



February 18, 2011

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

Re: Confidentiality Coalition Comments on “Protecting Consumer Privacy in an Era of Rapid Change”

Dear Sir or Madam:

The Confidentiality Coalition respectfully submits these comments in connection with the Preliminary Federal Trade Commission (FTC) Staff Report entitled “Protecting Consumer Privacy in an Era of Rapid Change: A Proposed Framework for Businesses and Policymakers.”

In this response, we (i) provide background on the Confidentiality Coalition; and (ii) offer comments on various aspects of the Preliminary FTC Staff Report. As discussed below, many of the principles identified in the Staff Report already are incorporated into the Health Insurance Portability and Accountability Act (HIPAA) framework that governs privacy and security issues for the healthcare industry and its service providers. Because these principles already have been implemented by the healthcare industry, we also wish to reiterate our view (expressed earlier in a separate comment letter on the Privacy Roundtables) 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. Following the approach that the FTC developed for its “Health Breach Notification Rule,” the proposed framework – if adopted – should be limited to those areas that are not regulated under the existing HIPAA structure and should not create or impose duplicative or inconsistent standards for healthcare companies and their service providers that are already subject to the details of the HIPAA framework.

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, pharmacies, pharmacy benefit managers, health information and research organizations, patient groups, and others¹ founded to advance effective patient confidentiality protections.

¹ A list of the Confidentiality Coalition members is attached to this letter. This comment letter reflects a consensus view of our members. It does not necessarily reflect on every point the view of each member of the Coalition.

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The Coalition's mission is to advocate for policies and practices that safeguard the privacy of patients and healthcare consumers while, at the same time, enable the essential flow of information that is critical to the timely and effective delivery of healthcare, 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 healthcare 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 healthcare privacy laws, rules, and guidelines with a strong, comprehensive national confidentiality standard for healthcare information.

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 believe that the general framework proposed by the FTC is consistent with the goals and activities of our members.

Moreover, we also understand that the primary focus of the FTC's efforts is not on the kinds of activities engaged in by many of our members, except tangentially. The report focuses primarily on the online environment, particularly those portions of the online environment that are less visible or less obvious to consumers. We support the development of appropriate practices in these new areas. However, because these efforts can have an impact on the proper business activities of our members, we believe it important to reiterate certain concerns that we have about the potential application of the FTC's principles, primarily to areas that already are subject to substantial regulation under the HIPAA Privacy and Security rules.

The focus of our comments, therefore, is on the appropriate scope of the FTC's efforts and how these efforts may interact with current regulation of the healthcare industry. We do not intend in these comments to address the more specific or technical questions raised by the FTC report, many of which focus on details related to the online collection of personal information.

- We support the general focus of the FTC report on improved privacy practices.

The FTC Report supports a broader emphasis across all commercial entities on the development and implementation of appropriate privacy and security practices. As advocates of privacy and security protections, we support these overall efforts. Our members have strong and longstanding practices related to effective security, reasonable data collection practices, safe disposal of protected information, and reasonable procedures for data accuracy (which obviously is a critical component of effective healthcare). We believe that meaningful consumer choice (which, as discussed below, already is a critical component of the HIPAA rules) is an important component of overall privacy protections. We also support the principles of transparency of company privacy and security practices in order to inform the individual's expectations about the

privacy and security of their information. It is in the interest of all consumers – and all businesses – to adopt reasonable and appropriate practices related to privacy and security. We believe that the proposed framework is a reasonable launching pad for exploring the right balance between the benefits of information collection and use activities and the interests of consumers in appropriate privacy and security practices.

- The FTC Framework incorporates many of the same ideas and standards that are included in existing HIPAA rules.

It is important to recognize that the FTC approach will be “new” only for businesses and other entities that have not previously adopted these kinds of practices. The framework relies upon many of the same ideas that have been incorporated into specific privacy laws and regulations in the past (typically limited to specific industries), such as the HIPAA Privacy and Security Rules. The healthcare industry has been subject to specific privacy and security obligations for many years (and in fact many healthcare companies had substantial privacy obligations well before HIPAA).² While we recognize that HIPAA does not regulate all use and disclosure of all 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.

The HIPAA standards include specific regulations on many of the concepts included in the FTC framework – for example, privacy notices,³ specific security practices, consumer access to information maintained by healthcare companies, designated “privacy officers,” employee training on privacy and security, patient authorization in certain situations, etc. The HIPAA approach also thoroughly and appropriately addresses how to obtain and provide patient consent, including implied and express consent options.

Therefore, for these covered entities and their service providers (called “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.

² For example, the FTC’s “Fair Information Practices” served as a critical data point in the development of the HIPAA rules.

³ We support the idea of clear and simple privacy notices. We have encouraged HHS to revise its approach to HIPAA privacy notices, and believe that HHS revisions remain the more appropriate step for revisions of the HIPAA rules, not a separate approach from the FTC.

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- There is no need for the FTC to alter or supplement the existing HIPAA framework.

Accordingly, because of this detailed framework – which includes elements far beyond the proposed FTC framework – the healthcare industry and its service providers currently engage in appropriate privacy and security practices, with recognition by the regulatory agencies with substantial subject matter expertise, as to how these “appropriate” practices should be defined. There is no need for the FTC to develop or mandate new privacy and security practices for those in the healthcare industry already regulated by these HIPAA standards.

In fact, we have substantial concerns 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. These standards have been developed by the relevant subject matter experts – the Office for Civil Rights within the Department of Health and Human Services (HHS) – with an understanding of not only the needs of consumers but the operations of healthcare entities and the delicate balance points for the overall needs of the healthcare system. The FTC should not – under a reasonable effort to develop “general” privacy practices – undertake to implement new or different standards for this industry. Simply put, 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. It is 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 healthcare entity. To impose different or additional standards for this information would create significant additional cost and unneeded complexity.

We encourage the FTC to make clear that its framework will not be applied to areas already subject to HIPAA regulation so that the healthcare industry can continue to focus its attention on the HIPAA standards – which often will be more strict than the general framework proposed by the FTC – without the need to develop multiple standards for the same information. 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.

- The FTC does not need to be involved in enforcement of privacy and security for the healthcare industry.

Beyond the specific details of the framework, we also see no need for the FTC to engage in enforcement activities related to areas already subject to regulation and enforcement through other agencies. The Confidentiality Coalition is very concerned about the FTC’s entrance into areas of regulation that are already occupied by HHS in the various HIPAA rules. Already,

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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 FTC 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 HHS to regulate HIPAA covered entities and their business associates.

There simply is no need for an additional regulator to oversee the privacy and security obligations of the healthcare industry. The HIPAA rules are in place and govern healthcare 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 FTC to enter this arena to provide additional (and potentially conflicting) regulatory oversight. To the extent that the FTC 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 HHS and the Attorneys General around the country.

Conclusion

The Confidentiality Coalition appreciates this opportunity to comment on the important issues raised by the FTC’s proposed framework. We believe strongly that there is no need for additional regulation by the FTC for entities and information already covered by the HIPAA rules. Please let us know if there are any comments or questions about the comments in this letter.

Sincerely,

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

Enclosure



2011 Steering Committee Membership

Aetna	Mayo Clinic
American Hospital Association	McKesson Corporation
America's Health Insurance Plans	Medco
Association of Clinical Research Organizations	National Association of Chain Drug Stores
Blue Cross Blue Shield Association	Pharmaceutical Care Management Association
CVS Caremark	Pharmaceutical Research and Manufacturers of America
Federation of American Hospitals	Premier healthcare alliance
Greenway Medical Technologies	Prime Therapeutics
Gundersen Lutheran	Surescripts
Healthcare Leadership Council	Texas Health Resources
Health Dialog	VHA
Health Industry Distributors Association	Walgreens
IMS Health	WellPoint
Marshfield Clinic	

General Membership

Abbott	ERISA Industry Committee	National Community Pharmacists Association
ACA International	Food Marketing Institute	National Rural Health Association
Adheris	Franciscan Missionaries of Our Lady Health System	NewYork-Presbyterian Hospital
American Academy of Nurse Practitioners	Fresenius Medical Care	NorthShore University HealthSystem
American Benefits Council	Genentech, Inc.	Novartis
American Clinical Laboratory Association	Genetic Alliance	Novo Nordisk
American Managed Behavioral Healthcare Association	Genzyme Corporation	Pfizer
Amerinet	Health Care Service Corporation	Quest Diagnostics
AmerisourceBergen	Healthways	ResMed
American Pharmacists Association	Humana, Inc.	SAS
Ascension Health	Ikaria	sanofi-aventis
Association of American Medical Colleges	Intermountain Healthcare	SCAN Health Plan
AstraZeneca	Johnson & Johnson	SCHOTT
Baylor Health Care System	Kaiser Permanente	Siemens Corporation
BlueCross BlueShield of Tennessee	Lahey Clinic	Society for Human Resource Management
Cardinal Health	Medical Banking Project	State Farm
CareFusion	MedAssets	Theragenics
Catalina Health Resource	Medtronic	Trinity Health
CIGNA Corporation	MemorialCare Health System	Vanderbilt University School of Nursing
Cleveland Clinic	Merck	U.S. Chamber of Commerce
Care Continuum Alliance	MetLife	Wal-Mart
Covidien	National Association of Health Underwriters	Weight Watchers International
C.R. Bard	National Association of Manufacturers	Wolters Kluwer Health
Eli Lilly	National Association of Psychiatric Health Systems	