April 14, 2010

Federal Trade Commission
Office of the Secretary
600 Pennsylvania Avenue N.W.
Room H-135 (Annex P)
Washington, DC 20580

Attention:

Re: Confidentiality Coalition Comments on "Privacy Roundtables – Comment, Project No. P095416."

Dear Sir or Madam:

The Confidentiality Coalition respectfully submits these comments in connection with the series of Privacy Roundtables recently held by the Federal Trade Commission.

In this response, we (i) provide background on the Confidentiality Coalition; and (ii) offer comments on two specific issues that have been addressed in the course of these Roundtables. These comments relate generally to the limited role that the Federal Trade Commission should take in connection with the regulation and oversight of health information. It is our view that the FTC should not become involved in the regulation and oversight of health information to the extent that these areas are already regulated, in substantial detail, by the HIPAA structure. The FTC's role in connection with health information should be limited (if it chooses to play any additional role) to those areas that are not regulated under the HIPAA structure.

Background

The Confidentiality Coalition is composed of a broad group of hospitals, medical teaching colleges, health plans, pharmaceutical companies, medical device manufacturers, vendors of electronic health records, biotech firms, employers, health produce distributors, pharmacy benefit managers, pharmacies, health information and research organizations, and others[1] founded to advance effective patient confidentiality protections.

The Coalition's mission is to advocate policies and practices that safeguard the privacy of patients and health care consumers while, at the same time, enabling the essential flow of

[1] A list of the Confidentiality Coalition members is attached to this letter.

information that is critical to the timely and effective delivery of health care, improvements in quality and safety, and the development of new lifesaving and life enhancing medical interventions. The Confidentiality Coalition is committed to ensuring that consumers and thought leaders are aware of the privacy protections that are currently in place. And, as health care providers make the transition to a nationwide, interoperable system of electronic health information, the Confidentiality Coalition members believe it is essential to replace the current mosaic of sometimes conflicting state privacy laws, rules, and guidelines with a strong, comprehensive national confidentiality standard.

Discussion

The Confidentiality Coalition applauds the FTC's efforts to explore the privacy challenges that are posed by technology and business practices that collect and use consumer data. We recognize that the three Roundtables addressed numerous broad questions about technology and how various forms of technology create both challenges and opportunities in connection with both privacy and security.

We also understand how the development of new technologies has affected the use and disclosure of health care information. For example, the development of a marketplace for personal health records, while not entirely dependent on new technologies, has flourished because of the use of web-based technologies. We understand and acknowledge the FTC's interest in developing standards and practices for these personal health records vendors, at least to the extent that these products are marketed by entities that are outside the scope of HIPAA regulation.

We believe that the FTC's cooperative efforts with the Department of Health and Human Services in connection with the HITECH security breach notification provisions has been appropriate and effective. While there obviously are some complications and areas of potential ambiguity, we believe that the FTC's approach on this issue – to develop a breach notification rule that essentially applies to personal health records vendors when they are not regulated by HIPAA – presents a model that can be used going forward.

The focus of our comments is on two related issues that go to the Federal Trade Commission's role in the oversight and regulation of the use and disclosure of medical information. We do not intend in these comments to address the other, more specific questions that have been raised in the roundtables (e.g., Can consumer access to and correction of their data be made cost effective? Are there specific accountability or enforcement regimes that are particularly effective?).

First, the Confidentiality Coalition is very concerned about the FTC's entrance into areas of regulation that are already occupied by the Department of Health and Human Services in the various HIPAA Rules. Already, through the HITECH Act, Congress has created a significant risk of inconsistent regulation through empowerment of State Attorneys General to engage in HIPAA enforcement efforts. We do not believe that it is appropriate for the Federal Trade

Commission to expand its reach into these areas as well. The FTC should continue the approach set out in its "Health Breach Notification Rule:" the FTC's jurisdiction – if any – should be mutually exclusive from the existing HIPAA jurisdiction of the Department of Health and Human Services to regulate HIPAA covered entities and their business associates.

Second, we also are concerned about the creation of inconsistent or different standards for areas that are already regulated under the HIPAA rules. Our members have engaged in substantial efforts to bring themselves into compliance with the HIPAA regime, both the original HIPAA Privacy and Security Rules and the new obligations imposed by the HITECH Act. We do not believe it appropriate for the FTC to develop or implement standards that will apply to information that already is regulated by HIPAA.

- Duplicative or additional Enforcement

The members of the Confidentiality Coalition recognize that HIPAA is not a comprehensive medical privacy law. Driven by the history of the law (which confined jurisdiction based on both "portability" issues involving insurance coverage and the participation in standardized electronic health care transactions), the HIPAA Privacy and Security Rules created comprehensive regulation on privacy and security for HIPAA covered entities (health care providers, health plans and health care clearinghouses). Initially, "business associates" under HIPAA – those companies that provided services to these covered entities – were regulated only through contracts with these covered entities. Now, as a result of the HITECH law, these business associates also face direct legal compliance obligations under HIPAA, subject to primary enforcement by the Department of Health and Human Services.

Accordingly, while HIPAA does not apply to all entities that might collect, use or disclose health-related information, HIPAA does create a comprehensive set of standards and an overall enforcement protocol for those entities – both covered entities and business associates – who are regulated directly under the HIPAA rules. Moreover, as a result of the HITECH law, both covered entities and business associates face significantly increased exposure for violations of these rules, as well as the ongoing possibility of criminal penalties.

Therefore, for these covered entities and business associates, regulation under HIPAA is both comprehensive and substantial. HIPAA incorporates a wide range of standards for the use and disclosure of health information, creating specific rules for all aspects of the operations of the covered entities and their business associates. Moreover, the HIPAA Security Rule imposes perhaps the most significant set of security–related requirements imposed by law under any standard.

With these standards in place, there is no need for an additional regulator to oversee these obligations. The HIPAA rules are in place and govern health care covered entities and their business associates. The Department of Health and Human Services has primary authority under these rules, with a significant new set of enforcement tools in its arsenal. There is no need for

the Federal Trade Commission to enter this arena to provide additional (and potentially inconsistent) regulatory oversight. To the extent that the Federal Trade Commission wishes to make inroads into the area of health information, it should limit its efforts (if any) to those entities who are outside the HIPAA structure. It should take no steps to regulate those companies – whether a covered entity or a business associate – who already face regulation by the Department of Health and Human Services and the Attorneys General around the country.

This approach is entirely consistent with the FTC's approach in the Health Breach Notification Rule. We support the FTC's efforts with that rule to harmonize its approach with the HHS approach. Even more important, however, we support the FTC's jurisdictional conclusion in that Rule – that the FTC's Rule "does not apply to HIPAA-covered entities, or to any other entity to the extent that it engages in activities as a business associate of a HIPAA-covered entity." See 74 Federal Register 42961, 42963 (Aug. 25, 2009); 16 C.F.R. Section 318.1(a). That approach should continue into the future, if the FTC decides that additional regulation or oversight of entities *outside* the HIPAA structure is appropriate.

- Additional or Inconsistent standards

At the same time, to the extent that the Federal Trade Commission seeks to set standards that apply to the use or disclosure of health related information, it also should ensure that these standards are not applied to information that already is protected and regulated under the HIPAA rules. HIPAA covered entities and their business associates already face significant and detailed regulation of their activities – ranging from how they use and disclose information to individual rights of patients and insureds to specific details for training, sanctions and documentation related to privacy and security practices. It is unfair, unreasonable and unnecessary to create new and/or different standards that would be applied to this same information. The HIPAA Rules – particularly with the additional (and still being defined) obligations imposed by the HITECH Act – create a challenging set of standards for any affected health care entity. To impose different or additional standards for this information would create significant additional cost and unneeded complexity.

In addition, the existence of multiple rules by itself can create adverse consequences and harmful confusion, particularly in situations (such as is often the case in the health care industry) where certain aspects of the flow of information is critical to the effective operations of the health care system and the protection of patient health interests. Accordingly, to the extent that the FTC develops standards for the use or disclosure of health related information, it should ensure that these standards are applied only to information that is outside the scope of HIPAA regulation, so that HIPAA covered entities and their business associates can rely on the single (yet very detailed and comprehensive) set of standards created by the HIPAA regime.

Conclusion

The Confidentiality Coalition appreciates this opportunity to work with the Federal Trade Commission in the ongoing development of workable rules and guidance in connection with the regulation of health and medical information. While we believe strongly that there is no need for additional regulation by the FTC for entities and information already covered by the HIPAA rules, we would be happy to assist the FTC in development of standards or principles for entities who are outside the scope of the HIPAA regime. In addition, please let us know if there are any comments or questions about the comments in this letter. We look forward to working with you.

Sincerely,

Mary R. Grealy
President, Healthcare Leadership Council
On Behalf of the Confidentiality Coalition

Enclosure

CONFIDENTIALITY COALITION

Advancing Health Care. Safeguarding Trust.

2010 Steering Committee Membership

Aetna
American Hospital Association
Association of Clinical Research Organizations
Blue Cross Blue Shield Association
CVS Caremark
Federation of American Hospitals
Fresenius Medical Care
Greenway Medical Technologies
Gundersen Lutheran
Health Dialog
Healthcare Leadership Council
IMS Health
Marshfield Clinic
Medco
National Association of Chain Drug Stores
Pharmaceutical Care Management Association
Pharmaceutical Research and Manufacturers of America
Premier, Inc.
Prime Therapeutics
Texas Health Resources
United Healthcare
VHA
Walgreens
Wellpoint

General Membership

ACA International
Adheris
American Academy of Nurse Practitioners
American Benefits Council
American Clinical Laboratory Association
American Electronics Association
American Managed Behavioral Healthcare Association
Amerinet
AstraZeneca
American Pharmacists Association
Ascension Health
Association of American Medical Colleges
Baxter Healthcare
BlueCross BlueShield of Tennessee
Catalina Health Resource
CIGNA Corporation
Cleveland Clinic
College of American Pathologists
DMAA: The Care Continuum Alliance
Eli Lilly
ERISA Industry Committee
Food Marketing Institute
Genentech, Inc.
Genetic Alliance
Genzyme Corporation
Health Care Service Corporation
Humana, Inc.
Integrated Benefits Institute
Intermountain Healthcare
Johnson & Johnson
Kaiser Permanente
Mayo Clinic
McKesson
Medical Banking Project
Merck
MetLife
National Association of Health Underwriters
National Association of Manufacturers
National Association of Psychiatric Health Systems
National Community Pharmacists Association
National Rural Health Association
Novartis
Pfizer
Quest Diagnostics
SAS
Siemens Corporation
Society for Human Resource Management
State Farm
TeraDact Solutions Inc.
Trinity Health
U.S. Chamber of Commerce
Wal-Mart
Wolters Kluwer Health