University of California San Francisco



Center for Digital Health Innovation (CDHI)

UCSF Mission Bay Campus 1700 Owens Street, Suite 541 San Francisco, CA 94158-0008

415.502.3305 cdhi.ucsf.edu October 5, 2020

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 the Calendar Year 2021 Physician Fee Schedule's Proposed Policies Regarding Medicare Telehealth Services and Remote Monitoring Services, File No. CMS-1734-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' proposed policies on Medicare telehealth services and remote monitoring services as part of the proposed calendar year 2021 revisions to the Physician Fee Schedule, published August 17, 2020. 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 reimbursement for Medicare telehealth services and remote monitoring services, and whether a particular service should fall within or without the definition of covered services for purposes of reimbursement, both during and beyond the public health emergency for the COVID-19 pandemic.² UC Health is submitting systemwide comments on specific definitions, provisions, and reimbursement of such critical



Digital Health Innovation at UCSF

¹ For brevity, these comments refer to "patient" and "care," given that many federal programs and initiatives are rooted in a clinical or medical model. Health and health care, however, embrace more than clinical settings and extend well beyond clinical treatment of episodes of illness and exclusive dependency on medical professionals. Any effort to improve patient and family engagement must include terminology that also resonates with the numerous consumer and community perspectives not adequately reflected by medical model terminology. For example, people with disabilities and others frequently refer to themselves as "consumers" or merely "persons" (rather than patients). Similarly, the health care community uses the terminology "caregivers" and "care plans," while the independent living movement may refer to "peer support" and "integrated person-centered planning."

² Centers for Medicare & Medicaid Services, CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies, 85 Federal Register 50074, 50095-50113 (Aug. 17, 2020), available at https://www.govinfo.gov/content/pkg/FR-2020-08-17/pdf/2020-17127.pdf.

services. In this comment letter, UCSF's Center for Digital Health Innovation instead describes the immediate impacts on one the nation's leading academic medical centers and digital health innovators trying to provide telehealth and remote monitoring services at the speed and intensity of COVID-19. The systemic benefits also extend well beyond COVID-19 and the current public health emergency. The conclusion is clear: **Medicare policy should reimburse such synchronous and asynchronous services because they are critical to enable better care, better health, and better value.**

I. The Ever-Increasing Importance of Providing and Reimbursing Telehealth and Remote Monitoring Services for Value-Based Health Care

By its very nature COVID-19 has put a premium on virtual care, and use of remote monitoring, device data, and patient-generated health data, in order to minimize potential exposure while maximizing timely testing and care. In February 2020, UCSF was one of the first health systems in the country to care for COVID-19-positive patients. In less than two weeks, we innovated, designed and implemented a virtual self-triage and self-scheduling tool to provide critical care for thousands of patients.

Here is a description published in the *Journal of the American Medical Informatics Association*:

One of the earliest effects on health systems was a sharp increase in the volume of phone calls, patient portal messages, and appointment requests from patients who had questions or concerns about COVID-19. The increased demand on ambulatory clinical capacity created several health system challenges. First, it was difficult to provide care to the patients who needed it most when front-line clinicians and staff were spending a large proportion of their time on triage. Second, the surge of patients walking into urgent care and primary care practices for advice created an infection control hazard. Third, in the setting of rapidly changing information and guidelines, it was difficult to maintain consistency in medical recommendations and advice. Lastly, patient experience suffered, with unusually long telephone hold times, delayed message responses, and limited appointment availability.

Electronic health record (EHR)-tethered patient portals enable patients to view test results, communicate with their care team, and schedule appointments, including telehealth visits. Portal use can improve satisfaction and engagement of both clinicians and patients. In most EHR-tethered patient portals, symptom triage and medical advice is only accessible through asynchronous secure messaging between patients and clinicians; inbound messages arrive unfiltered and without a triage mechanism to enhance clinical care efficiency, even in the case of repetitive and algorithmic tasks. More recently, some health systems have begun employing patient self-triage modules and symptom checkers as a first point of contact for patients with new symptoms. These tools have the potential to efficiently allocate resources by providing automated triage advice and by linking patients to the optimal level of care.

In response to this emergent demand upon our health system, we designed and rapidly implemented a patient portal-based self-triage and self-scheduling tool.

The goal was to direct patients to targeted intake, advice, information and care for respiratory symptoms and COVID-19 concerns.³

The individual logs into the patient portal and answers questions about symptoms, exposures, medical history, etc. Using the tool, dispositions include answering questions, ordering a test, scheduling a visit, answering questions, etc. During the first 16 days of use, it was completed 1,129 times by 950 unique patients. Of completed sessions, 814 (72%) were by symptomatic patients, and 315 (28%) were by asymptomatic patients. For symptomatic patients, dispositions were 193 emergent (24%), 193 urgent (24%), 99 non-urgent (12%), and 329 self-care (40%).⁴ In total, more than 10,000 patients have now used this virtual tool, and it has been replicated at dozens of other health systems.

Despite all of this virtual care delivered—as well as the cost to innovate, develop, and implement these virtual care tools in less than two weeks—most remains *unreimbursed* under existing Medicare and Medicaid reimbursement policy. Only in-person and video visits are reimbursed, not conversations over telephone, email, secure messaging portal, or other asynchronous communication methods and remote monitoring—but in the era of COVID-19, less than 25 percent of the care and dispositions occurred by in-person or video visits. Yet such services are enabling better and safer care and better value, both during and beyond the public health emergency. Medicare policy should reimburse virtual care services that use either synchronous or asynchronous communication or monitoring.

In turn, policies that limit or deny reimbursement embed some perverse incentives against moving toward value-based care.

Visits to the emergency department are reimbursed at high rates, while virtual care by telephone and secure messaging is unreimbursed. Instead, value-based care should add incentives to reimburse low-cost virtual care where more appropriate than in-person visits to the emergency room.

For the past six months, UCSF Health has also run and funded a COVID-19 hotline to provide timely, virtual care with significantly less unnecessary exposure. The hotline uses protocols established by clinical experts to assess callers' symptoms and provide them with guidance. Those staffing the hotline order tests directly, schedule visits if needed, and follow up on patients who test positive to ensure that they can care for themselves at home. Initially, UCSF Health made the hotline available to the general public as well as UCSF's patients and employees. In February, the hotline was receiving 75-100 calls per day. By the middle of March, there were nearly 500 calls per day. The wait time for callers then was between 30 and 40 minutes. Absent an appropriate reimbursement policy, UCSF Health has continued to fund the hotline out-of-pocket, but has had to restrict its availability to UCSF patients and employees.

³ Timothy Judson, Anobel Odisho, Aaron Neinstein, Jessica Chao, Aimee Williams, Christopher Miller, Tim Moriarty, Nathaniel Gleason, Gina Intinarelli & Ralph Gonzales, Rapid design and implementation of an integrated patient self-triage and self-scheduling tool for COVID-19, 27 J. Amer. Med. Inform. Ass'n 860, 861 (May 13, 2020) (footnotes omitted), available at https://doi.org/10.1093/jamia/ocaa051.

⁴ Id. at pp. 863-864.

Another example is hypertension management. UCSF Health is developing a model for virtual hypertension care, which in turn may provide a model for virtual care and chronic care management generally across a range of conditions.

Traditionally, treatment for hypertension entails 2-3 visits per year, perhaps with tests that entail additional visits to review the lab results and adjust medications. With synchronous and asynchronous virtual care, treatment instead can occur more frequently, with blood pressure cuffs at home that upload blood pressure results to hypertension programs, where algorithms and pharmacists suggest medication adjustments sooner, leading to better blood pressure control and better long-term outcomes.

These examples—UCSF's self-triage and self-scheduling tool for use with COVID-19, UCSF's COVID-19 hotline, and UCSF's hypertension program—illustrate the need to reimburse and shift the cost and value curve to virtual care wherever appropriate. As these examples illustrate, the imperatives for Medicare reimbursement of synchronous and asynchronous telehealth and remote monitoring services are widespread. COVID-19 shines the spotlight on that fact.

II. 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 FDAapproved medical products.

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

The Center for Digital Health Innovation is just one among many centers that UCSF has dedicated to helping the nation reach its digital health imperatives. For example, the **Bakar Computational Health Sciences Institute (BCHSI)** under Dr. Atul Butte leads nationally renowned work to advance precision medicine and big data. The **Center for Vulnerable Populations** under Dr. Kirsten Bibbins-Domingo and now Dr. Margot Kushel is known nationally and internationally for innovative research to prevent and treat chronic disease in populations for whom social conditions often conspire to increase various chronic diseases and make their management more challenging. The **Social Interventions Research and Evaluation Network (SIREN)** at the Center for

Health and Community under Dr. Laura Gottlieb and Dr. Nancy Adler is working to integrate social and environmental determinants of health. The **Center for Clinical Informatics and Improvement Research (CLIIR)** under Dr. Julia Adler-Milstein leads national research on use of EHRs and other digital tools to improve health care value. We bring the depth and breadth of these and many other efforts to bear in our comments below.

Conclusion

Thank you for the opportunity to provide these comments on the importance of providing and reimbursing synchronous and asynchronous telehealth and remote monitoring services for value-based care nationwide. 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,

Aaron Neinstein, MD Director, Clinical Informatics Center for Digital Health Innovation

avage

Mark Savage, JD Director, Health Policy Center for Digital Health Innovation

Anobel Odisho, MD, MPH Clinical Informatics Lead Center for Digital Health Innovation

Timothy Judson, MD, MPH Associate Director of Clinical Innovations Department of Medicine

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