITECH, if a covered entity, such as a physician practice, utilizes an EHR, the organization will be required to account for TPO disclosures. Upon receiving a request for such a disclosure, the physician practice will be required to provide individuals with an accounting of disclosures of PHI which occurred within the three years prior to the date of the request.

While HITECH requires the Secretary of the HHS to adopt regulations that take into consideration the individual's interest in knowing how PHI is used and disclosed, the legislation also directs the Secretary to determine the administrative burdens to covered entities in providing the accounting. HITECH states that "[s]uch regulations shall only require such information to be collected through an electronic health record in a manner that takes into account the interests of the individual in learning the circumstances under which their protected health information is being disclosed and takes into account the administrative burden of accounting for such disclosures." HITECH Section 13405(c)(2).

As Table 1 indicates, participants in the MGMA study overwhelmingly characterized the proposed rule as burdensome and unnecessary. Over 90 percent of respondents stated it would be "very" or "extremely" burdensome to produce a report that meets all of the reporting requirements laid out in the rule. Additionally, over 90 percent stated obtaining such a report from all business associates would be "very" or "extremely" burdensome.

Table 1

The government is proposing to require medical practices, upon a patient's request, to produce a report that meets the following conditions: a. lists the names of staff inside the practice who accessed PHI b. states when the PHI was accessed c. describes the purpose of the access d. itemizes all access events within the three year time period prior to the patient request e. must be completed within 30 days of the patient's request f. patients entitled to one free report per year. How burdensome would this be for your practice?								
Answer Options	**Not at all burdensome**	**Not very burdensome**	**Somewhat burdensome**	**Very burdensome**	**Extremely burdensome**	**Not applicable or do not know**	**Rating Av.**	**Response Count**
How burdensome will it be for your practice to produce these reports?	4	22	78	209	986	21	4.66	1320
Comments?								248
answered question								**1320**
skipped question								**173**

Providing an accounting of disclosures that includes payment and healthcare operations will be extremely onerous for physician practices. Despite HITECH's linking this new requirement directly to the increased adoption of EHRs by physician practices, payment and healthcare operations-related information (including claims and quality data and other information submitted to billing services, clearinghouses, health plans, or other authorized entities) typically is transmitted and stored through the organization's practice management system (PMS) software, not the EHR. In many physician practices, these systems are separated by function and, in some organizations, location. Compiling records that utilize administrative data over the required three-year span will be very difficult and time consuming.

Issue: Balancing test and patient requests for accounting reports-current environment

Discussion: To gauge the current need for such reports among the Medicare beneficiary community, MGMA asked respondents how often patients request this type of PHI disclosure accounting report. As shown in Table 2, 65.1 percent responded they received "0 or 1" request per FTE physician in the last 12 months. Only 5.9 percent reported that their physicians were receiving 10 or more requests for an accounting report per year.

Table 2

Approximately how many requests for PHI disclosure accounting reports has your practice received from patients in the past 12 months on a per FTE physician basis?		
Answer Options	**Response Percent**	**Response Count**
0 per FTE physician per year	55.3%	730
1 per FTE physician per year	9.5%	126
2 per FTE physician per year	3.5%	46
3 per FTE physician per year	1.5%	20
4 per FTE physician per year	0.9%	12
5 per FTE physician per year	0.8%	11
6 per FTE physician per year	0.6%	8
7 per FTE physician per year	0.5%	6
8 per FTE physician per year	0.5%	6
9 per FTE physician per year	0.1%	1
10 or more per FTE physician per year	5.9%	78
I do not know.	20.9%	276
answered question		**1320**
skipped question		**173**

Given the low number of requests, it is difficult to understand what patient privacy interest would be served by requiring a complicated new right to an access report. In the proposed rule, the agency acknowledges that few patients ever exercise their current right to request an accounting of disclosures report:

> "To date, we understand there have been relatively few requests for accountings of disclosures. While the availability of access reports may lead to an increased number of requests, we would continue to expect that only a small minority of individuals would exercise this right." 76 Fed. Reg. 31426, 31439 (May 31, 2011).

We concur with the agency's assessment that this new patient right will only be exercised by a very small number of individuals, a fact that statement must be evaluated as part of the statutorily required balancing test.

Issue: The president's Executive Order on burdensome regulations

Discussion: This regulation as proposed runs against President Obama's January 2011 Executive Order targeted at reform of the regulatory process. In section 1 of that order, the president states that the regulation,

> "…must identify and use the best, most innovative, and least burdensome tools for achieving regulatory ends. It must take into account benefits and costs, both quantitative and qualitative. It must ensure that regulations are accessible, consistent, written in plain

> language, and easy to understand. It must measure, and seek to improve, the actual results of regulatory requirements."

Executive Order No. 13563, 76 Fed. Reg. 3821 (Jan. 21, 2011). In its proposed rule, OCR has clearly not met this standard set by the president.

Issue: Compliance deadline

Discussion: The proposed rule requires physicians and their business associates to produce an access report upon request beginning with requests made by patients on or after Jan. 1, 2013, for any electronic designated record set systems that were acquired after Jan. 1, 2009. In addition, the rule requires physicians and their business associates to produce an access report upon request beginning with requests made by patients on or after Jan. 1, 2014, for electronic designated record set systems that were acquired on or before Jan. 1, 2009. While these staggered compliance dates mirror those included in the HITECH statute, the HITECH statute was limited to disclosures through EHRs. The proposed rule's expansion to all accesses through all electronic designated record set systems means that within a practice, different compliance dates may apply. For example, if an electronic billing system was acquired before Jan. 1, 2009 and an EHR was acquired after Jan. 1, 2009, a practice receiving a patient request on June 1, 2013 would be required to produce an access report from the billing system but not from the EHR. This further adds to the complexity and the burden of the agency's proposal.

In addition, in the preamble to the proposed rule, OCR assumes that because all covered entities should have been creating and retaining access logs in order to comply with the HIPAA security rule audit review requirements, a covered entity would be expected to have the capability to comply with a full three years of access reports, if requested, as of the first day of compliance. As we know this assumption is incorrect, we believe that this necessitates a significant modification in the proposed compliance dates.

It is clear that current electronic designated record sets, including EHRs, do not have the capability of producing the type of reports envisioned by OCR. HITECH permits the Secretary significant discretion to extend the compliance enforcement deadline to Dec. 31, 2016. Regardless of the type of report required in the final rule, we strongly recommend that the agency identify a compliance date that provides for sufficient time for vendors to produce the requisite software, for practices to acquire that software, and for OCR to conduct pilot tests to ensure that the functionality is widely available to permit the development of any report required by regulation.

Further, sections 1104 and 10109 of HITECH outline a broad set of administrative simplification requirements. In concert, implementation of these provisions will have a profound effect on the healthcare industry and will lead to significant streamlining of administrative processes and industry-wide cost savings. We strongly encourage HHS to focus its attention on expediting the development and implementation of these provisions of HITECH prior to imposing new costs on practices.

Issue: Designated record sets

Discussion: In developing its approach to expanding HIPAA Privacy accounting of disclosures, lawmakers were very clear in delineating the scope of this provision. HITECH expressly states that the new requirements apply when "a covered entity uses or maintains an electronic health record." Only then must "disclosures through an electronic health record" be included in an accounting. HITECH Section 13405(c).

Later the statute states "Such regulations shall only require such information to be collected through an electronic health record…" HITECH Section 13405(c)(2). Under "effective date" the statute is clear:

> "In the case of a covered entity insofar as it acquired an electronic health record as of January 1, 2009, paragraph (10 shall apply to disclosures, with respect to protected health information, made by the covered entity from such a record on and after January 1, 2014. '(B)' Others-In the case of a covered entity insofar as it acquires an electronic health record after January 1, 2009, paragraph (1) shall apply to disclosures, with respect to protected health information, made by the covered entity from such record on and after the later of the following: (i) January 1, 2011; or (ii) the date that it acquires an electronic health record." HITECH Section 13405(c)(4).

The proposed rule acknowledges that OCR has expanded this statutory limitation,

> "While the HITECH Act provision only addresses 'disclosures' and refers to an EHR, we are exercising our discretion under the more general HIPAA statute to expand this right to uses of information (*e.g.,* electronic access by members of a covered entity's or business associate's workforce) and to all electronic protected health information about an individual in any designated record set." 76 Fed. Reg. at 31436

Further, the proposed rule states,

> "We recognize that our proposal extends the right to an access report to all covered entities and business associates that maintain electronic designated record set information, including covered entities and business associates that do not have systems that could be categorized as EHRs. We believe that this is 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." 76 Fed. Reg. at 31437.

Expanding the scope beyond that of electronic PHI maintained and transmitted via an EHR clearly goes well beyond the scope of the statute. Not only is this expansion statutorily unjustified, but by doing so, the agency has perhaps unwittingly created an enormous administrative burden for physician practices and other entities now covered under this rule, despite not having an EHR .

Under the HIPAA Privacy Rule's definition of a designated record set found at 45 C.F.R. § 164.501, the term includes medical and billing records, as well as enrollment, payment, claims adjudication, and case/medical management record systems maintained by health plans. It also includes a catch-all provision applying the term "designated record set" to any records used to make decisions about individuals. In short, the proposed rule expands the scope of this requirement from a single EHR to any number of systems.

The majority of physician practices store their clinical data in an EHR and their administrative data (including payment information and data that would qualify as "healthcare operations") in their PMS. Much of the information collected above would be contained and/or transmitted from a practice using an electronic system other than that of an EHR. For example, the majority of physician practices utilize PMS software in order to generate the electronic transactions required as part of the claims adjudication and payment cycle. These transactions include but are not limited to the numerous transactions that are part of HIPAA administrative simplification, such as insurance eligibility verification request and response (270/271), claim submission (837), claim status inquiry (276), referral authorization (278), and remittance and advice (835), with others to follow in the next few years.

Satisfying an access report request for TPO is not a simple keystroke in most practices. MGMA members have made it clear that completing these types of reports requires a substantial amount of manual collection from multiple data sources. As seen in Table 3, practices report that that vast majority of their claims submission, for example, goes through their PMS not their EHR. When asked how their practices generate and submit patient billing and insurance claims data to payers and/or clearinghouses, as Table 3 indicates, 85.3 percent of our LEARN study respondents said "by using the practice's billing (practice management) system". Less than 10 percent responded "by using the practice's EHR."

Table 3

How does your practice generate and submit patient billing and insurance claim data to payers and/or clearinghouses?		
Answer Options	**Response Percent**	**Response Count**
By using the practice's billing (practice management) system	85.3%	1143
By using the practice's EHR	9.9%	132
Other	3.7%	49
Do not know or not applicable.	1.2%	16
Please describe "Other".		50
answered question		**1340**
skipped question		**153**

PMS software does not typically capture the type of data required to be included in the proposed access report, and it is highly unlikely that this type of software could ever be retrofitted to perform this task. Further, PMS software is not currently certified by any government or non-government accreditation organization. PMS software vendors are not covered entities under HIPAA and thus could not be mandated to produce this functionality.

We assert that there could also be an unintended consequence of requiring practices to track and disclose information relating to the claims payment cycle. Practices could revise their policies and require patients to pay in full at the time of service and submit claims on their own to their health plan, much like what is currently done for other health activities such as dentistry and cosmetic procedures. With practices submitting claims to health plans as a courtesy for their patients, and at the request of their patients, there should be no requirement to account for these types of disclosures.

Issue: Producing reports for business associates

Congress built flexibility into the HITECH statute by allowing a covered entity that receives a request for an accounting to either provide the patient with an accounting for itself and its business associates or to provide an accounting of disclosures made by the covered entity and provide the patients with a list of business associates. In its proposal, OCR eliminated that flexibility, instead proposing to require a covered entity to provide access reports for itself and its covered entities. In this aspect of the rule, OCR proposes to impose yet another burden on healthcare providers trying to comply with an increasing number of government mandates.

As discussed above, the proposed rule is extremely burdensome on covered entities. Table 4 shows the response from MGMA's LEARN study participants indicating that almost 91percent of respondents said providing access reports from all business associates would be "very burdensome" or "extremely burdensome." A covered entity could have any number of business associates. It would be unreasonable to require covered entities - in the business of providing healthcare - to serve as coordinator for all its business associates and to be able to do so within the 30-day timeframe. In any final rule on this issue, we urge OCR to maintain the flexibility built into this requirement by Congress and allow covered entities to provide patients with a list of business associates from which they will be able to request additional information as they see fit.

Table 4

How burdensome would it be to obtain from all your business associates a report of each time your patient's PHI was accessed by any staff of the business associate for any purpose, for the previous three years?								
Answer Options	**Not at all burdensome**	**Not very burdensome**	**Somewhat burdensome**	**Very burdensome**	**Extremely burdensome**	**Not applicable or do not know**	**Rating Av**	**Response Count**
Business associate burdensome rating	6	14	58	174	1025	41	4.72	1318
Comments?								129
answered question								**1318**
skipped question								**175**

Issue: The rule's proposed access report format and contents

Discussion: OCR proposes that the access report provide the following information to the patient upon request:
a.) The date of access
b.) The time of access
c.) The name of the natural person, if available, otherwise the name of the entity accessing the electronic designated record set of information
d.) A description of what information was accessed, if available
e.) A description of the action by the user, if available (e.g., "create," "modify," "access," or "delete")

The rule provides a suggested template for this information:

Date	Time	Name	Action
10/10/2011	02:30 p.m.	John, Andrew	Viewed

The report to the patient should not include specific names of individuals within the practice (or any other business associate or covered entity). There are important security concerns surrounding the release of the name of the individual who accessed the patient record or performed other appropriate tasks within the organization. Should the regulation require the disclosure of specific names, we are concerned that those individuals may become targets and subject to unwarranted threats, harassment or even potential physical harm, even when they have a legitimate need to access PHI to perform their clinical or administrative tasks.

This could also have the effect of discouraging legitimate access of medical records (for example, psychiatric notes) for fear of patient retaliation. Physicians should have the right to respond to a patient's request by providing the patient with a report that includes the date of the creation of the patient's record in the physician's EHR system and a total count of actions taken on the patient's record such as the number of EHR record creation(s), modification(s), viewing(s), and printing(s) within a specified period of time. In making any disclosures to patients, OCR should permit covered entities the latitude and discretion to limit the specificity of disclosures. This is particularly important in those cases where the disclosures are inadvertent (though do not rise to the level requiring a breach of PHI notification).

The rule also proposes that the report include the time of the access. As the rule also proposes that this report include access tracked for the previous three years, we would contend that the time of the access is superfluous soon after the access occurs. Thus, there is virtually no value knowing that the access occurred at 3:15 p.m. on a date three years ago.

It is important to note that there are no readily known parallel requirements to disclose the names of specific persons who access an individual's personal data in other industries that handle sensitive information. The financial industry, for example, does not provide this information—for the same security reasons we expressed earlier. An example of a related type of information disclosure would be the financial credit report provided to consumers upon their request. While these credit reports include the name of the entity accessing the individual's credit history, the report does not include the specific names of the employees at that entity that requested or accessed the financial information.

Issue: Thirty-day requirement to produce access report

Discussion: OCR has proposed that practices would have 30 days to provide the access report to a patient, including the logs of business associates that create, receive, maintain, or transmit an electronic designated record set of information. CMS also proposes that this time can be extended by 30 days when necessary, as long as the patient receives a written statement including the reason for the delay and the date when they will receive the report. The practice would only be permitted one extension of time per request.

This 30-day requirement is unreasonable on a number of levels. First, smaller practices with limited resources may experience difficulty in compiling the access report within this brief time period. Second, larger, more complex organizations will face the challenging task of compiling access data obtained from multiple - and in cases of large integrated health systems, literally hundreds of - systems. Third, a challenge for all practices will be to collect access data from previous years that had been stored in separate systems, perhaps at offsite locations. Fourth, coordinating the capture of access data from business associates (again, potentially hundreds of business associates in the case of large integrated health systems) will be an extremely difficult and time consuming task. Finally, it will be extremely challenging and time consuming to compile and combine this information, from potential dozens or even hundreds of separate systems, and creating a human readable report.

Prior to identifying a specific and arbitrary time period for covered entities to produce this type of report, we urge the agency to work directly with providers and others to develop a more reasonable time period and build in considerable flexibility to allow for difficulties in producing this type of data.

Issue: Access report fees

Discussion: OCR proposes that the patient not be charged for receiving the first access report in any 12 month period, but practices are permitted to charge a reasonable, cost-based amount for each additional access report that is requested within the 12 month period. This would include the reasonable costs of providing access reports of business associates as well. We anticipate that production of any type of access or disclosures report will require the practice to utilize consider resources, including the labor to compile and publish the reports, supplies, paper and copying expenses. As the current HIPAA Privacy Rule permits a practice to charge a reasonable cost-based fee for providing patients a copy of their health information, we feel that OCR should be consistent and permit the practice to charge a reasonable, cost-based fee for production of any access or disclosure report.

Issue: Three-year retention timeframe

Discussion: Under the proposed rule, practices would be required to retain the documentation necessary to produce an accounting of disclosures for three years and must retain a copy of any accounting that was provided to an individual for six years from the date the accounting was provided. Practices would also be required to retain documentation of the designee responsible for handling accounting requests for six years from the last date the designation was in effect. We assert that this length of retention would constitute a significant administrative burden for practices. Response from physicians and other healthcare providers suggests that there are extremely few requests for these types of disclosure reports and when there are requests, the patients overwhelmingly are seeking information on disclosures that occurred in the past year. We believe that the requirement for retaining documentation necessary to generate an accounting of disclosures report should be reduced to 12 months. Further, the amount of

time a practice should be required to retain the accounting of disclosures report should be limited to 12 months.

Issue: Reliance of existing Security Rule requirements

Discussion: In setting out the requirement for an access report, the agency asserts that such information "is information that a covered entity is already required to collect under the Security Rule." 76 Fed. Reg. at 31,429. In making this assertion, OCR/HHS references two specific provisions of the Security Rule, the administrative safeguard requirement to "[i]mplement procedures to regularly review records of information system activity, such as audit logs, access reports, and security incident tracking reports" and the technical safeguard to "implement hardware, software, and/or procedural mechanisms that record and examine activity in information systems that contain or use electronic protected health information." See 45 C.F.R. §§ 164.308(a)(1)(ii)(D) and 164.312(b). The agency does not, however, reference important language, also found within the Security Rule, entitled "Flexibility of Approach." The language of 45 C.F.R. § 306(b) states that,

> "[c] overed entities may use any security measures that allow the covered entity to reasonably and appropriately implement the standards and implementation specifications, taking into account several factors, including the covered entity's technical infrastructure, hardware, and software security capabilities and the costs of the security measures."

HHS continues to emphasize flexibility of approach for both the administrative and technical safeguard cited by OCR in the proposed rule in its HIPAA Security Series. Notably, in addressing the administrative safeguard requirement, HHS states in its HIPAA Security Series, Vol. 2, "Security Standards: Administrative Safeguards": "Information system activity review procedures may be different for each covered entity. The procedure should be customized to meet the covered entity's risk management strategy and *take into account the capabilities of all information systems with [electronic] PHI*." (emphasis added)

Moreover, in addressing the technical safeguard requirement the HIPAA Security Series, Vol. 4, "Security Standards: Technical Safeguards" the agency states:

> "Most information systems provide some level of audit controls with a reporting method, such as audit reports. These controls are useful for recording and examining information system activity, especially when determining if a security violation occurred. It is important to point out that the Security Rule does not identify data that must be gathered by the audit controls or how often the audit reports should be reviewed*. A covered entity must consider its risk analysis and organizational factors, such as current technical infrastructure, hardware and software security capabilities, to determine reasonable and appropriate audit controls for information systems that contain or use [electronic] PHI*." (emphasis added)

In short, HHS has consistently communicated to group practices and other covered entities that the requirements of the Security Rule should be scaled to the size and capabilities of each practice. That approach is inconsistent with the proposed rule, which erroneously assumes that all covered entities can easily produce an access report.

Accessing and reporting audit log data in practice systems is not currently a fully automated process, and, in many systems, cannot be easily done. Systems where electronic designated record sets are maintained may have very different capabilities, different levels of data, different technical platforms, different ways of identifying patients, different ways of tracking and indexing audit data, and different ways of producing output. Aggregating access log data across multiple internal systems would be administratively and financially burdensome. These systems would require significant development and reconfiguration in order to enable the capability to efficiently produce and compile the necessary information to consolidate and generate access reports. In some cases, we predict, the software vendor will either not have the capability to modify existing software to meet this requirement, or will not be able to offer the modification at a price that is affordable to the practice.

Issue: Disincentive for practice adoption of EHRs

Discussion: MGMA is a strong supporter of physician practices adopting health information technology to improve healthcare quality and efficiency and streamline wasteful administrative processes. We believe that the financial incentives included in HITECH through the Medicare and Medicaid programs will act as an important catalyst in facilitating the transition of large numbers of physician practices to this important technology. However, the burden and cost of providing an accounting for TPO disclosures and accesses may be such a significant impediment for physician practices that the requirement acts as a deterrent to adoption of this important technology.

The LEARN results suggest this rule would have a negative impact on physician practices implementation of EHRs. Nearly 60 percent of participants responded that, if finalized, the requirement to produce access reports would be a “strong” or “complete” disincentive for their practice to implement an EHR in the future (see Table 5).

Table 5

If the government moves forward with plans to require practices with EHRs to produce an accounting of disclosures and an access report for treatment, payment and healthcare operations for a three year period, how much of a disincentive would this be for your practice to implement an EHR in the future?								
Answer Options	**No disincentive**	**Slight disincentive**	**Moderate disincentive**	**Strong disincentive**	**Complete disincentive**	**I do not know or not applicable.**	**Rating Average**	**Response Count**
Short-run disincentive rating	157	75	169	370	198	371	3.39	1340
answered question								**1340**
skipped question								**153**

HITECH's financial incentives through the meaningful use program are meant to assist practices adopt important new technology to both enhance clinical performance and improve efficiency. It would be unfortunate if OCR promulgated a regulation whose result was to undermine the efforts of this landmark EHR incentive program.

Issue: Current patient rights under HIPAA; potential enhancement to current policies and procedures

Discussion: OCR should closely review how a combination of current and enhanced patient rights could achieve the goal of providing individuals with the ability to effectively control their health information, without imposing an undue burden on providers. Under the current HIPAA Privacy Rule, practices and other covered entities are required to monitor and audit accesses to PHI. In addition, should an improper use or disclosure of PHI be discovered, even if that disclosure was a result of an internal misuse by a member of the practice staff, the practice has an obligation to report such misuses to the individuals whose PHI is involved.

HIPAA also permits a patient to complain to a practice should the patient have a specific concern regarding how their PHI was handled. In addition, a patient with concerns about a particular practice staff may request that the practice restrict access to that patient's PHI. Therefore, existing requirements already provide mechanisms for patients to learn of and manage accesses by practice staff members when there is actual misuse or a concern of misuse.

Enhancements to this current approach could include augmenting the ability of practices to investigate potential inappropriate disclosures, improving covered entity training, and revising privacy notices and patient education regarding their ability to request that the covered entity restrict access to their health information.

Issue: Alternative approaches to addressing accounting of disclosures rulemaking

Discussion: Despite its intention to create a new privacy right for individuals, it is clear that the access report requirement is substantially flawed. We appreciated the agency's 2010 request for information (RFI), as it signaled that OCR was reaching out to industry prior to the development of a proposed rule. We were disappointed, however, that OCR did not include the concept of an access report in its list of RFI questions, nor the expansion of the requirements to electronic designated record sets. Had it done so, industry could have outlined the current technical capabilities of EHRs and the impact of the expansion to electronic designated record sets on practices and other covered entities, thus providing important feedback prior to the rule's development.

We recommend that the agency consider the following approaches, either singularly or in combination:

- Withdraw the current proposed rule.
- Once the current proposed rule comments are reviewed, issue a new RFI to solicit industry feedback.
- Convene with industry stakeholders to develop a consensus set of recommendations on how best to meet HITECH's balancing test. We recommend OCR request that the Workgroup for Electronic Data Interchange (WEDI) organize such a meeting. WEDI is named in HIPAA as an advisor to the HHS Secretary.
- Establish a negotiated rulemaking process to develop a consensus set of requirements that meet HITECH's balancing test.

Conclusion

In conclusion, MGMA is a strong supporter of patient access to and protection of their health information. We are concerned, however, that the current approach to meeting the accounting of disclosures provision in HITECH clearly runs counter to legislative intent and against the goal of decreasing healthcare costs through physician practices' adoption of EHRs. We urge that OCR withdraw this rule and work closely with impacted stakeholders to craft a regulation that meets the desire of patients for access to their health information while at the same time not overly burdening providers.

We thank you for the opportunity to provide comments on this important proposed rule and look forward to collaborating on this and other critical privacy issues. If you have any questions, please contact Robert Tennant at rtennant@mgma.org or (202) 293-3450.

Sincerely,

William F. Jessee, MD, FACMPE
President and Chief Executive Officer

Appendix

The following comments were provided to MGMA through our Legislative and Executive Advocacy Research Network (LEARN) study conducted between July 6-22, 2011. The study sought to determine the impact of the accounting of disclosures proposed rule on medical practices. It received one of the largest responses in MGMA's LEARN history, with more than 1400 participants. As part of the study, we provided the opportunity for participants to offer comments. Some of the comments are excerpted below.

Unnecessary

1. This requirement would be very burdensome and the use of the data is so infrequent that the cost far outweighs the benefits derived. Most of us can kluge together some sort of report on an as needed basis. In the three years I have been at this practice we have only had one patient request anything even close to this level of detail.

2. This would be very time consuming and cost prohibitive! I think we are getting so much further away from our true objective- taking care of patients.

3. Our paper system allows for this data to be readily produced, however, to incorporate into our upcoming EHR would require additional programming costs. Apparently the government wishes physicians' offices to waste more time on clerical issues than those of patient care.

4. Tracking this level of detail will bring even a good system to a halt - whether it's a computer system OR a physical process done by a staff person. Sure, computers can track who's logged in and which screens they go to, but if no buttons are pushed there's no way to know what the user did while on that screen. Did they get there on accident by typing in the wrong account number? Did they just view something? Did they look at the screen quickly to see the patient's age, but not exit the account so it appears they were in an account for a long period of time?

5. Disclosure outside practice is warranted. Recording inside practice is frivolous. If this were truly necessary and important, it would have been required with paper records.

6. Patients have complete access to their record as it stands now. I am not sure of the relevance of who accessed the record (especially within the practice) and why it is important to a patient. We are required to provide to their insurance company their records so I can't imagine why else a patient would want to know who accessed. This sounds like more administrative work without any reimbursement.

7. Creating rules for the 1/10 of 1percent of the population that thinks this is a good idea is not a good idea! Part of the rising cost of healthcare is due to non-value added things such as this.

8. Please let medical people practice medicine, not deal with continually increasing levels of extremely burdensome regulations. Privacy and security violations are already regulated sufficiently to provide adequate protections and rules.

9. This is a non-issue in our primary care practice. No patient has ever requested such a report. However if media and government promote this topic, it could rebound and have a large negative impact on our ability to serve our patients.

10. As medical practices downsize for efficiencies and cost savings, the challenge remains to meet external mandates without raising the overhead. There is a tacit assumption that because one has an EMR, everything is captured and formatted to share with the public in a way they will understand what they are receiving. Should we be able to provide proof to support compliance with HIPAA? Yes, but only with cause.

11. PHI is accessed continuously throughout the day by all clinical staff. The proposals, if even requested by just a couple patients per month, would create a crushing burden on the practice and serve no useful purpose.

12. We understand and respect the need for PHI security. We take this very seriously. Why mandate a big elaborate system for all physicians to cover the rare or infrequent aberrant situation?

13. It is too far reaching and serves no additional purpose that the current regulations could not cover in a civil or criminal suit.

14. This proposed requirement would be extremely burdensome and would serve no real purpose because we have had no requests for accounting under current regulation. Why make the reporting requirement even more burdensome, especially as it relates to TPO situations previously exempted.

Costly

15. Honestly, I do not know how we could ever comply with these requirements. It will be extremely expensive to implement amongst all of the EHR software in our practice. They would all have to be maintained as separate reports for the 5 different EHR's we use within our office. The labor involved to "try to track" would be cost prohibitive and create a decrease in quality of care to the patients without a doubt. Instead of taking care of the patients we will be worried about making sure we can account for every person accessing the record.

16. Being a solo practitioner, this requirement would ultimately cause our practice to dissolve due to the burdensome costs.

17. While our EHR can track access it can't track "why" our staff accessed the record. I believe that would require an entry by the staff person every time they went into a patient's record. Just the storage of all this data is cost prohibitive.

18. This would be a massive cost, nationally, unfunded, that will simply drain away true health care money for non-care purposes.

19. I currently have 1 FTE in the office handling the current requests for information (school forms, health forms, WIC, EIP, travel), I think we would need to start charging for all this non-reimbursable work we are required to do. People complain about the cost of health care, but we're forced to bundle all these costs into our visit fees...

20. Due to reduced reimbursements and expensive implementations of EHR, staff reductions will be necessary thereby burdening the practice.

21. For the amount of time it would take, plus the possibility of hundreds of patients requesting this "because they can" would be a herculean task. The fact that it would be free would make it even worse.

22. We now have to be responsible for monitoring everyone we interact with and make sure their systems can report this information and we have to track it all? This will drive up costs.

23. This is a demand that will have a high impact on the work load of medical records, billing staff and business associates.

24. This would impose a tremendous cost and waste of staff time and efficiency which will in turn increase the cost of care, which we are trying to contain with the use of EHR.

25. It will be very costly to our small office. We are understaffed as it is and everyone is already doing the maximum they can do. It's beginning to be more than we can handle and afford. Adding this to our already extremely busy day would not be feasible.

26. This will make using the system cost prohibitive. Until the system has been redesigned to meet these standards it will be almost impossible to comply with this standard let alone in a timely manner.

27. Although we do not bill 3rd parties we find the administrative cost of this legislation very burdensome

28. This concept would be unbelievable costly: EHR vendors would have to upgrade systems to produce this type of accounting, which would drive up costs; staff training and implementation of such a process would be very costly; so who pays for all this? Most, if not all practices would not be able to absorb this and would be forced to shut their doors. There is no reason for patients to need a report that says "this doctor told this nurse on this date about your care" and "this biller billed these diagnosis codes on this date because your doctor listed them on an encounter"...etc.

Require additional staff

29. We are so burdened already with regulations that have increased workloads exponentially, which increases staffing size while revenues decrease. There are times that we must access the PHI just to find out which of our staff members has contacted a patient to be able to transfer a call. A document is opened to look up one small piece of information and it would have to be documented. The added work would be huge.

30. Staffing patterns in our practices are very tight. It would cause undue hardship on our practices.

31. We would have to hire another employee to track, and our practice management system has no way to track electronically.

32. This ruling could potentially cause staff and providers to hesitate prior to accessing records and therefore, could lead to a potential for missed information. We are considered professionals and able to distinguish between necessary and unnecessary access to records. In addition, we have internal audits and processes to ensure staff/providers are accessing information appropriately. This requirement could potentially require additional staff and time - a cost not readily met.

33. We would have to hire additional staff if patients were to request this on a regular basis

34. To comply, we would have to hire additional FTEs solely devoted to this requirement. It would require an extensive amount of time and money to put the processes in place.

35. Not only does our current software not allow us to run access reports with the necessary detail, we do not have the staff or the time to run them.

36. For a busy practice with multiple providers, large patient load, and staff already overworked this would increase stress, probably require a part-time employee just to make sure all was done according to the new rules. Expensive and unnecessary.

37. As a specialist we constantly request information from other offices and hospitals. It would become a full-time job just to track all these transactions for a busy solo practice, much less a multi-specialty group.

38. This would be absurd and probably require an additional staff person just to do this in a timely manner.

39. This will require more documentation and time. Our clinic has cut staff hours and we are not filling vacant positions. Adding burdens of constant accounting to doing our daily jobs will be extremely stressful and will take away from patients and billing staff doing such things as collections. The clinical and billing staffs

jobs are 90 percent geared around accessing patient financial and medical information to do their jobs.

Extremely burdensome or impossible to track

40. Not only will this create a huge administrative burden, the bulk of reporting would be immense. On any given day, any one of 25 employees in my practice could be entering into a medical record for everything from billing functions, lab results, triaging, results review, etc. This proposed rule, while having merit at 50,000 foot level, is unreasonable and unnecessary.

41. I think it would be nearly impossible. If not, every transaction would require someone to enter why they were accessing the info. WE could not do that and could not comply.

42. Do you realize how often we access patient information on a daily basis? Do you realize how big these reports will be?

43. We access medical records daily to go over lab reports, radiology reports, medication requests, etc. This report could be quite lengthy on some patient records if they are having a lot of health related issues. In addition this would give no improvement in the quality of the health care being given. A total waste of time for a practice to perform this on a routine basis.

44. Our EMR can track who has accessed a record, but has no way to keep track of why the record was accessed. Because of this, we would need to implement some sort of manual tracking system for this which would be an enormous administrative burden and would take time and resources away from providing efficient, high-quality care to our patients.

45. Due to the sheer volume potential of such a requirement, this could be very burdensome. We get multiple requests daily for records. If we then had to produce a report for each patient for all activity for the 3 years prior to the request, it would be extremely time consuming. Not to mention the concern that if such a rule were publicized we could be inundated with numerous patient requests at once. This could be a hindrance to normal business function.

46. Many people end up touching the record at different times for reporting. The patient could well end up with a box of paper should they request this. Much depends on the level of details. For a non medical person, the patient/family could get really excited by the number of people who accessed the information. As we do research, we quite often request reports to identify potential study subjects. As we are asking for MRN's, diagnoses, names, ages, etc. This would qualify for reporting. It could get very confusing to the patient and/or their family.

47. If we can't be trusted by our patients, then we have no business to be in health care. I see no problem with being held accountable, but to have to give a report like this is extremely counterproductive to operation.

48. Trying to manage and document each access would be overwhelming when you consider scheduling, phone calls, Rx refill request, procedures, test results, etc. as well as the access points when a patient is in the office. One office visit could easily create multiple access times when a patient goes from check in to medical assistant to physician to medical assistant, to referral coordinator to check out, etc...

49. It would be impossible to track every time information was accessed for any reason. Staff and providers are routinely looking at charts to determine if reports are back, follow-up needed, etc. If the anticipated report is NOT back, for example, then there is no action taken (other than to continue waiting) and no discernable way to track what they were looking for 3 years later.

50. This seems ridiculous and nearly impossible, especially for a small practice with a lean staff. This absolutely cannot be done while still practicing medicine. After 6 years of using an EMR, this would be enough to cause me to return to paper charts.

51. The amount of time and money used in non-clinical areas of practice is very excessive at this time. The question should be how to "best" protect privacy of our information. This is way beyond what my bank or a credit reporting company would be required to do. How would TransUnion produce a report of all the secondary business partners' employees' use and access of information? Who at BCBS in Alabama and across the country access and use this information?

52. This would be impossible as there is little to no tracking of this type of detailed access.

53. Virtually impossible to generate a report including all of that data within a 30 day window for the past look 3 years.

54. Our current billing software does not keep record of each time a patient account is accessed and as billing is in and out of accounts to do their job this would be a tremendous undertaking and extremely time consuming.

55. PHI Disclosure recording is a manual process for our practice. The most common disclosure is mandatory reporting. It is difficult to assure every verbal reporting is documented on our disclosure grid.

56. I don't know how we could even do it. No one keeps track of when an account is accessed or why. I could be for an appointment, billing, disability form or phone call.

57. The overhead on our systems to accomplish this accounting would slow it down to the point as to make it untenable.

58. Even in a small practice of 2 physicians and a staff of eight, PHI is constantly being accessed. Daily access is used for: (1) payment from insurance companies (primary and secondary), patient assistance programs, as well as from patients; (2) treatment to complete authorizations for office visits and prescriptions as well

as E-prescribe; to complete laboratory requisitions and completing orders for diagnostic imaging (3) daily operations for transcriptionists...The requirement to track PHI disclosures may cause a decrease in access and therefore lessen efficiency in all the above practice aspects.

Outside of EHR/system capability

59. I am truly glad I have not started to implement an EHR and this is another reason not to. Maybe I can retire before I have to implement an EHR

60. This will also depend on the EHR Vendors. Can vendors build these reports into the system so it is less burdensome to print them out when asked by the patient?

61. Even with upcoming implementation of EHR, many records including EOB's, consult letters, and business associates communication are outside the EHR which would require manual tracking and reporting.

62. I am assuming that the EHR will have such a tracking system built in and the burden will be handling the requests, compiling the data and preparing the reports.

63. Although we have an EHR I do not believe that it has the capability to perform such a task.

64. In our system there are over 700 physicians at over 100 practice locations. Many of these practices had EHRs prior to becoming part of the IDS. The interfaces between all these systems are fraught with problems.

65. With all the requirements to meet meaningful use, we are already overextended and have hired additional staff members and the existing staff is working more hours. EHR was supposed to lessen the burden, not increase it. It has been a nightmare already and the government is going to be adding more requirements for meaningful use-this PHI requirement will just add fuel to the fire. We are exhausted and regret implementing EHR. We are considering not seeing Medicare patients and discontinuing use of our EHR.

66. With an EHR that does not account for these type of requests, we are looking at setting up a whole new tracking process which will be very costly to the practice and time consuming for staff. With the original HIPAA regulation, not one of our patients has ever requested an accounting of disclosures and I worry that this is yet another government regulation which, while well-intended, will end up being a flashpoint for problems in medical practices.

67. We will turn off our EHR if it comes to this.

68. We are still in the implementation phase of EHR adoption within our practice with a meaningful use system upgrade occurring in mid-process. Staff are faced with a steep initial learning curve further complicated by MU issues and reporting needs and a product certification process that lagged behind system

investments. The OIG/HHS/CMS/Congressional/MedPAC's essentially uncoordinated and unrealistic scatter-shot approach to the entire EHR issue is arguably doing everything BUT contributing to the achievement of quality care.

69. Much of the info is provided by our EHR system is in an abridged version - such as User ID instead of User Name. To convert this data would be difficult at best.

Impact of providing reports on behalf of business associates

70. We do not know if they kept records of this or if they could produce accurate reports. Who would be responsible if they could not produce such a report?

71. We have trouble getting a reports from other offices regarding patients condition much less who accessed the patient PHI

72. This regulation could possibly close down smaller business associates.

73. This type of undertaking ongoing would be cause for added personnel at our facility, and at the business associates location I would imagine. Again, there is no money to do this extra work.

74. In theory it sounds very time consuming. Funding will need to be provided. At this time, we have no business associates who do not exercise and have same HIPAA regulations as we do that would access a patient's record. So an extended version of HIPAA from our perspective would be overkill.

75. It would be very difficult for our practice to do this within our own organization, and then to also have to depend on business associates to do the same creates an additional burden on us to somehow ensure that the associates follow through.

76. We currently have no way to track our business associates' access.

77. Many of our business associates do not have an electronic mechanism to track such info. We are not a 'care as usual setting' and we'd have to query each organization and take time to understand how this process would work. This would be added to our already long list of tasks that need to be done in a busy practice.

78. I believe some business associates struggle because they are small companies keeping up with these laws, therefore it is going to be difficult for them to track as well.

79. We have a billing service that needs to chart information, plus people in the office that have different duties regarding our patients' care. It will jeopardize time for patient care to have to complete reports that aren't even necessary.

80. Some business associates will be a real problem, for example, our affiliated hospitals. Our requests won't necessarily be a priority for them. Plus knowing the roles of each of their employees will be a real challenge.

81. We have a large number of business associates. This requirement would significantly add to our staffing costs to monitor and track all of this data.

82. I suspect that most business associates will not have the ability to produce this. Business associates who have exposure to our patient data may not be working within software that tracks all this.

83. EHR and PM systems are designed to record employee login and data stamp it. Outside business associates including marketing firms, shredding companies, etc have no system to track access.

84. I have had business associates who have threatened to stop doing business with us (i.e. records storage facilities) if it meant being held to these regulations like we, the practice, would be. This would create yet another burden on the practice of trying to find records storage for all files that we must eventually put into our EHR but have not yet had the staffing, time, or money to do.

85. I am uncertain how we will know the extent of work this will be and how we ensure we contact all of our business associates who might have accessed the patient information. It will again add unreasonable dollars to the expense of health care.

86. I feel that it would be extremely burdensome for our business associates to provide us with this type of record and do not think that they would be able to provide this sort of record to us.

87. Right now there is no system in place for business associates to meet these requirements. It will take a substantial amount of time and resources to develop systems to achieve these standards.

88. This is not only "burdensome" but also essentially impossible. Our hospital-owned practices have absolutely no control over actions of their business associates. Who will get penalized when a business associate fails to respond to a request for the information? Physicians?

89. As a radiology group our PACS system gets accessed dozens of time everyday by referring physicians for reports and images. This would be very burdensome for those offices to keep track of.

Hinders Patient Care

90. Our staff routinely accesses the patient's record in preparation of a visit, during a visit (which is commonly multiple times) and after a visit. This requirement would slow the overall patient care process dramatically.

91. We are going to spend more time and money producing reports than treating the patients.

92. Increased cost and coordination offers the potential to slow down patient care.

93. This proposal places even more burdens upon practicing physicians who are increasingly becoming overwhelmed with responsibilities that add nothing to patient care, while reimbursement for primary care plummets.

94. Any practice that accesses a patient's file does so for legitimate reasons. There should be trust between the patient and his physician and his staff to be used for their health and benefit. This is ridiculous.

95. When are we supposed to find time to see patients?

96. We are a surgery practice. This requirement would consume a considerable amount of time and potentially slow down our ability to provide some surgeries in a timely manner.

97. A patient's chart is accessed many times when they are ill based on phone calls, labs and diagnostic reports, exams, etc. To have to account for every time a staff member accesses a chart and why would consume more of the staff's time, leaving less time for us to spend with the patient and their health issues.

98. All of these requirements take away from the quality of patient care we provide. Providers are becoming very discouraged at the cost of running a clinic -- it’s becoming more and more expensive and less appealing.

99. If government promotes these requests, it will have a large negative impact on our ability to serve our patients.

100. This report would take an enormous amount of time to document what is already carefully administered. It takes time away from patient care and requires more manpower than most small offices have available.

101. We want to protect patients but this is extreme. Why can't we get back to basic medicine where physicians can care for the patient and not worry about a lawsuit?

102. The potential requirement to create additional reporting mechanisms and additional manpower to accomplish the detail requested, reduces the funds being spent on medical care. As we continue to move in alignment with the federal and state compliance measures, more emphasis is placed on report of care versus spending time providing the care, which reduces the ability of the physician to practice medicine as the priority and instead places the priority on the reporting and technical compliance process.

103. This requirement takes even more time away from patient care and creates more hassle for physicians and their staff.