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By electronic submission

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

Re: UCSF Center for Digital Health Innovation's Comments on Draft 2020-2025 Federal Health IT Strategic Plan

Dear National Coordinator Rucker:

The University of California, San Francisco's Center for Digital Health Innovation submits these comments on the Office of the National Coordinator's draft 2020-2025 Federal Health IT Strategic Plan, published January 15, 2020. 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 and best practices to give health care providers and patients,[1] researchers and scientists, educators and students, the interoperability and transformative tools to succeed in this rapidly evolving digital health age. We thank you for the opportunity to offer these comments.

The Office of the National Coordinator for Health Information Technology (ONC) invites public comment on the draft Strategic Plan.[2] We appreciate the work that ONC and the federal agencies have devoted to this draft.

[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."

[2] Office of the National Coordinator for Health Information Technology, 2020-2025 Federal Health IT Strategic Plan: Draft for Public Comment (Jan. 15, 2020) (hereinafter "Draft Strategic Plan"), available at https://www.healthit.gov/sites/default/files/page/2020-01/2020-2025FederalHealthIT%20StrategicPlan_0.pdf

The Draft Strategic Plan sketches high-level goals and objectives, with little detail for public comment about concrete actions that federal agencies plan to undertake, or not, to achieve those goals. In the comments below, UCSF's Center for Digital Health Innovation focuses on two concrete recommendations to help accomplish the four strategic goals and objectives in 2020-2025 and measure the progress:

- First, the 2020-2025 Strategic Plan should include an interoperability measurement framework, developed and vetted by ONC and the National Quality Forum in 2017, to **measure the quality, gaps, and impact of interoperability across key settings and users of health care**. We cannot improve what we do not measure.

- Second, the 2020-2025 Strategic Plan should include an **explicit program and timeline for bi-directional exchange and "write" access to people's electronic health records. Stakeholders such as developers, doctors and hospitals, patients, researchers, and policymakers need to begin preparing *now* so bi-directional exchange and access can become a reality well before 2025**. Bi-directional exchange and "write" access are essential for better patient outcomes, to begin integrating patient-generated health data, patients' social services, and social and environmental determinants of health.

We explain these two recommendations in turn.

I. A Strategic Plan for Measuring Real-World Interoperability in 2020-2025

The Draft Strategic Plan makes nationwide interoperability an overarching strategic goal—the interoperability necessary to connect healthcare and health data, to promote health and wellness, to enhance the delivery and experience of care, to accelerate research and innovation.[3] Effective programs must include effective evaluation and measurement. ONC will not know where we are and what needs to be done unless ONC measures that interoperability.

Fortunately, ONC has at hand a good framework for measuring interoperability across these strategic dimensions, and we urge ONC to implement it in the 2020-2025 Strategic Plan. ONC commissioned the National Quality Forum (NQF) to develop the Interoperability Measurement Framework with a committee of 25 national subject-matter experts. Published in September 2017, it provides the

[3] 2020-2025 Draft Strategic Plan, p. 6 (goals 1-4). Likewise, the 21st Century Cures Act proclaimed interoperability a national imperative. 21st Century Cures Act, Pub. L. 114-255, § 4003, 130 Stat. 1033, 1165 (2016) (adding 42 U.S.C. § 300jj-12(b)(2)(B)(i), (c)(2)).

first national framework for measuring the quality, gaps, and impact of interoperability across key settings and users of health care. It measures 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.[4]

The table below shows the Interoperability Measurement Framework's domains and subdomains of interoperability:[5]

Domain	Subdomain
Exchange of Electronic Health Information	• Availability of Electronic Health Information • Quality of Data Content • Method of Exchange
Usability of Exchanged Electronic Health Information	• Relevance • Accessibility • Comprehensibility
Application of Exchanged Electronic Health Information	• Human Use • Computable
Impact of Interoperability	• Patient Safety • Cost Savings • Productivity • Care Coordination • Improved Healthcare Processes and Health Outcomes • Patient/Caregiver Engagement

NQF's framework covers interoperability across the continuum of care and health information technology, not just EHR-to-EHR exchange—because real-world care delivery and coordination extend well beyond the reach of electronic health records. For example, the framework includes measure concepts for nonclinical settings, such as housing, community health centers, schools, social services and jails, as well as clinical settings. It includes measure concepts for patient-generated health data, patient-reported outcomes, and social and environmental determinants of health—which may be critical for shared care planning with patients and family caregivers, and understanding and serving diverse populations with complex needs—alongside measure concepts for the range of clinical data.

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[4] 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.

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

Obviously just one measure of interoperability does not suffice to demonstrate successful real-world use of a health IT module in the intended care or practice settings. A measure of exchange might suggest interoperability, while a measure of usability might reveal barriers. At best, only an outcome ("impact") measure might begin to include other domains of interoperability as well; and the range of impact subdomains above illustrates that even one outcome measure could not measure interoperability across the board.

NQF's Interoperability Measurement Framework already provides a well-vetted, multi-stakeholder framework well-suited to the Strategic Plan's four goals. **CDHI recommends that the 2020-2025 Strategic Plan implement this Interoperability Measurement Framework and begin measuring, at a minimum, a core set of interoperability measures, comprising at least one or two measures for each of the Framework's domains, and separately, at least one measure for each of the "patient safety," "care coordination," "improved processes and outcomes," and "patient/caregiver engagement" subdomains of impact.** Thus, consistent with the Cures Act, agencies would have a baseline and could begin measuring the improvement and effectiveness of interoperability across the various domains and subdomains.

II. A Strategic Plan for Doctors' Access to Patient-Generated Health Data and Data on Patients' Social Determinants of Health

The Draft Strategic Plan acknowledges the need for "bi-directional, secure exchange of data across healthcare and human services settings to improve care," including data on social determinants of health.[6] Yet in its proposed regulations to implement the 21st Century Cures Act, ONC omitted "write" access for bi-directional or multi-directional interoperability from the technical requirements for standardized, FHIR-based APIs under section 170.315(g)(10). Instead, ONC envisions revising the certification criterion in the future to provide "write" access "once FHIR-based APIs are widely adopted."[7]

Bi-directional exchange, access, and use still remain essential now for person-centered healthcare. Social determinants of health and other factors outside the clinical setting account for 85-90 percent of one's health status.[8] "Write" access is critical to receive patients' corrections and amendments to their designated record set under the Privacy Rule, 45 C.F.R. §§ 164.526, and to integrate patient-generated health data, patient-reported outcomes, and social determinants of

[6] 2020-2025 Draft Strategic Plan, p. 14.
[7] 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program, 84 Federal Register 7424, 7481-7482 (Mar. 4, 2019), available at https://www.govinfo.gov/content/pkg/FR-2019-03-04/pdf/2019-02224.pdf.
[8] 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.

health. Were "write" access in place now, clinicians could already begin integrating data virtually from patients with COVID-19 and patients in need of testing. CDHI urges ONC to **include a program and timeline in the Strategic Plan *now* so that stakeholders—developers and innovators, doctors and hospitals, patients, researchers, policymakers—can begin preparing and bi-directional exchange, access, and use can become a reality well before 2025**.

If ONC deems it prudent initially to require "write" access for some priority use cases, we suggest "patient goals," "patient-generated health data" (including patient-reported outcomes, patient-generated device data, and questionnaires), "care plans" for shared care planning, and the right to correct and amend one's health information under the HIPAA Privacy Rule. As more and more care, and more and more data, occur outside the clinical setting, it becomes important for doctors to have access to these data originating outside their own electronic health records. Health care occurs at the pharmacy, the urgent care clinic, the school clinic, the dentist, people's homes, as well as the doctor's office and hospital. Individuals and family caregivers coordinate care among diverse non-clinical settings, such as social services, community centers, nutritionists, and physical therapists. Shared care planning, accountable care organizations, precision medicine, multi-sector data sharing to integrate social determinants of health, the learning health system—all depend upon bi-directional, even multi-directional data flows. We urge ONC to specify in the Strategic Plan how "write" access shall be included in the digital health ecosystem well before 2025 to meet the needs of providers and patients nationwide.

III. Expertise of University of California, San Francisco, and UCSF's Center for Digital Health Innovation

We take a moment to share the depth and breadth of real-world experience that CDHI brings to these strategic recommendations. 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 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 the **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, building 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 focuses on implementing and evaluating 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 about 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 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 and recommendations above.

Conclusion

Thank you very much for the opportunity to provide these comments on ONC's draft 2020-2025 Strategic Plan. UCSF's Center for Digital Health Innovation looks forward to working with the Office of the National Coordinator, federal agencies, providers, vendors, developers, 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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Mark Savage, JD
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cc: Steve Posnack, Deputy National Coordinator for Health Information Technology
Elise Anthony, Executive Director, Office of Policy