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September 27, 2019

By electronic submission

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, D.C. 20201

Re: UCSF Center for Digital Health Innovation's Comments on Integrating Patient-Generated Health Data into Electronic Health Records, File No. CMS-1715-P

Dear Administrator Verma:

The University of California, San Francisco's Center for Digital Health Innovation submits these comments on the Centers for Medicare & Medicaid Services' request for information on integrating patient-generated health data into electronic health records using certified EHR technology, published August 14, 2019, as part of the Calendar Year 2020 Revisions to Payment Policies Under the Physician Fee Schedule. The University of California, San Francisco (UCSF) is a worldwide leader in health care delivery, discovery, and education. Consistent with this public imperative, UCSF invests heavily in developing a variety of health information technology, innovation, and management resources to give health care providers and patients,[1] researchers and scientists, educators and students the interoperability and transformative tools to succeed in the rapidly evolving digital health age. We thank you for the opportunity to provide these comments.

The Centers for Medicare & Medicaid Services (CMS) invites public comment on integrating patient-generated health data (PGHD) into electronic health records. Patient-generated health data and patient-reported outcomes are cornerstones of the data that providers and patients alike need for patient-centered care and shared care planning. **We applaud CMS for moving forward to integrate patient-generated health data and patient-reported outcomes into the nation's digital health ecosystem as soon as possible,** whether as part of CMS's forthcoming final rule on interoperability and patient access, or as part of this physician fee schedule, or other rules.

[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."

In the comments below, we describe our perspective on the importance and landscape of patient-generated health data, which provides context for our responses to CMS's questions. **We recommend that CMS focus on widespread integration of patient-generated health data as Congress envisioned in the 21st Century Cures Act, not just a few use cases.** Secondly, we recommend that CMS move well beyond the suggested idea of initial, incremental pilots or experiments, and instead **focus on systematic implementation of patient-generated health data to meet the nation's needs and demands**.

Thirdly, providers should be expected to collect patient-generated health information or patient-reported outcomes outside of scheduled appointments or procedures. We **cannot afford to delay and confine providers' access to critical PGHD and patient-reported outcomes to the intermittent scheduled appointment or procedure**. Lastly, providers should not need nor depend upon an incentive program before a provider will collect, review, and analyze patient-generated health data and patient-reported outcomes. Instead, **professional services to review and analyze PGHD and remote monitoring data as part of treatment and care coordination should be compensated**, wherever one is in the transition from fee-for-service to accountable-care and value-based care.

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

UC San Francisco is a worldwide leader in health care delivery, discovery, and education, with a mission of "Advancing Health Worldwide." In recent years, we have invested heavily in developing the information technology resources to help health care providers, patients, researchers, innovators, educators, and students have the interoperability and tools needed to succeed in the rapidly evolving digital age. UCSF's medical centers consistently rank among the nation's top hospitals, according to *U.S. News & World Report*, and see approximately 43,000 hospital admissions and 1.2 million outpatient visits annually, including care of the county's underserved and veteran populations.

UCSF focuses on solving real and important problems at national, regional, and global levels. UCSF's own scope extends beyond tertiary/quaternary care at UCSF facilities, to our level one trauma center at Zuckerberg San Francisco General Hospital, the county and safety net hospital for San Francisco; to the San Francisco Veterans Affairs Medical Center; and to our accountable care organizations (ACOs) including community hospitals and clinics across the Bay Area. Additionally, through UC Health, we have access to 15 million patient health records at six academic medical centers across California, representing an incredibly diverse set of individuals and approximately one third of California's population in the world's fifth largest economy. Therefore, we represent the full continuum of health care, with access to patient- and population-level data on myriad disease conditions and demographics.

We have played a seminal role in developing precision medicine, an emerging field that aims to harness vast amounts of molecular, clinical, environmental and population-wide data to transform the future of health diagnosis, treatment and prevention for people worldwide. Indeed, UCSF's policy and research leadership helped stimulate the

nation's Precision Medicine Initiative, urgently moving forward under the 21st Century Cures Act to improve care and health for individuals across the nation. UCSF research has spawned more than 185 startups, including pioneers Genentech and Chiron, and helped establish the Bay Area as the nation's premier biotech hub.

In 2013, UCSF founded its **Center for Digital Health Innovation (CDHI)**, which partners with technology companies to solve real-world health problems and speed implementation of innovation into everyday health care. CDHI is renowned for its thought leadership in digital health. Currently, our work focuses on enabling the ecosystem of innovative health apps and open application programming interfaces that improve workflows, care quality, and patient engagement by creating true health data interoperability.

For example, CDHI partners with Intel and GE to build deep learning prediction algorithms to be leveraged behind the scenes and at the point of care by frontline providers. This program, **SmarterHealth**, integrates our evidence-based research and clinically rigorous approaches to digital health innovation into a collaborative approach with leading industry partners to build infrastructure, processes, and products that address high priority, real-world problems in care delivery. SmarterHealth creates methodologies and tools to access, harness, and annotate multi-modal data in scalable and repeatable processes using advanced analytics and deep learning (artificial intelligence approaches).

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

In conjunction with CERSI, UCSF and CDHI launched a national collaboration in 2018—the **Accelerated Digital Clinical Ecosystem (ADviCE)**—which is focusing on implementation and evaluation of digital health software tools in clinical care, including software as a medical device (SaMD) and the FDA's pilot Software Precertification Program. A collaboration initially among UCSF, leading national health systems, SaMD innovators, payers, and consumers, ADviCE aims to identify best practices around use of digital health software tools in clinical care delivery and in monitoring the effectiveness of these tools in clinical practice using real world data. ADviCE collaborators are providing important insights around the role of real-world performance analytics, evaluation, and regulation in the deployment of software as a medical device.

The Center for Digital Health Innovation is just one among many centers that UCSF has dedicated to helping the nation reach its digital health imperatives. For example, the **Bakar Computational Health Sciences Institute (BCHSI)** under Dr. Atul Butte leads nationally renowned work to advance precision medicine and big data. The **Center for Vulnerable Populations** 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. Background: The Ever-Burgeoning Importance of Person-Generated Health Data

CDHI applauds CMS for re-introducing this initiative and these questions about patient-generated health data.[2] Although CMS withdrew the measure of patient-generated health data from the Promoting Interoperability program in 2018,[3] the importance of patient-generated health data and use cases requiring PGHD remains, and indeed, continues to grow.

Providers, patients, researchers, and payers all recognize that one-way access to health information is not enough. The vast majority of a person's health care occurs outside the traditional health care system and has not been captured by an electronic health record. People with chronic illnesses such as diabetes, rheumatoid arthritis, asthma, or inflammatory bowel disease, increasingly have the opportunity to use medical devices, wearables, and smartphone applications to capture data highly relevant to their health status. Successful chronic disease management requires providers' access to blood pressures, weights, or blood glucose levels measured on a regular basis in the home. Successful long-term ambulatory chemotherapy or immunotherapy requires providers' access to patient-reported symptoms such as nausea, headaches, or diarrhea.

Access, interoperability, and data portability therefore must be bi-directional, so that not only do patients have access to their electronic health data, but health care teams have access to real-time patient-reported outcomes, device data, and environmental health data. 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. Shared care planning,

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[2] Medicare Program: CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies, 84 Federal Register 40482, 40783 (Aug. 14, 2019), available at https://www.govinfo.gov/content/pkg/FR-2019-08-14/pdf/2019-16041.pdf.

[3] Medicare Program: Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2019 Rates, 83 Federal Register 41144, 41634, 41637 (Aug. 17, 2018) ("we are finalizing the removal of the Coordination of Care Through Patient Engagement objective and its associated measures Secure Messaging, View, Download or Transmit, and Patient Generated Health Data as well as the measures Request/Accept Summary of Care, Clinical Information Reconciliation and Patient-Specific Education"), available at https://www.govinfo.gov/content/pkg/FR-2018-08-17/pdf/2018-16766.pdf; Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019, 83 Federal Register 59452, 59786, 59799, 59813 (Nov. 23, 2018) ("Four of the measures—Patient-Specific Education; Secure Messaging; View, Download, or Transmit; and Patient-Generated Health Data—would be removed because they have proven burdensome to MIPS eligible clinicians in ways that were unintended and may detract from clinicians' progress on current program priorities."), available at https://www.govinfo.gov/content/pkg/FR-2018-11-23/pdf/2018-24170.pdf.

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. Oftentimes the patient—not the provider—is the single source of truth. Accountable care organizations (ACOs), precision medicine initiatives, and efforts to reduce health disparities all depend on the ability to know and integrate patient-reported outcomes and patient-contributed health data.

As the Interoperability Roadmap summarizes, "Changing the paradigm to a person-centered ecosystem is vital to improving health, given that an individual's actions inside and outside the clinical care delivery system greatly impact health outcomes. Moving forward, the health IT ecosystem needs to put greater focus on (1) incorporating patient-generated health data across health IT products and services . . . ."[4]

Innovators might even assert that patient-generated health data *are* health care. Startup companies building modern care delivery models today, such as Omada, Livongo, Virta, Onduo, and others, rely almost exclusively on patient-generated health data for the care they deliver. In today's and tomorrow's delivery models, PGHD are not extraneous or foreign—they are patient-centered data and care!

In the 21st Century Cures Act, Congress explicitly highlighted the importance of interoperability for and access to patient-generated health data—"the patient's ability to electronically communicate patient-reported information (such as family history and medical history)."[5] Congress declared "interoperability" a national imperative, to assure electronic access, exchange, and use of health information, nationally and locally.[6] Congress also declared "patient access" a national priority and imperative, and directed 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."[7] **In particular, Congress highlighted usability for patients to contribute patient-generated health data and patient-reported outcomes and to contribute to research.**[8] Congress mandated access, exchange and use "without special effort on the part of the user," and specifically highlighted the importance of open application programming interfaces (APIs)—including patient-generated health data.[9]

With this as context, we turn to CMS's questions about patient-generated health data.[10]

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[4] Office of the National Coordinator for Health Information Technology, *Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap*, p. 44 (Oct. 6, 2015), available at https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf.

[5] 21st Century Cures Act, Pub. L. 114-255, § 4006(a), 130 Stat. 1033, 1181 (2016).

[6] 21st Century Cures Act, § 4003 (adding 42 U.S.C. § 300jj-12(b)(2)(B)(i), (c)(2)).

[7] 21st Century Cures Act, § 4003 (adding 42 U.S.C. § 300jj-12(b)(2)(B)(iii)); id. § 4006(a).

[8] 21st Century Cures Act, § 4006(a).

[9] 21st Century Cures Act, § 4003(a)(2). Section 4002(a) requires that certified EHR technology "has published application programming interfaces and allows health information from such technology to be accessed, exchanged, and used without special effort through the use of application programming interfaces or successor technology or standards."

[10] We understand CMS to be using the term "patient-generated health data" broadly. The white paper that CMS cites in the request for information defined patient-generated health data as "health-related data created and recorded by or from patients outside of the clinical setting to help address a health concern." Conceptualizing a Data Infrastructure for the Capture, Use, and Sharing of Patient-Generated Health Data in Care Delivery and Research through 2024, p. 1 (Jan. 2018), available at https://www.healthit.gov/sites/default/files/onc_pghd_practical_guide.pdf. Likewise, in its final rule for Stage 3, CMS described "patient-generated health data" as data obtained from individuals and patients themselves, generated predominantly through self-monitoring of their health (whether on their own initiative or at their clinical care teams' direction). Medicare and Medicaid Programs: Electronic Health Record Incentive Program—Stage 3 and

III. CMS's Request for Information on Integration of Patient-Generated Health Data

CMS asks four questions, about priority use cases for PGHD; incentives and rewards to capture PGHD; collecting PGHD outside the office visit; and incentives and rewards to improve workflows for reviewing and analyzing PGHD.

1. Priority Use Cases for Patient-Generated Health Data

CMS begins by asking which specific use cases for capture of PGHD as part of treatment and care coordination are most promising for improving patient outcomes.

For perspective, it might help to consider the converse question first: What are the use cases where patient outcomes improved *without* any patient-reported outcomes or health data from the patient? Hard to imagine. We rely on the patient (or family caregiver) to call the doctor or hospital, or reach out electronically, or visit the emergency department about new symptoms. Those are patient-generated health data. We rely on the patient to supply family health history, form after form. We often rely on the patient visiting one clinical setting to supply his health data from other clinical and non-clinical settings such as schools, environmental hazards in housing, fitness centers, and over-the-counter medications. As ONC's white paper on patient-generated health data summarized, "The collection of PGHD is not new."[11]

Patients' rights to submit some forms of patient-generated health data are likewise long-established by law: The HIPAA Privacy Rule requires that patients be able to submit corrections and amendments to their designated record set.[12] These are quintessential

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Modifications to Meaningful Use in 2015 Through 2017, 80 Federal Register 62762, 62850 (Oct. 16, 2015), available at https://www.govinfo.gov/content/pkg/FR-2015-10-16/pdf/2015-25595.pdf. Similarly, ONC described its "patient health information capture" module for the 2015 Edition of Certified EHR Technology to be one mechanism (but not the only one) to capture patient-generated health data, and used the term broadly to include documents (such as advanced directives or birth plans), or health information from devices or applications (such as fitness or nutrition applications, and home health or personal health monitoring devices), perhaps collected directly and electronically through the patient portal, an API, or email, from the individual or an authorized representative. 2015 Edition Health Information Technology (Health IT) Certification Criteria, 80 Federal Register 62602, 62662 (Oct. 16, 2015), available at https://www.govinfo.gov/content/pkg/FR-2015-10-16/pdf/2015-25597.pdf.

In clinical settings, clinicians may distinguish between (1) patient-generated health data, such as device data, patient-reported outcomes, etc., and (2) patient-contributed health data, or data that traditionally have been captured by the EHR but can be added or supplemented by patients, such as family history or medical history. Different categories and sources of patient-generated health data include:

- home medical devices (e.g. continuous glucose monitors, insulin pumps, pacemakers),
- home pseudo-medical devices (e.g. blood pressure cuffs, scales, thermometers, peak flow meters),
- home medical sensors or "invisibles" (e.g. thermal or WiFi sensors for sleep, breathing, and gait),
- consumer health devices (e.g. activity trackers, sleep trackers),
- connected health things (e.g. smart pill bottles, asthma inhalers),
- consumer Internet of Things (e.g. ambient sensors, temperature, air quality),
- health history (e.g. patient medical history, but collected from a patient)
- patient-reported outcomes (e.g. symptom diary),
- ambient tracking (e.g. Ginger.io data about texts, calls, keystrokes on an iPhone)

We understand CMS's questions to include these and other patient-generated health data broadly.

[11] Conceptualizing a Data Infrastructure for the Capture, Use, and Sharing of Patient-Generated Health Data in Care Delivery and Research through 2024, p. 5 (Jan. 2018), available at https://www.healthit.gov/sites/default/files/onc_pghd_practical_guide.pdf.

[12] 45 C.F.R. §§ 164.526.

patient-generated health data, for better data integrity, better patient safety, and better treatment and care coordination.

In short, the needs and use cases for patient-generated health data are widespread and warrant widespread inclusion as Congress envisioned in the 21st Century Cures Act,[13] not just a few use cases.

If CMS nonetheless needs to prioritize some types or use cases of patient-generated health data over others, CDHI would respond here as we did to the Office of the National Coordinator in our public comments submitted May 24, 2019:

> 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.[14]

2. Incentives and Rewards to Capture Patient-Generated Health Data

Secondly, CMS asks whether the Promoting Interoperability category should reward providers for capturing patient-generated health data in certified EHR technology using standards-based approaches.

We repeat at the outset that providers already have legal obligations, as well as medical imperatives, to capture PGHD irrespective of rewards, namely patient-reported corrections and amendments pursuant to the HIPAA Privacy Rule.[15] Considering the landscape described above, CDHI submits that **the nation's digital health ecosystem needs to be and to move well beyond initial, incremental pilots or experiments, to systematic implementation**. The ability to capture PGHD in CEHRT using standards-based approaches would benefit considerably from a decision by ONC and CMS to include "write" APIs in certified EHR technology for providers and payers in the forthcoming final rules. If CMS wants to reward something, it could reward providers' mature implementation of "write" APIs before January 1, 2022.

3. Collecting Patient-Generated Health Data Outside the Office Visit

Thirdly, CMS asks whether providers should be expected to collect patient-generated health information or patient-reported outcomes outside of scheduled appointments or procedures. Yes!

Electronic integration of patient-generated health data and remote monitoring data outside of the 15-minute office visit is one of the core benefits provided by the national

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[13] 21st Century Cures Act, § 4006(a).
[14] 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, p. 11 (May 24, 2019), available at https://static1.squarespace.com/static/5be4eafda2772ceaae90810b/t/5ce85e287817f7dff5726025/1558732329421/UCSF+CDHI+Comment+Letter+on+ONC%27s+Proposed+Regulations+on+Interoperability+and+Information+Blocking+%285-24-2019%29.pdf .
[15] 45 C.F.R. §§ 164.526.

transformation from a paper-based health record and information exchange system to an electronic health record and information exchange system. Much is happening in individuals' health and care the other 23 hours 45 minutes of the day and 364 days of the year, both expected and unexpected. **We cannot afford to delay and confine providers' access to critical PGHD and patient-reported outcomes to the intermittent scheduled appointment or procedure.**

Moreover, integrating patient-generated health data in real time allows all members of the care team to deliver care more efficiently to large groups of patients, making simple preventative or treatment decisions sooner for some, and escalating care for others to the appropriate level of provider (administrative staff, nurse, physician assistant, or doctor). Patients are increasingly far from their specialists as regionalization of complex care increases, and even from their primary care physicians when travelling. Many assessments, labs, imaging studies, etc. can be done locally and interpreted remotely, and diagnosis can even use remote access through the patient's mobile phone with photographs or video.

We note that CMS has already stated that information collected during an office visit or hospital stay is not "patient-generated health data" and "does not meet the intent of the measure to support care coordination and patient engagement in a wide range of settings outside the provider's immediate scope of practice."[16] The white paper that CMS cites in the request for information, "Conceptualizing a Data Infrastructure for the Capture, Use, and Sharing of Patient-Generated Health Data in Care Delivery and Research through 2024," defined patient-generated health data as "health-related data created and recorded by or from patients outside of the clinical setting to help address a health concern."[17] That remains true today as it was in 2015 and 2018.

4. Incentives and Rewards to Improve Workflows for Reviewing and Analyzing Patient-Generated Health Data

Fourthly, CMS asks whether the Promoting Interoperability category should reward providers for implementing best practices to optimize clinical workflows for obtaining, reviewing, and analyzing patient-generated health data.

It is unclear whether the question asks more about *incentives* to review and analyze PGHD, or about *compensation* for professional services to review and analyze patient-generated health data. **Professional services to review and analyze PGHD as part of treatment and care coordination should be compensated, wherever one is on the spectrum from fee-for-service to accountable-care and value-based care.** The services are relevant and important, and they deserve compensation. For the same reason, they should not need nor depend upon an incentive program before a provider will collect, review, and analyze patient-generated health data and patient-reported outcomes.

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[16] Medicare and Medicaid Programs: Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 Through 2017, 80 Federal Register 62762, 62851 (Oct. 16, 2015), available at https://www.govinfo.gov/content/pkg/FR-2015-10-16/pdf/2015-25595.pdf.

[17] Conceptualizing a Data Infrastructure for the Capture, Use, and Sharing of Patient-Generated Health Data in Care Delivery and Research through 2024, p. 1 (Jan. 2018), available at https://www.healthit.gov/sites/default/files/onc_pghd_practical_guide.pdf.

Conclusion

Thank you for the opportunity to provide these comments on integrating patient-generated health data (PGHD) into the digital health ecosystem, including electronic health records. UCSF's Center for Digital Health Innovation looks forward to working with the Centers for Medicare & Medicaid Services, Office of the National Coordinator, providers, vendors, and consumers across the nation to leverage technology to improve interoperability and access, enhance the quality of care, foster trust with patients, bolster meaningful engagement, and improve health outcomes. If you have any thoughts or questions about these comments, please contact Mark Savage at Mark.Savage@ucsf.edu.

Sincerely,

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cc: Dr. Donald Rucker, National Coordinator for Health Information Technology