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Assistant Secretary for Mental Health and Substance Use
5600 Fishers Lane
Rockville, MD 20857

RE: Medications for the Treatment of Opioid Use Disorder (RIN 0930-AA39)

Dear Assistant Secretary Delphin-Rittmon,

The American Psychiatric Association (APA) is the nation's medical specialty society that represents more than 38,000 psychiatric physicians and their patients. We appreciate having the opportunity to respond to SAMHSA's notice of proposed rulemaking modifying regulations regarding medications for the treatment of opioid use disorder.

The number of drug overdose deaths in the United States has been increasing over the last 20 years, with a sharp rise in the last half-decade that has been largely attributed to synthetic opioids (primarily fentanyl). In 2020 alone, the number of drug overdose deaths exceeded 100,000, a 28% increase from the prior year, with three out of four deaths involving opioids. Medications for opioid use disorder (MOUD) are an evidence-based practice effective at reducing opioid overdose mortality.

Methadone is a particularly effective form of MOUD. When used to treat opioid use disorder (OUD), methadone is available only when dispensed at an opioid treatment program (OTP). There are more than 1,900 OTPs in the US, serving more than 650,000 patients. Unfortunately, the regulations governing methadone access have created significant barriers to care for many of those who need and want treatment. Flexibilities granted by SAMHSA due to the COVID-19 public health emergency (PHE) served as a starting point for reimagining methadone access in this time of vital need. Given the effectiveness of methadone at reducing overdose mortality and relatively unchanged rates of diversion and overdose deaths involving methadone since the onset of the COVID-19 PHE flexibilities, APA supports SAMHSA's decision to expand access to this life-saving medication. APA encourages SAMHSA to consider several issues highlighted below to maximize the effectiveness of these changes and avert any potential unintended consequences and provides potential actions that SAMHSA should consider to address them.

Language Changes to Reduce Stigma

APA applauds the efforts made to change regulatory language to reduce stigma towards people who use drugs, people with OUD, and towards MOUD as a means of treatment and recovery. It is important to understand MOUD as a valid form of treatment rather than as something that merely assists treatment, helping dispel the myth of “replacing one addiction with another”.

Definitional Changes

APA appreciates SAMHSA’s efforts to create regulatory definitions for harm reduction, individualized dosing, and split dosing. These definitions help grow understanding of harm reduction and split dosing as vital evidence-based practices which center patient autonomy and shared decision-making in the clinical setting.

APA supports expanding access to care for people with OUD at this time of significant need and urgency, however we encourage that patient safety and quality of care are not sacrificed. One method that the Notice of Proposed Rule Making (NPRM) takes to accomplish this goal is to expand the definition of qualified practitioners who may prescribe or dispense medications at an OTP. The complex interactions between OUD and physical health conditions and the medications used to treat them, require advanced medical training in order to ensure high-quality clinical care through adherence to best practices, which typically leads to highly positive health outcomes. For complex medical conditions, physician oversight is often critical to the development and implementation of a plan of care. If SAMHSA expands the definition of qualified providers who may prescribe or dispense medications at an OTP, there must be evidence that this change would increase safe access to care. **For these reasons, APA suggests that other qualified practitioners practice in team-based environments with physician oversight, preventing unintentional consequences for the most vulnerable patients.**

Mobile Medication Units

APA is encouraged by SAMHSA’s collaboration with DEA to facilitate operation of mobile medication units to increase access to methadone treatment for underserved populations. In combination with the proposed take-home dosing changes, mobile medication units can enable patients who lack access to an OTP to gain access to treatment while requiring only intermittent visits from the mobile unit. Mobile medication units can also help address important barriers related to social determinants of health, such as lack of transportation. Access to telehealth services for methadone in conjunction with mobile units and collaboration with local healthcare professionals who can perform occasional medical monitoring is another important step to take to increase access to care for people without access to transportation. Ideally, mobile medication units functioning with well-staffed teams of qualified health professionals could function as a telehealth hub. Adequate mobile data technology and shared records are required to facilitate successful implantation of mobile medication units.

Patient Admission Criteria

APA supports the elimination of the requirement that patients must have had a one-year history of OUD prior to qualifying for methadone treatment. By removing this language and adding language centering clinical decision making and accepted medical criteria, SAMHSA puts OTP providers in position to expand care to meet patients where they are. However, **APA questions the appropriateness of limiting methadone treatment to people with moderate to severe OUD, excluding those with a diagnosis of mild OUD and urges SAMHSA to reconsider the evidence behind this exclusion.**

APA also applauds SAMHSA's efforts to expand access to methadone for minor patients. Under the current criteria, access to care for minors is extremely limited. By removing the requirement that a minor patient must have had two prior documented attempts at other forms of treatment, SAMHSA succeeds in creating the opportunity for many more minors to receive care for their OUD. Importantly, parental guardian consent may be problematic for certain minor patients, especially those who are experiencing homelessness and/or are disconnected from that form of support. APA encourages SAMHSA to research methods that could ensure minor patients receive methadone treatment even when parental consent is not possible and to provide education on best-practices for states as possible.

Patient Screening & Assessment

APA supports SAMHSA's efforts to expand entry points to methadone treatment by enabling patients to utilize telehealth services for their initial screening and assessment. The pandemic-related temporary allowance of telehealth services has been life saving for many patients and has made treatment access much less intimidating. Importantly, the proposed rule does not explicitly clarify whether periodic assessment services are also able to be performed over telehealth in the same manner as the initial assessment. **APA encourages SAMSHA to clarify that periodic assessments can also be performed via telehealth in order to prevent the unintended consequence of treatment drop-out.** Additionally, APA supports SAMHSA's attention to the physical and behavioral health needs that must be evaluated during initial and periodic assessments.

Counseling Services

APA supports SAMHSA's changes with regards to patient autonomy and clinical decision making. The proposed rule removes participation in counseling services as required for medication continuation and expands the definition of counseling services to include harm reduction education and recovery-oriented counseling. By expanding the allowable counseling services and removing the mandate, SAMHSA helps emphasize the value of person-centered care, harm reduction, and recovery-support services. **APA applauds this change and appreciates that patients will have more options to receive the care that is clinically indicated for their needs.**

Patients should have meaningful access to counseling services when they are interested in them. **APA suggests that SAMHSA provide guidance on methods to ensure quality counseling services through-** or

coordinated with- the OTP. These could include updating accreditation standards to include benchmarks ensuring that OTPs offer adequate access to services that are easily accessible by those patients who are interested.

Take-home Dosing: Criteria & Amount

APA supports SAMHSA's revisions to the take-home criteria which give latitude to prescribers to utilize clinical-decision making by creating patient-specific criteria. This reinforces SAMHSA's stated goal of improving person-centered and individualized care. The proposed rule introduces significant changes to the amount of take-home doses that can be dispensed in a given amount of time while enrolled in treatment. These changes make it possible for patients to get take-home doses much sooner in the course of treatment, lessening the burden and life-disruptions imposed by the need to receive in person daily dosing.

While APA generally supports these changes because they allow physicians to make take-home dosing plans that attend to the individualized needs and goals of their patients, we also caution against blanket allowances of 7 take home doses within the initial 14 days of treatment; rather, APA suggests that the clinical reason for this amount of take home doses within the first 14 days of treatment be documented within the patient's medical record. At the same time, APA understands that the take-home flexibilities are not required for every patient; rather, they are for patients for whom an OTP provider has exercised their sound clinical judgment to determine the benefits outweigh the risks. APA recommends SAMHSA gather data on implantation of the new take-home frequencies so that efficacy and safety can be evaluated. With this in mind, APA remains supportive of these allowances.

Split Dosing

The NPRM makes a noted effort to improve care for pregnant patients by creating a definition for "split dosing" and allowing use of such regimens when clinically appropriate. **APA applauds this measure to align OTP treatment standards with the current standard of care for pregnant patients with OUD.** APA encourages SAMHSA to emphasize the utility of split dosing regimens with other patient populations as well, such as people with chronic pain.

Geographic Access

Because of the complex regulations requiring daily or frequent in-person attendance, patients accessing care at OTPs may face disruptions in care during travel or when physically displaced due to disaster. The NPRM mitigates some of this issue by changing the take-home protocols as well as by revising the interim treatment protocols. **APA supports the increase of time allowable in interim treatment from 120 to 180 days and believes this will help patients continue care despite circumstances that take them far from their home clinic.**

APA encourages SAMHSA to research the possibility of other facility-based dispensation of methadone for OUD, such as pharmacies with qualified health-professionals. Because pharmacies are open for more hours during the day than OTPs, they provide greater flexibility for patients who may have commitments during the day. Pharmacies are also more plentiful within communities than are OTPs, expanding access points to care.

Thank you for the opportunity to respond to this Request for Comments on the NPRM RE: Medications for the Treatment of Opioid Use Disorder. If you have questions or would like to discuss these comments in more details, please contact Brooke Trainum, Director of Practice Policy, at btrainum@psych.org.

Sincerely,

A handwritten signature in black ink that reads "Saul Levin, MD, MPA". The signature is written in a cursive, flowing style.

Saul Levin, MD, MPA, FRCP-E, FRPsych
CEO and Medical Director
American Psychiatric Association