

United States Senate

WASHINGTON, DC 20510

November 15, 2019

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:

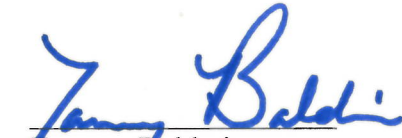
Advancing interoperability for the secure exchange of electronic health information is a primary goal of the bipartisan 21st Century Cures Act (Pub. L. 114-255). Patients should be in control of their health information, and their providers should have access to the information they need to deliver the best care. As such, we strongly support the goals of Title IV of the 21st Century Cures Act and the intent of the *21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule*. In an effort to facilitate the meaningful exchange of electronic health information and ensure that regulated actors are able to comply with the proposed rule, we recommend that the rule be revised to focus on enabling the exchange of an achievable, well-defined, and standards-based dataset.


Under the proposed rule from Office of the National Coordinator for Health Information Technology (ONC), health systems and health IT developers will be required to ensure the ability to export a patient's "electronic health information" (EHI) to the patient, their third party designee, or a health care provider. We strongly believe that patients should have access to their personal health information, and we are encouraged that ONC is taking significant steps to advance this effort. However, we continue to hear concerns surrounding the lack of clarity and standards for what constitutes EHI. This largely undefined patient data set is much more expansive than the ONC-backed standard, the U.S. Core Data for Interoperability (USCDI), which many systems are still working toward implementing. Furthermore, we have concerns about how the ambiguity surrounding the definition of EHI and regulated actors' confusion about what data must be exchanged in order to avoid accusations of information blocking could increase burden across the industry and create risks to patient privacy and security.

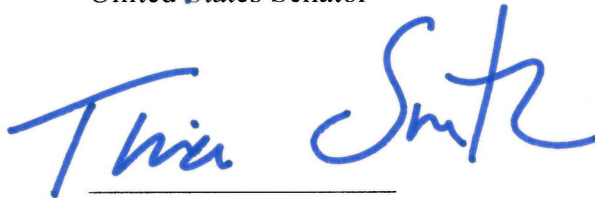
Health systems currently struggling to exchange electronic health information and meet regulatory requirements will be most successful if they can focus their compliance efforts on an existing core set of electronically standardized health information. USCDI contains critical clinical information in an interoperable format that can be readily used by all industry participants. In addition, ONC is empowered to expand USCDI over time to build on the clinical information with billing and financial data relevant to a patient's care. It is clear that we have more work to do to achieve full interoperability, and we appreciate the efforts that are underway to advance this goal. We can't fix this overnight, so we believe that we must also take care to establish a clear standards-based approach as the foundation for interoperability to ensure that all stakeholders can meet this critical goal. We encourage ONC to examine the definition of EHI to

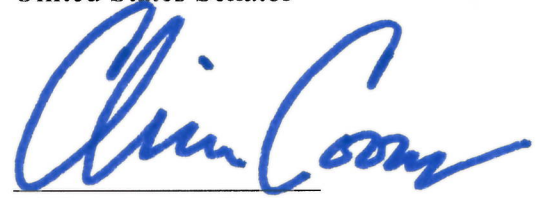
align with the USCDI to better establish clear parameters for what electronic health information must be made available for access, exchange, and use. Reframing the definition of EHI in this manner would enable ONC to finalize a rule that requires compliance with ambitious yet manageable standards for interoperability.

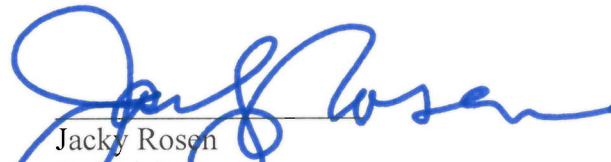
Sincerely,



Tammy Baldwin
United States Senator


Ron Johnson
United States Senator



Tina Smith
United States Senator


Christopher A. Coons
United States Senator


Jacky Rosen
United States Senator


James Lankford
United States Senator


Richard J. Durbin
United States Senator


Martha McSally
United States Senator

Cc: Russell Vought, Acting Director, Office of Management and Budget
Joe Grogan, Director, Domestic Policy Council