

April 6, 2020

The Honorable Dr. Elinore F. McCance-Katz  
Assistant Secretary for Mental Health and Substance Use  
5600 Fishers Lane  
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Dear Dr. McCance-Katz:

As addiction specialist physicians and concerned physician colleagues, we write to you today with a sense of utmost urgency. The COVID-19 pandemic has ushered in an unprecedented time in the nation's living memory. It has upended life as we know it, including how we deliver addiction treatment in opioid treatment programs (OTPs).

From the beginning of this pandemic, we've all had to come together to ensure continued delivery of high-quality and effective treatment for people with opioid use disorder (OUD) who rely on OTPs for life-saving medication and other services. At the same time, we've quickly had to rethink how we structure our services to align with public health recommendations on physical distancing to minimize spread of SARS-CoV-2. We are grateful for SAMHSA's guidance and support to date, which has allowed us to do our part in fighting this virus, while continuing to deliver lifesaving addiction care.

We now turn to you for additional guidance and flexibility, because we have grave concerns about the days, weeks, and months ahead.

Our primary concerns fall into three categories: (1) concern for the safety and well-being of ourselves and our colleagues practicing in OTPs; (2) concern for the safety and well-being of our patients, and (3) concern for the safety and well-being of our communities.

One driver of these concerns stems from SAMHSA's continued requirement for face-to-face, in-person visits with new OTP patients who are to be treated with methadone for their OUD. As a result, we respectfully request that SAMHSA pre-emptively and immediately exercise its authority to exempt OTPs located in federally declared, major disaster areas from the requirement to perform an in-person physical evaluation under 42 C.F.R. §8.12(f)(2) for any patient who will be treated by the OTP with methadone if a program physician, primary care physician, or an authorized healthcare professional under the supervision of a program physician, determines that an adequate evaluation of the patient can be accomplished via telemedicine communication that is conducted using an audio-visual, real-time, two-way interactive communication system. Additionally, we request that such updated emergency exemption related to initiation of methadone via audio-visual telehealth for new patients in OTPs also allow for the medical director to determine the parameters for the provision of take-home methadone

for each such patient until that patient reaches a steady state with their medication, subject to the prior approval of those parameters from the governing State Opioid Treatment Authority (SOTA). In support of this urgent request, we would like to share the following for your consideration.

First, we fully agree with, and greatly appreciate, the designation of OTPs as essential healthcare services. However, we are extremely concerned about the paucity of personal protective equipment (PPE) for front-line healthcare workers despite that designation. That concern includes us, as well as our colleagues in emergency departments and hospitals. Across this country, even in states recently designated as major disaster areas by the US government, clinicians do not have the facemasks, eye shields, gloves, and gowns recommended for face-to-face, in-person contact with patients who may present with COVID-19 symptoms or have the disease. We are aware that many OTP physicians are currently unwilling to perform physical examinations without adequate PPE, which may lead to a significant decrease in access for new or readmitted methadone patients.

By SAMHSA allowing OTP medical evaluations in these major disaster areas to be done via audio-visual telehealth technology, in accordance with applicable standards of care, SAMHSA can help preserve our nation's scarce PPE resources for those healthcare workers in OTPs (e.g., dispensing nurses), emergency departments, hospitals, pharmacies, and residential addiction treatment settings for whom in-person patient contact is unavoidable. Our requested additional guidance and flexibility would also align the delivery of critical OTP services with the delivery of other ambulatory healthcare services for new patients that is rapidly transitioning to the use of telehealth as much as possible during this public health emergency.

Second, we appreciate and share SAMHSA's concerns about how to titrate, safely and effectively, methadone for a new patient starting on the medication at a time when physical distancing and reductions in clinic visits are also being recommended. Medical care of all types is being rapidly transitioned to default telemedicine visits unless hands-on physical examination is urgently required. Methadone is not a medication any of us take lightly. Even under the best of circumstances, balancing adverse individual and community-related impacts associated with the medication with the goal of effective OUD treatment and the well-established public health benefits of methadone can be challenging. However, the increasing risk of COVID-19 virus exposure for staff, patients, and people in the broader community who are located in newly designated, major disaster areas has further complicated this balancing act and now warrants additional flexibility for OTPs and their SOTA's, as proposed above. As SAMHSA's own website correctly acknowledges, "because buprenorphine is unlikely to be as effective as more optimal-dose methadone, it may not be the treatment of choice for patients with high levels of physical dependency." As addiction specialist physicians and concerned physician colleagues, when we see the ability to care properly for seriously ill and complicated patients unnecessarily restricted, we can't ethically stay quiet. We must bring these issues directly to your attention.

We also fully understand that our requested exemption would be temporary - continuing only for the period of the national emergency declared in response to the COVID-19 pandemic.

Again, we are grateful for your urgent actions to date. We stand ready to discuss this request further with you and your team, if needed, so that we may continue working together now, and in the future, to save as many lives as possible. We hope for your prompt response and your continued partnership.

Sincerely,

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The views expressed are those of the authors and do not necessarily represent the views of their institutions.

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