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Saul Levin, M.D., M.P.A. (E0 and Medical Director July 9, 2020

Secretary Alex M. Azar, II United States Department of Health and Human Services Washington, DC Via email: Secretary@HHS.gov

Dear Secretary Azar:

On behalf of the American Psychiatric Association (APA), the medical specialty society representing over 38,800 physicians who specialize in the treatment of mental illnesses, including substance use disorders, we thank you for considering our comments in response to President Trump's Executive Order 13924, issued on May 19, 2020: Regulatory Relief To Support Economic Recovery https://www.federalregister.gov/documents/2020/05/22/2020-11301/regulatory-relief-to-support-economic-recovery. We applaud the Administration and Congress for the rapid and decisive government action to make needed regulatory changes during the COVID-19 public health emergency, including improved access to telehealth, among other things. In response to the Executive Order, and as the Administration begins to focus on the impact that the COVID-19 virus has had on our economy, APA would like to provide these comments and recommendations.

Mental health and substance use disorders were already at epidemic levels in the United States before COVID-19. Its outbreak has added considerable emotional and financial stress to many Americans. According to the results of a weekly Census Bureau <u>survey</u>, 24% of those surveyed showed clinically significant symptoms of major depressive disorder and 30% showed symptoms of generalized anxiety disorder, with significantly higher rates of anxiety and depression among younger adults, women, and the poor. A recent SAMHSA report shows an 891% increase in call volume to the Disaster Distress Hotline over the last year. A recent APA survey indicated that more than one-third of Americans (36%) say the coronavirus is having a serious impact on their mental health.¹ Meanwhile, unemployment claims are at historical levels, and a staggering number of formerly employed workers may have lost their employer-sponsored health care coverage.²

The APA remains deeply concerned about the country's ability to address the coming surge in demand for mental health and substance use disorder care as people return

¹ <u>https://www.psychiatry.org/newsroom/news-releases/new-poll-covid-19-impacting-mental-well-being-americans-feeling-anxious-especially-for-loved-ones-older-adults-are-less-anxious</u>

² <u>https://www.kff.org/coronavirus-covid-19/issue-brief/eligibility-for-aca-health-coverage-following-job-loss/</u>

to work and our nation begins to rebuild the economy. Employers are already expressing concerns about the huge mental health toll the pandemic is having on their labor force and how this will impact their bottom lines.³ There is substantial data showing that untreated mental health needs cost American companies billions in lost productivity. Depression alone has been found to cause 200 million lost workdays a year and cost employers between \$17 to \$44 billion.⁴ Only about half of employees with depression get necessary treatment.⁵ Further, this problem goes well beyond the United States. In 2019 the <u>World Health Organization estimated</u> that depression and anxiety cost the global economy \$1 trillion per year in lost productivity. If our nation is to be successful in recovering economically from COVID-19, we must also address this coming second pandemic⁶ and ensure we have the ability to most efficiently accommodate the expected rise in demand for mental healthcare at all levels of the healthcare system. Our comments below have this objective in mind.

Improving Access to Mental Health and Substance Abuse Care in Primary Care

Almost a third of Americans in urban areas and over half in rural areas receive their mental health care through their primary care physicians. These primary care physicians often serve as the sole providers, treating both the mental and physical health needs of children, adolescents, and adults. As sole providers, primary care practices – including pediatric and OB/GYN practices--are the front line for mental health and substance use disorder care.

In order to best equip primary care physicians in their front-line role of meeting mental health needs, in 2017, the Centers for Medicare and Medicaid Services (CMS) approved specific billing codes for an evidence-based model of care to deliver mental health and substance use disorder care in primary care settings – the Collaborative Care Model (CoCM). This model treats patients in the primary care office by pairing them with a behavioral health care manager and a psychiatric consultant. The model includes measurement and accountability protocols to ensure universal screening and detection that enables early intervention and treatment efficacy for mental illnesses and substance use disorders. There are more than 90 randomized controlled studies showing this model expands access to care, decreases costs, and improves outcomes.⁷ Primary care physicians on the front lines have been found to greatly appreciate the support provided by this model.

³ https://www.cnbc.com/2020/04/06/coronavirus-is-taking-a-toll-on-workers-mental-health-across-america.html

⁴ <u>https://www.cdc.gov/workplacehealthpromotion/health-strategies/depression/evaluation-measures/index.html</u>

⁵ http://workplacementalhealth.org/Mental-Health-Topics/Depression

⁶ <u>https://www.keyministry.org/church4everychild/2020/3/22/flattening-the-curve-of-the-covid-19-mental-health-epidemic-to-come</u>

⁷https://www.medicaid.gov/state-resource-center/medicaid-state-technical-assistance/health-home-informationresource-center/downloads/hh-irc-collaborative-5-13.pdf; http://www.e4enterprise.com/NCC/G1/alcohol/ NEJM_MedicarePmtArticle_508.pdf; https://milliman-cdn.azureedge.net/-/media/milliman/importedfiles/ uploadedfiles/insight/2018/potential-economic-impact-integrated-healthcare.ashx

The CoCM reduces costs to the overall health system. Economic studies demonstrate that Collaborative Care is more cost-effective than care as usual, and a number of evaluations have found cost-savings associated with its use. ⁸ The largest randomized controlled trial to date of the CoCM - the IMPACT study involving adults 60+ across 5 states and 18 primary care clinics - found that patients in Collaborative Care had substantially lower overall health care costs than those receiving usual care.⁹

It is vital that we support primary care providers as the need for mental health and substance use disorder treatment increases. As our nation works to address the crisis created by this pandemic, CMS must ensure that Americans receive timely access to effective mental health and substance use treatment now and in the future by:

- Providing a minimum of a 75% increase in the current Medicare payment for CoCM billing codes for the first year to ensure these practices can expand access to cover escalating demand for evaluation and initiation of treatment for mental health and substance use disorders; a 50% increase in the second year; and a 25% increase in subsequent year.
- Mandating Medicaid coverage for the CoCM billing codes in all 50 states at a minimum of Medicare rates, including the 75% increase in the initial year; 50% in the second year; and 25% in subsequent years.
- Mandating commercial insurer coverage (including coverage by ERISA plans) for the CoCM billing codes at a minimum of Medicare rates, including the 75% increase in the initial year; 50% in the second year; and 25% in subsequent years.

Finally, we encourage the CMS Center for Clinical Standards and Quality to establish a national technical assistance (TA) center and 60 regional extension centers that can provide technical assistance to 6,000 primary care practices (100 per center) per year (costing \$300 million over five years). This is modeled on the strategy used in 2010 to accelerate use of electronic health records (EHRs) in primary care settings. It translates into approximately 30,000 practitioners per year out of the 250,000 practicing nationally, 60% of whom (150,000 total) can be reached across five years. Key components of TA should include:

⁸Gilbody S et al. "Costs and Consequences of Enhanced Primary Care for Depression: Systematic Review of Randomised Economic Evaluations." The British Journal of Psychiatry. October 2006;189:297-308. <u>https://www.cambridge.org/core/journals/the-british-journal-of-psychiatry/article/costs-and-consequences-of-enhanced-primary-care-for-depression/68164F069FF5191E0AB0A1C8978BAE66</u>

Glied S et al "Review: The Net Benefits of Depression Management in Primary Care." Medical Care Research and Review. June 2010;67(3):251-274. <u>https://journals.sagepub.com/doi/abs/10.1177/1077558709356357?</u> journalCode=mcrd

⁹ Unützer J et al. "Long-term Cost Effects of Collaborative Care for Late-life Depression." American Journal of Managed Care. Feb 2008;14(2):95-100 <u>https://www.ajmc.com/journals/issue/2008/2008-02-vol14-n2/feb08-2835p095-100</u>

- Developing financial models and budgets for program launch and sustainability based on practice size.
- Developing staffing models for essential staff roles, including care managers and consulting psychiatrists.
- Providing information technology (IT) expertise to assist with building the model requirements into EHRs, including assistance with care manager tools, patient registries, ongoing monitoring, and records.
- Training support for all key staff and operational consultation to develop practice workflows.

Prior Authorization

The APA urges greater transparency and streamlining of all prior authorization processes with an option for clinicians to have all such processes occur electronically. According to a report by the American Medical Association, 92 % of physicians report that "prior authorization programs have a negative impact on patient clinical outcomes." Indeed, the AMA study revealed that "every week a medical practice completes an average of 29.1 prior authorization requirements per physician, which takes an average of 14.6 hours to process—the equivalent of nearly two business days." The APA's experience supports these results. We note that insurers' prior authorization protocols generally require the submission of an extensive amount of required paperwork, multiple phone calls back-and-forth, and significant wait times for prior authorization, often resulting in delayed or disrupted medical care for patients.

The burden of prior authorization needs to be permanently addressed. Prior authorization determinations should be made available to the prescribing physician rapidly and at the point of care. For prior authorizations for prescription medications, a single form should be developed to be used by all payers. EHR certification criteria should include the ability to handle prior authorizations efficiently within the e-prescribing workflow. Prescribers should be able to request that prescription- related information from payers and pharmacies be transmitted electronically to reduce confusing (and potentially unsafe) duplications in communication.

Additionally, payers should be prohibited from requiring repeated prior authorizations of the same medication for individuals with chronic conditions who have been stabilized but need ongoing pharmacological treatment. For individuals with psychiatric disorders, including those with serious mental illness or substance use disorders, gaps in treatment due to prior authorization denials can lead to relapse, with increased health care costs and devastating effects for individuals and their families.

<u>Telehealth</u>

We urge CMS to permanently maintain a number of the recently implemented telehealth flexibilities. These changes would ensure a smooth transition to in-person care and increase access via telehealth and telephone to necessary care. This is especially important for mental health and substance use care, where the ability to establish and maintain a strong, uninterrupted therapeutic alliance with a patient is crucial to effective interventions. **To ensure continuity of care and continued improved access we recommend that CMS permanently:**

- Remove limitations around originating site and geographical restrictions for mental health services. This was done for patients with substance use disorders under the SUPPORT ACT and has improved access to care for this population.
- Permit physicians who are providing treatment within professionally accepted standards of care to use clinical discretion as to whether telehealth consultations should include a synchronous or asynchronous consultation with a patient by regular telephone, text, or videoconferencing.
- Continue to pay telehealth services on par within person visits.
- Include all services on the expanded Medicare approved telehealth list, including group psychotherapy (90853 and G0410). This addition affords an opportunity to provide necessary and effective services to individuals in a variety of settings.
- Maintain coverage and the increased payment for the telephone evaluation and management services that matches reimbursement for the traditional outpatient evaluation and management services that may be provided in-person or via telehealth. We also ask that CMS remove the frequency limitations that are imposed for those codes. This change allows those patients who receive all their care via telephone alone (and not in-person or via telehealth) access to care as often as is medically necessary (potentially more frequently than once every seven days).
- Allow for the use of telephone (audio) only communications for evaluation and management of behavioral health services, including care for opioid use disorders, when it is in the patient's best interest. Examples of this include when a patient has a lack of access to pertinent technology or broadband access, or in the event a medical or behavioral health condition of a patient (e.g., specific diagnosis) precludes the use of live video conferencing (i.e., a patient with schizophrenia who is paranoid). In addition, payment rates for audio-only care should be no less than what was established during the emergency. According to our survey, about 60% of respondents stated between 1 and 25% of their patients cannot access care via audio and video platforms due to technical issues, such as the lack of broadband access; because they cannot afford video technology; or because they are unable to work the technology. Flexibility is needed to continue to ensure this population, often the most vulnerable, has access to care.
- Remove frequency limitations for existing telehealth services in inpatient settings and nursing facilities. Prior to the public health emergency, some CPT codes for inpatient settings could only be used every 3 days; and for certain CPT codes used within skilled nursing facilities, only every 30 days. Care should be based on clinical judgement and medical necessity rather than influenced by arbitrary restrictions that create a barrier to care, particularly given the higher level of acuity of patients in these settings.
- Allow teaching physicians to provide direct supervision of medical residents remotely through telehealth. This will maximize the workforce and ensure the continuity of training of residents.

Telehealth Research

Research should be prioritized to understand the successes, challenges, barriers, innovations, safety, and nuances of delivering mental health care via telehealth across primary care and mental health care systems that have emerged during this public health emergency, as well as the training needs, and the effect workforce utilization of telehealth has had across the healthcare delivery landscape. New research methodologies and funding mechanisms should be advanced that are rapid, flexible, and adaptable in order to provide timely information in the current dynamic environment.

Research should be prioritized to understand the successes, challenges, barriers, innovations, safety, training needs, and workforce utilization of telehealth across the healthcare delivery landscape during the public health emergency. Specifically, funds should be allocated to mental health care delivery system across primary care and specialty mental health care. New research methodologies and funding mechanisms should be advanced that are rapid, flexible and adaptive in order to provide timely information in the current dynamic environment.

- Field research is needed to take advantage of the rapid transition to telehealth so we can continue to effectively use and refine telehealth to meet patient needs and improve access, especially for hard-to-reach patients.
- Some telehealth legislation currently being considered by Congress (e.g., CONNECT Act) already has language around mandating at least some degree of research, but given the nature of the public health emergency, a swifter response is warranted.

Waivers for telehealth prescribing of controlled substances

The Drug Enforcement Agency should permanently issue waivers for telehealth prescribing of controlled substances as a priority, allowing telehealth prescribing to be the same as in-person when the telehealth assessment is conducted via live, interactive, audio-video technology. The Ryan Haight Act's original intent of preventing diversion of controlled substances by combatting the proliferation of rogue internet pharmacies in the late 1990s, while successful, has had the unfortunate consequence of circumventing legitimate healthcare providers' use of telemedicine to prescribe controlled substances in their regular practice of medicine. This has become increasingly relevant to the physician community and their patients in the decade following the passage of the Act, when access to high speed broadband internet coupled with ubiquitous mobile devices has resulted in a significant uptake in the practice of telemedicine. This is especially relevant in a time when a geographic and numeric maldistribution of board-certified addiction psychiatrists and physicians across the United States could potentially be offset by using telepsychiatry, which has the potential to combat the current epidemic of opioid use disorder.

Although not in CMS's authority, but relevant to expanding access to needed mental health and substance us services, we encourage you to work with the DEA to issue waivers for telehealth

prescribing of controlled substances as a priority, allowing telehealth prescribing to be the same as inperson when the telehealth assessment is conducted via live, interactive, audio-video technology. This should reflect the seven exceptions to the Ryan Haight Act, including the Special Registration for Telemedicine, for which the DEA has yet to promulgate notice of proposed rulemaking, despite having been mandated to do so by October 2019 by the 21st Century Cures Act.

Mental Health Parity

Mental health parity has been the law of the land for over 12 years but has yet to be effectively enforced. As a result, people seeking mental health and substance use disorder care continue to face widespread discriminatory practices, such as frequent and more arduous prior authorizations practices, less robust provider networks, more interference in medical decision making, and improper denials of their claims than do people seeking care for a physical condition. APA has long advocated for parity enforcement, and, most recently, urged appropriations of at least \$15 million in the Labor, Health and Human Services, Education, and Related Agencies appropriations bill to support the parity oversight efforts of the U.S. Department of Labor's Employee Benefits Security Administration (EBSA). As more Americans seek help for behavioral health challenges, it is imperative that they be able to access this care without encountering illegal roadblocks and discrimination. We urge the Administration to direct the enforcement bodies, including the EBSA, to prioritize enforcement of mental health parity.

Inpatient Psychiatric Unit Relief

To ensure that patients have access to timely and appropriate care, regulations that impose significant burdens on providers without yielding meaningful benefits should be modified, suspended, or removed. There has recently been a proliferation of standards and requirements related to ligature risks in the inpatient setting. This has caused confusion and uncertainty with regard to interpretation and application of requirements, and as a result of costly changes--up to \$1 million for inpatient psychiatric facilities-- has led to a reduction in the number of available psychiatric beds as hospitals close or scale back inpatient psychiatric units to avoid citations and possible loss of accreditation. The APA is very concerned about the inability to access higher levels of care. The United States now has one third to one quarter the number of psychiatric beds per 100,000 population compared to most European Union countries. We urge CMS to clarify its guidance on ligature risk reduction, and to consider suspending enforcement of citations based on ligature-point and other self-harm onsite survey assessments until such clarification is provided.

The APA appreciates this opportunity share our ideas to providing regulatory relief in order to support an economic recovery. If you have any questions, please contact Kristin Kroeger, APA Chief of Policy, Programs and Partnerships <u>kkroeger@psych.org</u>.

Sincerely,

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

cc: Seema Verma, Administrator, Centers for Medicare and Medicaid Services Elinore F. McCance-Katz, M.D., Ph.D. Assistant Secretary for Mental Health and Substance Use, Substance Abuse and Mental Health Services Administration

