



**National
Business
Group on
Health**

20 F Street, NW, Suite 200
Washington, D.C. 20001
202.558.3000 • Fax 202.628.9244
www.businessgrouphealth.org

Creative Health Benefits Solutions for Today, Strong Policy for Tomorrow

August 1, 2011

Submitted electronically via: www.regulations.gov

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

Re: RIN 0991-AB62 – HIPAA Privacy Rule Accounting of Disclosures under the Health Information Technology for Economic and Clinical Health Act

Dear Secretary Sebelius:

The National Business Group on Health is pleased to comment on the Department of Health and Human Services' (HHS's) notice of proposed rulemaking (NPRM) to modify the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule's standard for accounting of disclosures of protected health information (PHI).

The National Business Group on Health represents approximately 330 primarily large employers, including 65 of the Fortune 100, who voluntarily provide health benefits and other health programs to over 50 million American employees, retirees, and their families.

As our members continue to implement the Health Information Technology for Economic and Clinical Health (HITECH) Act's requirements, a primary concern will be minimizing the administrative and cost burdens associated with these requirements. Allowing group health plans flexibility to adapt their compliance measures to existing plan recordkeeping and information technology systems will reduce these burdens and allow plan sponsors to devote more resources toward maintaining and improving health benefits for their employees. Therefore, the National Business Group on Health welcomes and supports the NPRM's provisions that:

- Limit the accounting of disclosures provision to PHI about the individual in a designated record set;
- Require covered entities to account for disclosures over a three-year period instead of a six-year period;
- Explicitly list the types of disclosures that are subject to the accounting of disclosures requirement; and
- Exempt from the accounting of disclosures requirement disclosures for which a covered entity has provided breach notices under 45 C.F.R. § 164.404.

The National Business Group on Health believes that these provisions will reduce administrative and cost burdens and allow plan sponsors much-needed flexibility in complying with the HITECH Act's requirements.

The National Business Group on Health supports HHS's efforts to provide individuals with greater transparency regarding the use and disclosure of their PHI. However, our members continue to have serious concerns with the administrative burdens and substantial costs involved with certain of the NPRM's requirements. **Therefore, the National Business Group on Health supports:**

- (1) Clarifying in final regulations that for purposes of Subtitle D of the HITECH Act, the definition of "electronic health records" does not include information created, gathered, maintained, managed, or consulted by group health plans;**
- (2) Allowing group health plans flexibility to adapt their compliance methods for accounting of disclosures to existing recordkeeping and information technology systems;**
- (3) Eliminating the access report requirement in the proposed 45 C.F.R. § 164.528(b); and**
- (4) Incorporating the requirements of section 13405(c) of the HITECH Act into the accounting of disclosures rules under the current 45 C.F.R. § 164.528.**

We provide further discussion of these recommendations below.

I. Scope of "Electronic Health Records"

The HITECH Act defines "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." However, the statute does not specify whether a group health plan's records will become "electronic health records" if the plan

receives records from health care clinicians and staff for payment or claims substantiation purposes, for example. We do not believe that this was the intent of the statute, given that the statute specifically refers to health care clinicians and staff but no other covered entities. Because the definition of “electronic health records” determines which covered entities (e.g., health care clinicians, group health plans) are required to comply with the requirements of section 13405(c) of the HITECH Act, we recommend that HHS clarify in final regulations that the definition of “electronic health records” does not include information created, gathered, maintained, managed, or consulted by group health plans.

II. Right to an Accounting of Disclosures of Protected Health Information

The National Business Group on Health supports the HITECH Act’s purpose of addressing privacy and security concerns associated with the electronic transmission of health information. However, many of our members will face significant administrative and cost burdens if they are required to customize accountings of disclosures in accordance with the proposed 45 C.F.R. § 164.528(a)(2)(ii) and 45 C.F.R. § 164.528(a)(3)(ii). As HHS acknowledges in the Preamble to the NPRM, generating an accounting of disclosures often involves a manual process and both electronic and paper records. Furthermore, our members often operate multiple lines of business in multiple states, which means that a single member may provide health benefits through a number of different plans, provider networks, and business associates. Therefore, requiring a group health plan to tailor accountings of disclosures to specific time periods, types of disclosures, recipients, or requested formats may involve reprogramming many different recordkeeping and information technology systems. This process would increase the administrative and cost burdens involved with this process, thereby diminishing resources available for maintaining and improving health benefits for plan participants and beneficiaries. We believe that these burdens would outweigh any benefits to plan participants and beneficiaries.

In addition, our members are concerned with the proposal to shorten the initial timeframe for providing an accounting of disclosures to thirty days. Although HHS proposes to reduce the scope of the required accounting to designated record set information, the definition of “designated record set” still encompasses a substantial portion of a group health plan’s records. Generating an accounting of disclosures is particularly time-consuming if a plan must coordinate with multiple business associates, as will often be the case for our members. Thus, shortening the existing sixty-day initial timeframe to thirty days will present a substantial burden on our members with minimal benefit to plan participants and beneficiaries.

For the reasons described above, the National Business Group on Health recommends:

- (1) Eliminating the requirement in the proposed 45 C.F.R. § 164.528(a)(2)(ii) that a covered entity provide an individual with the option to limit the accounting of disclosures to a specific time period, type of disclosure, or recipient;

- (2) Eliminating the requirement in the proposed 45 C.F.R. § 164.528(a)(3)(ii) that an accounting of disclosures be provided in the form and format requested by the individual if it is readily producible in such form and format; and
- (3) Retaining the current sixty-day time frame for responding to a request for an accounting of disclosures.

III. Right to an Access Report

National Business Group on Health members are particularly concerned with the new access report requirement in the proposed 45 C.F.R. § 164.528(b). As noted above, the National Business Group on Health supports the HITECH Act's purpose of addressing privacy and security concerns associated with the electronic transmission of health information. However, our members believe that current Privacy Rule and Security Rule requirements, including the Breach Notification Rule, which will continue to apply to covered entities, adequately address these concerns. Adding the access report requirement would create substantial administrative and cost burdens on group health plans with minimal benefit to plan participants and beneficiaries.

First, the National Business Group on Health believes that the access report requirement, as applied to group health plans, exceeds HHS's statutory authority. HITECH Act § 13405(c) specifically applies to the "case that a covered entity uses or maintains an electronic health record." As noted above, the definition of "electronic health record" does not apply to any covered entities other than health care clinicians and staff. In our view, this statutory language signifies that Congress's primary focus with § 13405(c) was the privacy and security interests of individuals as patients—not the routine operations of group health plans. An access report generated by a group health plan would, in most cases, consist of routine uses and disclosures that would be of little interest or use to plan participants. Thus, applying the access report requirement to group health plans not only would be contrary to the intent of the HITECH Act but also would not protect any substantial privacy or security interest of group health plan participants and beneficiaries.

In addition, the Preamble to the NPRM states that covered entities should already have electronic systems in place sufficient to create access reports as described in the proposed 45 C.F.R. § 164.528(b). We strongly disagree with this assumption. Currently, 45 C.F.R. § 164.312(b) requires covered entities to "implement hardware, software, and/or procedural mechanisms that record and examine activity in information systems that contain or use electronic protected information." However, the Security Rule's "flexibility of approach" provision allows covered entities to use measures that allow them to "reasonably and appropriately" implement such specifications. The Security Rule permits covered entities to take into account their size, complexity, and capabilities; technical infrastructure, hardware, and software security capabilities; costs; and the probability and criticality of potential risks to electronic PHI. 45 C.F.R. § 164.306(b). Thus, the methods by which group health plans "record and examine activity in information systems that contain or use electronic protected information" vary widely

and often depend on the specific information technology systems of business associates who provide information technology services to plans. These systems do not necessarily record and examine activity in a manner consistent with the access report requirements in the proposed 45 C.F.R. § 164.528(b). Furthermore, if existing information technology systems do record the information required for the proposed access reports, such information may not be in an electronic format that is readily converted to a format understandable to the individual.

Likewise, 45 C.F.R. § 164.308(a) requires covered entities to “implement procedures to regularly review records of information system activity, such as audit logs, access reports, and security incident tracking reports,” but again, the Security Rule’s “flexibility of approach standard” means that group health plans may employ a wide variety of methods of “regularly reviewing records of information system activity”—often through multiple business associates. Audit logs, access reports, and security incident tracking reports are only examples of the possible methods of doing so. For example, while group health plans generally require their business associates to track security incidents, business associates’ reporting of such incidents to group health plans may take many different forms, including quarterly or yearly summaries of security incidents. This is because “security incidents” in a given month may number in the hundreds (or even thousands), and such information is only useful in the aggregate for evaluating the security of a business associates’ information systems. Our members are deeply concerned that implementing the proposed 45 C.F.R. § 164.528(b) will, in many cases, involve developing a new “access log” system, extensive reprogramming of existing recordkeeping and information technology systems, and coordination between multiple business associates. Such measures would involve substantial costs, which would diminish resources available for participants’ and beneficiaries’ health benefits.

Our members’ concerns with the access report requirement also include the following:

- Because group health plans may contract with a number of different business associates, aggregating access reports of all business associates in response to a request will present significant administrative and cost burdens.
- For group health plans, most of the activity documented in an access report will pertain to routine uses and disclosures such as those for payment, claims processing, cost management and planning activities, and other routine administrative tasks—information that will not be useful or of interest to participants and beneficiaries.
- For group health plans, identifying individuals who use or disclose electronic PHI by name will involve reprogramming of existing information technology systems. These individuals generally will be staff members of business associates or group health plan staff, and identifying these individuals will not provide useful information to plan participants and beneficiaries.

- As described above, requiring group health plans to tailor access reports to specific dates, time periods, persons, or requested formats may involve reprogramming many different recordkeeping and information technology systems.
- As described above, shortening the existing sixty-day initial timeframe to thirty days will present a substantial burden on our members—especially given the requirement to aggregate access reports of business associates—with minimal benefit to plan participants and beneficiaries.

For the reasons described above, the National Business Group on Health recommends:

- (1) Eliminating the access report requirement in the proposed 45 C.F.R. § 164.528(b).
- (2) As provided in the HITECH Act, incorporating the requirements of § 13405(c) into the accounting of disclosures rules under the current 45 C.F.R. § 164.528;
- (3) Requiring covered entities to provide an accounting of only disclosures (not uses) of PHI to carry out treatment, payment, and health care operations when providing an accounting of disclosures under § 13405(c);
- (4) Limiting the accounting of disclosures required under § 13405(c) to PHI in electronic health records (not all electronic PHI in a designated record set);
- (5) Allowing covered entities, when providing an accounting of disclosures, to provide a summary of disclosures to carry out treatment, payment, and health care operations, where appropriate;
- (6) Retaining the rule in HITECH Act § 13405(c)(3)(B) that permits a covered entity, in response to a request from an individual for an accounting, to provide a list of all business associates acting on behalf of the covered entity; and
- (7) With respect to the requirements of HITECH Act § 13405(c), allowing an effective date of January 1, 2013 for electronic health records acquired after January 1, 2009 and an effective date of January 1, 2016 for electronic health records acquired as of January 1, 2009, as permitted by statute.

Thank you for considering our comments and recommendations on the notice of proposed rulemaking regarding the Privacy Rule's standard for accounting of disclosures of PHI. Please contact me or Steven Wojcik, the National Business Group on Health's Vice President of Public Policy, at (202) 558-3012 if you would like to discuss our comments in more detail.

Sincerely,

A handwritten signature in black ink that reads "Helen Darling". The signature is written in a cursive, flowing style.

Helen Darling
President