



Center for Digital Health
Innovation (CDHI)

UCSF Mission Bay Campus
1700 Owens Street, Suite 541
San Francisco, CA 94158-0008

415.502.3305
cdhi.ucsf.edu

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By email to Cures2@mail.house.gov

The Honorable Diane DeGette
Member of Congress
United States House of Representatives
2111 Rayburn House Office Building
Washington, D.C. 20515-4329

The Honorable Fred Upton
Member of Congress
United States House of Representatives
2183 Rayburn House Office Building
Washington, D.C. 20515

Re: Cures 2.0—UCSF Center for Digital Health Innovation’s Suggestions for Digital Health and Shared Care Planning Provisions

Dear Congresswoman DeGette and Congressman Upton:

The University of California, San Francisco’s Center for Digital Health Innovation submits these comments in response to your letter, issued November 22, 2019, requesting ideas for “Cures 2.0” in the areas of digital health technology, coverage, data and real-world evidence, and shared care planning.

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 digital health tools and interoperability needed to succeed in this rapidly evolving digital health age.

UCSF’s Center for Digital Health Innovation appreciates the request for input on what’s needed for Cures 2.0. We focus here on three specific recommendations in the areas of shared care planning, digital health interoperability, and patient access to their health data collected by mobile health apps and devices. To complement the Cures Act’s provision on patients’ access to their health data, **Cures 2.0 should add an equally critical vision for shared care planning that includes patients, clinical settings, and non-clinical settings and caregivers.** Secondly, the Cures Act defined and established interoperability as a national imperative. **Cures 2.0 should integrate a comprehensive interoperability measurement framework from the Office of the National Coordinator for Health Information Technology (ONC) and National Quality Forum (NQF) in order to measure and evaluate where interoperability does and does not exist.** Lastly, the Cures Act, like the Health Insurance Portability and

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.”

Accountability Act (HIPAA) and its implementing regulations, covered patients' right to access their health information in HIPAA-covered settings. But today's digital health ecosystem collects significant amounts of health data in patients' third-party mobile health apps. **Cures 2.0 should extend patients' right of access to include health information collected by the mobile health apps and devices that patients (and providers and plans) increasingly use these days to monitor, diagnose, and treat.**

1. 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, with a mission of "Advancing Health Worldwide." 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 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 this experience and expertise to bear in our comments above.

2. Shared Care Planning for Better Care, Health, and Value

We applaud the request for ideas “to improve the ability of families and caregivers to support their loved ones.” The original Cures Act captured and implemented a powerful vision of patients’ access to their health information, directing 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.”² Cures 2.0 is just the place to articulate an equally powerful vision of shared care planning, by directing the Secretary to provide “patients and their providers, family, and caregivers access to shared care planning and a single dynamic, longitudinal shared care plan, updated automatically.”

Better care, health, and value depend upon better communication and coordination among providers, patients, family caregivers, and others who coordinate a person’s care outside the clinical setting. A dynamic, longitudinal “care plan” is distinct from an episodic “plan of care” or “plan of treatment.” The plan of treatment focuses on a particular episode, condition, diagnosis, etc. The shared care plan synthesizes the multiple plans of treatment for each of the patient’s health goals, conditions, or diseases into a dynamic, longitudinal shared care plan for the patient, various providers and caregivers, and other relevant entities. **Shared care planning enables providers, patients, and payers to share and retrieve a patient’s dynamic**

² 21st Century Cures Act, Pub. L. 114-255, § 4003, 130 Stat. 1033, 1165 (2016) (adding 42 U.S.C. § 300jj-12(b)(2)(B)(iii)); id. § 4006(a).

shared care plan for purposes of coordinating care among the patient’s care teams and family caregivers, improving patient outcomes and health, providing continuity of care, and optimizing clinical processes in support of value-based care arrangements and the patient’s health goals. Shared care planning requires a dynamic, electronic process, not a static document.

Shared care planning would be designed to anticipate and work across the diversity of patients, care providers, and payers. For example:

- Individuals’ health and health care goals range in complexity from wellness checks to management of multiple chronic conditions, and range in duration from short-term to long-term.
- A patient might have one main doctor, or multiple providers, entities, and caregivers involved in her health care. For example, one patient might have a primary care physician (PCP), a cardiologist, an oncologist, a physical therapist, perhaps a diabetes consultant, and a health plan’s care management nurse or program. She might have one or more family caregivers, and one or more social or community services relevant to her health and care, such as school clinics, foster-care services, special education plans for children with disabilities, or assisted living. Pharmacies, labs, skilled nursing facilities, physical therapists, and nutritionists might also have regular planning updates to contribute.
- Payers have different models and roles. For example, not all payers require and use a primary care physician (e.g. PPOs). Different payers might provide differing levels of clinical or case management services.

Cures 2.0 could do much to advance such a vision of shared care planning and access to shared care plans for patients, providers, and caregivers.

3. Improving Interoperability with ONC’s and NQF’s Interoperability Measurement Framework

The Cures Act requires developers to test health information technology for interoperability in the real world settings and uses for which it would be marketed.³ The Office of the National Coordinator for Health Information Technology, in turn, has recognized that such real-world testing must assess interoperability “within the workflow, health IT architecture, and care or practice setting in which the health IT is implemented,” including detailed annual plans and annual results for real-world testing of interoperability.⁴ However, neither specifies what domains and gaps in interoperability to measure. Cures 2.0 would contribute significantly to national interoperability by directing the Secretary to consider and apply the interoperability measurement framework recently developed by ONC and the National Quality Forum.

³ 21st Century Cures Act, § 4002(a) (adding 42 U.S.C. § 300jj-11(c)(5)(D)(v)).

⁴ 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program, 84 Federal Register 7424, 7495-7496 (Mar. 4, 2019), available at <https://www.govinfo.gov/content/pkg/FR-2019-03-04/pdf/2019-02224.pdf>; see also id. at pp. 7429-7430, 7495-7501.

Effective programs include evaluation and measurement. Fortunately, ONC already has at hand an excellent framework for measuring interoperability. ONC commissioned the National Quality Forum to develop the Interoperability Measurement Framework, published in September 2017. It provides the first national framework for measuring the quality, gaps and impact of interoperability across key settings and users of health care. It covers availability and exchange of electronic health information across the continuum of care; the usability of that exchanged information; its applicability and effectiveness; and—the holy grail—the impact of interoperability on outcomes such as care coordination, patient engagement, health outcomes, and cost savings.⁵

The table below shows the Interoperability Measurement Framework’s domains and subdomains of interoperability:⁶

Domain	Subdomain
Exchange of Electronic Health Information	<ul style="list-style-type: none"> • Availability of Electronic Health Information • Quality of Data Content • Method of Exchange
Usability of Exchanged Electronic Health Information	<ul style="list-style-type: none"> • Relevance • Accessibility • Comprehensibility
Application of Exchanged Electronic Health Information	<ul style="list-style-type: none"> • Human Use • Computable
Impact of Interoperability	<ul style="list-style-type: none"> • Patient Safety • Cost Savings • Productivity • Care Coordination • Improved Healthcare Processes and Health Outcomes • Patient/Caregiver Engagement

Obviously, just one measure of interoperability does not suffice to demonstrate complete interoperability and successful real-world use across care or practice settings. At best, only an outcome (“impact”) measure might begin to include other domains of interoperability as well, and the range of subdomains above illustrates that even one outcome measure could not measure the module’s interoperability across the board. National interoperability requires evaluation across all of these domains. **We recommend that Cures 2.0 direct the Secretary to integrate this comprehensive interoperability measurement framework in order to measure and evaluate where interoperability does and does not exist,** so ONC and the public can gauge improvement and effectiveness of interoperability.

⁵ National Quality Forum, *A Measurement Framework to Assess Nationwide Progress Related to Interoperable Health Information Exchange to Support the National Quality Strategy* (Sept. 1, 2017) (report funded by the Department of Health and Human Services), available at <https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=85827>.

⁶ Id., p. 11. See also id., p. 20, app. A (measure concepts); id., p. 24, app. B (existing measures).

4. Patient Access to Data Collected by Mobile Health Applications

Lastly, we recommend a provision that would significantly increase patients' ability to access information about their health and care so that patients can make more informed decisions with their doctors: **Extend the patient's right of access to her health information in her doctors' and health plan's records, to her health information collected by mobile health apps and devices that patients (and providers and plans) increasingly use to monitor, diagnose, and treat.**

The Health Insurance Portability and Accountability Act, through the Privacy Rule, gives patients the right to access and receive copies of the information in their medical and other health records maintained by their health care providers and health plans.⁷

Increasingly, however, patients' electronic health data are found in health applications (apps) and devices that patients use outside the clinical setting to collect or integrate their health information such as patient-generated health data and social determinants of health. The patient's health care provider or health plan might prescribe the app or device (such as a continuous glucose monitor for diabetes), or the patient might select the health app herself to help manage her health and care (such as a nutrition or activity tracker). National health initiatives such as the Precision Medicine Initiative often depend upon patients' being able to access and share these data, too. Doctors at UCSF do as well.

Unlike the patient's right under HIPAA to access, download and use her health information in her doctor's or plan's records, the patient might well *not* be able to download and share her health data from such health apps or devices. As the Office of the National Coordinator recently summarized, "Where HIPAA does not apply, however, it is unclear whether individuals have any rights to access data about themselves held by others. NCEs [non-covered entities] may grant individuals such access through the terms of use for their products or services, but such access may not be required by law."⁸

We suggest that the patient's right of access to her health information in her doctors' and health plan's records should extend as well to her health information in mobile health apps and devices that patients and providers increasingly use to monitor, diagnose, and even treat. This approach would be entirely consistent with Congress's directive in the 21st Century Cures Act that the Secretary of Health and Human Services provide "patients access to their electronic health information in a single, longitudinal format that is easy to understand, secure, and may be updated automatically."⁹

Conclusion

Thank you for the opportunity to provide these suggestions for Cures 2.0. CDHI recommends that you consider and incorporate these recommendations for shared care

⁷ 45 C.F.R. § 164.524.

⁸ Office of the National Coordinator for Health Information Technology, Examining Oversight of the Privacy & Security of Health Data Collected by Entities Not Regulated by HIPAA, p. 5 (July 15, 2016), available at https://www.healthit.gov/sites/default/files/non-covered_entities_report_june_17_2016.pdf; see also pp. 20-22.

⁹ 21st Century Cures Act, § 4003 (adding 42 U.S.C. § 300jj-12(b)(2)(B)(iii)); id. § 4006(a).

planning, improving interoperability by measuring where it does and does not exist, and extending the patient's right of access to her health information to health information collected by mobile health apps and devices that patients and providers increasingly use to monitor, diagnose, and treat. Collectively, these recommendations would help patients, doctors, and care teams make integrated decisions about care planning, and help patients to share important health data with their health care providers, health plans, and digital health tools.

We would be happy to discuss these comments or any other ideas with your staff. 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
Associate Professor of Medicine
University of California, San Francisco



Mark Savage
Director, Health Policy
Center for Digital Health Innovation