April 8, 2019

The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independent Avenue S.W.
Washington, D.C. 20201

Dear Secretary Azar:

We are writing to request urgent federal action to expand access to pharmacotherapy for persons struggling with opioid use disorder (OUD) in response to the opioid epidemic impacting all of our states and the nation. The current requirements to obtain a waiver to prescribe buprenorphine under the Drug Addiction Treatment Act (DATA 2000) place limits on the medical community's capacity to respond to the needs of opioid-dependent individuals.

The DATA 2000 regulatory framework was implemented prior to the current wave of opioid addiction. The limitations in the legislation and regulations have been intended to preserve safety and to promote comprehensive care. The need for buprenorphine has grown exponentially, while the supply of waived prescribers' pales in comparison. Our understanding of the potential role of—and appropriate prescribing practices for—buprenorphine has grown substantially, even since the 2016 amendments to DATA 2000. For example, we have learned that buprenorphine, even in the absence of comprehensive services, is highly effective in preventing morbidity and mortality associated with OUD. Furthermore, the number of buprenorphine-associated deaths is dwarfed by those related to full agonist opioids.

Although reforms have been implemented, more aggressive and more comprehensive measures of reform are urgently needed to stem the overwhelming tide of this epidemic. We, in the undersigned states, are working to lower the barriers to accessing medications that treat OUD, including buprenorphine, methadone and naltrexone, but we need the help of our federal partners to continue to offer these proven interventions to individuals who need them.

Ideally, legislation should be passed eliminating the waiver requirements and allowing all practitioners who are registered with the Drug Enforcement Administration (DEA) to prescribe controlled substances to also prescribe buprenorphine for the treatment of OUD. Researchers in policy have noted that the waiver requirements are burdensome and reduce prescribing. They have also suggested that deregulating buprenorphine would help in reducing stigma associated with treating OUD.[i,ii]

In the absence of this change, we recommend that the Secretary of Health and Human Services use the power under 21 USC §823(g)(2)(B)(iii) to allow newly waived practitioners to prescribe to 100 patients immediately. We also recommend that 21 CFR §1306.07(b) be modified. This regulation, unmodified since 1974, allows any practitioner registered with the DEA to administer (but not prescribe) an opioid 3 days in a row to mitigate opioid withdrawal. This emergency exception could be changed to allow for prescribing of buprenorphine by practitioners without waivers for a limited period, perhaps 2-4 weeks, allowing the patient to find ongoing treatment. The harms caused by suppressing prescribing are greater than the benefits of the DATA 2000 strictures in regulating buprenorphine. It is vital that we take advantage of every opportunity to increase access to this medication.

Sincerely,

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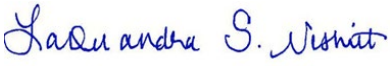

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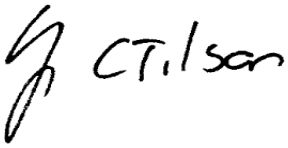

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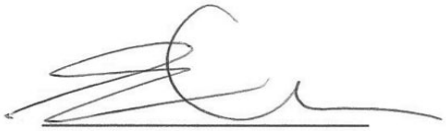

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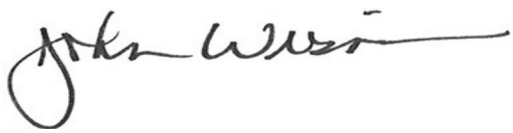

John Wiesman, DrPH, MPH
Secretary of Health
Washington State Department of Health

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[i] Haffajee, R. L., et al. (2018). "Policy Pathways to Address Provider Workforce Barriers to Buprenorphine Treatment." Am J Prev Med 54(6s3): S230-s242.

[ii] Fiscella K, Wakeman SE, Beletsky L. Buprenorphine Deregulation and Mainstreaming Treatment for Opioid Use Disorder: X the X Waiver. JAMA Psychiatry. Published online December 26, 2018. doi:10.1001/jamapsychiatry.2018.3685