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September 7, 2018

By electronic submission

The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, D.C. 20201

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
CMS'S PROPOSED AMENDMENTS TO THE QUALITY PAYMENT PROGRAM'S
ADVANCING CARE INFORMATION (PROMOTING INTEROPERABILITY)
PERFORMANCE CATEGORY, FILE NO. CMS-1693-P**

Dear Secretary Azar and Administrator Verma:

The University of California, San Francisco's Center for Digital Health Innovation submits these comments on CMS's proposed amendments to the Quality Payment Program, issued July 12, 2018, as part of the proposed physician fee schedule for Medicare in 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 innovators, educators and students the digital health tools and interoperability needed to succeed in this rapidly evolving digital health age. We thank you for the opportunity to provide these comments.

In the comments below, UCSF's Center for Digital Health Innovation focuses on the proposed changes to the Quality Payment Program's Advancing Care Information and Promoting Interoperability performance categories because of their central role in building a national digital health ecosystem. **We applaud CMS's decision not to delay**

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 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."

required use of the 2015 Edition of certified EHR technology, which introduces new functionality and standards essential for interoperability and shared care planning. As CMS acknowledges, “it is clear the 2014 Edition certification criteria are out of date and insufficient for clinician needs in the evolving health information technology (IT) industry.” (83 Fed. Reg. 35704, 35912 (July 27, 2018).) However, **we urge CMS *not* to drop core measures of meaningful uses such as patient access to view, download, transmit or use apps and APIs** with their electronic health information to manage their health, nor secure messaging with doctors, patient-generated health data, and patient-specific education. Genuine interoperability for patient-centered care and health depends upon such functions and basic use of them. For these very reasons, Congress instead directed the Secretary to make interoperability and patient access a national priority, not a nationwide repeal.

EXPERTISE OF UNIVERSITY OF CALIFORNIA, SAN FRANCISCO AND UCSF’S CENTER FOR DIGITAL HEALTH INNOVATION

UC San Francisco is a worldwide leader in health care delivery, discovery, and education. In recent years, 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 the State of California, representing an incredibly diverse set of individuals and approximately one third of California’s population in the world’s seventh largest economy. Therefore, we represent the full continuum of healthcare, with access to patient and population-level data on myriad disease conditions and patient 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 the

implementation of innovation into everyday health care. CDHI is renowned for its thought leadership in digital health. For example, CDHI creates tools and services that allow developers to create, test, and distribute apps and decision-support algorithms in a scalable, EHR-agnostic manner. Currently, our work focuses on enabling the ecosystem of innovative health apps and open application programming interfaces (APIs) that improve workflows, care quality, and patient engagement by creating true health data interoperability.

CDHI also 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, called 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 a scalable and repeatable process using advanced analytics and deep learning (artificial intelligence approaches).

The Center for Digital Health Innovation is just one among many centers that UCSF has dedicated to helping the nation reach its digital health imperatives. For example, the Institute for Computational Health Sciences (ICHS) under Dr. Atul Butte leads nationally renowned work to advance precision medicine and big data. The Center for Vulnerable Populations is known nationally and internationally for innovative research to prevent and treat chronic disease in populations for whom social conditions often conspire to promote various chronic diseases and make their management more challenging. The Social Interventions Research and Evaluation Network (SIREN) at the Center for Health and Community is working to integrate social and environmental determinants of health. The Center for Clinical Informatics and Improvement Research (CLIIR) under Dr. Julia Adler-Milstein leads national research on use of EHRs and other digital tools to improve health care value. We bring the breadth and depth of these and many other efforts to bear in our comments below.

CMS'S PROPOSED REPEAL OF THE PATIENT ENGAGEMENT OBJECTIVE AND ALL PATIENT ENGAGEMENT AND INTEROPERABILITY MEASURES

In the 21st Century Cures Act, Congress declared “interoperability” a national priority and imperative, to assure electronic access, exchange, and use of health information, nationally and locally.² 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.”³

For both interoperability and patient access, Congress mandated more than abstract availability of access and exchange. Congress directed the Secretary to “promote policies that ensure that a patient’s electronic health information is accessible to that patient and the patient’s designees, in a manner that facilitates communication with the

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

³ 21st Century Cures Act, § 4003 (adding 42 U.S.C. § 300jj-12(b)(2)(B)(iii)); id. § 4006(a).

patient’s health care providers and other individuals, including researchers, consistent with such patient’s consent.”⁴ Likewise, Congress highlighted usability for patients to contribute patient-generated health data and patient-reported outcomes and to contribute to research.⁵ 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).⁶ In short, Congress required interoperability, access, and use for patients and family caregivers as well as providers, and specifically included patient access and use, communication with doctors, and patient-generated health data.

Yet the four measures CMS proposes to drop—patient access and use to view, download, transmit, or manage with apps and APIs; secure messaging; patient-generated health data; and patient-specific educational material—have one thing in common: they promote patient engagement and measure actual interoperability with patients. Indeed, **they are the only measures of actual interoperability with and use by patients.**

The table below summarizes and compares current Stage 3 measures and minimum thresholds with the substantially diminished measures and thresholds proposed in this rule. The key patient-facing measures would disappear, and for the remaining measures, minimum thresholds would drop to just one patient. (E.g. 83 Fed. Reg. at 35917-35918.)

Stage 3 (2019)			NPRM (2019+)	
Objective	Measure	Threshold	Measure	Threshold
Protect Patient Health Information	Security Risk Analysis	yes		yes
Electronic Prescribing	e-Prescribing	> 25%		one patient
			Query Prescription Drug Monitoring Program	one patient
			Verify Opioid Treatment Agreement	one patient
Patient Electronic Access to Health Information	Provide Patient Access	> 50%	Provide Patients Electronic Access to Their Health Information	one patient
	Patient-Specific Education	> 10%	<i>[repealed]</i>	
Coordination of Care Through Patient Engagement	View, Download or Transmit	one patient	<i>[repealed]</i>	
	Secure Messaging	> 5%	<i>[repealed]</i>	
	Patient-Generated Health Data	> 5%	<i>[repealed]</i>	
Health Information Exchange	Send Summary of Care	> 10%	Support Electronic Referral Loops by Sending Health Information	one patient
	Request/Accept Summary of Care	> 10%	Support Electronic Referral Loops by Receiving and Incorporating Health Information	one patient
	Clinical Information Reconciliation	> 50%	<i>[incorporated in preceding measure]</i>	

⁴ 21st Century Cures Act, § 4006(a).

⁵ 21st Century Cures Act, § 4006(a).

⁶ 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.”

Stage 3 (2019)			NPRM (2019+)	
Objective	Measure	Threshold	Measure	Threshold
Public Health and Clinical Data Registry Reporting	Immunization Registry Reporting	yes/no		yes/no
	Syndromic Surveillance Reporting	yes/no		yes/no
	Electronic Case Reporting	yes/no		yes/no
	Public Health Registry Reporting	yes/no		yes/no
	Clinical Data Registry Reporting	yes/no		yes/no

We appreciate CMS’s articulated goal to improve interoperability and patient access, but on the contrary, **the proposed amendments instead undermine patient interoperability and access, and CMS should not adopt them.**

CMS proposes to repeal the patient-engagement objective and all of its associated patient-facing measures and uses “because they have proven burdensome to MIPS eligible clinicians in ways that were unintended and may detract from clinicians’ progress on current program priorities.” (83 Fed. Reg. at 35920.) We appreciate CMS’s attention to the needs of doctors and hospitals for better interoperability, better workflows and usability, and less burden. As one of the nation’s leading academic medical centers, participating in a Bay Area-wide accountable care organization and running the county hospital and VA hospital in a major metropolitan county, UCSF monitors and manages those workflows and burdens and their impact on patient care every day. This is not an artificial dichotomy, where reducing clinicians’ burden requires reducing patient’s access and use of their health information for better care and health. On the contrary, patient-centered care, and shared care planning and decision-making, require both.

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 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 data essential for effective clinical decision support and prevention. Shared care planning and information coordination are essential and require that CMS *promote* secure messaging, patient access and use of health information, patient-generated health data, and patient-specific education, *not eliminate* these measures.

Put another way, **eliminating the patient engagement objective and all of the patient-facing measures will instead substantially increase the long-term burden upon doctors, patients, and the national health ecosystem.** These are the real-world performance data and patient-reported outcomes for measuring and validating interoperability with patients and family caregivers. We urge CMS not to repeal these four measures and their minimal thresholds.

CMS'S PROPOSED REQUIREMENT TO USE THE 2015 EDITION WITH NO FURTHER DELAY

CMS proposes to retain the current requirement that eligible clinicians use the 2015 Edition of Certified EHR Technology beginning January 1, 2019. (83 Fed. Reg. at 35912.) As CMS acknowledges, “it is clear the 2014 Edition certification criteria are out of date and insufficient for clinician needs in the evolving health information technology (IT) industry.” (Ibid.) Indeed, the 2014 Edition “can impose limits on interoperability and the access, exchange, and use of health information.” (Ibid.) CDHI wholeheartedly agrees that the nation’s transition to the 2015 Edition should remain as scheduled for 2019 with no further delay, and strongly supports CMS’s decision. Any further delay would only further delay innovation that depends upon new functionality and criteria in the 2015 Edition such as patient-facing APIs and the patient-generated health data (PGHD) module.

CMS notes that health care providers and health IT developers need the “more up-to-date standards and functions that better support interoperable exchange of health information and improve clinical workflows.” (Ibid.) The 2015 Edition has functionalities “that were not available in the 2014 Edition that we believe will increase interoperability and the flow of information between providers and patients.” (Id. at 20498.)

- 2015 Edition “move[s] to more up-to-date standards and functions that . . . improve clinical workflows.” (Id. at 35912.)
- 2015 Edition produces “reduced burden across many settings.” (Ibid.)
- 2015 Edition will “better streamline workflows and utilize more comprehensive functions to meet patient safety goals and improve care coordination across the continuum.” (Ibid.)
- 2015 Edition’s new API functionality is a “major improvement” which
 - “supports health care providers and patient electronic access to health information,”
 - “contribute[s] to quality improvement and greater interoperability between systems,”
 - “allows for third-party application usage with more flexibility and smoother workflow,” and
 - “allow[s] for patient data to move between systems and assist patients with making key decisions about their health care.” (Ibid.)

For these reasons and others, the transition to the 2015 Edition should remain as scheduled for 2019 with no further delay.

Conclusion

Thank you for the opportunity to provide these comments on the proposed amendments to the Quality Payment Program’s Advancing Care Information and Promoting Interoperability performance categories. CDHI **urges CMS *not* to drop the core patient uses and measures, and *not* to dilute the threshold minimum performance to just one patient for each measure**, and instead to retain these measures and minimum thresholds in the current regulations. Repealing these basic meaningful uses

and thresholds would cripple the digital health ecosystem in significant ways and substantially increase the long-term burden upon doctors, patients, and the national health system.

If you have any thoughts or questions about these comments, please contact Mark Savage at Mark.Savage@ucsf.edu.

Sincerely,



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Center for Digital Health Innovation



Mark Savage
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cc: Donald Rucker, M.D., National Coordinator for Health Information Technology