



Center for Digital Health  
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**Health Stack**

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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  
DRAFT U.S. CORE DATA FOR INTEROPERABILITY AND PROPOSED EXPANSION  
PROCESS**

Dear National Coordinator Rucker:

The University of California, San Francisco's Center for Digital Health Innovation submits these comments on the draft U.S. Core Data for Interoperability (USCDI) and Proposed Expansion Process, released January 5, 2018. 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,<sup>1</sup> 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 the proposed expansion of the Common Clinical Data Set promulgated in the 2015 Edition of Health Information Technology Certification Criteria. We appreciate the considerable work ONC has devoted to this draft and the effort to expand interoperability, access, and use of core electronic health data for providers, patients, and caregivers across the nation. In the comments below, UCSF's Center for Digital Health Innovation **recommends an approach and criteria for objectively selecting data classes for U.S. Core Data for Interoperability, candidate status, and emerging status.** We also provide **specific recommendations regarding listed and missing data classes.**

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<sup>1</sup> 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."

At the outset, CDHI also strongly supports adding clinical notes and provenance immediately to the Common Clinical Data Set, and strongly affirms ONC's consideration of data classes that span the wide variety of use cases and target populations across the nation.

#### **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. 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 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. For example, CDHI and Cisco are working together to build technology platforms and ecosystems that power digital health innovations, 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 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.

**CRITERIA FOR OBJECTIVELY SELECTING DATA CLASSES FOR U.S. CORE DATA FOR INTEROPERABILITY, CANDIDATE STATUS, AND EMERGING STATUS**

ONC requests comment on the characteristics or attributes to use for selection and assignment of data classes to candidate status and emerging status. We have some concern with language in the draft that appears to await “industry . . . coalescing” around selection and timing. National health and health information technology priorities are at stake. We recommend an approach used by the HIT Policy Committee’s Advanced Health Models and Meaningful Use Workgroup in 2015 to prioritize use cases for the Interoperability Roadmap.

The Workgroup used a process that weighed strategic impact, programmatic needs, technical readiness, and beneficiaries to inform national policy decisions.<sup>2</sup>

1. Strategic impact: The method first looked at the strategic impact on the Triple Aim of better health, better health care, and better value. It did so by rating each use case’s ability (a) to improve the health of the U.S. population by supporting proven interventions to address behavioral, social, and environmental determinants of health in addition to delivering higher-quality care (*better health*); (b) to improve overall quality, by making health care more patient-centered, reliable, accessible, and safe (*better care*); and (c) to reduce the cost of quality health care for individuals, families, employers, and government (*better value*).
2. Programmatic needs: The method next assessed the relevance and criticality for key national programmatic priorities, namely the National Quality Strategy’s priorities (safety, patient engagement, care prevention, community, affordability, and coordination); the Secretary’s delivery system reform goals; and the Interoperability Roadmap’s goals (for 2015-2017, send, receive, find and use priority data domains to improve health care quality and outcomes).
3. Market/industry readiness: The method next assessed the current barriers and facilitators affecting the timing of widespread adoption of the use case, namely the business and cultural environment, the technical environment, stakeholder cost/benefit considerations, and the policy environment.
4. Beneficiaries: Finally, the method included a multi-stakeholder assessment of the primary beneficiaries of the use case, namely individuals, communities, health professionals, public health, research, and payers.

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<sup>2</sup> Health IT Policy Committee, Advanced Health Models and Meaningful Use Workgroup (Apr. 7, 2015), available at [https://www.healthit.gov/archive/archive\\_files/HIT%20Policy%20Committee/2015/2015-04-07/HITPC\\_AHMWG\\_Presentation\\_Slides\\_2015-04-07\\_PT.pdf](https://www.healthit.gov/archive/archive_files/HIT%20Policy%20Committee/2015/2015-04-07/HITPC_AHMWG_Presentation_Slides_2015-04-07_PT.pdf).

A similar, objective approach could apply well to selecting data classes for subsequent versions, candidate status, and emerging status.

#### **CDHI'S RECOMMENDATIONS REGARDING LISTED AND MISSING DATA CLASSES**

ONC invites comment on (a) the draft's initial addition of clinical notes and provenance to Version 1 of the US Core Data for Interoperability, (b) candidates for versions 2 through 4 in years 2019 through 2021, and (c) considerations for "emerging" status.

As we stated above, CDHI strongly supports adding clinical notes and provenance immediately to the Common Clinical Data Set.

The draft acknowledges that technical specifications are already available for 46 of the 50 data classes listed for both candidate status and emerging status, and they are all "critical to achieving nationwide interoperability."<sup>3</sup> From a health entity's perspective, these standardized datasets cannot come fast enough to help meet national health imperatives. Under the draft's proposed timeline, however, 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 submit, 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.

Within ONC's tables of candidate and emerging data classes, we also suggest some revision of priorities.

- 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 Common Clinical Data Set 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.
- For providers, patients and family caregivers as partners in care, the datasets that help care planning and coordination, advance care planning, and 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, and researchers.

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<sup>3</sup> Draft U.S. Core Data for Interoperability and Proposed Expansion Process, p. 9 (Jan. 5, 2018).

Accordingly, for Table 2 – Candidate Datasets, we recommend:

- Move “Diagnostic Image Reports (DIR)” from 2020 to 2019. This should be relatively simple to do technologically and would help with specialty referrals.
- Add Pathology Reports to 2019. 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.
- Move “Reason for Referral” and “Referring or Transitioning Provider’s Name and Contact Information” from 2021 to 2020.
- “Cognitive Status,” “Functional Status” and “Gender Identity”, as critical datasets about the individual, should be moved to version 1, and at the very least should not be delayed beyond 2019.
- “Pregnancy Status” should be moved to version 1, and at the very least should not be delayed beyond 2019, given its implications for care on multiple levels.
- Given the critical importance for shared care planning and new delivery models, move “Individual Goals and Priorities,” “Provider Goals and Priorities,” “Care Team Member Roles/Relationships,” “Care Team Members Contact Information,” and “Care Provider Demographics” up to 2019.

For Table 3 – Emerging Datasets, we recommend:

- “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.”<sup>4</sup>
- “Health Insurance Information” should also be available sooner, to help determine costs and affordability up front for patients.
- “Personal Representative” should also move to Table 2, if not Table 1, 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.<sup>5</sup>
- “Reconciled Medication List” should be advanced. Medication errors represent the most common patient safety error,<sup>6</sup> and more than 40 percent of medication errors result from inadequate reconciliation in handoffs during admission, transfer, and discharge of patients.<sup>7</sup> According to the Institute of Medicine’s seminal report, *Preventing Medication Errors*, the average hospitalized patient suffers at least one medication error per day.<sup>8</sup>
- “Social, psychological, and behavioral data,” or social determinants of health, should be advanced, and “Depression” at the very least. Depression is

<sup>4</sup> 2015 Edition Health Information Technology Certification Criteria, 80 Federal Register 62602, 62661-62662 (Oct. 16, 2015).

<sup>5</sup> *Id.*, p. 62658.

<sup>6</sup> 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).

<sup>7</sup> 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).

<sup>8</sup> Institute of Medicine, *Preventing Medication Errors*, p. 1 (Dec. 11, 2006).

captured now.<sup>9</sup> Social determinants of health and other factors outside the clinical setting account for 85-90 percent of one's health status.<sup>10</sup>

- “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). The care plan module in the 2015 Edition already incorporates patient reported outcomes.<sup>11</sup>

Lastly, the draft is silent about the source of the datasets. CDHI recommends that the draft flag the importance of integrating core data classes from all relevant sources, so that individuals, family caregivers, and authorized nonclinical data sources can contribute to these datasets as well, and clinicians can access and use the health data they need beyond the EHR. This would include broadcast query, directed query, and population-level data query from ONC's draft Trusted Exchange Framework, but would also include integration through other important means as well, such as write APIs, SMART-on-FHIR applications, and other approaches to achieve interoperability and usability.

We recommend that the draft also specifically incorporate the different ways to access patient-generated health data in these data classes, such as write APIs, SMART-on-FHIR apps that access PGHD (perhaps stored in the cloud), and CDS Hooks. For example, perhaps patients should be able to integrate their family medical history or allergy list through write APIs, while a clinician or vendor prefers to use a SMART-on-FHIR app or CDS Hooks for other kinds of patient-generated health data. Providers, patients, researchers, payers—all recognize that 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. The draft should specifically address this core need.

### *Conclusion*

Thank you for the opportunity to provide these comments on the draft U.S. Core Data for Interoperability (USCDI) and Proposed Expansion Process Framework. UCSF's Center for Digital Health Innovation looks forward to working with the Office of the National Coordinator, providers, developers and consumers across the nation to leverage

<sup>9</sup> 2015 Edition Health Information Technology Certification Criteria, 80 Federal Register 62602, 62631-62632 (Oct. 16, 2015).

<sup>10</sup> 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>.

<sup>11</sup> 2015 Edition Health Information Technology Certification Criteria, 80 Federal Register 62602, 62648-62649 (Oct. 16, 2015).

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](mailto:Mark.Savage@ucsf.edu).

Sincerely,



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