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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 U.S. Core Data for
        Interoperability version 2**

Dear National Coordinator Rucker:

The University of California, San Francisco's Center for Digital Health Innovation submits these comments and proposals for version 2 of the U.S. Core Data for Interoperability. 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 and proposed data classes and data elements for version 2 of the U.S. Core Data for Interoperability. The U.S. Core Data for Interoperability (USCDI) is the set of structured data included with electronic exchanges for patient care and patient access, including transitions of care, data exchange through standardized application programming interfaces (APIs), and patient access to view, download, and transmit health data to any third party, including patients' third-party health applications (apps).[2] In short, the USCDI is the standardized set of health data

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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 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, 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program, 85 Federal Register 25642, 25670 (May 1, 2020), available at https://www.govinfo.gov/content/pkg/FR-2020-05-01/pdf/2020-07419.pdf.

classes and elements essential for nationwide interoperability, electronic health information exchange, and usability without special effort.[3]

Clearly, what ONC does and does not include in the U.S. Core Data for Interoperability matters. Moreover, the same data element often serves multiple use cases, multiplying its importance. Structured data elements missing from the USCDI are essential for a number of key national use cases, such as

- COVID-19 and remote care;
- Patient-generated health data, patient-reported outcomes, and social determinants of health;
- Value-based care delivery;
- Interoperability and the 2015-2024 Nationwide Interoperability Roadmap;
- Patient access, shared care planning, and care coordination across clinical and non-clinical settings;
- CMS's work to build digital quality measures;
- Precision Medicine Initiative; and
- A robust health app ecosystem, which is constrained by the data available to design and use innovative health apps with FHIR APIs.

We appreciate the considerable work that ONC has devoted to the Common Clinical Data Set (CCDS) and its next evolution, the U.S. Core Data for Interoperability version 1. Version 1, however, was only a "modest expansion" of the Common Clinical Data Set.[4] **As a health care provider, USCDI version 1 and these few additions are not enough to meet national health imperatives. Technical specifications are already available for 46 of 50 data classes ONC has listed for candidate and emerging status, and all 50 are "critical to achieving nationwide interoperability."[5] We urge ONC to add numerous additional data elements *now* so that they, too, become available for better health care, for the key national use cases above, and for the nationwide learning health system we need.**

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.

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[3] Id. at 25644, 25669-26671.

[4] Id. at 25665.

[5] Office of the National Coordinator for Health Information Technology, Draft U.S. Core Data for Interoperability and Proposed Expansion Process, p. 9 (Jan. 5, 2018), available at https://www.healthit.gov/sites/default/files/draft-uscdi.pdf.

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 nine-county 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 launched a national collaboration in 2018—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. 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** under Dr. Kirsten Bibbins-Domingo and now Dr. Margot Kushel 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 under Dr. Laura Gottlieb and Dr. Nancy Adler 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.   CDHI's Recommendations Regarding the U.S. Core Data for Interoperability, Version 2

In May, ONC adopted version 1 of the U.S. Core Data for Interoperability, comprising the former Common Clinical Data Set of 20 standardized data elements and a "modest" expansion of new data elements.

As ONC has acknowledged, the Common Clinical Data Set "became a symbolic and practical limit to the industry's collective interests to go beyond the CCDS data for access, exchange, and use."[6] It functioned as a ceiling, not floor, for the structured data available for interoperable exchange specifically and the nation's shared learning health system generally. Instead, the nation needs additional structured data elements now as we move towards value-based care, more virtual care, and better health care outside clinical settings. **Based on our experience described above, CDHI urges ONC to add additional data elements *now* so that they, too, become available for better health care of individual patients, better public and population health care, and developing a shared nationwide learning health system.**

A. Expanding U.S. Core Data for Interoperability To Meet Immediate National Needs in Version 2

ONC's original draft U.S. Core Data for Interoperability (USCDI) and Proposed Expansion Process, released January 5, 2018, acknowledged that technical specifications are already

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[6] 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program, 84 Federal Register 7424, 7440 (Mar. 4, 2019), available at https://www.govinfo.gov/content/pkg/FR-2019-03-04/pdf/2019-02224.pdf.

available for 46 of the 50 data classes it listed for both candidate status and emerging status, and they are all "critical to achieving nationwide interoperability."[7]

As we stated then,[8] from our perspective as a health care provider, these standardized datasets cannot come fast enough to help meet national health imperatives. Under that draft's proposed timeline, a critical dataset with technical specifications already available could still take four years or more to reach real-world application: some unstated time to move from emerging status to candidate status; followed by 12, 18, or 24 months, or 2 to 3 years, to move from candidate status to the U.S. Core Data for Interoperability; followed by another 12 months at least for industry to implement or upgrade technology for real-world operation.

The better question, we submitted, is not whether the data classes should have candidate status or emerging status and which version and year, but conversely, **whether there are objective reasons to delay adding any of them now**. Merely postulating a "burden that rapidly expanding the USCDI v1 beyond the CCDS could cause" [9] **does not change our experience that we need these standardized datasets now, as fast as possible, to help provide better health care and a better national digital health ecosystem**. The *benefits* far outweigh any potential burden. And as ONC acknowledged, technical specifications are already available for 46 of the 50 data classes, and many of them have already been included as voluntary health IT modules in the 2015 Edition. We repeat our specific recommendations below.

Overall, we recommend the following strategic priorities as ONC considers which missing data elements to omit or add:

- For delivery of care, the datasets that help advance referrals, especially from primary care physician to specialty care, and continuity of care and care coordination, have great importance.

- For patients and family caregivers (who access and use the USCDI as well), the datasets that help care planning and coordination are especially important. Key demographic datasets that help meet and understand the individual patient where she is are critical as well, such as cognitive and functional status.

- For providers, patients and family caregivers as partners in care, the datasets that help care planning and coordination, advance care planning, and enable bi-directional access so providers have critical access to patient-reported outcomes, patient-generated health data, and social determinants of health, are especially important.

- Similar assessments should be considered for payers, public health, researchers, and other core stakeholders.

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[7] Office of the National Coordinator for Health Information Technology, Draft U.S. Core Data for Interoperability and Proposed Expansion Process, p. 9 (Jan. 5, 2018), available at https://www.healthit.gov/sites/default/files/draft-uscdi.pdf.

[8] Comment Letter from Michael Blum, Aaron Neinstein, Mark Savage and Ed Martin, UCSF's Center for Digital Health Innovation, to Donald Rucker, Office of the National Coordinator for Health Information Technology (Feb. 20, 2018), available at https://static1.squarespace.com/static/5be4eafda2772ceaae90810b/t/5bff3ca11ae6cf82da8fff59/1543453859051/UCSF-CDHIs-Comments-on-ONCs-Draft-US-Core-Data-for-Interoperability-and-Expansion-Process-2-20-2018.pdf .

[9] 84 Federal Register at p. 7441.

Accordingly, we suggested and continue to suggest the following additions to version 2 now:

- "Cognitive Status," "Functional Status," and "Gender Identity," as critical datasets about the individual, should be added to version 2.
- "Pregnancy Status" should be added to version 2, given its implications for care on multiple levels.
- "Diagnostic Image Reports (DIR)" should be added to version 2. This should be relatively simple to do technologically and would help with specialty referrals.
- "Pathology Reports" should be added to version 2. Like diagnostic image reports, pathology reports are critically important in care coordination, particularly when receiving a specialty referral. Specialists need access to a person's lab results, imaging results, and pathology results, at a minimum.
- "Reason for Referral" and "Referring or Transitioning Provider's Name and Contact Information" should be added to version 2.
- Given their critical importance for shared care planning and new delivery models, "Individual Goals and Priorities," "Provider Goals and Priorities," "Care Team Member Roles/Relationships," "Care Team Members Contact Information," and "Care Provider Demographics" should be added to version 2. "Care Team Members" are also important for security and access functions.

We have also recommended that the following data elements be available much sooner:

- "Advance Care Planning" should be available sooner. "Advance Directive" is already an optional criterion in the 2015 Edition under the broader module "Patient Health Information Capture."[10]
- "Health Insurance Information" must be available sooner, to help determine costs and affordability up front for patients.
- "Personal Representative" should also be available sooner, as it is already a core component of patients' and their authorized representatives' ability to view, download, transmit, and access by API their health information, and personal representatives' existing rights under HIPAA's Privacy Rule.[11]
- "Reconciled Medication List" should be advanced. Medication errors represent the most common patient safety error,[12] and more than 40 percent of medication errors result from inadequate reconciliation in handoffs during admission, transfer, and discharge of patients.[13] According to the Institute of Medicine's seminal report, *Preventing Medication Errors*, the average hospitalized patient suffers at least one medication error per day.[14]
- "Social, psychological, and behavioral data," or social determinants of health, should be advanced, and "Depression" at the very least. Depression is captured now.[15] Social determinants of health and other factors outside the clinical setting account for

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[10] 2015 Edition Health Information Technology Certification Criteria, 80 Federal Register 62602, 62661-62662 (Oct. 16, 2015), available at https://www.govinfo.gov/content/pkg/FR-2015-10-16/pdf/2015-25597.pdf.

[11] Id. at p. 62658.

[12] David Bates, Nathan Spell, David Cullen, et al., The Costs of Adverse Drug Events in Hospitalized Patients, Journal of the American Medical Association, 277:307–11 (Jan. 22, 1997).

[13] John Rozich, Ramona Howard, Jane Justeson, et al., Standardization as a Mechanism To Improve Safety in Health Care, Joint Commission Journal on Quality and Patient Safety, 30(1):5–14 (Jan. 2004).

[14] Institute of Medicine, Preventing Medication Errors, p. 1 (Dec. 11, 2006).

[15] 80 Federal Register at pp. 62631-62632.

85-90 percent of one's health status.[16]

▪ "Patient Reported Outcome Measures" or PROMs are a set of standardized measures that are increasingly built into EHRs, and will be critical going forward for care coordination, remote patient monitoring, and shared care planning, among other core health care activities. They will also be a key part of data transactions between EHRs and innovative apps, and alternative payment models (APMs). We increasingly need to leverage bi-directional read-write of PROMs for care, and this is essential for real-world innovation by vendors building apps and devices. The care plan module in the 2015 Edition already incorporates patient reported outcomes.[17]

Given the passage of time already, ONC could and should announce that these data classes are also added as version 2.

B. The COVID-19 Pandemic Illustrates Why Adding These Data Elements in Version 2 Remains So Important.

To illustrate the importance of adding the missing data elements now, we tested the missing data elements against two COVID-19 use cases and asked one of CDHI's most knowledgeable doctors in the area which missing structured data elements are necessary or important *now* for health care in the midst of the COVID-19 pandemic.

First, we assessed which are necessary or important to test for COVID-19 and provide outpatient care, end to end. This would include, for example, scheduling the appointment, a visit for the test, processing the test, processing the results, and consulting with the patient. In this use case, we assumed that the COVID-19 test result was positive, but outpatient care was sufficient.

Secondly, we assessed which missing data elements are necessary or important assuming instead that full emergency hospitalization was required.

The table below identifies which missing structured data elements are necessary or important *now* for health care in the midst of the COVID-19 pandemic.

Data Elements Missing from USCDI	COVID-19 with Outpatient Care	COVID-19 with Emergency Hospitalization
Cognitive status	x	
Encounter	x	x
Discharge instructions		x
Family health history	x	x
Gender identity	x	x
Pregnancy status	x	x
Reason for hospitalization		x
Care provider demographics	x	x
Care team members—contact info		x

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[16] 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.
[17] 80 Federal Register at pp. 62648-62649.

Care team members—roles/relationships		x
Diagnostic image reports	x	x
Individual goals, priorities	x	x
Practitioner responsible for care	x	x
Provider goals, priorities		
Reason for referral	x	x
Referring or transitioning providers—name & contact info	x	x
Advance care planning	x	x
Advance directive	x	x
Power of attorney	x	x
POLST	x	x
Alive status/date of death	x	x
Communication facilitators	x	x
Minor consent	x	x
Disability status	x	x
Durable medical equipment		x
Health insurance info	x	x
Minor status	x	x
Personal representative	x	x
Social, psychological & behavioral data	x	x
Education	x	x
Overall financial resource strain	x	x
Social support & isolation	x	x
Domestic violence	x	x
Employment status	x	x
Depression	x	x
Stress	x	x
Physical activity	x	x
Alcohol use	x	x
Military history	x	x
Reconciled medication list	x	x
Travel status/history	x	x
Weight-based dosing	x	x

In short, these two use cases affirm our experience and policy recommendations that we need these standardized datasets now, as fast as possible, and the Office of the National Coordinator should add them now to USCDI version 2 to help provide better health care and a better national digital health ecosystem.

Conclusion

Thank you for the opportunity to provide these comments on the importance of adding numerous key data elements now to the U.S. Core Data for Interoperability, version 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 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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cc: Steve Posnack, Deputy National Coordinator
     Elise Anthony, Executive Director, Office of Policy