

United States Senate

WASHINGTON, DC 20510

February 8, 2019

The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Ave. SW
Washington, DC 20201

Dear Mr. Secretary,

We write to express our concerns regarding the recent Request for Information (RFI) issued by your Department asking about a number of potentially significant changes to regulations and policies governing the privacy and security of health information pursuant to the Health Insurance Portability and Accountability Act (HIPAA).¹ These potential changes, which are part of an initiative led by Deputy Secretary Eric Hargan known as the Regulatory Sprint to Coordinated Care, are described as an effort to improve coordination of care and to respond to the ongoing opioid epidemic. The proposed changes, however, could extend far beyond these purposes and could dramatically reduce HIPAA protections by allowing greater access to an individual's health information by others while reducing the rights currently afforded patients. While we strongly support improving information sharing to improve health outcomes, improve health care quality, and lower costs, we are concerned that pursuing such policies without protecting patients' privacy may lead patients to withhold information from health care providers, or worse, forgo care altogether. In addition to the concerns regarding the RFI, we are also concerned the Office for Civil Rights, the organization within HHS charged with enforcing HIPAA, is failing to meet its statutory obligations to report to Congress on its efforts to ensure compliance with HIPAA and on the frequency of breaches that disclose protected health information held by covered entities under HIPAA.

In the December 14, 2018 RFI, HHS is seeking comment on potential proposals that may lead to greater disclosures of protected health information, including sensitive information on reproductive, genetic, and mental health, to entities and individuals who are not health care providers. Specifically, HHS requests comment on whether it should allow greater access to highly personal health information by companies and agencies that are not HIPAA-covered entities by creating express permission to disclose protected health information to social service agencies and community-based support programs. Additionally, HHS also proposes that other individuals – parents, spouses, and adult children – have greater access to a patient's protected health information. For example, HHS requests comment on the appropriateness of allowing greater access by parents or guardians to a child's records – both for minor children and adults – and to no longer defer to state laws with respect to whether a parent or guardian or personal

¹ <https://www.hhs.gov/about/news/2018/12/12/hhs-seeks-public-input-improving-care-coordination-and-reducing-regulatory-burdens-hipaa-rules.html>

representative has a right to such access. HHS also proposes to allow spouses to have greater access to a patient's protected health information, as well as access by children to their parents' information, while also no longer deferring to state laws governing such access. Family members are a critical part of a patient's care, which is why the HIPAA privacy rule establishes a process for sharing information with family and friends. Congress recently enacted policies to provide better training and education to health care providers about when and how to share information regarding mental health and substance use disorder diagnosis and treatment.

The RFI also seeks comment on major changes to the existing HIPAA structure. One question relates to removing the "minimum necessary" requirement regarding the amount of information that covered entities can disclose to one another. Several other questions relate to changing the permissive structure of HIPAA entirely and, instead, requiring covered entities to share records upon request instead of permitting it. These questions appear to be intended to stop information blocking in order to improve care coordination. Congress already came together, on a bipartisan basis, to prohibit the practice of information blocking and is currently awaiting a proposed rule from the Department to implement this prohibition. How can stakeholders adequately consider the implications of major changes to the HIPAA privacy rule when the administration has not even published its proposed rule on information blocking?

Finally, HHS is required by law to provide annual reports to the Congress on its efforts to ensure compliance with HIPAA (known as Section 13424 reports) and breaches of health care providers' health information databases (known as Section 13402 reports). It appears the last time the Department issued these reports was in August 2016, and those reports were for calendar years 2013 and 2014. While these reports in themselves do not constitute enforcement, they provide Congress with information necessary to determine whether the Department and covered entities are adequately safeguarding patients' protected health information. The fact the Department has failed to produce these statutorily-required reports suggests that adequately safeguarding protected health information is not a priority for this administration.

To begin addressing the concerns outlined in this letter, we request you direct Deputy Secretary Hargan and the Director of the Office for Civil Rights, Roger Severino, or their designees, to brief our staffs by no later than February 28, 2019, on the intent of each of the potential proposals discussed in the December 14, 2018 RFI and to explain the Department's failure to provide the required annual reports. In addition, so that we can better understand the basis for the Department's potential proposals, we request the Department provide the following information by no later than February 18, 2018:

- 1) The Office for Civil Rights FY2018 and FY2019 strategic and annual work plans.
- 2) Any and all strategic or work plans of the Regulatory Sprint to Coordinated Care initiative.
- 3) Any and all written or electronic requests made to you or any other Department officials since January 2017, including but not limited to the Office for Civil Rights, requesting any of the proposed changes to the Department's HIPAA regulations and policies made in the December 14, 2018 RFI.

If you or your staff have any questions concerning these requests, please contact Elizabeth Letter of Ranking Member Murray's staff at 202-224-0767 or David Berick of Ranking Member Wyden's staff at 202-224-4515.

Sincerely,



Patty Murray
Ranking Member
Committee on Health, Education,
Labor and Pensions



Ron Wyden
Ranking Member
Committee on Finance