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By electronic submission

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

The Honorable Donald Rucker, M.D.
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C Street SW, 7th Floor
Washington, D.C. 20201

The Honorable Seema Verma, M.P.H.
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, D.C. 20201

**RE: UCSF CENTER FOR DIGITAL HEALTH INNOVATION'S COMMENTS ON
DRAFT STRATEGY ON REDUCING REGULATORY AND ADMINISTRATIVE
BURDEN RELATING TO THE USE OF HEALTH IT AND EHRS**

Dear Secretary Azar, National Coordinator Rucker, and Administrator Verma:

The University of California, San Francisco's Center for Digital Health Innovation
submits these comments on the draft Strategy on Reducing Regulatory and
Administrative Burden Relating to the Use of Health IT and EHRs, issued November
28, 2018. The University of California, San Francisco (UCSF) is a worldwide leader in
health care delivery, discovery, innovation, and education. Consistent with this public
imperative, UCSF invests heavily in developing a variety of health information
technology, innovation, and management resources and best practices to give health
care providers and patients,[1] researchers and innovators, educators and students the

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[1] For brevity, these comments refer to "patient" and "care," given that many federal programs and initiatives are rooted in
a clinical or medical model. Health and health care, however, embrace more than clinical settings and extend well
beyond clinical treatment of episodes of illness and exclusive dependency on professionals. Any effort to improve patient
and family engagement must include terminology that also resonates with the numerous consumer and community
perspectives not adequately reflected by medical model terminology. For example, people with disabilities and others
frequently refer to themselves as "consumers" or merely "persons" (rather than patients). Similarly, the health care
community uses the terminology "caregivers" and "care plans," while the independent living movement may refer to
"peer support" and "integrated person-centered planning."

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digital health tools and interoperability needed to succeed in this rapidly evolving digital health age. We thank you for the opportunity to provide these comments.

UCSF's Center for Digital Health Innovation appreciates the Department's lengthy summary and proposed strategies and recommendations to reduce regulatory and administrative burdens for clinicians. We focus instead on the half that is missing from the draft strategy: **the experiences of and reducing the burdens on America's patients**. Each of you notes in your opening messages that the Department must improve the experience of both clinicians and patients, and put patients at the center of care. Yet the draft focuses only on clinicians' burdens and fails to address patients' burdens. (E.g., Draft Strategy, pp. 9-10.) Even with respect to clinicians' burdens, the draft omits to assess how the strategies and recommendations to reduce clinicians' burdens might concurrently *increase* burdens on and barriers to access for America's patients. We recommend that the Department **revisit the draft strategy, consider as well the burdens and adverse impacts upon patients, and develop an integrated approach** that considers and, where necessary, balances the respective impacts and burdens upon clinicians and patients.

For example, the draft strategy highlights how the Department has reduced the number of required measures and simplified the scoring methodology for clinicians and hospitals in what was Stage 3 of the Meaningful Use Program, now the Promoting Interoperability Program. (E.g., Draft Strategy, pp. 16-17.) CMS repealed the patient-engagement objective and four core measures of patients' meaningful uses: patient access to view, download, transmit, or manage their health data with apps and APIs; secure messaging with their doctors; sharing patient-generated health data with their doctors; and patient-specific educational material. CMS repealed them "because they have proven burdensome to MIPS eligible clinicians in ways that were unintended and may detract from clinicians' progress on current program priorities." (83 Fed. Reg. at 35920.)

As we wrote in our public comment letter at the time, this repeal not only increased the burdens on the nation's patients; it increased the burdens on the nation's doctors and hospitals as well. As one of the nation's leading academic medical centers, participating in a Bay Area-wide accountable care organization, and running the county trauma center and the VA hospital in a major metropolitan county, UCSF monitors and manages those workflows and burdens and their impact on patient care every day. Better care, better health and lower cost depend upon better communication and coordination among providers, patients and family caregivers, and others who coordinate the patient's care after the 15-minute office visit. Providers cannot succeed under new models of care without activated and engaged patients accessing and using their health information, ready access to patient-generated health data and outcomes, and more granular data essential for effective clinical decision support and prevention. **Eliminating the patient engagement objective and all of the patient-facing measures instead substantially *increases* the long-term burden upon doctors, patients, and the national health ecosystem**.

Accordingly, we recommend that the Department revisit the draft strategy, consider as well the burdens and adverse impacts upon patients, and develop an integrated strategy that considers and, where necessary, balances the respective impacts and burdens upon clinicians and patients.

The 21st Century Cures Act agrees. A bipartisan Congress directed the Secretary to improve the impact of health IT and electronic health records on both clinicians and patients together. The Cures Act did not bifurcate clinicians from patients and focus on clinicians' needs to the exclusion of patients' needs. Rather, Congress enacted a holistic approach. It declared "interoperability" a national priority and imperative, to assure electronic access, exchange, and use of health information—for clinicians and patients alike.[2] Congress likewise declared "patient access" a national priority and imperative, and directed the Secretary to work to provide "patients access to their electronic health information in a single, longitudinal format that is easy to understand, secure, and may be updated automatically."[3] The draft strategy should be looking at burdens for clinicians and patients together.

EXPERTISE OF UNIVERSITY OF CALIFORNIA, SAN FRANCISCO AND UCSF'S CENTER FOR DIGITAL HEALTH INNOVATION

UC San Francisco is a worldwide leader in health care delivery, discovery, and education. In recent years, we have invested heavily in developing the information technology resources to help health care providers, patients, researchers, innovators, educators, and students have the interoperability and tools needed to succeed in the rapidly evolving digital age. UCSF's medical centers consistently rank among the nation's top hospitals, according to U.S. News & World Report, and see approximately 43,000 hospital admissions and 1.2 million outpatient visits annually, including care of the county's underserved and veteran populations.

UCSF focuses on solving real and important problems at national, regional, and global levels. UCSF's own scope extends beyond tertiary/quaternary care at UCSF facilities, to our level one trauma center at Zuckerberg San Francisco General Hospital, the county hospital and safety net hospital for San Francisco; to the San Francisco Veterans Affairs Medical Center; and to our accountable care organizations (ACOs) including community hospitals and clinics across the Bay Area. Additionally, through UC Health, we have access to 15 million patient health records at six academic medical centers across the State of California, representing an incredibly diverse set of individuals and approximately one third of California's population in the world's seventh largest economy. Therefore, we represent the full continuum of healthcare, with access to patient and population-level data on myriad disease conditions and patient demographics.

We have played a seminal role in developing precision medicine, an emerging field that aims to harness vast amounts of molecular, clinical, environmental and population-wide

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[2] 21st Century Cures Act, § 4003 (adding 42 U.S.C. § 300jj-12(b)(2)(B)(i), (c)(2)).

[3] 21st Century Cures Act, § 4003 (adding 42 U.S.C. § 300jj-12(b)(2)(B)(iii)); id. § 4006(a). Congress directed the Secretary to "promote policies that ensure that a patient's electronic health information is accessible to that patient and the patient's designees, in a manner that facilitates communication with the patient's health care providers and other individuals, including researchers, consistent with such patient's consent." (21st Century Cures Act, § 4006(a).) Likewise, Congress highlighted usability for patients to contribute patient-generated health data and patient-reported outcomes and to contribute to research. (Ibid.) Congress mandated access, exchange and use "without special effort on the part of the user," and specifically highlighted the importance of open application programming interfaces (APIs). (21st Century Cures Act, § 4003(a)(2).) In short, Congress required interoperability, access, and use for patients and family caregivers as well as providers, and specifically included patient access and use, communication with doctors, and patient-generated health data.

data to transform the future of health diagnosis, treatment and prevention for people worldwide. Indeed, UCSF's policy and research leadership helped stimulate the nation's Precision Medicine Initiative, urgently moving forward under the 21st Century Cures Act to improve care and health for individuals across the nation. UCSF research has spawned more than 185 startups, including pioneers Genentech and Chiron, and helped establish the Bay Area as the nation's premier biotech hub.

In 2013, UCSF founded its Center for Digital Health Innovation (CDHI), which partners with technology companies to solve real-world health problems and speed the implementation of innovation into everyday health care. CDHI is renowned for its thought leadership in digital health. Currently, our work focuses on enabling the ecosystem of innovative health apps and open application programming interfaces (APIs) that improve workflows, care quality, and patient engagement by creating true health data interoperability.

CDHI also partners with Intel and GE to build deep learning prediction algorithms to be leveraged behind the scenes and at the point of care by frontline providers. This program, called SmarterHealth, integrates our evidence-based research and clinically rigorous approaches to digital health innovation into a collaborative approach with leading industry partners to build infrastructure, processes, and products that address high priority, real-world problems in care delivery. SmarterHealth creates methodologies and tools to access, harness, and annotate multi-modal data in a scalable and repeatable process using advanced analytics and deep learning (artificial intelligence approaches).

The Center for Digital Health Innovation is just one among many centers that UCSF has dedicated to helping the nation reach its digital health imperatives. For example, the Institute for Computational Health Sciences (ICHS) under Dr. Atul Butte leads nationally renowned work to advance precision medicine and big data. The Center for Vulnerable Populations is known nationally and internationally for innovative research to prevent and treat chronic disease in populations for whom social conditions often conspire to promote various chronic diseases and make their management more challenging. The Social Interventions Research and Evaluation Network (SIREN) at the Center for Health and Community is working to integrate social and environmental determinants of health. The Center for Clinical Informatics and Improvement Research (CLIIR) under Dr. Julia Adler-Milstein leads national research on use of EHRs and other digital tools to improve health care value. We bring the breadth and depth of these and many other efforts to bear in our comments above.

Conclusion

Thank you for the opportunity to provide these comments on the draft Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs. CDHI **urges the Department revisit the draft strategy, consider as well the burdens and adverse impacts upon patients, and develop an integrated approach that considers and, where necessary, balances the respective impacts and burdens upon clinicians and patients.** This will avoid crippling the digital health ecosystem in significant ways and substantially increasing the long-term burden upon doctors, patients, and the national health system.

If you have any thoughts or questions about these comments, please contact Mark Savage at Mark.Savage@ucsf.edu.

Sincerely,

Aaron Neinstein, M.D.
Director, Clinical Informatics
Center for Digital Health Innovation

Mark Savage
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Center for Digital Health Innovation