

United States Senate

April 17, 2020

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health & Human Services
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Elinore F. McCance-Katz
Assistant Secretary for Mental Health and Substance Use
Substance Abuse and Mental Health Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

Dear Secretary Azar and Assistant Secretary McCance-Katz:

We write to seek your help in ensuring that patients with opioid use disorder (OUD) can continue to access life-saving medication assisted treatment — in particular, buprenorphine — during the coronavirus pandemic. Individuals struggling with OUD are particularly vulnerable to the impacts of COVID-19. We must do more to address their needs at this perilous time.

In the best of circumstances, those with OUD face significant health care challenges. The unfair stigma surrounding OUD has resulted in barriers to treatment. At the same time, those suffering from OUD face a higher risk of significant respiratory problems.¹ And when medication assisted treatment is interrupted, individuals with OUD are at heightened risk of relapse, overdose, and overdose death.²

All these concerns — barriers to treatment; risk of respiratory problems; and dangers of treatment interruption — are magnified during this pandemic. Moreover, physicians who prescribe medication assisted treatment may be unavailable — whether due to workload, illness, or other unforeseen circumstances — further placing patients with OUD at risk. You can and should take immediate action to ensure that patients with OUD are not denied the medication

¹ Kelsey C. Priest, *The COVID-19 Pandemic: Practice And Policy Considerations For Patients With Opioid Use Disorder*, Health Affairs (Apr. 3, 2020), <https://www.healthaffairs.org/doi/10.1377/hblog20200331.557887/full/>.

² Nat'l Acads of Scis., Eng'g, and Med., *Medications for Opioid Use Disorder Save Lives* 99-100, 124 (2019) <https://www.ncbi.nlm.nih.gov/books/NBK541389/>.

they need, do not exacerbate the strain on our nation's emergency departments and hospitals, and, most importantly, are not added to the COVID-19 death count.

First, we ask Secretary Azar to immediately increase the number of patients that physicians authorized to treat the highest number of OUD patients may see from 275 to 500. Under existing statutory authority, the Secretary of Health and Human Services may increase the DATA 2000 patient limit on treatment for those practitioners who meet the requirements for supervision of the highest number of patients.³ Expanding the treatment capacity of our nation's addiction specialist physicians and those who work in qualified practice settings can help ensure continued access to evidence-based treatment for existing patients with OUD during this crisis. It will also help new patients with OUD find qualified clinicians with the capacity to treat them, rather than ending up on a waiting list or going outside the health care system for relief from their symptoms.

Second, we call on Assistant Secretary McCance-Katz, with the urgency befitting this crisis, to process requests for emergency patient-limit increases. We understand that many clinicians who currently hold a DATA 2000 waiver to prescribe buprenorphine to 100 patients, and who would not otherwise qualify for a higher patient limit, have submitted applications to temporarily increase their patient limit to 275 under emergency provisions in SAMHSA's regulations.⁴ We also understand that some of these clinicians have received responses from SAMHSA requesting that they individually justify the need for this expansion.

These emergency provisions in SAMHSA's regulations were put in place to address precisely the situation in which we find ourselves. Those emergency provisions were intended to ensure continuity of treatment when "a State, tribal, or local system for substance use disorder services is overwhelmed or unable to meet the existing need for medication-assisted treatment as a direct consequence of a clear precipitating event."⁵ The coronavirus pandemic has already overwhelmed many of our state and local health care systems; many more will be unable to meet demand in the coming days and weeks. Moreover, the impact of COVID-19 on our health care system is unpredictable, which makes it all the more important that providers have flexibility to meet the needs of their patients. To that end, we urge SAMHSA to expedite approval of applications for emergency patient limit increases and not require individual justifications amid a global pandemic. We must empower our heroic health care providers to treat and save as many lives as possible in this time of crisis.

We look forward to hearing that you will quickly implement the recommendations we have made. Thank you in advance for your attention to this important matter.

³ See 21 U.S.C. § 823(g)(2)(B)(iii)(II)(dd), (g)(2)(B)(iii)(III).

⁴ 42 C.F.R. § 8.655.

⁵ *Id.* §§ 8.2., 8.655.

Secretary Azar and Assistant Secretary McCance-Katz

April 17, 2020

Page 3

Sincerely,

Edward J. Markey
United States Senator

Elizabeth Warren
United States Senator

Jeanne Shaheen
United States Senator

Dianne Feinstein
United States Senator

Margaret Wood Hassan
United States Senator