February 18, 2021

The Honorable Norris Cochran
Acting Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 120F
Washington, DC 20201

The Honorable Regina LaBelle, J.D.
Acting Director
Office of National Drug Control Policy
750 17th Street, NW
Room 810
Washington, DC 20503

Dear Acting Secretary Cochran and Acting Director LaBelle:

In response to the January 27, 2021 announcement of the Office of National Drug Control Policy (ONDCP) that the Administration of President Joseph R. Biden decided to withdraw the previous administration's *Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder*, we stand ready to work with you and join with the Department of Health and Human Services and ONDCP in their "commitment to working with inter-agency partners to examine ways to increase access to buprenorphine, reduce overdose rates and save lives." We are writing on behalf of addiction psychiatrists and osteopathic physicians who are members of the American Academy of Addiction Psychiatry (AAAP), the American Osteopathic Academy of Addiction Medicine (AOAAM), and the American Psychiatric Nurses Association (APNA), the American Association for the Treatment of Opioid Dependence (AATOD), the Behavioral Health Association of Providers (BHAP), National Association for Alcoholism and Drug Abuse Counselors (NAADAC) National Alliance for Medication Assisted Recovery (NAMA) and Young People in Recovery (YPR). Collectively, we represent more than 150,000 health professionals, 2,200 treatment programs, and over 20,000 individuals in recovery.

We fully support President Biden's goal to increase access to science-based opioid use disorder (OUD) treatment, including the use of buprenorphine and the other federally approved medications, methadone and naltrexone, and offer our support, expertise and experience in the addictions field.

In particular, we welcome the opportunity to join the discussions among any inter-agency review of buprenorphine access and to assist in ensuring that any recommendations produced by that review are evidence based; take into account the factors that helped contribute to the opioid epidemic, namely the lack of universal and systemic education and training of providers prescribing pain medications; ensure the promotion of best practices that result in the most effective use of buprenorphine to prevent

overdoses; and expand current programs for physicians, nurses, physician assistants (PAs) and other clinicians who provide education and training to assess and treat addiction.

We urge the administration to develop policies and programs that will support accredited medical schools and residency programs in training future physicians, and training programs for physician assistants and advanced practice registered nurses to fulfill the training requirement through a comprehensive curriculum.

The Need for Training

The DATA 2000 legislation required physicians seeking to treat OUD with buprenorphine receive 8 hours of training. This training was integrally linked to obtaining a waiver that allowed prescribing of buprenorphine-containing medications for OUD. Subsequent amendments expanded buprenorphine prescribing to physician assistants and advanced practice nurses, with a training requirement of 24 hours. Such requirements recognized that health professional education, including post-graduate training, did not adequately prepare practitioners for prevention, recognition or treatment of OUD.

A 2019 AMA article[1] concluded that "the current state of ethical education and opioid-related courses in medical schools has proven to be ineffective when it comes to the opioid epidemic… It is therefore imperative that measures be taken in order to properly equip future physicians, physicians' assistants and nurse practitioners to properly prescribe opioids."

To meet this need, SAMHSA funded the *Providers Clinical Support System (PCSS),* a training program led by AAAP in collaboration with over 22 national professional organizations representing over 1.5 million health professionals. PCSS provides critically needed education on OUD prevention through effective, safe pain management and science-based OUD identification and treatment. PCSS provides over 800 online educational resources as well as waiver training and mentorship at no cost for all health professionals. Demand for these ***free*** continuing education resources continues to grow. AAAP and AOAAM as DATA 2000 organizations, along with the PCSS partner organizations, have seen PCSS trainings increase 400% in the past 5 years, including an 800% increase in waiver trainings. PCSS also provides ongoing mentorship and learning collaboratives for prevention and treatment of OUD and other substance use disorders for all health professionals at no cost.

Through our collective work in PCSS, we have learned that the waiver training requirement in most cases has **not** been a primary barrier for practitioners treating opioid use disorder. In fact, PCSS's Mentoring Program has found there is a strong desire by practitioners for *additional* training rather than an elimination of training. Waivered providers and their care management teams want **more** education on managing common co-occurring mental disorders, hepatitis and HIV, and overcoming social determinants of health and healthcare disparities. Data shows there are currently 9,000 waivered prescribers with 100 slots per prescriber providing 9 million slots for an estimated 2 million Americans with OUD.[2] Unfortunately, 40 percent of waivered practitioners do not prescribe buprenorphine at all and many others prescribe at far below their authorized capacity. Clearly, there are other important barriers to overcome in providing treatment that need to be addressed.

A recent national survey of DATA waivered providers[3] found that impediments to having practitioners prescribe buprenorphine include: 1) preauthorization insurance requirements, 2) limited reimbursement when treating such patients, 3) sometimes frequent DEA monitoring, 4) not having

access to behavioral health providers and 5) stigma around this patient population. This mirrors a second review[4] that identified concerns about: lack of training and lack of confidence in one's ability to treat OUD; time constraints; low insurance reimbursement; the inability to refer to psychosocial supports; care management or an addiction specialist; concern about buprenorphine diversion; and stigma more often than cumbersome regulatory requirements. Stigma was noted to be an underlying driver of many of the barriers and that education specifically targeting stigma is key. Healthcare professionals need more education and assistance with other barriers in order to make OUD medication accessible. These barriers are not addressed by waiver removal, which we feel is the incorrect focus in trying to improve the use of medications to treat OUD, as the above data indicates, that waiver removal would not improve treatment of OUD or lower the tragic consequences of the opioid epidemic.

Prior to moving forward, it is imperative to consider potential downsides to eliminating the X-waiver and strategies that would mitigate against these risks. Importantly, removing the waiver will eliminate the training requirement, removing an important incentive for medical training programs. Elimination of waiver training may increase risk for incorrect prescribing practices, which could increase the amount of buprenorphine diversion. In addition, lack of training may increase the risk of exposure of opioid-naïve individuals and individuals not screened for alcohol and benzodiazepine co-use with buprenorphine, conditions that greatly increase the risk of overdose death.

Therefore, in an effort to minimize the possibility of negative consequences should the waiver training be removed as a condition of prescribing, **we advocate for development of improved training platforms to replace waiver training prior to waiver elimination**. It is also important to point out that removal of the X-waiver without other regulatory actions would eliminate SAMHSA's ability to track buprenorphine prescribing practices and hence monitor efficacy of such treatment.

The Need for a Comprehensive Solution When Treating a Complex Disorder

Let us not forget how our nation became victim to an opioid epidemic. It began, in part, with the overprescribing of opioid pain medications because of inadequate training of prescribers for safe and responsible opioid prescribing, lack of appropriate medical monitoring and patient education. In our judgment, successful prevention and treatment of opioid use disorder will require (1) education of the entire prescribing workforce to prevent and provide evidence-based treatment of less complex and stable opioid use disorder and (2) building the addiction specialist workforce to treat severe and unstable OUD and its common co-occurring conditions. Improper prescribing of buprenorphine could lead to ineffective treatment of OUD, increased diversion, and exposure of opioid naïve individuals to buprenorphine, in which case, as described above, the agent itself could contribute to significant harms.

We encourage the Biden Administration to initiate a thorough review and discussion with Congress, Federal policymakers, and experts in the field of addiction treatment to develop and implement science-based policies and programs to accomplish our shared goal of ending the opioid epidemic and providing effective treatment for our patients.

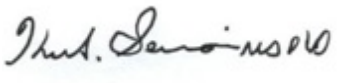
A comprehensive approach includes ensuring access to the most effective delivery of all three federally indicated OUD medications, including buprenorphine, methadone and naltrexone, and addressing barriers and facilitators to the use of these medications based on current data in the scientific literature and in the SUPPORT Act with its mandated survey of waivered providers.

We urge adoption of policies and programs that expand education and training of current and future healthcare providers, through foundational health education in medicine, nursing, physician assistant, pharmacy, allied health programs and other venues.

In summary, the undersigned organizations reiterate our collective gratitude for your actions to create an inter-agency evaluation of the potential risks and benefits of eliminating waiver training. We pledge to work with you and the administration to increase access to opioid use disorder treatment, ensuring effective evidence-based training for practitioners and removing all barriers to providing safe and effective opioid treatment.

Thank you for your consideration of our concerns and offer to provide assistance in this important task.

Sincerely,



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References:

1. Rohanit Singh, Gary W Pushkin (2019) How Should Medical Education Better Prepare Physicians for Opioid Prescribing? AMA J Ethics 21: E636-641.

2. Moran, M. (2016). Why aren't more physicians prescribing buprenorphine. *Psychiatric News*.

3. 2020 Report to Congress: Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act [DRAFT].

4. Mackey K, Veazie S, Anderson J, Bourne D, Peterson K. Barriers and Facilitators to the Use of Medications for Opioid Use Disorder: a Rapid Review. J Gen Intern Med. 2020 Dec;35(Suppl 3):954-963. doi: 10.1007/s11606-020-06257-4. Epub 2020 Nov 3. PMID: 33145687; PMCID: PMC7728943.