National Business Group on Health®

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Creative Health Benefits Solutions for Today, Strong Policy for Tomorrow

February 12, 2019

Submitted electronically via: www.regulations.gov

U.S. Department of Health and Human Services
Office for Civil Rights
Attention: RFI, RIN 0945-AA00
Hubert H Humphrey Building
Room 509F
200 Independence Avenue SW
Washington, DC 20201

Re: RIN 0945-AA00 – Request for Information on Modifying HIPAA Rules to Improve Coordinated Care

Dear Sir or Madam:

The National Business Group on Health appreciates the opportunity to respond to the Office for Civil Rights' Request for Information regarding potential revisions to the HIPAA privacy and security regulations to aid the transformation to value-based health care and encourage coordinated care.

The National Business Group on Health represents 433 primarily large employers, including 74 of the Fortune 100, who voluntarily provide health benefits and other health programs to over 55 million American employees, retirees, and their families. Our members employ and provide health coverage under a wide variety of arrangements, including full-time, part-time, seasonal, and temporary. They often have multiple lines of business in multiple locations and tailor employee work and benefit plans to the specific needs of each line of business.

As our members continue to comply with HIPAA regulations and other group health plan requirements, primary concerns remain:

(1) Minimizing the administrative and cost burdens associated with these requirements and

(2) Having flexibility to provide comprehensive benefits packages in an efficient, cost-effective way while ensuring access to health care providers and facilities that provide high-quality, evidence-based care.

Therefore, we support OCR's efforts to encourage the transformation to value-based care, encourage coordinated care among individual sand covered entities, remove regulatory obstacles, and decrease regulatory burdens. Our recommendations follow.

I. Large Employers' Group Health & Welfare Plans

Our members' group health plans generally are self-insured or a combination of self-insured and insured. We encourage OCR, as it considers revisions to the HIPAA privacy and security regulations, to take into account the administrative structures of these large group health plans. Specifically:

- Our members often operate in 50 states and offer a variety of health benefits options tailored to (1) different lines of business, (2) coverage availability in different geographic areas, and (3) full-time, part-time, seasonal, and temporary work arrangements. Therefore, our members' group health plans will enter into agreements with multiple third-party administrators to provide major medical, prescription drug, enrollment/disenrollment, claims processing, and payment services—among other services integral to group health plan administration.

- Often, large group health plan sponsors will not perform most health care transactions such as eligibility determinations or claims status and instead engage third-party administrators to perform these functions on their behalf. In some cases, plan sponsors will perform only some of these functions and engage third-party administrators to perform the others.

- Many Business Group members offer health benefits that consist of multiple components. For example, a plan sponsor may offer both insured and self-insured group health plan options that provide major medical and prescription drug coverage and offer those options with health flexible spending arrangements, employee assistance programs, wellness programs, telehealth services, or on-site health centers—different combinations of which provide complete packages of health and welfare benefits for employees and their dependents. These components may constitute a single group health plan or separate group health plans (and therefore separate covered entities). These components may be available simultaneously to plan participants.

- Large group health plans may also contract directly with covered entities such as accountable care organizations (ACOs) or high-performance networks. In such arrangements, providers may provide services as both covered entities and business associates.

- Business Group members also offer benefits that do not constitute HIPAA covered entities but nevertheless may retain information relevant to population health and health trends. These benefits include but are not limited to short and long-term disability coverage, life insurance coverage, and leave benefits.

Because large employers, as plan sponsors, do not perform most health care transactions but will contract with multiple covered entities and business associates to provide comprehensive benefits packages, they will, by necessity, rely on third parties to ensure compliance with the HIPAA privacy and security regulations. Therefore, we recommend:

- That OCR streamline HIPAA compliance for group health plans by, for example, providing model policies and procedures that group health plans can adapt to their specific benefit arrangements and

- Providing clear guidance on when business associate agreements are required.

II. Encouraging Coordinated Care

As noted above, large employers' benefit offerings often include a wide variety of services and service providers designed not only to provide medical coverage but also to promote employee engagement, maintain a productive workforce, and minimize absenteeism, among other goals. Increasingly, employers are relying on entities such as health care clearinghouses and data analysts to examine plan data for ways to reach these goals. We therefore encourage OCR, when examining the HIPAA regulations, to consider revising the regulations to ease data sharing among an employer's health and welfare plan offerings. For example, our members believe that being able to combine and analyze group health plan, leave, and disability plan data without authorization would allow them to better identify patterns in workplace injury, absence, and treatment; prevent future injuries; and improve treatment plans. Because this data would remain with a single employer, there would be minimal (if any) impacts on plan participants' data privacy and security. We believe that this type of data sharing could be particularly useful in identifying health issues such as opioid misuse or mental health conditions.

III. Accounting of Disclosures

Business Group members strongly support OCR's proposal to withdraw the 2011 NPRM's, as discussed in the RFI. Specifically, while we support the HITECH Act's purpose of addressing privacy and security concerns associated with the electronic transmission of health information, many of our members would face significant administrative and cost burdens if they were required to customize accountings of disclosures in accordance with the NPRM. As HHS acknowledged 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. We believe that these burdens would outweigh any benefits to plan participants and beneficiaries.

In addition, our members were concerned with the 30-day initial timeframe for providing an accounting of disclosures. Although the NPRM proposed 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, a 30-day timeframe would present a substantial burden on our members with minimal benefit to plan participants and beneficiaries.

IV. Right to an Access Report

Similarly, Business Group members were concerned with the access report requirement in the NPRM. 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 and security regulations, 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." 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. We 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 NPRM. 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.

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.

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

- Eliminating the access report requirement, as suggested in the RFI;

- 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;

- 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);

- Limiting the accounting of disclosures required under § 13405(c) to PHI in electronic health records (not all electronic PHI in a designated record set);

- Allowing group health plans, when providing an accounting of disclosures, to provide a summary of disclosures to carry out treatment, payment, and health care operations, where appropriate; and

- Retaining the rule in HITECH Act § 13405(c)(3)(B) that permits a covered entity, in response to a request from in individual for an accounting, to provide a list of all business associates acting on behalf of the covered entity.

V. Notice of Privacy Practices

Our members' experience with the notice of privacy practices (NPP) is largely consistent with their experiences with other disclosures such as those required under ERISA. Specifically:

- Generally, plan participants do not read these documents and do not find them useful.
- When plan participants do need information related to their group health coverage, the most critical information (such as methods for mitigating any harm) often will not be found in mandated disclosures.
- While documents such as NPPs, which include information on participants' HIPAA rights, may be useful in some circumstances, it is not certain that a plan participant will have the relevant version of the NPP on hand. Most often, the participant will contact the health care provider or plan sponsor at to request relevant documents.

As the health care system undergoes rapid change, the information plan participants need also will change. We therefore recommend that any future regulatory guidance take into account the need for flexibility in how group health plans communicate with plan participants. Disclosures such as NPPs will continue to play a role in protecting plan participants and sponsors. However, we believe the most critical communications for group health plans will be the tools that plan sponsors and insurers develop to assist participants in making decisions—including decisions related to PHI—at or near the time of service.

To communicate plan offerings and designs, our members rely on a mix of communications methods. For example, in 2016, we conducted a Quick Survey[1] on how employers communicate health and well-being programs and initiatives. The responses show that while intranet, email, and print communications are the most common, employers use a wide variety of communication methods in the effort to engage their employee populations, including in-person meetings, webinars, and text messages. In this same Quick Survey, member responses indicated that they viewed email as the most effective communication method.

While we support a requirement to provide paper copies of NPPs upon request, future regulatory guidance should permit electronic communications as a default option. Electronic documents allow greater flexibility and availability of information by:

- Allowing plan sponsors and participants access to the all health plan-related information in a single location at all times;
- Allowing plans sponsors the ability to provide additional information that may be useful to plan participants; and
- Making it possible to easily access prior versions of NPPs.

[1] Ridgley, Lisa, *Quick Survey Findings: Health and Well-Being Communications – Innovative Tactics and Strategies* (2016).

We believe that the above recommendations, if implemented, will reduce administrative and cost burdens and allow group health plan sponsors much-needed flexibility in complying with HIPAA.

Thank you for considering our comments and recommendations. We would welcome the opportunity to work with OCR on potential revisions to the privacy and security regulations and would be happy to provide additional details on the employer and group health plan perspectives. Please contact me or Debbie Harrison, the National Business Group on Health's Assistant Director of Public Policy, at (202) 798-4421 if you would like to discuss.

Sincerely,

Brian Marcotte
President