

Congress of the United States
Washington, DC 20515

March 9, 2016

The Honorable Sylvia Mathews Burwell
Secretary of Health and Human Services
United States Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Burwell:

We write today regarding firm commitments made to Congress in November, 2014¹ to address insufficient guidance from the Department of Health and Human Services (HHS) on the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules (the "HIPAA Rules") for technology companies producing groundbreaking innovation through mobile health apps and connected devices.

More than fifteen months have passed since you outlined a number of commitments to Congress. The sluggish pace of work since has been very disappointing. While HHS can point to the publication of a single document earlier this month as progress, the sum of its efforts reveals a worrisome lack of urgency. At this stage, a detailed plan with concrete deadlines is required.

We have serious concerns about the consequences of HHS inaction. Advances in mobile health technology have the potential to dramatically improve patient outcomes and the accessibility of health care. This innovation is coming at a rapid pace, but your agency has done little to demonstrate it can manage the significance.

Over five-and-a-half billion iPhone and Android devices have been sold in the past decade.² Smartphones have become the fastest adopted technology in human history. During the time in which these devices had been updated or improved more than 24,000 times³, HHS failed to provide any guidance on how HIPAA applies to these mobile technologies. We have already seen incredible results from early investment in connected health innovation, and the slow pace of government should not stand in the way of patient access to the benefits of this life-changing technology.

Connected Health Improves Patient Outcomes

Smartphones and tablets have dramatically changed how we communicate and share information. They have transformed our society, connecting us in ways we never would have

¹ Letter from Sec. Sylvia Burwell, Department of Health and Human Services, to Reps. Tom Marino and Peter DeFazio, U.S. House of Representatives (Nov. 21, 2014).

² "Global smartphone shipments from 2007 to 2015, by vendor," Statista. Available at: <http://www.statista.com/statistics/271539/worldwide-shipments-of-leading-smartphone-vendors-since-2007/>. Last accessed February 12, 2016.

³ "Android Fragmentation Visualized (August 2015)," Open Signal. Available at: <http://opensignal.com/reports/2015/08/android-fragmentation/>. Last Accessed February 12, 2016.

imagined a decade ago. This connectivity has also given rise to a new class of services like Fitbit, that monitors fitness, and AirStrip®, that transmits critical health data to medical professionals.

AirStrip® is a model example of the potential of connected health care. Its apps and connectivity services allow physicians to remotely view live patient data. Emergency medical staff are able to send live, waveform data from an ambulance to the emergency room so that a trauma center or cath lab can be readied by the time the patient arrives. The minutes, or even seconds, that are saved by this technology can make a critical difference in patients' lives.

Rimidi offers another example of the impact connected health companies can have in patient care. Its diabetes management product Diabetes+Me™ allows patient-entered information to be easily shared with a healthcare team. Physicians can remotely monitor adherence to care plans, communicate with patients directly, and make adjustments when necessary. Research has demonstrated that its app can produce better patient outcomes at a lower cost.⁴

Connected health has the potential to impact a broad segment of the population with chronic conditions such as diabetes, asthma, and heart disease. Through apps and connected devices, patients have the ability to communicate and share readings from a home blood pressure cuff, connected glucometer, or smart inhaler. These new technologies bridge the gap between patient and physician, providing a continuous record of readings between doctor visits leading to earlier diagnoses, speedier recoveries, and better patient outcomes.

Lack of HIPAA Clarity Denies Patient Access to New Technology

Consumers and care providers are eager to adopt connected health technologies – 86 percent of physicians believe mobile apps can improve patient health management.⁵ But, the persistent lack of clarity around HIPAA applicability in a mobile environment prevents many patients from benefiting from these services. Many physicians are reluctant to receive health readings from their patients electronically without clear regulatory guidance. This uncertainty also discourages hospital systems from adopting patient-centered technologies. HHS has failed to provide even the simplest guidance to explain whether physicians and patients can text each other.

We recognize the highly sensitive nature of personal health information and strongly support the privacy and security protections under HIPAA. Connected health companies that are covered by HIPAA want to meet these requirements, but are unsure how to without clear guidance from HHS.

⁴ Lindsey Valenzuela, Lucienne Ide, Michael Jardula, Mena Salib, Jade Le. "Early Results Support Efficacy and Clinical Efficiency of Diabetes Management Decision Support Software for Blood Glucose." Annual Diabetes Technology Meeting, San Diego, CA, October 2015.

⁵ "Top health industry issues of 2015" PwC Health Research Institute (December, 2014) Available at: <https://www.pwc.com/us/en/health-industries/top-health-industry-issues/assets/2015/pwc-hri-2015.pdf> (last accessed February 9, 2016).

In 2014, you committed to several measures to ensure connected health companies understand their HIPAA compliance obligations.⁶ Specifically, you committed to:

- 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.
- Provide more clarity on HIPAA obligations for companies and services that store data in the cloud.
- Engage regularly with technology companies to provide compliance assistance.

We welcomed these commitments in 2014, but have seen little evidence of meaningful follow through. Directing queries to outdated content on the HHS website does not meet our expectations for sufficient guidance. And the February 10, 2016 release of the *Health App Use Scenarios and HIPAA*⁷ document underscores persistent shortcomings in the HHS response.

2014 HHS Commitments Unmet

Up-to-date and clear information about obligations under HIPAA is critical. The February 10th release addresses specific scenarios which may be helpful in a narrow range of circumstances, but the guidance is intended only for the community of app makers. And in some areas, this effort has led to more questions than answers.

Connected health can best improve patient outcomes when it facilitates the sharing of information among patients, physicians, and caregivers. App companies and device makers offer services to meet the needs of each of these entities. HHS must provide clear guidance to all participants about HIPAA's applicability in a mobile environment for patients to receive the full benefits of this technology. Disappointingly, this guidance fails to address anything beyond consumer-focused apps.

Another 2014 commitment was to provide clarity for the storage of health data in the cloud. Mobile device users expect to remotely store and access a wide range of information. This will greatly improve patient awareness and engagement, but to meet this demand requires clear guidance from HHS. The connected health community has seen no indication of progress in this area.

The last of your 2014 commitments was to engage regularly with technology companies. We are unaware of meaningful results in this area. Moreover, we saw minimal effort to draw attention to the only HIPAA guidance document on mobile use that HHS has published in the past decade.

⁶ Letter from Reps. Tom Marino and Peter DeFazio, U.S. House of Representatives, to Sec. Sylvia Burwell, Department of Health and Human Services (September 18, 2014).

⁷ "Health App Use Scenarios & HIPAA" HHS Office of Civil Rights (February 9, 2016) <http://hipaaportal.hhs.gov/community-library/accounts/92/925889/OCR-health-app-developer-scenarios-2-2016.pdf> (last accessed February 15, 2016)

Next Steps Required

We appreciate the work of industry organizations to highlight these concerns. It bears mention, however, that Members of Congress raised these issues directly with you and have not received updates, or been consulted, on any efforts in this area for the past fifteen months.

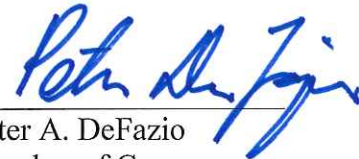
Given the concerns outlined above, we request your presence for a Member briefing to review the progress of previous commitments, and identify ways in which HHS, Congress, and industry stakeholders can work together to achieve real progress.

We thank you for your attention to these issues, and look forward to achieving real results that help patients benefit from improved care through connected health.

Sincerely,



Tom Marino
Member of Congress



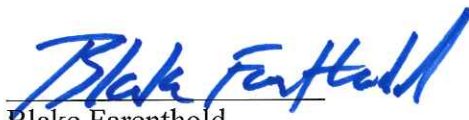
Peter A. DeFazio
Member of Congress



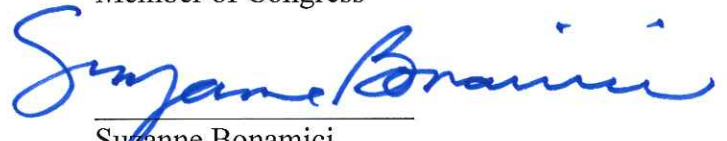
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Member of Congress



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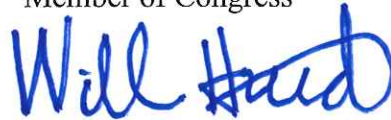
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