

United States Senate

WASHINGTON, DC 20510

November 15, 2019

The Honorable Alex M. Azar II
Department of Health and Human Services
Office of the Secretary
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Azar:

I am writing regarding the proposed rule from the Center for Medicare and Medicaid Services (CMS) on Interoperability and Patient Access that would enable third party consumer applications to access sensitive patient and health plan data through application programming interfaces (APIs) [1]. I share the goals of advancing interoperability in patient health information and believe that – implemented appropriately – this proposal could represent a significant step in that direction. However, I urge CMS to take additional steps to address the potential for misuse of these features in developing the rules around APIs. In just the last three years, technology providers and policymakers have been unable to anticipate – or preemptively address – the misuse of consumer technology which has had profound impacts across our society and economy. As I have stated repeatedly, third-party data stewardship is a critical component of information security, and a failure to ensure robust requirements and controls are in place is often the cause of the most devastating breaches of sensitive personal information.


Congress passed the *21st Century Cures Act (P.L. 114-255)* with a key objective of improving the protected exchange of electronic health records across the care continuum. Notably, Section 4003 and 4004 included specific provisions to establish a trusted health information exchange framework and reduce information blocking; it stated that there should be regulation over unreasonable practices to interfere with, prevent, or materially discourage access, exchange, or use of a patient's electronic health records. While your agency has taken substantial steps to implement fundamental aspects of this legislation, it is critical that there are proper safeguards in place to protect patient privacy and sensitive health information. Moreover, there should be more work done by HHS to facilitate greater access to, and transfer of, electronic health information that does not inadvertently enable dominant IT providers to leverage their control over user data outside of the health care context into nascent markets for personalized health products.

In your proposed rule CMS would specifically require Medicare Advantage (MA) organizations, state Medicaid and Children's Health Insurance Program (CHIP) Fee-for-Service (FFS) programs, Medicaid managed care plans, CHIP managed care entities, and qualified health plans (QHPs) on the federally-facilitated exchanges (FFEs) to allow patients to access their personal health information electronically through an open application programming interface (API). Data

which the patient has expressly given informed proactive consent, including cases where patient information may be sold, and that patients retain the right to direct any party that has acquired their data to delete it upon request. Further, those accessing patient data should be prohibited from conditioning continued access on agreement by the patient to share their data with third parties.

Thank you for your consideration your commitment to advancing interoperability to improve patient care. I believe the outline I have shared would strengthen and ensure the rule achieves its intended purpose. It is my hope and belief that we can achieve both a higher level of interoperability and patient access to their data, as well as, strong protections for that information. I look forward to continued work with you on this important issue and our shared goals.

Sincerely,


Mark R. Warner
United States Senator