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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 Center for Digital Health Innovation's Comments on
ONC's Trusted Exchange Framework Draft 2**

Dear National Coordinator Rucker:

The University of California, San Francisco's Center for Digital Health Innovation submits these comments on draft 2 of the Trusted Exchange Framework, released April 19, 2019. The University of California, San Francisco (UCSF) is a worldwide leader in health care delivery, discovery, and education. Consistent with this public 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 public comment on draft 2 of the Trusted Exchange Framework and considerations for interoperability and exchange of health data across diverse networks, users, and data sources. We appreciate the considerable work that ONC has devoted to this draft in order to improve interoperability, access, and use across the digital health care ecosystem, not just a series of electronic filing cabinets.

In the comments below, UCSF's Center for Digital Health Innovation strongly recommends that ONC add a requirement that Qualified Health Information Networks (QHINs), Health Information Networks (HINs), Participants, and Participant Members **each include access and transmission through standardized application programming interfaces (APIs)** conforming to the technical, content, and vocabulary standards that ONC and CMS are now proposing to adopt for providers, payers, and individuals. These two networks—TEFCA, and ONC's and CMS's standardized API

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 medical 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."

exchange—must be fully interoperable and able to leverage each other. **Without such a requirement, a Trusted Exchange Framework for document-based exchange will never provide the interoperability that Congress, ONC, CMS, and the nation all expect with forthcoming standardized APIs.**

Secondly, Draft 2 limits patients' use of the Trusted Exchange Framework to requests for a copy of one's health information, and directing that a copy be sent to a third party. **Patients need and use interoperability for the spectrum of health care needs, not just exercising these two rights under HIPAA's Privacy Rule. ONC should broaden Individual Access Services to include other core health use cases for patients and individuals so that they have a full and equal on-ramp.**

Lastly, we recommend adding "Interoperability" as a core principle, and requiring the Recognized Coordinating Entity and Qualified Health Information Networks to use NQF's Interoperability Measurement Framework to measure and evaluate the ongoing impact of the Trusted Exchange Framework.

I. 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 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 California, representing an incredibly diverse set of individuals and approximately one third of California's population in the world's fifth largest economy. Therefore, we represent the full continuum of health care, with access to patient- and population-level data on myriad disease conditions and 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 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 that improve workflows, care quality, and patient engagement by creating true health data interoperability.

For example, CDHI 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, **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 scalable and repeatable processes using advanced analytics and deep learning (artificial intelligence approaches).

Similarly, our UCSF-Stanford Center of Excellence in Regulatory Science and Innovation (CERSI) was the first regulatory science and innovation center on the West Coast. Collaborating with the U.S. Food and Drug Administration (FDA), the three partners work on projects that promote the emerging field of regulatory science—including innovative research, education, outreach, and scientific exchange—together with foundations and commercial entities interested in the development of FDA-approved medical products.

In conjunction with CERSI, UCSF and CDHI recently launched a national collaboration—the **Accelerated Digital Clinical Ecosystem (ADviCE)**—which is focusing on implementation and evaluation of digital health software tools in clinical care, including software as a medical device (SaMD) and the FDA's pilot Software Precertification Program. A collaboration initially among UCSF, leading national health systems, SaMD innovators, payers, and consumers, ADviCE aims to identify best practices around use of digital health software tools in clinical care delivery and in monitoring the effectiveness of these tools in clinical practice using real world data. We plan to launch a 'collaborative community' that will apply these best practices to software as a medical device. ADviCE collaborators are providing important insights around the role of real-world performance analytics, evaluation, and regulation in the deployment of software as a medical device.

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 **Bakar Computational Health Sciences Institute (BCHSI)** 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 increase 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 depth and breadth of these and many other efforts to bear in our comments below.

II. The Trusted Exchange Framework Should Integrate ONC's and CMS's Proposals To Require Standardized APIs for Interoperability and Access Without Special Effort

Both ONC and CMS recently proposed regulations that require providers and payers to integrate *standardized* application programming interfaces (APIs) for patient and population services. **Yet the draft Framework is silent and fails to include a like requirement for QHINs, HINs, Participants, and Participant Members. The Trusted Exchange Framework must include and use standardized APIs in order to promote interoperability and efficiency among the two networks.** CDHI strongly urges ONC to add a requirement that QHINs, HINs, Participants, and Participant Members each include access and transmission through standardized APIs conforming to the technical, content, and vocabulary standards that ONC and CMS adopt for payers, providers, and individuals. **This will ensure that the two exchange networks are fully interoperable and can leverage each other as intended.**

The 21st Century Cures Act mandates access, exchange, and use “without special effort on the part of the user,” and specifically highlights the central importance of open APIs,² 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 for both patients and providers.³ ONC has proposed to take a giant leap forward for interoperability, better care and coordination, and a learning health system, by requiring standardized APIs and FHIR-based technical, content, and vocabulary standards for patient and population services.⁴ The Centers for Medicare & Medicaid Services (CMS) has proposed to require payers within its programs to implement, test, and monitor open, standardized APIs in order to make patients’ claims and other health information available to patients and their plans without special effort through third-party applications and developers.⁵ In addition to requirements for patient access and interoperability, CMS proposes API

² 21st Century Cures Act, § 4002(a) (adding 42 U.S.C. § 300jj-11(c)(5)(D)(iv)); *id.*, § 4003(a)(2) (adding 42 U.S.C. § 300jj(10), now 42 U.S.C. § 300jj(9)). Section 4002(a) requires 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.”

³ The standardized API could not only allow patients to access and use their health information, but also allow providers to connect software applications to add or enhance their own internal clinical care tools and workflows, quality measurement and improvement tools, population health management tools, cost or value management tools. 84 Federal Register at p. 7482.

⁴ 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program, 84 Federal Register 7424, 7476-7487 (Mar. 4, 2019), available at <https://www.govinfo.gov/content/pkg/FR-2019-03-04/pdf/2019-02224.pdf>.

⁵ Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-Facilitated Exchanges and Health Care Providers, 84 Federal Register 7610, 7618-7620, 7626-7634 (Mar. 4, 2019), available at <https://www.govinfo.gov/content/pkg/FR-2019-03-04/pdf/2019-02200.pdf>.

requirements for payers' access to and exchange of health information for care and benefits coordination.⁶

The draft Framework acknowledges the advent of dynamic API-enabled interoperability,⁷ yet only proposes to build a trusted exchange framework based on static document exchange instead, such as CDAs. ONC states that it “seeks to facilitate the immediate availability of QHIN services . . . and leverage their [QHINs] existing, deployed technical infrastructure (i.e., services based on IHE profiles) to support network-to-network exchange.”⁸ ONC's and CMS's proposals for API-enabled interoperability, on the other hand, would likely reach implementation in two years, by January 1, 2022.⁹

The two approaches, however, are *not* mutually exclusive. APIs are equally capable of document-based exchange and structured data exchange. ONC could continue to build the initial Qualified Health Information Network (QHIN) Technical Framework around clinical document exchange *and* require QHINs, HINs, Participants, and Participant Members to incorporate standardized APIs for document and structured data exchange in conformance with ONC's and CMS's proposed regulations and timelines. Thus, in two years, providers, payers, and individuals using dynamic APIs and apps could also use the Trusted Exchange Framework.

Moreover, document exchange (e.g. CDAs) effectively prevents interoperability because various institutions put variable content in the documents. API-based document exchange may be a good intermediate step, but ultimately everyone—providers, payers, QHINs, and Participants alike—should use standardized APIs. ONC should integrate API capability and workflow in TEFCA *now* so that they are available from the outset when needed and TEFCA can remain an effective solution over time.

III. The Draft Provides Only a Limited On-Ramp for Patients and Fails To Meet Core Interoperability Use Cases for Patients and Family Caregivers

Draft 2 allows patients (“Individual Users”) to use the Trusted Exchange Framework only for “Individual Access Services.” Individual Access Services, in turn, are limited to “the services provided to satisfy an Individual’s right to access and to obtain a copy of the Individual’s EHI and to direct that it be sent to a third party”¹⁰ **Patients need and use interoperability for much more than exercising these two rights under HIPAA’s Privacy Rule, and ONC should broaden Individual Access Services to include other core health use cases for patients and individuals.**

As the 21st Century Cures Act itself recognized, individuals, patients, and family caregivers have a far broader range of core use cases for interoperability than merely

⁶ 84 Federal Register at pp. 7617, 7640-7642.

⁷ Draft 2 notes that health information networks “may also consider developing tools to test the quality of data exchange using Health Level Seven (HL7[®]) Fast Healthcare Interoperability Resources (FHIR[®]) APIs.” Trusted Exchange Framework Draft 2, p. 25.

⁸ *Id.*, pp. 70-71.

⁹ The proposed regulations require that the standardized APIs be in place within 24 months of the final rule’s effective date. The preamble uses a likely scenario where the final rule takes effect on January 1, 2020, and thus standardized APIs must be in place by January 1, 2022. 84 Federal Register at p. 7479.

¹⁰ Trusted Exchange Framework Draft 2, p. 35 (definition of “Individual Access Services”).

requesting an electronic copy of one's record or directing the provider to transmit it to a third party. Individuals want to submit corrections and amendments to their designated record set under the Privacy Rule, 45 C.F.R. §§ 164.526. They want to participate in shared care planning and shared decision-making with their primary care physician, specialists, community services and social services, etc. They want to share remote monitoring data, patient-generated health data, and patient-reported outcomes with their relevant doctors.¹¹ They want to move beyond piecemeal requests to individual providers to a single, longitudinal health record that is easy to understand, use, and update automatically.¹²

Such basic needs and uses go far beyond just exercising one's right under 45 C.F.R. § 164.524(a)(1) (right "to inspect and obtain a copy of protected health information about the individual in a designated record set") or § 164.524(c)(2) (right to "direct[] the covered entity to transmit the copy of protected health information directly to another person"). By analogy, this would be akin to limiting a banking consumer to merely accessing her checking or savings account statement or directing the bank to send her statement to a third party—beyond that, no deposits, no withdrawals, no transfers, no online banking or bill payment, no emails to customer service. In effect, no banking.

The Cures Act declares "patient access" a national priority and imperative, and directs 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."¹³ Congress mandated more than abstract availability of access and exchange. 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."¹⁴ Congress highlighted usability for patients to contribute patient-generated health data and patient-reported outcomes, such as "the *patient's ability to electronically communicate patient-reported information (such as family history and medical history)*," and to contribute to research.¹⁵

Consistent with the Cures Act, TEFCA must meet patients' and individuals' basic use cases such as shared care planning, secure messaging, accessing and using their electronic health information, contributing patient-generated health data and patient-reported outcomes, etc. The Trusted Exchange Framework should provide individuals with a basic on-ramp and interoperability for better health, better care, and better value. ONC should broaden Individual Access Services to include access, use, and contribution of electronic health information beyond just requesting a copy of one's health information or directing that it be transmitted to a third party. Health care is far more than that, and for patients, the Trusted Exchange Framework should be, too.

¹¹ According to a national survey of consumers in 2014, 77 percent of patients reported that they share health information all of the time or most of the time with their health care providers. National Partnership for Women & Families, *Engaging Patients and Families: How Consumers Value and Use Health IT*, p. 28 (Dec. 2014), available at <http://www.nationalpartnership.org/research-library/health-care/HIT/engaging-patients-and-families.pdf>.

¹² 21st Century Cures Act, § 4006(a) (adding 42 U.S.C. § 300jj-19(c)(1)).

¹³ *Id.*, § 4003 (adding 42 U.S.C. § 300jj-12(b)(2)(B)(iii)); *id.* § 4006(a).

¹⁴ *Id.*, § 4006(a) (italics added) (adding 42 U.S.C. § 300jj-19(e)(1)(A)).

¹⁵ *Id.*, § 4006(a) (italics added) (adding 42 U.S.C. § 300jj-19(e)(2)(A)).

IV. CDHI Recommends Adding “Interoperability” to the Trusted Exchange Framework’s Principles

We continue to urge ONC to add “Interoperability” as a core principle of the Trusted Exchange Framework. The six draft principles—standardization, transparency, cooperation and non-discrimination, privacy and security, access, and population-level data¹⁶—are prerequisites for interoperability, but together they do not yet constitute or establish interoperability.

For example, adhering to standards (“standardization”) does not necessarily require that all parties adhere to the same standards, to the degree necessary for nationwide interoperability. Prohibiting information blocking (“cooperation and non-discrimination”) does not necessarily require affirmatively enabling interoperability with disparate networks. As ONC states in the draft, “Continuing with the status quo is not enough to ensure all stakeholders have efficient methods for engaging in health information exchange.” Even if ONC believes that the six draft principles collectively constitute or imply interoperability, it remains important to highlight “interoperability” *explicitly* as a principle, not remain silent about it. Interoperability should be a seventh core principle.

ONC could employ the 21st Century Cures Act’s principle and definition of interoperability:

INTEROPERABILITY.—The term ‘interoperability’, with respect to health information technology, means such health information technology that—

- (A) enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user;
- (B) allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and
- (C) does not constitute information blocking as defined in section 3022(a).¹⁷

ONC could also use the principle and definition in its ten-year Interoperability Roadmap published in 2015:

the ability of a system to exchange electronic health information with and use electronic health information from other systems without special effort on the part of the user. This means that all individuals, their families and health care providers should be able to send, receive, find and use electronic health information in a manner that is appropriate, secure, timely and reliable to support the health and

¹⁶ Office of the National Coordinator for Health Information Technology, “Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2,” pp. 24-30 (Apr. 19, 2019), available at <https://www.healthit.gov/sites/default/files/page/2019-04/FINALTEFCAQTF41719508version.pdf>.

¹⁷ 21st Century Cures Act, Pub. L. 114-255, § 4003(a)(2), 130 Stat. 1033, 1165 (2016) (adding 42 U.S.C. § 300jj(10), now 42 U.S.C. § 300jj(9)).

wellness of individuals through informed, shared decision-making. With the right information available at the right time, individuals and caregivers can be active partners and participants in their health and care. An interoperable health IT ecosystem should support critical public health functions, including real-time case reporting, disease surveillance and disaster response. Additionally, interoperability can support data aggregation for research, which can lead to improved clinical guidelines and practices. Over time, interoperability will also need to support the combining of administrative and clinical data to enhance transparency and enable value-based payment. The work and collaborative efforts of all stakeholders over the next 10 years will yield interoperability achievements in a variety of areas that, in turn, will advance the industry toward a learning health system.¹⁸

The Interoperability Roadmap's definition adds context and objectives that help explain the principle and its importance.

Nowhere does the draft Framework explain how it interacts with ONC's Interoperability Roadmap nor the Federal Health IT Strategic Plan that 39 federal agencies and departments adopted for 2015-2020.¹⁹ This is an important, missed opportunity, and we urge ONC to do so. For example, the Framework appears to support the Roadmap's "B. Shared Decision-Making, Rules of Engagement and Accountability" and "C. Ubiquitous, Secure Network Infrastructure," among others.

While the Trusted Exchange Framework is voluntary, the 21st Century Cures Act provides one important exception: federal agencies may require adoption of the trusted exchange framework and common agreement in federal contracts.²⁰ As the Federal Health IT Strategic Plan notes, the federal government is the nation's largest provider and payer of care.²¹ In light of the commitment to interoperability in the Cures Act, Federal Health IT Strategic Plan, and Interoperability Roadmap, ONC should consider requiring adoption of the Trusted Exchange Framework in federal contracts, such as Medicare and Medicaid contracts, and federal grants for health research and precision medicine.

Lastly, we note that currently the principles tend to describe their application in treatment contexts, but payers, public health, government agencies, and others are also core stakeholders. We recommend that ONC weave into each principle examples of how the principle applies to the various stakeholders.

¹⁸ Office of the National Coordinator for Health Information Technology, *Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap*, p. x (Oct. 6, 2015), available at <https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf>.

¹⁹ Office of the National Coordinator for Health Information Technology, *Federal Health IT Strategic Plan 2015-2020*, pp. 23-24, 42 (Sept. 2015), available at https://www.healthit.gov/sites/default/files/9-5-federalhealthitstratplanfinal_0.pdf.

²⁰ 21st Century Cures Act, § 4003(b).

²¹ *Federal Health IT Strategic Plan 2015-2020*, p. 18.

V. Measuring Interoperability as a Component of the Trusted Exchange Framework

Good programs include a component for evaluation and measurement. Fortunately, ONC already has at hand a measurement framework to assess the degree to which the Recognized Coordinating Entity (RCE), Qualified Health Information Networks, and others are achieving interoperability under the Framework and where the disparities and opportunities for improvement exist.

ONC commissioned the National Quality Forum to develop the Interoperability Measurement Framework, which NQF 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 the 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.²²

The Framework should require the RCE and QHINs to measure the degree of interoperability across the various domains and subdomains, so ONC and the public can gauge improvement and the effectiveness of the Trusted Exchange Framework. NQF's Interoperability Measurement Framework provides such a well-vetted, multi-stakeholder framework.

Conclusion

Thank you for the opportunity to provide these comments on the Trusted Exchange Framework draft 2. UCSF's Center for Digital Health Innovation looks forward to working with the Office of the National Coordinator, 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

²² 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>.

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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