Archived Policy Statement

Genetic Alliance Argues New Proposed Rule is on HIPAA is Misguided

August 1, 2011

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

Attn: HIPAA Privacy Rule Accounting of Disclosures, RIN 0991-AB62

Dear Secretary Sebelius:

Genetic Alliance appreciates this opportunity to respond to the above-referenced proposed rule. As explained below, while we appreciate the direction of the proposed changes to the accounting of disclosures (164 CFR §164.528(a)), we are troubled by the overwhelming cost and unworkability of the proposed access report (164 CRF §164.528(b)). Despite the Department's intent to ease some of the existing administrative burdens on biomedical research, the net effect of the proposed rule, unfortunately, would be to magnify those burdens. Unnecessary and inappropriate burdens on biomedical research – even when purportedly imposed to serve patients' interests – actually are hostile to the interests of patients, for they add needless health care costs that are borne by all and impede breakthrough medical advancements urgently needed by individuals. We urge the Department to withdraw the proposed rule entirely and instead conduct a comprehensive and updated re-examination of the costs and benefits of any version of accounting of disclosure requirements.

Founded in 1986 as the Alliance for Genetic Support Groups, Genetic Alliance has become the world's leading nonprofit health advocacy organization committed to transforming health through genetics. Our open network of over 10,000 organizations connects members of parent and family groups, community organizations, disease-specific advocacy organizations, professional societies, educational institutions, corporations, and government agencies to create novel partnerships. We actively engage in improving access to information for individuals, families, and communities, while supporting the translation of research into services and care. We recognize the promise of modernized health information technology (HIT) to lower healthcare costs, improve quality and coordination of care, and reduce medical errors, and we are committed to HIT advancements accompanied by privacy protections. To that end, Sharon Terry, Genetic Alliance President & CEO, serves on the Health IT Standards

Committee, a federal advisory body established by law to provide recommendations to the National Coordinator for Health Information Technology on the advancement of health information technology (HIT) as an integral component of health reform.

Sharon Terry also has personal knowledge of how genetic conditions and the resulting disease issues can disrupt families. Because her children have a genetic condition called pseudoxanthoma elasticum (PXE), she worked intensely to identify and patent the associated gene and serves as CEO of PXE International, a nonprofit advocacy group she founded, which seeks to accelerate tests and treatments for the condition. Her own experience, magnified many thousands of times over by the experiences of individuals and families served by Genetic Alliance, helps fuel our organization's passion to seek medical advances through research. The guiding principle for our public policy work is to support meaningful, efficacious protections for health information privacy, maximize consumer engagement in healthcare, and seek broader dissemination of knowledge, improved efficiency of health care systems, better health outcomes, and research breakthroughs to ease suffering and improve health.

After a careful review, we have concluded that the proposed access report is fundamentally misguided insofar as its burdensomeness and impracticality vastly outweigh its purported value. We also note that numerous research institutions and health care policy experts, including the Secretary's Advisory Committee for Human Research Protections (SACHRP) and the Institute of Medicine (IOM), have concluded that even the existing version of the accounting of disclosures rule, which has been in place since 2003, places burdens on research and health care that vastly exceed any potential value to patients. Given the broad expert consensus that this existing accounting right, which is very rarely used by patients, flunks rational cost-benefit analysis, we are troubled that Congress chose in HITECH to expand the requirement by removing exemptions for treatment, payment, and healthcare operations, and we are even more troubled that the Department proposes to go far beyond Congress's direction by expanding the rule to allow individuals to demand a detailed report about all internal access to and uses of health information. We are shocked that the Department would require Covered Entities (CEs) and certain Business Associates (BAs) to identify the names of all their employees and contractors who have *appropriately* accessed health data in the course of doing their jobs. We would like to explain our **reasons as follows:**
But as to the proposed rule's effect on research as a whole, we conclude that what the Department has given with one hand – an easing of undue administrative burdens on research vis-à-vis the accounting requirement – it has more than taken away with the other hand, by requiring inclusion in the access report of all uses and electronic disclosures of Protected Health Information (PHI). The appropriate exceptions listed above would not apply in the context of the access report; even uses approved by an IRB or Privacy Board that concluded the study was of "minimal risk" to patient privacy, tightly controlled access preparatory to research, and arguably even uses in which PHI use was confined to a Limited Data Set (with 16 identifiers removed) would have to be identified and reported.

To give a practical example of the role of just one employee in the overall clinical research environment, consider the activities of a research monitor. To protect the rights and welfare of

a research participant and as part of the oversight of a clinical trial required of the trial's sponsor, a research monitor regularly reviews the clinical trial record, assessing compliance with the trial protocol and ensuring accurate and complete informed consent. Today that clinical trial documentation is frequently maintained electronically, often as part of the clinician's electronic health record. The monitor accesses the EHR – most often in-person, but increasingly by way of electronic access – pursuant to a HIPAA Authorization provided by the trial participant, and that disclosure to a person outside of the clinician's workforce is excluded from the accounting of disclosures requirement, both currently and under the proposed rule. However, the proposed rule would require the monitor's access to electronic designated record set information to be included in an access report, notwithstanding the HIPAA Authorization. Similarly, if the monitor engaged in activities preparatory to research, such as by screening EHRs without recording any information or having any PHI leave the covered entity, but only informing the clinician of potential clinical trial participants in his/her practice, that also would be included in an access report. At the extreme, Genetic Alliance is concerned that even electronic access to thousands or millions of subjects within a Limited Data Set, which is defined as PHI and is clearly comprised of electronic designated record set information, would have to be included in an access report. Failing to exempt Limited Data Set information would create the nonsensical – but troubling - problem of having to re-identify an entire data set of individuals, thereby defeating the very purpose of using a Limited Data Set to protect privacy, just in order to fulfill the request of a single person.

We are doubtful that the electronic health systems (EHRs) used by the physicians and hospitals today could accurately and completely capture these disparate research activities. Even more to the point, as an advocacy organization committed to accelerating biomedical research, we are astonished that by including research uses and disclosures of electronic designated record set information in the access report requirement, HHS has proposed not a reduction in the burden on research, but a significant increase – and we are hard-pressed to understand what the benefit of this requirement would be to an individual who has provided an Authorization or whose information has been accessed legitimately under §164.512(i) or §164.514(e), activities that the Department has previously, and in our opinion appropriately, decided need not be included in an accounting of disclosures.

We thank you for this opportunity to submit our comments, and we would be happy to provide additional information if that would be useful to the Department.