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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 PROPOSED REGULATIONS TO IMPLEMENT 21ST CENTURY CURES ACT'S PROVISIONS ON INTEROPERABILITY, INFORMATION BLOCKING, AND APPLICATION PROGRAMMING INTERFACES, FILE NO. RIN 0955-AA01

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 regulations to implement the 21st Century Cures Act's provisions on interoperability, information blocking, application programming interfaces, patient access, and conditions of certification, published March 4, 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 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 regulations to implement key provisions of the 21st Century Cures Act (Cures Act). We appreciate the considerable work that ONC has devoted to this draft in order to improve interoperability, access, and use, and to create a connected health record of electronic health information across the health care ecosystem, not just a series of electronic filing cabinets. In the comments below,

[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."

UCSF's Center for Digital Health Innovation focuses on key provisions throughout the proposed regulations, based upon our real-world experience.

The proposed regulations take a giant leap forward for interoperability and health care by requiring *standardized* application programming interfaces (APIs) for patient and population services. **We applaud and wholeheartedly support this requirement as an essential prerequisite for moving digital health forward and establishing a national digital health ecosystem.** Based on our experience, we recommend that ONC adopt FHIR Release 4 as the API standard. We urge ONC to require API access to "all data elements of a patient's electronic health record" as the Cures Act requires, not "API access to a limited set of data elements" as ONC proposes. **This would effectively place a significant cap on data available for nationwide interoperability, and we propose two solutions for ONC's consideration.** We also urge ONC to include "write" access now as well as "read" access for bi-directional or multi-directional interoperability. ONC already plans to include "write" access when FHIR-based APIs are widely adopted—which they will be under the proposed regulations—so ONC should include "write" access now so that it will be widely available in two years as well.

With respect to information blocking, ONC has proposed a careful, balanced regulatory structure to address the breadth and depth of documented information blocking and stop the damage. We **applaud and wholeheartedly support these requirements** for the most part. At UCSF, we know real-world examples where EHR vendors are engaged in such behavior, and we experience the adverse effects that information blocking has on our efforts to provide better care, interoperability, and access, exchange, and use in the digital health ecosystem.

With respect to the U.S. Core Data for Interoperability, ONC proposes only a "modest expansion" of the Common Clinical Data Set. CDHI strongly supports adding clinical notes and provenance immediately. **As a health care provider, however, 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." We urge ONC to add additional data elements *now* so that they, too, become available for better health care and developing a shared nationwide learning health system.**

Lastly, we explain that the Cures Act's information blocking provisions apply to health IT developers generally, not just health IT developers of certified health IT, and we urge ONC to correct the final regulation. **Left uncorrected, it could become the exception that swallows the rule and create perverse incentives where health IT developers avoid certified health IT and escape the information blocking prohibitions altogether—clearly frustrating Congress's policy in the Cures Act.**

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 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 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 REGULATIONS' SCOPE AND APPLICABILITY

The proposed regulations implement key provisions of the Cures Act regarding application programming interfaces (APIs) and information blocking. In general, the Cures Act limits the API provisions to *certified* health information technology; the proposed regulations, in turn, limit their API provisions to certified APIs and technology suppliers, data providers, and users of certified APIs. Conversely, the Cures Act applies the information blocking provisions to health information technology broadly, not just certified health IT, and to health information technology developers, exchanges, and networks and health care providers broadly. Consistent with the Cures Act, the

proposed regulations apply their information blocking provisions to health information technology broadly, and to exchanges, networks, and providers broadly.

With respect to developers, however, ONC proposes to limit the information blocking provisions to health IT developers of certified health IT only, not health IT developers broadly. As we explain below, this limitation is inconsistent with the plain language of the Cures Act, and ONC should correct the final regulation to apply the information blocking provisions to health IT developers broadly, like the rest of the information blocking provisions. **Left uncorrected, the proposed regulations create a perverse incentive that health IT developers avoid certified health IT and escape the information blocking prohibitions altogether—clearly frustrating Congress's policy in the Cures Act.**

A. Background

In the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009, Congress enacted separate definitions for "health information technology" and "certified EHR technology,"[2] and clearly knows the difference and which scope it intends to apply. For example, the National Coordinator is not limited to developing and overseeing a "certified EHR technology" infrastructure, but instead is responsible for developing and overseeing "a nationwide health information technology infrastructure" broadly.[3]

The Cures Act clearly specifies which scope Congress intended for its provisions on application programming interfaces and information blocking. With respect to APIs, the Cures Act limits these provisions to *certified* health information technology. Section 4002(a) adds the API requirements as amendments to conditions of certification and maintenance of certification under 42 U.S.C. § 300jj-11(c)(5).[4]

On the other hand, section 4003 on interoperability and section 4004 on information blocking apply to health information technology broadly, not just certified EHR technology. Section 4003(a) defines interoperability generally "with respect to health information technology."[5] Section 4004 likewise describes information blocking in terms of "health information technology" generally, "including transitions between certified health information technologies."[6] Illustrating that the information blocking provisions apply to health information technology and health IT developers generally, section 4004 specifies that the information blocking prohibitions should not penalize health care *providers* "for the failure of developers of health information technology or other entities offering health information technology to such providers to ensure that

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[2] "Certified EHR technology" is "a qualified electronic health record that is certified pursuant to section 3001(c)(5) as meeting standards adopted under section 3004." 42 U.S.C. § 300jj(1). "Health information technology" is broader: "hardware, software, integrated technologies or related licenses, intellectual property, upgrades, or packaged solutions sold as services that are designed for or support the use by health care entities or patients for the electronic creation, maintenance, access, or exchange of health information." 42 U.S.C. § 300jj(5).

[3] Health Information Technology for Economic and Clinical Health Act of 2009, Pub. L. 111-5, § 13101, 123 Stat. 115, 226, 228 (2009) (adding 42 U.S.C. § 300jj-11(b)).

[4] 21st Century Cures Act, Pub. L. 114-255, § 4002(a), 130 Stat. 1033, 1159 (2016) (adding 42 U.S.C. § 300jj-11(c)(5)(D)(iv)).

[5] Id. § 4003(a)(2) (adding 42 U.S.C. § 300jj(10), now 42 U.S.C. § 300jj(9)).

[6] Id. § 4004 (adding 42 U.S.C. § 300jj-52(a)(1)-(2)).

such technology meets the requirements to be certified under this title."[7] Clearly, section 4004 applies broadly to health IT developers, not just developers of certified health IT.

B. The Proposed Information Blocking Provisions Should Apply to Health IT Developers Generally

ONC's proposed regulations must be consistent with the Cures Act's plain language.[8] ONC discusses this issue in the preamble,[9] and acknowledges that the Cures Act's information blocking provisions are not limited to certified health IT.[10] Nonetheless, ONC reasons that there is no definition of "health information technology developer," and so it administratively interprets the term to be and mean the same as "health information technology developer of certified health information technology," a term in the Cures Act's separate provisions regarding the Inspector General's authority when the health IT and developer specifically concern certified health IT.[11] On the contrary, the Cures Act's plain language and basic rules of statutory construction dictate that Congress intended them to have different meanings.

First, the Cures Act uses two different terms in the two different sections, which demonstrates that "health information technology developer" in the section 3022(a)(1) does *not* mean "health information technology developer of certified health information technology" in section 3022(b)(1)(A). Different terms have different meanings.[12]

Second, the term ONC interprets in the preamble is not "health information technology developer"—it is "health information technology developer, exchange, or network." The meaning of "health information technology" is the same across all three—developers, exchanges, and networks alike—and as ONC explains with respect to exchanges and networks,[13] that is health information technology broadly, not certified health IT only. Where a word or phrase—"health information technology"—appears at the beginning of a series of terms, it modifies all of the terms with the same meaning.[14]

Lastly, ONC relies on section 3022(b)'s specific remedies where certified health IT is involved. Those remedies are not exclusive; other remedies cover health IT developers generally. Section 3022(d) provides broad remedies for all cases: a process for public claims and reports when health IT products or developers generally are not interoperable

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[7] Id. § 4004 (adding 42 U.S.C. § 300jj-52(a)(7)).
[8] See, e.g., United States v. Larionoff, 431 U.S. 864, 873 & n.12 (1977).
[9] 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program, 84 Federal Register 7424, 7510-7512 (Mar. 4, 2019), available at https://www.govinfo.gov/content/pkg/FR-2019-03-04/pdf/2019-02224.pdf.
[10] Id. at p. 7510.
[11] 21st Century Cures Act, § 4004 (adding 42 U.S.C. § 300jj-52(b)(1)(A)).
[12] See, e.g., PPC Broadband, Inc. v. Corning Optical Communs. RF, LLC, 815 F.3d 747, 752 (Fed. Cir. 2016); 2A Norman J. Singer, Sutherland Statutes and Statutory Construction § 46.06 (6th ed. 2000) ("The courts do not construe different terms within a statute to embody the same meaning . . . . When the legislature uses certain language in one part of the statute and different language in another, the court assumes different meanings were intended. In like manner, where the legislature has carefully employed a term in one place and excluded it in another, it should not be implied where excluded. The use of different terms within related statutes generally implies that different meanings were intended.").
[13] 84 Federal Register at p. 7512.
[14] See, e.g., Porto Rico R., Light & Power Co. v. Mor, 253 U.S. 345, 348 (1920); United States v. Lockhart, 749 F.3d 148, 152 (2d Cir. 2014).

or are resulting in information blocking; and specifically a process for public claims and reports when information blocking under section 3022(b) (e.g. developers of certified health IT) is also information blocking under section 3022(a) (e.g. health IT developers generally).

We have covered the issue in such depth because the consequences are significant for a shared nationwide, interoperable health ecosystem. As ONC described in its report to Congress in 2016, there is a range of health IT that is not certified but is necessary for clinical practice, such as practice management software, care coordination, population management, advanced patient engagement, and telehealth.[15] It may include non-certified EHRs such as lab, pharmacy, or radiology EHR systems that are not certified. It may include third-party devices and apps, and digital diagnostic and therapeutic tools such as software as a medical device. **The Cures Act applies to health information technology broadly so that all are developing for a digital health ecosystem where information blocking is prohibited. There should be no exception for health IT developers of non-certified health IT, for that could be the exception that swallows the rule.**

ONC should correct the final regulation to apply the information blocking provisions to health IT developers broadly, consistent with the Cures Act.

III. INTEROPERABILITY AND PATIENT ACCESS: STANDARDIZED APIS AND EHI EXPORT

The Cures Act establishes "interoperability" as a national priority and imperative, to assure electronic access, exchange, and use of health information nationally and locally.[16] It also 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."[17] Congress mandated access, exchange, and use "without special effort on the part of the user," and specifically highlighted the central importance of open application programming interfaces (APIs),[18] 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.[19]

The final regulations promulgating the 2015 Edition of Certified Health IT require open but not standardized APIs. The proposed regulations now take a giant leap forward for

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[15] Office of the National Coordinator for Health Information Technology, Report to Congress on Feasibility of Mechanisms to Assist Providers in Comparing and Selecting Certified EHR Technology Products (Apr. 2016), available at https://www.healthit.gov/sites/default/files/macraehrpct_final_4-2016.pdf.
[16] 21st Century Cures Act, § 4003 (adding 42 U.S.C. § 300jj-12(b)(2)(B)(i), (c)(2)).
[17] Id. § 4003 (adding 42 U.S.C. § 300jj-12(b)(2)(B)(iii)); id. § 4006(a).
[18] Id. § 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)).
[19] 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.

interoperability, better care and coordination, and a learning health system by requiring *standardized* APIs for patient and population services. **We applaud and wholeheartedly support this requirement as an essential prerequisite for moving digital health forward and establishing a national digital health ecosystem.** It is also an overdue leap forward, so we strongly urge ONC not to delay this requirement in the final rule. Indeed, **we urge ONC to consider moving the requisite implementation date forward from January 1, 2022,[20] to January 1, 2021, or to provide incentives that encourage earlier implementation such as working with Centers for Medicare & Medicaid Services (CMS) to provide bonus points in reimbursement models for earlier implementation.**

In addition to all of the reasons in the Cures Act that dictate requirement of standardized APIs,[21] we note that use of standardized APIs also aligns with CDHI's five cross-cutting principles for interoperability, based upon years of experience in the field.[22] An interoperable digital health ecosystem requires standardized APIs:

1. For *dynamic access and use* of electronic health information without special effort in order to meet basic use cases and real-world needs, not just static access and viewing;
2. For *bi-directional, even multi-directional interoperability and exchange* of electronic health information, not just point-to-point, EHR-to-EHR exchange;
3. For exchange and usability across *multiple different settings of care*, health apps, and stakeholders such as public and population health, payors, registries, and researchers, not just clinical settings;
4. For *designing and building universally* for the diversity of uses and users; and
5. For *usability and workflow interoperability* without special effort, which depends upon interoperability to pull and push diverse data from diverse sources as needed to solve the user's problem or question, in ways integrated with the individual user's workflows—whether a primary care physician, an accountable care organization, a patient or family caregiver, a public health agency, or a precision medicine initiative.

In summary, all of the reasons above strongly support requiring standardized APIs now to establish and advance nationwide interoperability.

A. FHIR Release 4

ONC presents and discusses three options for the standard to adopt: FHIR Draft Standard for Trial Use 2, or Release 2; Release 3; or Release 4. The preamble notes that Release 2 already enjoys substantial adoption at the moment and "best reflects the

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[20] 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.

[21] See, e.g., id. at pp. 7476-7477.

[22] See Letter from Michael Blum, Aaron Neinstein, Mark Savage & Ed Martin, UCSF's Center for Digital Health Information, to Donald Rucker, Office of the National Coordinator for Health Information Technology, pp. 4-8 (Feb. 20, 2018), available at https://static1.squarespace.com/static/5be4eafda2772ceaae90810b/t/5bff403d758d46406fd09453/1543454782830/UCSF-CDHIs-Comments-on-ONCs-Draft-Trusted-Exchange-Framework-2-20-2018.pdf.

industry's current maturity and implementation readiness" with only limited incremental burden for developers, while Release 4 will soon be the "de facto version" for the industry and provides the first set of "normative" FHIR resources so that future changes are backwards compatible for the first time. Normative resources and content are critical for implementing FHIR consistently and uniformly—which is critical for standardized APIs and for interoperability. Release 4 also has key improvements for population health and a nationwide learning health system.[23]

Based on our experience, CDHI recommends that ONC adopt Release 4 ("Option 4") as the API standard. As ONC acknowledges in the preamble, adopting Release 2 and Release 4 jointly could well delay the national transition to a common standard for APIs and delay FHIR-based interoperability.[24] This, in turn, delays compliance with other deadlines in the Cures Act, such as the requirement that conditions *and maintenance* of certification require, within one year of enactment, APIs that provide access, exchange, and use of "all data elements of a patient's electronic health record" without special effort, and successful testing of real-world use.[25] Release 2 does not provide access, exchange, and use of all data elements as the Cures Act requires; Release 4 does. Release 2 does not provide the API functionality ONC requires for population-level services and advancing a learning health system; Release 4 does. Furthermore, delay here would delay other key national initiatives as well, such as the forthcoming Trusted Exchange Framework and Common Agreement.

B. "All Data Elements," not "Limited Set of Data Elements"

The Cures Act requires API access to "all data elements of a patient's electronic health record," but ONC proposes only to require "API access to a limited set of data elements (*i.e.*, from the FHIR resources that ARCH Version 1)."[26] As ONC notes, this essentially constricts electronic data access to just the Common Clinical Data Set or U.S. Core Data for Interoperability v1.0, not all available data as the Cures Act requires, nor the designated record set as the HIPAA Privacy Rule provides.[27]

Obviously, asserting that a limited set of data elements is "all data elements" under the Cures Act cannot make it so. CDHI urges ONC to require API access to all data elements in a patient's electronic health record. We suggest two approaches that ONC might take, or ONC might identify other approaches as well that comply with the Cures Act's mandate.

Firstly, the API Resource Collection in Health (ARCH) is a set of implementation specifications that further define and constrain how to structure those 15 specific data elements. ONC superimposes these further, more granular specifications because those 15 elements are the especially structured Core Data for Interoperability that must be part of every transition of care, patient access, etc. Why must API access to "all data

[23] 84 Federal Register at pp. 7476-7479, 7558.
[24] Id. at p. 7479.
[25] 21st Century Cures Act, § 4002(a) (adding 42 U.S.C. § 300jj-11(c)(5)(D)(iv)-(v)).
[26] 84 Federal Register at pp. 7476, 7485; see also 21st Century Cures Act, § 4002(a) (adding 42 U.S.C. § 300jj-11(c)(5)(D)(iv)).
[27] 45 CFR §§ 160.103, 164.501 (protected health information in a designated record set); id. § 164.524 (patient's right of access to all protected health information in designated record sets).

elements" be limited to just the data elements that have implementation specifications in ARCH? Instead, ONC could require API access to (a) the 15 data elements structured in accordance with the ARCH/FHIR implementation specifications, *and* (b) all other data elements in the patient's electronic health record albeit without further benefit of corresponding implementation specifications.

Alternatively, as Josh Mandel has described, ONC could require that the electronic health information (EHI) export certification criterion include and support export through a published and standardized API.[28] The EHI export criterion's scope is comprehensive.[29] In this alternative, ONC would further specify that (a) the 15 data elements constituting the Core Data for Interoperability also use the corresponding implementation specifications, and (b) the standardized API use the standard in FHIR Release 4. ONC already intends to do this "ultimately," so it could just do so now.[30]

Adopting either alternative will help ONC avoid rather than exacerbate the problem it laments in the preamble, that the Common Clinical Data Set functions as a cap on the structured data available for interoperable exchange specifically and the nation's shared learning health system generally.[31] **Limiting the standardized API to the Core Data for Interoperability would effectively place a ceiling on the minimum data elements available for nationwide shared interoperability through standardized APIs,[32] whereas the Cures Act mandates standardized API access to all data elements in a patient's electronic health record.**[33] Just as providers routinely transmit far more than the Common Clinical Data Set, standardized APIs should likewise provide access to far more than the Core Data for Interoperability.

C. Electronic Health Information (EHI) Export

For all the reasons stated above in support of access to all data elements in the patient's electronic health record, CDHI applauds and strongly supports ONC's proposed EHI export certification criterion for individual and population services.[34]

D. "Write" APIs

ONC proposes to require a standardized API under section 170.315(g)(10), but unfortunately for true interoperability, ONC proposes that it only provide "read" access to the patient's or population's health information. "Write" access for bi- or multi-directional interoperability—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 health, for example—is not included. Instead, ONC envisions revising the certification criterion in the future to provide "write" access, too, "once FHIR-based APIs are widely

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[28] Josh Mandel, "To meet the Cures API intent, ONC's EHI Export just needs an API" (Feb. 15, 2019), available at https://github.com/jmandel/interop-2019-nprms/blob/master/ehi-export.md.
[29] 84 Federal Register at p. 7448.
[30] Id. at p. 7447.
[31] Id. at p. 7440.
[32] Id. at p. 7440.
[33] See 21st Century Cures Act, § 4002(a) (adding 42 U.S.C. § 300jj-11(c)(5)(D)(iv)).
[34] 84 Federal Register at pp. 7446-7449.

adopted."[35] But section 170.315(g)(10) proposes to do exactly that—make standardized, FHIR-based APIs widely adopted within two years. **If ONC requires "write" access now as well as "read" access, then the benefits of "write" access can be widely available in two years as well.**

CDHI urges ONC to require "write" access as well. If ONC deems it more 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. Payers and employers provide care management, not just clinicians and hospitals. Individuals and family caregivers coordinate care among diverse non-clinical settings, such as social services, community centers, nutritionists, and physical therapists. Requiring "read" access but postponing "write" access seems akin to building only one direction of a city's highway, outbound, and waiting indefinitely to build the other direction into the city. Naturally, it is far more efficient and useful to build both directions and the whole road at the same time. 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 telegraph now that "write" access, too, should be in place within 24 months to meet the needs of providers and patients nationwide.

E. Mandatory "Refresh" Tokens

Lastly, ONC proposes to require mandatory refresh tokens, with a minimum refresh token life of three months, to enable patients' persistent access "without special effort," that is, without having to interrupt, re-authenticate, and re-authorize frequently while using their preferred health app or apps.[36] We agree that refresh tokens should be mandatory and support the proposed minimum of three months. Developers may incorporate a longer duration. Given this fact, we recommend that ONC include in the final rule guidance about how patients and other users should be able to revoke access tokens if desired.

IV. INFORMATION BLOCKING: NON-DISCRIMINATION, UNREASONABLE FEES (INCLUDING API FEES), COMMUNICATIONS, GAG CLAUSES, ETC.

Information blocking by EHR developers, providers, and others routinely poses substantial barriers to interoperability. As ONC notes, *half* of the respondents in a recent nationwide survey reported that EHR developers "routinely engage in

[35] Id. at pp. 7481-7482.
[36] Id. at pp. 7480-7481.

information blocking," and one fourth of the respondents reported that hospitals and health systems "routinely do so." Interoperability and health information sharing are essential for better care, health, and value; yet developers and providers instead "routinely" engage in information blocking to resist or thwart competition, capture revenues, or retain market share.[37]

In April 2015, the Office of the National Coordinator submitted a lengthy report to Congress documenting the nature and extent of information blocking.[38] Investigative reporters have documented practices by EHR developers charging substantial fees for API access and imposing gag clauses.[39] A recent article on the intersection of information blocking and antitrust discusses anticompetitive motivations for health information blocking.[40] And at UCSF, we know real-world examples where EHR vendors are engaged in such behavior, and we experience the adverse effects that information blocking has on our efforts to provide better care, interoperability, and access, exchange, and use in the digital health ecosystem.

The Cures Act prohibits information blocking.[41] Faced with this record, ONC has proposed a careful, balanced regulatory structure to address the breadth and depth of information blocking and stop the damage. We **applaud and wholeheartedly support these requirements** for the most part.[42] We agree with the approach to prohibit all information blocking unless the particular conduct meets every condition of one of seven explicit exceptions. With respect to API technology suppliers and their practices and fees for API access, we agree with ONC's approach to prohibit all fees unless they are explicitly permitted. In particular, we especially support:

- Prohibiting terms based in any part on whether the API user is a competitor or potential competitor with the API technology supplier (such as a third-party app innovator with a competing approach to providing an EHR function), or might use the data in a way that competes with the API technology supplier;[43]
- Prohibiting terms based on the revenue or value the API user may derive from access, exchange, or use of the electronic health information;[44]

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[37] Id. at p. 7508.
[38] Office of the National Coordinator for Health Information Technology, Report to Congress on Health Information Blocking (Apr. 9, 2015), available at https://www.healthit.gov/sites/default/files/reports/info_blocking_040915.pdf.
[39] E.g., Arthur Allen, "Developers complain of high EHR fees for SMART apps," Politico eHealth, Aug. 6, 2018, available behind paywall at https://subscriber.politicopro.com/article/2018/08/developers-complain-of-high-ehr-fees-for-smart-apps-721486; Darius Tahir, "EHR gag clauses exist—and, critics say, threaten safety," Politico eHealth, Aug. 27, 2015, available behind paywall at https://subscriber.politicopro.com/article/2015/08/politico-investigation-ehr-gag-clauses-exist-and-critics-say-threaten-safety-052815; Darius Tahir, "ONC interop forum kicks off: Costly APIs," Politico eHealth, Aug. 6, 2018, available at https://www.politico.com/newsletters/morning-ehealth/2018/08/06/onc-interop-forum-kicks-off-306709.
[40] Lucia Savage, Martin Gaynor & Julia Adler-Milstein, Digital Health Data and Information Sharing: A New Frontier for Health Care Competition, 82 ABA Antitrust Law Journal 593 (Apr. 2019), available at https://www.researchgate.net/publication/332530889_Digital_Health_Data_and_Information_Sharing_A_New_Frontier_for_Health_Care_Competition.
[41] 21st Century Cures Act, § 4004; id. § 4002(a) (adding 42 U.S.C. § 300jj-11(c)(5)(D)(i)-(iii)).
[42] For example, we explain above that some of these prohibitions should apply to health IT developers broadly, not just health IT developers of certified health IT.
[43] 84 Federal Register at pp. 7487-7488, 7492-7493.
[44] Id. at pp. 7492-7493.

- Prohibiting restrictions (such as gag clauses) against information sharing about usability, interoperability, security, user experiences, and business practices regarding a developer's health information technology;[45] and
- Prohibiting fees for patients' use of API technology for access, exchange, or use of their electronic health information.[46]

A shared, nationwide learning health system depends upon multi-directional interoperability and exchange of electronic health information among providers, patients, public health agencies, payors, researchers, and others—not a culture of information blocking where actors hoard data and erect barriers to innovation and exchange in order to lock market share. Achieving better health outcomes and accountable care requires dynamic access and use of electronic health information and innovative new apps connecting multiple electronic health records in real time—not barriers to innovation where health IT developers erect discriminatory terms or prohibitive costs that thwart or stall innovation. Improving user experience, reducing burdens, and simplifying workflows depend upon sharing lessons learned and user evaluations—not gag clauses to prevent such information sharing about usability, interoperability, security, etc.

APIs and apps underpin our ability today to connect data, knowledge, and action seamlessly across so many walks of life, including social services, government services, banking, education, commerce, and transportation. Achieving nationwide interoperability and electronic information exchange in health care will likewise depend upon open, standardized APIs, and innovative apps just as it has in so many other parts of our lives. We need a robust digital health ecosystem where open, standardized APIs allow third-party apps to provide constantly improving functionality or new functionalities. Given the evidence to date, we agree that these prohibitions—especially around APIs and third-party apps—are necessary to protect against discrimination or anticompetitive behavior by API technology suppliers and health IT developers.

V. CDHI'S RECOMMENDATIONS REGARDING THE U.S. CORE DATA FOR INTEROPERABILITY

The draft regulations propose to adopt version 1 of the U.S. Core Data for Interoperability, which would comprise the former Common Clinical Data Set of 20 standardized data elements and three new ones. The Core Data for Interoperability itself would be a core set of structured data included with every electronic exchange for patient care and patient access.

As the preamble acknowledges, 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."[47] It functions as a ceiling, not floor, for the structured data available for interoperable exchange specifically and the nation's shared learning

[45] Id. at pp. 7467-7476.
[46] Id. at pp. 7489-7490.
[47] Id. at p. 7440.

health system generally. Instead, the nation needs additional structured data elements now, as we move towards value-based care and better health and care outside clinical settings.[48]

Against this backdrop, ONC proposes only a "modest expansion" of the Common Clinical Data Set,[49] adding address and phone number, clinical notes, pediatric vital signs, and provenance. CDHI strongly supports adding clinical notes and provenance immediately to the Common Clinical Data Set. **However, these few additions are not enough. 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 and developing a shared nationwide learning health system.**

A. Expanding U.S. Core Data for Interoperability v1 To Meet Immediate National Needs

ONC's draft U.S. Core Data for Interoperability (USCDI) and Proposed Expansion Process, released January 5, 2018, acknowledged that technical specifications are already 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."[50] As we stated in our comments then,[51] from our perspective as a health care provider, these standardized datasets cannot come fast enough to help meet national health imperatives. The proposed regulations include no timeline for further expansion, but 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" [52] 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 are already included as voluntary health IT modules in the 2015 Edition. We repeat our recommendations below.

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[48] Id. at p. 7440.
[49] Id. at p. 7441.
[50] 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.
[51] 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 .
[52] 84 Federal Register at p. 7441.

Within ONC's tables of candidate and emerging data classes, we suggested 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.

Accordingly, from ONC's list then, we suggested and continue to suggest the following additions to version 1 now:

- "Cognitive Status," "Functional Status," and "Gender Identity," as critical datasets about the individual, should be moved to version 1.
- "Pregnancy Status" should be moved to version 1, given its implications for care on multiple levels.

For Table 2 – Candidate Datasets, we recommended:

- 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.
- 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.

Given that it is 2019 now, and the proposed regulations will likely take effect January 1, 2020, all should be added to version 1.

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."[53]

- "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.[54]
- "Reconciled Medication List" should be advanced. Medication errors represent the most common patient safety error,[55] and more than 40 percent of medication errors result from inadequate reconciliation in handoffs during admission, transfer, and discharge of patients.[56] According to the Institute of Medicine's seminal report, *Preventing Medication Errors*, the average hospitalized patient suffers at least one medication error per day.[57]
- "Social, psychological, and behavioral data," or social determinants of health, should be advanced, and "Depression" at the very least. Depression is captured now.[58] Social determinants of health and other factors outside the clinical setting account for 85-90 percent of one's health status.[59]
- "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.[60]

Given the passage of time, ONC could and should announce in the final rule that these data classes are added as a version 2, effective January 1, 2021.

B. Provenance

ONC requests comment on whether any other provenance data elements should be included besides the three proposed (author, organization, and time stamp). Besides ONC's suggestion of the "last hop,"[61] provenance should also include an electronic signature or flag to validate that the original data element or value has not been tampered or altered. For example, adding an electronic signature, encrypted with

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[53] 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.
[54] 80 Federal Register at p. 62658.
[55] 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).
[56] 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).
[57] Institute of Medicine, Preventing Medication Errors, p. 1 (Dec. 11, 2006).
[58] 2015 Edition Health Information Technology Certification Criteria, 80 Federal Register 62602, 62631-62632 (Oct. 16, 2015), available at https://www.govinfo.gov/content/pkg/FR-2015-10-16/pdf/2015-25597.pdf.
[59] 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.
[60] 2015 Edition Health Information Technology Certifiction Criteria, 80 Federal Register 62602, 62648-62649 (Oct. 16, 2015), available at https://www.govinfo.gov/content/pkg/FR-2015-10-16/pdf/2015-25597.pdf.
[61] 84 Federal Register at p. 7443.

information such as a MD5 hash function of the other data elements included from the originator, to prove the data were not modified. There is already a trust technology network in place, so this should not be technologically difficult to do.

VI. HEALTH IT FOR THE CARE CONTINUUM: SHARED CARE PLANS AND PLANNING

As ONC states, a shared care plan is "critical . . . for managing an individual's health across a continuum that includes both clinical and non-clinical settings."[62] We **wholeheartedly agree that ONC should accelerate implementation of dynamic, shared, longitudinal care plans that incorporate information from both clinical and non-clinical settings and empower individuals to manage their own health and care.**[63]

ONC requests comment on the maturity of existing and forthcoming standards. We note that the 2015 Edition's Care Plan certification criterion and accompany standards have already been in effect since January 1, 2019, based on HL7's Implementation Guide for CDA release 2.1.[64] We also note the recent work of the FHIR At Scale Taskforce's (FAST) Ecosystem Use Case Tiger Team to develop a Shared Care Planning Ecosystem Use Case.[65]

ONC's question also implicates what ONC should add now as data classes in the U.S. Core Data for Interoperability, including CDHI's recommendations above to add more data classes now. For example, dynamic shared care plans include health goals, health concerns, health status evaluations and outcomes, interventions, and care team members, among others. The proposed USCDI version 1 does not name health status evaluations and outcomes, nor interventions, as included data elements. If ONC includes those now, for example, ONC simultaneously advances the standards for shared care plans. Dynamic shared care planning would also benefit from adding cognitive status, functional status, disability status, the eight initial categories of social determinants of health, and advance directive/POLST.

VII. EVALUATING AND EXPLAINING THE FINAL REGULATIONS WITH FOUR CORE USE CASES

The draft regulations are complex and highly technical, significantly complicating how well the public, patients and even providers and developers understand how the

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[62] 84 Federal Register at p. 7463 (quoting Advanced Health Models and Meaningful Use Workgroup, Health Information Technology Policy Committee, "Findings and Recommendations from Hearing on Advanced Health Models," p. 6 (June 23, 2015), available at https://www.healthit.gov/sites/default/files/facas/AHMWG_Meeting_Slides_2015-06-23_v3.pptx).
[63] 84 Federal Register at p. 7463.
[64] 2015 Edition Health Information Technology Certification Criteria, 80 Federal Register 62602, 62648-62649 (Oct. 16, 2015), available at https://www.govinfo.gov/content/pkg/FR-2015-10-16/pdf/2015-25597.pdf.
[65] Ecosystem Use Case Tiger Team, FHIR at Scale Taskforce, "Use Case – Shared Care Planning: Provider(s) & Care Teams, Patient & Family Caregivers, Payers" (Mar. 28, 2019), available at https://oncprojectracking.healthit.gov/wiki/display/TechLabSC/The+FAST+Initiative+Use+Cases+Repository?preview=/88146023/98631926/FAST%20Shared%20Care%20Planning%20Use%20Case%20v1.07%20(3-28-2019).docx

regulations operate in practice. CDHI urges ONC to explain in the final rule how the regulations will work in the real world with four concrete use cases that are current national priorities for interoperability, in order to help ONC and stakeholders align abstract discussions to real and immediate needs. The preamble's examples of how the information blocking provisions apply to current real-world issues helped tremendously. We recommend a similar approach for the final regulations overall, to explain to stakeholders and the public how the final rule works in real-world situations.

We iterate below the four core use cases we use at CDHI:

- **Individuals' and patients' electronic access** to their digital health information, not only to view it, but to use it—to download it, to transmit it to a provider or other recipient of the person's choice, and to use it in innovative new ways with apps of the person's choice such as those on smartphones through open APIs.[66] Individuals cannot effectively manage their health and health care without ready and convenient access to their medications, health status, diagnoses and treatment instructions whenever and wherever needed. This is *not* just a use case limited to certified EHRs and the View/Download/Transmit/API criterion. It applies to individuals' and patients' electronic access and interoperability across the board—across diverse modes and settings of access and use, from personal health records to home monitoring devices, from community health centers to urgent care clinics to nutritionists.

- **Patient- or person-generated health data.** Providers, patients, researchers, payers—all recognize that one-way access to health information is not enough. Access, interoperability and data portability must be bi-directional, so patients have access to their electronic health data, but providers, too, have electronic access in real time to patient-reported outcomes and critical health data in the patient's hands outside the clinical setting. Accountable care organizations, precision medicine initiatives, delivery system reform and reducing health disparities will depend for success upon this ability to know and integrate patient-reported outcomes and patient-contributed health data.

- **Shared care planning and shared care and information coordination.** Better care, better health and lower cost depend upon better communication and coordination among providers, patients and family caregivers, and others who coordinate the patient's care and health the vast amount of time outside the 15-minute office visit. Providers cannot succeed under new models of care without activated and engaged patients, ready access to patient-generated health data and outcomes, and more granular demographics essential for effective clinical decision support and prevention. Shared care planning and information coordination are essential—not a static, episodic "plan of care" buried in an EHR, but a "multidimensional, person-centered health and care planning process facilitated by a dynamic, electronic platform that connects individuals, their family and other

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

personal caregivers"[67] so that all members of one's care teams can update the plan electronically in real time with results and changes to advance the person's health and wellness goals.

- **Social and environmental determinants of health.** Medical care delivery determines only an estimated 10-15 percent of health; the remaining 85-90 percent of health is determined by factors outside the clinical setting, such as the socioeconomic and physical environment, health behaviors and genetics.[68] Providers need a standardized method for collecting and integrating non-clinical patient health indicators to improve health and care. Patients, community resources and researchers stand ready to contribute. Frameworks must include interoperability with non-clinical settings and exchange of non-clinical data, such as social services, housing and schools, and environment and nutrition.

These four use cases already inform many of our recommendations herein, and illustrate why employing them to explain how the final regulations work in real-world situations could help ONC and readers of the final rule.

VIII. FDA'S SOFTWARE PRECERTIFICATION PROGRAM

The Food and Drug Administration (FDA) is currently testing a pilot Software Precertification Program for software as a medical device (SaMD). ONC invites comment on whether it should exempt health IT developers that the FDA has precertified under the Software Precertification Program from certain requirements for testing and certification of health IT under ONC's Health IT Certification Program.[69]

In summary, the FDA's Software Precertification Program would shift the traditional regulatory paradigm and focus on pre-market assessment of the developer and its culture of quality and excellence, rather than the medical device. It would also shift validation to post-market surveillance and real-world performance data of the medical device, rather than pre-market clinical trials. Depending upon the risk level of the software, the FDA may engage in streamlined review of the SaMD, or allow the precertified developer to go directly to market and use post-market surveillance.[70] CDHI has been actively working on the Software Precertification Program since its inception.

Whether to borrow or recognize the FDA's *precertification* of a developer and apply it to the extent that the developer also produces certified EHR technology or health IT is

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

[68] Robert Wood Johnson Foundation, *Frequently asked questions about the social determinants of health* (Oct. 10, 2010), available at http://www.rwjf.org/content/dam/files/rwjfwebfiles/Research/2010/faqsocialdeterminants20101029.pdf.

[69] 84 Federal Register at pp. 7438-7439. Specifically, ONC asks about the quality management systems criterion, the safety-enhanced design criterion, the computerized provider order entry (CPOE) criterion, the clinical decision support criterion, the implantable device list criterion, the problem list criterion, the medication list criterion, the medication allergy list criterion, the drug-formulary and preferred drug list checks criterion, and the smoking status criterion.

[70] U.S. Food and Drug Administration, Developing a Software Precertification Program: A Working Model, v1.0 (Jan. 2019), available at https://www.fda.gov/files/medical%20devices/published/Pre-Cert-Working-Model-v1.0.pdf.

an intriguing question. However, ONC's proposed regulations do not include the other three critical parts of the FDA's program—*risk assessment*, *streamlined review in advance for higher-risk products*, and *post-market surveillance* and *collection and evaluation of real-world performance data*—which apply to the product or criterion, not the developer. We do not know whether and how ONC might apply them to certified health IT. Just as the FDA would not allow a precertified developer to market SaMD without applying the other three components, so ONC should not borrow or recognize the FDA's precertification of the developer without establishing and integrating the other three components for review of the products. We note as well that, as a pilot, significant elements of the program could change before any formal adoption.

The same answer holds true for ONC's alternative question, whether it should instead develop an independent program to precertify developers rather than rely on the FDA's precertification.[71] In the absence of the traditional comprehensive pre-market assessment of a product, some streamlined review for higher risk criteria before they are permitted in the marketplace, and a robust, ongoing regulatory program for post-market surveillance and evaluation of real-world performance analytics, are essential.[72]

IX. REAL-WORLD TESTING AND MEASURING INTEROPERABILITY

The Cures Act requires developers to test the health information technology for interoperability in the real world settings and uses for which it would be marketed.[73] ONC proposes that this condition of certification should assess interoperability "within the workflow, health IT architecture, and care or practice setting in which the health IT is implemented," including detailed annual plans and annual results for real-world testing of interoperability. Although the Cures Act does not limit its requirement only to particular health IT modules, ONC proposes real-world testing only for the care coordination criterion; clinical quality measures criterion; view, download, and transmit criterion; application programming interface criteria; and transport criteria. **We have extensive experience with the importance of real-world testing in digital health ecosystems, and strongly support ONC's proposal to require real-world testing of interoperability of these five certification criteria (although we recommend below real-world testing of other criteria as well).** We appreciate the detail of the annual plan, including testing methods, care and practice settings, timelines and plans for updates, testing milestones, and expected outcomes.[74]

A. Measuring Interoperability

ONC proposes that the annual plan need only include one measurement or metric associated with the real-world testing, but invites comment on whether ONC should instead require real-world testing for a minimum "core" set of measurements or

[71] 84 Federal Register at p. 7439.
[72] We note that the scope of this proposal to borrow FDA precertification for certain criteria does not overlap at all the scope of ONC's proposal to implement real-world testing of interoperability for certain criteria. Consequently, the real-world testing proposal would not provide any real-world performance measurement for covered criteria here.
[73] 21st Century Cures Act, § 4002(a) (adding 42 U.S.C. § 300jj-11(c)(5)(D)(v)).
[74] 84 Federal Register at pp. 7495-7496; see also id. at pp. 7429-7430, 7495-7501.

metrics.[75] As we explain, ONC should *not* allow just one measurement to suffice for real-world testing of interoperability, and *should* specify and require results for a core set of interoperability measures.

Effective programs include a component for evaluation and measurement. Fortunately, ONC already has at hand a good framework for measuring interoperability. ONC commissioned the National Quality Forum to develop the Interoperability Measurement Framework, 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.[76]

The table below shows the Interoperability Measurement Framework's domains and subdomains of interoperability:[77]

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

Obviously just one measure of interoperability does not suffice to demonstrate successful real-world use of a module in the intended care or practice settings. At best, only an outcome ("impact") measure might begin to include other domains of interoperability as well, and the range of subdomains illustrates that even one outcome measure could not measure the module's interoperability across the board. **We recommend that ONC require a minimum, core set of interoperability measures,**

[75] 84 Federal Register at pp. 7496, 7497.
[76] 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.
[77] Id., p. 11. See also id., p. 20, app. A (measure concepts); id., p. 24, app. B (existing measures).

comprising at least one measure for each of the Framework's domains, and separately, 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, developers are beginning to measure the degree of interoperability across the various domains and subdomains, so ONC and the public can gauge improvement and effectiveness of interoperability. NQF's Interoperability Measurement Framework provides such a well-vetted, multi-stakeholder framework.

B. Patient-Generated Health Data

ONC solicits comment on whether to apply real-world testing to the "patient health information capture" criterion as well.[78] This criterion includes patient-generated health data and patient-reported outcomes.[79] It is the epitome of interoperability: bi-directional access and exchange of data between non-clinical settings such as the patient's home, device, or smartphone, and the EHR in the clinical setting. Yes, the regulations should require real-world testing of the patient health information capture criterion for interoperability.

ONC also asks whether any other criteria should also be included. As we explained above, the Cures Act does not limit this condition of certification only to specific criteria, and we submit that the Cures Act mandates real-world testing for interoperability of each and all criteria. **The Act does not envision piecemeal interoperability, where some criteria demonstrate interoperability in relevant care or practice settings, but others do not and continue to pose barriers to interoperability, perhaps with unanticipated consequences for an individual's care in specific situations.** If ONC does not apply real-world testing to all criteria, however, we recommend that it require real-world testing at least for the essential criteria in the Base EHR Definition, i.e., "those necessary to meet the HITECH Act requirements and our policy goals."[80] At the very least, we recommend that ONC require real-world testing of the following additional criteria:

- Demographics
- Common Clinical Data Set (i.e. U.S. Core Data for Interoperability)
- Social, psychological, and behavioral data
- Care plan

As ONC found in its final rule for the 2015 Edition, the "demographics" criterion has a crucial role in clinical decision support, and improving and evaluating quality of care; the criteria collected as the "Common Clinical Data Set" are the core data for interoperability, API access, and transitions of care; the "social, psychological, and behavioral data" criterion helps a wide array of stakeholders to improve health outcomes and other use cases such as the Precision Medicine Initiative and delivery system reform (emphasizing the need for interoperability); and the "care plan" criterion provides a

[78] 84 Federal Register at pp. 7496, 7497.
[79] 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.
[80] Id. at p. 62691.

shared, dynamic, longitudinal synthesis of a patient's multiple plans of care among providers and is thus essential for improving coordination of care (again emphasizing the need for interoperability).[81] As such, these criteria surely warrant real-world testing for interoperability to improve care and ensure safety for patients.

Conclusion

Thank you for the opportunity to provide these comments on ONC's draft regulations to implement key provisions of the 21st Century Cures Act. UCSF's Center for Digital Health Innovation looks forward to working with the Office of the National Coordinator, 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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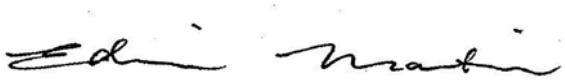

Edwin C. Martin
Director, Technology
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cc: Elise Anthony, Director, Office of Policy
Steve Posnack, Director, Office of Standards and Technology

[81] Id. at pp. 62661-62662; id. at p. 62619 (demographics, in the course of discussing sexual orientation/gender identity); id. at pp. 62603, 62635, 62644-62645, 62693-62702 (Common Clinical Data Set); id. at pp. 62631-62632 (social, psychological, and behavioral data); id. at pp. 62648-62649 (care plan).