FTC, FDA, OCR and ONC: A New Culture of Collaboration?

On April 5, 2016, the Federal Trade Commission (FTC) announced the release of a new web-based tool for mobile health app developers, which is designed to help those developers identify which federal privacy laws might apply to their products. In a potentially significant display of interagency cooperation, the FTC partnered with the Department of Health and Human Services' Office of National Coordinator for Health Information Technology (ONC), the Office for Civil Rights (OCR) and the Food and Drug Administration (FDA) to design the tool.

The tool features a series of high-level "yes" or "no" questions about the app's function, the data it collects, and the services it offers to users, that aim to help developers figure out which federal laws and regulations apply to their particular app. Based upon the answers, the tool highlights whether the Health Insurance Portability and Accountability Act (HIPAA), the FTC Act, the FTC's Health Breach Notification Rule, and the Federal Food, Drug and Cosmetics Act, might apply, and the tool directs users to the appropriate agency's site for more information.

What is notable for all healthcare organizations—not just mobile health app developers—is that all four agencies acknowledged that that there is confusion and a lack of clarity as to which privacy and security laws might apply to mobile health technology, and have acknowledged that the regulations are interrelated. According to Jessica Rich, director of the FTC's Bureau of Consumer Protection, "by working with our partner agencies, we're helping these businesses … comply with the law and provide more protection for consumers." Bakul Patel, associate director for digital health in the FDA's Center for Devices and Radiological Health echoed Ms. Rich's concerns about confusion developers face in app development, and declared "This effort is part of the FDA's continued commitment to protecting patient safety while encouraging innovation in digital health." ONC's chief privacy officer, Lucia C. Savage indicated her agency was "proud to have collaborated with FTC" on helping to clarify the regulatory landscape.

One underlying message of this multi-agency collaboration may be that these departments are seeking to cooperate on privacy enforcement in a broader healthcare context. For example, OCR has the authority to audit and investigate covered entities for alleged HIPAA privacy and security violations. If a privacy breach is uncovered, OCR may fine or take other enforcement action against the entity for the HIPAA violation. However, under Section 5 of the FTC Act, FTC has independent oversight of the covered entity's privacy practices. When a covered entity's notice of privacy practices does not reflect the entity's actual privacy practices, FTC has the authority to fine the entity for committing unfair and deceptive practices. Although the agencies are not prevented from notifying one another of potential violations of one another's regulations, in the past, FTC and OCR have typically appeared to pursue enforcement actions separate and apart from one another. It may now be more likely that one agency would aid the other in parallel investigations.

The release of the new decision tool also reflects an overall trend toward increased regulatory oversight of health data privacy and security generally. As part of this increased scrutiny, OCR, ONC and FDA regulators may now be more cognizant of potential deceptive practices, and FTC may be more cognizant of potential HIPAA or other privacy breaches. The long-range implications of this inter-agency alliance are clear: all healthcare and healthcare-related entities will need to take an integrative approach to evaluating the impact of FTC, FDA and HIPAA privacy and security regulations on their businesses.

MOSES & SINGER LLP

Since 1919, Moses & Singer has provided legal services to diverse businesses and to prominent individuals and their families. Among the firm's broad array of U.S. and international clients are leaders in banking and finance, entertainment, media, real estate, healthcare, advertising, and the hotel and hospitality industries. We provide cost-effective and result-focused legal services in the following areas:

- Accounting Law Practice
- Advertising
- Asset Protection
- Banking and Finance
- Business Reorganization, Bankruptcy and Creditors' Rights
- Corporate/M&A
- Corporate Trust
- Equipment Lease Financing
- Family Offices
- Global Outsourcing and Procurement
- Healthcare
- Hospitality, Food Service and Restaurants
- Income Tax
- Intellectual Property
- Internet/Technology
- Labor, Employment & Employee Benefits
- Legal Ethics & Law Firm Practice
- Litigation
- Matrimonial and Family Law
- Privacy and Cybersecurity
- Private Funds
- Promotions
- Real Estate
- Securities and Capital Markets
- Securities Litigation
- Sports & Entertainment
- Trusts and Estates
- White Collar Criminal Defense and Government Investigations

---

Moses & Singer LLP is the New York City law firm member of the MSI Global Alliance (MSI). MSI is one of the world's leading international alliances of independent legal and accounting firms, with over 250 member firms in 100 countries - www.msiglobal.org.

Moses & Singer LLP
The Chrysler Building
405 Lexington Avenue
New York, NY 10174-1299
Tel: 212.554.7800, Fax: 212.554.7700

2200 Fletcher Avenue
Fort Lee, NJ 07024
Tel: 201.363.1210, Fax: 201.363.9210
Abraham Y. Skoff, Esq.
Managing Attorney for New Jersey

10 Cuttermill Road – Suite 201
Great Neck, NY 11021
Tel: 516.498.8828, Fax: 516.498.8810
James Alterbaum, Esq.
Managing Attorney for Long Island

Disclaimer
Viewing this or contacting Moses & Singer LLP does not create an attorney-client relationship.

This does not contain a complete legal analysis or constitute an opinion of Moses & Singer LLP or any member of the firm on the legal issues herein described. This contains information that may be modified or rendered incorrect by future legislative or judicial developments. It is recommended that readers not rely on this in structuring or analyzing individual transactions or matters but that professional advice be sought in connection with any such transaction or matter.

Attorney Advertising
It is possible that under the laws, rules or regulations of certain jurisdictions, this may be construed as an advertisement or solicitation.