

August 25, 2017

Submitted Electronically

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, DC 20201

**RE: UCSF'S CENTER FOR DIGITAL HEALTH INNOVATION'S OPENING COMMENTS ON
THE NATIONWIDE INTEROPERABILITY AND TRUSTED EXCHANGE FRAMEWORK**

Dear National Coordinator Rucker:

The University of California, San Francisco's Center for Digital Health Innovation submits these opening comments on implementing the 21st Century Cures Act's nationwide interoperability and trusted exchange framework. The University of California, San Francisco (UCSF) is a worldwide leader in health care delivery, discovery, and education. Consistent with this public mission and imperative, UCSF invests heavily in developing a variety of health information technology, innovation and management resources to give health care providers and patients,¹ researchers and scientists, educators and students the interoperability and transformative tools to succeed in the rapidly evolving digital health age. We thank you for the opportunity to provide these comments.

The Office of the National Coordinator for Health Information Technology (ONC) invites initial public comment on considerations and concerns for the interoperability and exchange of health data across networks, including access, data-driven choice, cooperation and non-discrimination, standardization, transparency, and security and patient safety. Section 4003 of the 21st Century Cures Act makes clear in its overarching definition of "interoperability" that these considerations embrace both the exchange and the usability of exchanged electronic health information for all users—the "complete access, exchange, and use of all electronically accessible health information."² Recognizing the national imperatives, section 4003 directed that **interoperability and patient access are immediate national priorities** and set six-month, one-year, and longer-term requirements to move those priorities forward now. One key strategy is patient (and provider) access to electronic health records (EHRs) with applications of the individual's choice through open application programming interfaces (APIs), much as smartphones have spurred innovation and transformed access and usability across so many areas of modern life. Many see access through apps and APIs as a critical strategy to address interoperability and usability issues.

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."

² 21st Century Cures Act, § 4003(a)(2).

In the comments below, UCSF's Center for Digital Health Innovation lifts up **four core use cases that the framework must address and integrate to meet the 21st Century Cures Act's national priorities**, and **five cross-cutting principles that the framework must meet for success**.

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

UCSF is a worldwide leader in health care delivery, discovery and education. In recent years, UCSF has invested heavily in developing the information technology resources to help health care providers, patients, educators, scientists 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.

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 Inc. and Chiron Corp, and helped establish the Bay Area as the nation's premier biotech hub.

In 2013, UC San Francisco 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. For example, CDHI and Cisco are working together to build technology platforms and ecosystems that power digital health innovations and connect clinical data with dispersed patient-consumer data and synthesize them with powerful analytics to revolutionize health care nationwide. This service, called Health Stack, will consist of a digital health application marketplace, API services, and secure, cloud-hosted data interoperability across EHRs, devices, and apps. Health Stack will create and enable an ecosystem of innovative health apps that improve workflows, care quality, and patient engagement by creating true health data interoperability. Similarly, CDHI is partnering with Intel and GE to build algorithms and data models for enhanced clinical decision support behind the scenes and at the point of care.

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 new 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 depth and breadth of these and many other efforts to bear in our comments below.

CDHI'S OPENING COMMENTS ON DEVELOPING AND IMPLEMENTING THE INTEROPERABILITY AND EXCHANGE FRAMEWORK

The Center for Digital Health Innovation urges ONC to **develop and test its framework with core, concrete use cases that are current national priorities for interoperability**. These use cases can serve as polestars to help ONC and stakeholders align abstract discussions to real and immediate needs.

We urge that the nationwide interoperability and exchange framework must cohere with, and thus integrate and advance, the following core national use cases, among others:

- **Individuals' and patients' electronic access** to their digital health information, not only to view it, but to use it—to download it, to transmit it to a provider or other recipient of the person's choice, and to use it in innovative new ways with apps of the person's choice such as those on smartphones through open APIs.³ Individuals cannot effectively manage their health and health care without ready and convenient access to their medications, health status, diagnoses and treatment instructions whenever and wherever needed. This is *not* just a use case limited to certified EHRs and the View/Download/Transmit/API criterion. It applies to individuals' and patients' electronic access and interoperability across the board—across diverse modes and settings of access and use, from personal health records to home monitoring devices, from community health centers to urgent care clinics to nutritionists.
- **Patient- or person-generated health data.** Providers, patients, researchers, payers—all recognize that one-way access to health information is not enough. Access, interoperability and data portability must be bi-directional, so patients have access to their electronic health data, but providers, too, have electronic access in real time to patient-reported outcomes and critical health data in the patient's hands outside the clinical setting. Accountable care organizations, precision medicine initiatives, delivery system reform and reducing health disparities will depend for success upon this ability to know and integrate patient-reported outcomes and patient-contributed health data.
- **Shared care planning and shared care and information coordination.** 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 and health the vast amount of time outside the 15-minute office visit. Providers cannot succeed under new models of care without activated and engaged patients, ready access to patient-generated health data and outcomes, and more granular demographics essential for effective clinical decision support and prevention. Shared care planning and information coordination are essential—not a static, episodic “plan of care” buried in an EHR, but a “multidimensional, person-centered health and care planning process facilitated by a dynamic, electronic platform that connects individuals, their family and other personal caregivers”⁴ so that all members of one's care teams can update the plan electronically in real time with results and changes to advance the person's health and wellness goals.

³ Section 4002 of the 21st Century Cures Act requires, within one year or December 13, 2017, that certified EHR technology “has published application programming interfaces and allows health information from such technology to be accessed, exchanged, and used without special effort through the use of application programming interfaces or successor technology or standards”

⁴ Consumer Partnership for eHealth, *Care Plans 2.0: Consumer Principles for Health and Care Planning in an Electronic Environment* (Nov. 2013), available at <http://www.nationalpartnership.org/research-library/health-care/HIT/consumer-principles-for-1.pdf>.

- **Social and environmental determinants of health.** Medical care delivery determines only an estimated 10-15 percent of health; the remaining 85-90 percent of health is determined by factors outside the clinical setting, such as the socioeconomic and physical environment, health behaviors and genetics.⁵ Providers need a standardized method for collecting and integrating non-clinical patient health indicators to improve health and care. Patients, community resources and researchers stand ready to contribute. The framework must include interoperability with non-clinical settings and exchange of non-clinical data, such as social services, housing and schools, and environment and nutrition.

Underlying these priority use cases are some cross-cutting principles or themes that must inform the interoperability and exchange framework:

- Basic interoperability requires **far more than mere static “access”** to view information. Basic interoperability and the framework must integrate dynamic use of electronic health information to meet real use cases and basic needs.
- The framework cannot be limited to point-to-point exchange. We already realize that interoperability requires far more than EHR-to-EHR, point-to-point exchange. It must include interoperability with patients and family caregivers for patient access and use. It must embrace bi-directional exchange, and read-write APIs as well as read-only APIs, to integrate patient-generated health data, social determinants of health, and other data we are coming to find increasingly important. Shared care planning, accountable care organizations, patient-generated health data, precision medicine, multi-sector data sharing to integrate social determinants of health—all depend upon **bi-directional, even multi-directional** data flows.
- The framework must cover **exchange and usability across multiple different settings of care and health apps**. Health care occurs at the pharmacy, urgent care clinic and school clinic as well as the doctor’s office and hospital. Payers and employers provide care management, not just clinicians and hospitals. Individuals and family caregivers coordinate care among diverse non-clinical settings, such as social services, community centers, nutritionists, and physical therapists. The learning health system of the Nationwide Interoperability Roadmap includes registries, public health, population health and researchers. The framework should be anticipating and designing for the range of settings, users and apps, and bridging the gaps among them so that *all* stakeholders are served.
- The framework cannot assume a homogeneous or average user. We must **design and build for the diversity of uses and users**, and even if we cannot yet build and meet all needs now, we must consider and anticipate that diversity of uses and users so we do not inadvertently build in significant barriers now to future exchanges and uses. This is the simple principle of universal design. Universal design anticipates and accommodates, for example, the different needs of people who read languages other than English in order to ensure basic understanding of treatment, discharge, and prescription instructions. It anticipates the range of literacy in reading, health care, and health IT, and the needs of people with diverse abilities and disabilities. It asks, “Interoperability for whom?”, and builds in the necessary granularity of demographic data such as race, ethnicity, sexual orientation, gender identity, language, and functional and cognitive status needed for competent care, effective clinical decision support,

⁵ Robert Wood Johnson Foundation, *Frequently asked questions about the social determinants of health* (2010), available at <http://www.rwjf.org/content/dam/files/rwjfwebfiles/Research/2010/faqsocialdeterminants20101029.pdf>.

and identifying and reducing health disparities. It integrates the patient's health goals with the provider's clinical goals, and the patient's family and other caregivers with the provider's care team. To the extent that we cannot yet incorporate one or more such functions at this time, we can **at least identify them now and avoid inadvertently designing and building barriers to subsequent improvement**, e.g. write APIs. We save ourselves the substantial delay and cost of retrofitting these systems later.

- The **requisite usability** of exchanged electronic health information for all users **depends upon the requisite data flows and work flows**. Interoperability and usability require that hundreds and thousands of chunks of data (and their provenance) can be and are pulled together as needed from diverse sources to solve the user's problem or question—whether the primary care physician's question, the accountable care organization's question, the patient or family caregiver's question, the public health agency's question, the precision medicine initiative's question. The integrated use of open APIs and apps is crucial, for they enable exchange of discrete data elements rather than documents, and ready exchange, filtering and visualization of data behind the scenes. It is the difference between a static PDF and a dynamic Excel spreadsheet.

Workflow interoperability and improving workflows, in turn, depend upon this structure and fluidity of data. We cannot improve workflow if we cannot improve and readily weave these data flows. We cannot standardize workflows for all users; instead, if interoperability solves these data flows, diverse users can use tools and apps to customize the data flows to their respective workflow needs. Successful use of these tools, of course, also depends upon how well coordinated and integrated they are and how well the user can remain within the flow of her use or work.

Thank you for this opportunity to provide opening comments on the forthcoming interoperability and exchange framework. UCSF's Center for Digital Health Innovation looks forward to working with the Office of the National Coordinator, Centers for Medicare & Medicaid Services, providers, vendors and consumers across the nation to leverage technology to improve interoperability and access, enhance the quality of care, foster trust with patients, bolster meaningful engagement and improve health outcomes. If you have any thoughts or questions about these comments, please contact Mark Savage at Mark.Savage@ucsf.edu.

Sincerely,



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