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The U.S. Department of Health & Human Services

Hubert H. Humphrey Building

200 Independence Avenue, S.W.

Washington, D.C. 20201

Re: FR Doc. 2020–25795 Effective and Innovative Approaches/Best Practices in Health Care in Response to the COVID-19 Pandemic; Request for Information (RFI)

Dear Secretary Azar,

On behalf of the American Psychiatric Association (APA), the national medical specialty society representing 38,800 physicians specializing in psychiatry, we appreciate the opportunity to provide information on innovative approaches and best practices in health care in responses to the COVID-19 pandemic.

The impact of the unprecedented pandemic on the nation's healthcare system has impacted the safety, quality, continuity of care, outcomes, value, and access to timely health care in numerous healthcare settings. Due to new limitations and necessary safety precautions, there has been the opportunity for expedited innovations in healthcare. The need to physically distance caused a sudden distribution in care that was mitigated by the availability of telehealth. However, as the pandemic continues, the stress associated has led to a dramatic increase in mental health and substance use conditions. A study by the CDC found three times the amount of reported anxiety symptoms as compared to reported symptoms from same time last year in 2019, as well as four times the amount of reported depression symptoms as compared to reported symptoms from same time last year, with 13.3% of respondents reporting beginning or increased substance use to cope with stress or emotions related to COVID-19.¹

Therefore, we have identified strategies to safely and effectively improve access to care, including the use of telehealth and evidence-based integrated care. Supporting the use of telehealth and investing in evidence-base models of integrated care like the Collaborative Care Model are necessary to meet the growing demand for treatment across the country.

Telehealth

¹ Mark É. Czeisler^{1,2}; Rashon I. Lane, MA³; Emiko Petrosky, MD³; Joshua F. Wiley, PhD¹; Aleta Christensen, MPH³; Rashid Njai, PhD³; Matthew D. Weaver, PhD^{1,4,5}; Rebecca Robbins, PhD^{4,5}; Elise R. Facer-Childs, PhD¹; Laura K. Barger, PhD^{4,5}; Charles A. Czeisler, MD, PhD^{1,4,5}; Mark E. Howard, MBBS, PhD^{1,2,6}; Shantha M.W. Rajaratnam, PhD. Mental Health, Substance Use, and Suicidal Ideation During the COVID-19 Pandemic — United States. June 24–30, 2020. CDC. 2020 June.

The use of telehealth in the practice of psychiatry, telepsychiatry, is a well-established therapeutic modality that increases access to high-quality psychiatric care for a variety of patient populations, including those residing in rural/remote locations, in urban areas with transportation deserts, and for those whose physical or psychiatric conditions preclude a patient from traveling to a doctor's office. There has been an ever-growing evidence base that suggests that treatment via telepsychiatry demonstrates similar outcomes to in-person care and, in some cases, better—especially with certain populations, cultural groups, or clinical diagnoses.^{2,3} Telepsychiatry can also help to mitigate the stigma around seeking treatment for mental health conditions (in rural and urban locations alike) and also be used to address the geographic and numeric maldistribution of psychiatrists across the country, as well as the lack of psychiatrists in certain treatment settings, such as long-term, post-acute care settings (e.g., nursing homes) and emergency departments within federally qualified health centers (FQHCs).

Additionally, the disparity in quality between in-person care and telepsychiatry seems to be minimal, as the standard of care between in-person psychiatry and telepsychiatry doesn't change; that is, the components of quality mental health care (i.e., good patient-doctor engagement; a solid therapeutic alliance; biopsychosocial treatment considerations; integrated care) remains consistent. Moreover, telepsychiatry has the potential to magnify the positive effects of these factors underlying high quality standard of care.⁴ These positive effects have been shown to increase medication adherence, decrease presentations at emergency departments, decrease time spent in the emergency department when a psychiatrist can be available via telepsychiatry for consultation, and decrease inpatient admissions. With around forty-two percent of psychiatrists formally opting out of Medicare⁵—a population already underserved by the mental health care community—telepsychiatry has the potential to reach our nation's most vulnerable citizens.

Numerous regulatory burdens were lifted around the use of and reimbursement for telehealth in light of the COVID-19 public health emergency. For instance, psychiatrists providing care to Medicare beneficiaries were able to connect with patients in their homes, without the need for the patient to travel to a Medicare-qualifying Originating Site. Additionally, psychiatrists were able to connect with patients using audio-only (telephone) encounters and be reimbursed according to the Medicare telehealth payment model. Finally, physicians were able to use telepsychiatry to electronically prescribe controlled substances to vulnerable patients without first having to conduct in an-person, initial examination, per the Ryan Haight Act. With these barriers to care removed or eased, psychiatrists, almost overnight, were able to connect with their patients and to offer a seamless, continuity of care while everyone remained safe at home during a global pandemic.

² Yellowlees P, Marks S, Hilty D, Shore JH: Using e-health to enable culturally appropriate mental healthcare in rural areas. *Telemed J E Health* 2008; 14:486–492

³ Hilty DM, Yellowlees PM, Parish MB, et al. Telepsychiatry: Effective, evidence-based and at a tipping point in healthcare delivery. *Psych Clin N Amer* 2015;38(3):559-592.

⁴ Hilty DM, Ferrer DC, Parish MB, et al. The Effectiveness of telemental health: A 2013 review. *Telemed J E Health* 2013;(19):444-454

⁵ Boccuti, C., et al. December 2013. "Issue Brief: Medicare Patients' Access to Physicians: A Synthesis of the Evidence." Kaiser Family Foundation

In light of this, it is unsurprising that physicians and patients are worried about what will happen to the current telehealth delivery model once the public health emergency declaration is lifted. Results from a survey conducted by the APA on a sample of its membership revealed that psychiatrists and their patients are generally satisfied or happy with the new virtual delivery system, and that appointment no-show rates have been substantially reduced. The percentage of psychiatrists who reported that *all* of their patients kept their appointments increased from 9% to 32% from before to after their respective states declared a public health emergency due to COVID-19. In conjunction, about 85% of respondents said that patients who were seen for the first time via telehealth were either somewhat satisfied or satisfied with their experience in using telepsychiatry.⁶ This is consistent with nearly a decade of research on telepsychiatry that correlates patient satisfaction with using telehealth for treatment.

It is imperative that the increased access to telepsychiatry that patients and doctors have relied on during the COVID-19 PHE continue when the pandemic ends. In the digital age, it makes good sense to allow for patients to connect with their doctors using technology that has become ubiquitous in our daily lives. With telepsychiatry, the house call is back.

The Collaborative Care Model

During this challenging time for all Americans, we are seeing increased rates of anxiety, depression, substance use, and trauma. We must meet the increasing demand for early identification and treatment of mental health and substance use disorders (MH/SUDs). If we do not address these illnesses early, they can lead to long term chronic issues, greater use of emergency care, or the need for higher levels of care. As demands on our already strained and specialty-focused mental health care system increase, one of the most promising solutions for the pandemic's unique needs is expediting the integration of mental and physical health care in the primary care setting, with the Collaborative Care Model (CoCM) being an extensively evidence-based strategy.⁷

The Collaborative Care Model (CoCM) offers a proven evidenced-based model for providing mental health and substance use disorder services to patients within the primary care setting. This model, already implemented in many large health systems and individual practices, can detect and prevent suicide and overdoses in the primary care setting before they become crises. The Collaborative Care team is led by a primary care provider (PCP) and includes behavioral health care managers, psychiatrists and frequently other mental health professionals all empowered to work at the top of their license. The team implements a measurement-guided care plan based on evidence-based practice guidelines and focuses particular attention on patients not meeting their clinical goals. CoCM is the only integrated care model covered by Medicare, as well as nearly all commercial and many Medicaid payers.

⁶ American Psychiatric Association. "Psychiatrists Use of Telepsychiatry During COVID-19 Public Health Emergency Policy Recommendations." May 2020

⁷ Carlo AD, Barnett BS, Unützer J. Harnessing Collaborative Care to Meet Mental Health Demands in the Era of COVID-19. *JAMA Psychiatry*. Published online October 21, 2020. doi:10.1001/jamapsychiatry.2020.3216

With over 90 randomized control trials it is the only model with strong evidence of cost-savings.⁸ A major mechanism driving cost-savings is the ability to detect illness and begin treatment sooner, just as we have accomplished over the last two decades for heart disease and cancer. The potential cost-savings from widespread implementation are considerable. The 2013 Center for Health Care Strategies study found savings in Medicare and Medicaid settings of up to 6 to 1 in total medical costs and an estimated \$15 billion in Medicaid savings if only 20% of beneficiaries with depression receive such care.⁹ While CMS has covered CoCM since 2017, expansion of the model requires upfront staffing and infrastructure investments that slow implementation.

The integration of behavioral health and general medical services has been shown to improve patient outcomes, save money, and reduce stigma related to mental health and substance use disorders. By providing primary care physicians support through the psychiatric consultant and care manager, they are better equipped to meet the psychiatric needs of patients and learn how to best care for them. This helps to break down stigma and deliver care more efficiently.

FDA Changes to Clozapine Prescribing

Access to clozapine is essential for certain patients with severe mental illness. It has been proven effective for patients with treatment-resistant schizophrenia or those with substantial risk of suicide or suicide attempts. However, one of the biggest barriers to prescribing clozapine is the requirement for patients to receive routine hematologic monitoring to monitor for agranulocytosis (weekly 0-6 months, every other week 6-12 months, and monthly at 1 year and beyond). Due to COVID-19 in April 2020, the FDA [released guidance on clozapine](#) stating, “consider whether there are compelling reasons not to obtain an ANC and use your best medical judgment in weighing the benefits and risks of continuing treatment in the absence of laboratory testing.” In addition, a [consensus statement](#) was released from a group of clozapine experts which suggested reducing the frequency of ANC monitoring to every three months if people met certain criteria. Part of the rationale on this recommendation is based on the research findings that people taking clozapine have essentially negligible risks of developing agranulocytosis after one year of taking the medication. Keeping this consensus statement guidance (especially Recommendation 1) in place after COVID-19 would ease the burden on patients and may help to expand clozapine use.

Mobile Interdisciplinary Teams

The use of mobile teams in some community mental health settings to deliver medication, obtain labs, and administer long acting injectables has been essential to continue services for a vulnerable population. These teams have access to PPE and are typically staffed by nurses or technicians. These

⁸ American Psychiatric Association. Model Legislation for Private Insurance Coverage of the Psychiatric Collaborative Care Model (CoCM) Codes. Retrieved from: <https://www.psychiatry.org/psychiatrists/advocacy/state-affairs/model-cocm-legislation>

⁹ Jürgen Unützer, MD, MPH, University of Washington; Henry Harbin, MD, Health Care Consultant and former CEO of Magellan Health Services; Michael Schoenbaum, PhD, National Institute of Mental Health; and Benjamin Druss, MD, MPH, Emory University. Centers for Healthcare Strategies. The Collaborative Care Model: An Approach for Integrating Physical and Mental Health Care in Medicaid Health Homes. Retrieved from: https://www.chcs.org/media/HH_IRC_Collaborative_Care_Model__052113_2.pdf

teams have also been used for people who are taking clozapine and have helped to coordinate the labs, medication delivery, and vital signs needed to initiate the medication. We urge support for the use of mobile interdisciplinary teams to meet the needs of patients safely and efficiently.

Thank you for soliciting input on this important issue. The APA appreciates the opportunity to provide this input on evidence-based models of care. We look forward to continued collaboration with the Department of Health and Human Services. If you have any further questions, please contact Michelle Dirst at mdirst@psych.org.

Sincerely,

A handwritten signature in black ink that reads "Saul Levin, MD, MPA". The signature is written in a cursive style and is positioned above the printed name and title.

Saul Levin, MD, MPA, FRCP-E, FRCPsych
CEO and Medical Director