



THE SECRETARY OF HEALTH AND HUMAN SERVICES

WASHINGTON, D.C. 20201

NOV 21 2014

The Honorable Tom Marino
U.S. House of Representatives
Washington, DC 20515

Dear Representative Marino:

Thank you for your letter and suggestions regarding the development and use of mobile health applications that comply with the requirements of the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules (the "HIPAA Rules"). I appreciate learning of your views on this important matter and agree that the Department should strive to provide the best compliance guidance possible to the industry.

You asked the Department to take several steps to ensure that developers of mobile applications and other new health technology understand their HIPAA compliance obligations. I am pleased to note that the Department is moving forward in a number of ways to directly address the concerns raised in your letter. Below is information about the Department's efforts in response to your suggestions.

- *Provide up to date and clear information about what is expected of technology companies for compliance with the HIPAA Rules and identify the implementation standards that can help technology companies conform to the regulations.*

We recognize that mobile health technology is a rapidly growing field and that developers have questions about how the HIPAA Rules may apply to or affect their businesses. The Department's Office for Civil Rights (OCR), which administers and enforces the HIPAA Rules, develops guidance and technical assistance tools to assist HIPAA covered entities and their business associates with their compliance obligations. The first question for any entity, therefore, is whether it is a covered entity or a business associate within the meaning of the HIPAA Rules. The OCR website contains information and tools that can help to address that question (please see <http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/index.html>; and http://www.hhs.gov/ocr/privacy/hipaa/faq/business_associates/index.html#businessassociate). In addition, OCR and the Office of the National Coordinator for Health Information Technology (ONC), work collaboratively to develop guidance and other tools to educate all stakeholders regarding safe and secure use of health information technology. These tools are available at <http://www.healthit.gov>.

We understand that existing guidance materials may not address all of the questions that companies in this emerging field may have. To begin to address these issues, OCR has already met with ACT | The App Association, which represents over 5,000 app companies and information technology firms, to discuss the needs of companies and to ensure that OCR can provide technical assistance and guidance in appropriate and useful ways. We expect

this dialogue with ACT | The App Association to continue. OCR and ONC also are exploring the feasibility of several real time solutions to hear from mobile application and other technology developers themselves on the most pressing issues that the community would like to see addressed through guidance materials. We will use this feedback to inform our ongoing efforts to provide the most useful guidance possible to this industry.

- *Provide more clarity on HIPAA obligations for companies and services that store data in the cloud.*

We recognize the benefit of providing additional HIPAA guidance directed to cloud storage and related services and are examining how best to address these and other questions from the mobile health technology community.

- *Engage regularly with technology companies to provide compliance assistance.*

We agree that outreach to this industry is critical. As noted above, we have begun a dialogue with ACT | The App Association to identify ways in which we can best address the questions and concerns of the technology companies. Further, we are also exploring the possibility of holding a series of “listening sessions” through which we can hear directly from stakeholders in the mobile health field about privacy and security concerns that can be addressed through guidance.

Thank you again for bringing these concerns and your views to my attention. I value your input and look forward to working together on these important issues. I will also provide this response to Representative DeFazio.

Sincerely,



Sylvia M. Burwell