May 10, 2022

The Honorable Frank Pallone, Jr.
Chairman
U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20510

The Honorable Cathy McMorris Rodgers
Ranking Member
U.S. House of Representatives
Committee on Energy and Commerce
Washington DC, 20510

The Honorable Anna Eshoo
Chairwoman
U.S. House of Representatives
Health Subcommittee of the Committee
on Energy and Commerce
Washington, DC 20515

The Honorable Brett Guthrie
Ranking Member
U.S. House of Representatives
Health Subcommittee of the Committee
on Energy and Commerce
Washington, DC 20515

RE: Proposed Amendment to the Restoring Hope for Mental Health and Well-Being Act of 2022 - Expanding Access to Methadone for the Treatment of Opioid Use Disorder

Dear Chairman Pallone, Ranking Member McMorris Rodgers, Chairwoman Eshoo and Ranking Member Guthrie:

On behalf of the American Society of Addiction Medicine (ASAM), and the National Alliance for Medication Assisted Recovery (NAMA Recovery), we write to thank Chair Pallone and Ranking Member McMorris Rodgers for recently introducing the **H.R. 7666 - Restoring Hope for Mental Health and Well-Being Act of 2022** and to express our strong support for amending said legislation to include **Section 4 of H.R.6279, the Opioid Treatment Access Act (the "OTAA")**, as set forth in the attached Exhibit A.

ASAM is a national medical society representing over 7,000 physicians, clinicians, and associated professionals in the field of addiction medicine. ASAM is dedicated to increasing access and improving the quality of addiction treatment, educating physicians and the public, supporting research and prevention, and promoting the appropriate role of physicians in the care of patients with addiction. NAMA Recovery is an organization comprised of and led by individuals living in medication assisted recovery from opioid use disorder, health care professionals, and family of individuals with opioid use disorder that are supporters of quality, comprehensive treatment that includes medications for opioid use disorder.

Section 4 of the OTAA would play a critical role in expanding access to a lifesaving treatment for individuals with opioid use disorder (OUD), by allowing certain specially registered prescribers, including addiction specialist physicians[*]—representing some of the most educated and experienced physicians using pharmacotherapies for OUD in the nation,[†] to prescribe up to a one-month supply of methadone for OUD—to be dispensed from a pharmacy, subject to the Substance Abuse and Mental Health Services Administration (SAMHSA)'s "time in treatment" regulations and guidance.

Methadone, a synthetic, long-lasting opioid agonist, is a gold standard medical treatment for OUD. The importance of expanding access to methadone treatment for OUD cannot be overstated. OUD is associated with a 20-fold greater risk of early death due to overdose, infectious disease, trauma, and suicide.[1] Methadone is the most well-studied pharmacotherapy for OUD, with the longest track record.[2] According to myriad experts, methadone is safe and effective for patients when indicated, dispensed, and consumed properly.[3] Treatment with methadone brings stability for patients with OUD by mitigating the "lows" of painful withdrawal, and by attenuating the euphoric "highs" of shorter-acting opioids, such as fentanyl and heroin.[4] In so doing, methadone assists patients with OUD with remission and recovery and allows them to function well in daily life. Methadone treatment for OUD is associated with reduced overdose mortality,[5] and an abundance of improved clinical and community outcomes.[4]

While the OTAA's liberalization of take-home methadone doses for OUD has received widespread stakeholder support, some concerns have been expressed with the provisions that would allow addiction specialist physicians—who may practice outside of opioid treatment programs (OTPs)—to prescribe methadone for OUD. Critics often cite the risks of methadone overdose and diversion as the primary reasons for this singular concern. However, when more closely examined, the totality of the position is illogical and puts more patients with OUD at risk for overdose in a time of a rising death toll. Inaction is a risk this country cannot continue to take.

First, an analysis of Section 4 of the OTAA must be situated in a contemporary framework for the opioid overdose crisis. The adulteration of the illicit drug supply with illicit fentanyl and fentanyl analogs has created an unprecedented and catastrophic moment in U.S. history. Now is a more dangerous time than it has ever been to be an individual with OUD, because of the proliferation of fentanyl. The Centers for Disease Control and Injury Prevention (CDC) has predicted a record 106,854 drug overdose deaths from November 2020 to November 2021.[6] Illicit fentanyl has been a driver behind drug overdoses since 2013.[7] While interventions have been largely unsuccessful in stemming overdose mortality rates, we know that patients with

[*] In 2015, the American Board of Medical Specialties (ABMS) officially recognized addiction medicine as a medical subspecialty. Addiction specialist physicians' certification is through the American Board of Preventive Medicine (ABPM), American Board of Psychiatry and Neurology (ABPN), American Osteopathic Association (AOA), or the American Board of Addiction Medicine (ABAM).

[†] The American College of Graduate Medical Education (ACGME) sets the program requirements for graduate medical education in addiction medicine and addiction psychiatry. ACGME common core program requirements for addiction medicine fellowships include: *pharmacotherapy and psychosocial interventions for SUDs across the age spectrum,* (IV.B.1.c.).(1).(k)); *the mechanisms of action and effects of use and abuse of alcohol, sedatives, opioids, and other drugs, and the pharmacotherapies and other modalities used to treat these* (IV.B.1.c).(1).(m)); *the safe prescribing and monitoring of controlled medications to patients with or without SUDs* (IV.B.1.c).(1).(n)); *at least three months of structured inpatient rotations, including inpatient addiction treatment programs, hospital-based rehabilitation programs, medically-managed residential programs where the fellow is directly involved with patient assessment and treatment planning, and/or general medical facilities or teaching hospitals where the fellow provides consultation services to other physicians in the Emergency Department for patients admitted with a primary medical, surgical, obstetrical, or psychiatric diagnosis;* (IV.C.3.a).(1)); *at least three months of outpatient experience, including intensive outpatient treatment or "day treatment" programs, addiction medicine consult services in an ambulatory care setting, pharmacotherapy, and/or other medical services where the fellow is directly involved with patient assessment, counseling, treatment planning, and coordination with outpatient services* (IV.C.3.a).(2)).

OUD who are engaged in addiction treatment are less likely to die than those who remain untreated, and that for some patients, methadone is essential to a successful recovery.[8] For patients with OUD who use illicitly manufactured fentanyl, methadone can facilitate abstinence from illicit substance use, support recovery, and prevent overdose deaths.[9] Moreover, methadone does not have the same risk of severe painful, precipitated withdrawal as buprenorphine, the partial opioid agonist/antagonist.[10]

Thus, restrictions that continue to limit methadone treatment for OUD to OTPs are a well-recognized vulnerability in the response to the opioid overdose crisis.[11] Methadone remains the most socially stigmatized medication for OUD.[12,13] Many patients have a negative perception, often based on lived experience, that methadone treatment at OTPs is like "liquid handcuffs," and this deters patients' engagement with treatment and recovery.[14] Further, the limitations on methadone for OUD have created unequal and segregated access to medications for OUD. People of color with OUD are less likely to receive medications for OUD, while White people with OUD are more likely to receive treatment with buprenorphine, which can be prescribed in office-based settings.[15–17] It is clear that methadone's restrictions are contributing to alarming trends of inequities in worsening overdose mortality rates, particularly for Black Americans and other people of color—trends that have been accelerated during the COVID-19 pandemic.[18]

In contrast, the critically important way that Section 4 of the OTAA expands access to this treatment is by allowing addiction specialist physicians to prescribe up to one month of methadone doses for OUD, which may be dispensed from a pharmacy. As noted above, these prescriptions would remain subject to SAMHSA's "time in treatment" regulations and guidance, in recognition that exposure to methadone poisoning most frequently occurs during the phase in which methadone is initiated in treatment for OUD.[19] In light of the vulnerability of new patients with OUD during this time, the Act would maintain the ability to use clinical judgement in liberalizing, appropriately, the amount of methadone that patients can take home. Increased physician decision-making with methadone take-home doses for treatment of OUD is associated with lower risks of opioid overdose, treatment interruption, and treatment discontinuation in the subsequent six months.[20] The evidence base supports the beneficence of clinical decision-making in methadone treatment for OUD as far back as the rigorous review of the National Academies of Sciences (then the Institute of Medicine) in 1995.[21]

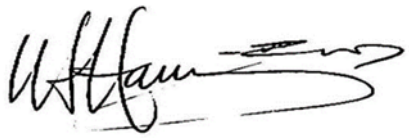
Second, there are underlying complexities in the trends of diversion of methadone and the exposure to poisoning which are, in large part, associated with historical trends in the relaxation of prescribing opioids for chronic, non-cancer pain.[22–24] Methadone has unique pharmacologic properties[19] and when used to treat chronic pain—especially by prescribers lacking training in pain medicine—the dosing regimens tend to play into methadone's pharmacological risks.[25] Section 4 of the OTAA does not increase methadone prescribing for chronic pain. Historical and contemporary research supports access to methadone treatment through office-based settings for stable patients with OUD.[26–28] Importantly, the Office of National Drug Control Policy highlights the need to review and update regulations for OTPs in the 2022 National Drug Control Strategy, stating, "federal OTP regulations should be updated to permit safer and better access to methadone treatment for OUD. . . . Regulators should consider allowing methadone dispensing from pharmacies as is done in the United Kingdom because of their greater accessibility in most communities relative to OTPs."[29]

In conclusion, U.S. federal laws and regulations have severely restricted access to methadone for OUD: more than ninety percent of OTPs are in urban areas,[10] and most U.S. counties have no

OTPs.[30] While it is true that methadone-related poisoning deaths can and do happen, science informs that the lethality of take-home methadone does not depend on the physical place from where it is dispensed, nor does it depend on whether an addiction specialist physician has a financial relationship with an OTP. The lethality of utmost concern, which Section 4 of the OTAA can and does address, involves an illicit drug supply adulterated with fentanyl. Indeed, the failure of methadone treatment capacity to meet the needs of Americans with OUD has come with high financial, societal, and human costs, during a declared opioid public health emergency.[31] Put simply, Section 4 of the OTAA is a measured but critical down payment that cannot be made soon enough.

We thank you for your leadership on the Act and urge you to amend it to include Section 4 of the OTAA, as set forth in the attached Exhibit A. Thank you for the opportunity to share our input. If you have any questions or concerns, please contact Kelly Corredor, ASAM's Chief Advocacy Officer, at kcorredor@asam.org.

Sincerely,



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President, American Society of Addiction Medicine

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President, National Alliance for Medication Assisted Recovery

CC: The Honorable Donald Norcross

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Exhibit A: Section 4 of the OTAA

SEC. 4. EXPANSION OF TAKE-HOME PRESCRIBING OF METHADONE THROUGH PHARMACIES.

(a) Registration; Other Care by Telehealth.--Section 303(g) of the Controlled Substances Act (21 U.S.C. 823(g)) is amended--

(1) in paragraph (1), by striking ``in paragraph (2)'' and inserting ``in paragraphs (2) and (3)''; and

(2) by adding at the end the following:

``(3)(A) At the request of a State, the Attorney General, in consultation with the Secretary, may, pursuant to paragraph (1), register persons described in subparagraph (B) to prescribe methadone to be dispensed through a pharmacy for individuals for unsupervised use.

``(B) Persons described in this subparagraph are persons who--

``(i) are licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which they practice, to prescribe controlled substances in the course of professional practice; and

``(ii) are--

``(I) employees or contractors of an opioid treatment program; or

``(II) addiction medicine physicians or addiction psychiatrists who hold a subspecialty board certification in addiction medicine from the American Board of Preventive Medicine, a board certification in addiction medicine from the American Board of Addiction Medicine, a subspecialty board certification in addiction psychiatry from the American Board of Psychiatry and Neurology, or a subspecialty board certification in addiction medicine from the American Osteopathic Association.

``(C) The prescribing of methadone pursuant to subparagraph (A) shall be--

``(i) exclusively by electronic prescribing;

``(ii) for a supply of not more than 1 month pursuant to each prescription; and

``(iii) subject to the restrictions listed in section 8.12(i)(3) of title 42, Code of Federal Regulations, including any amendments or exemptions to such section pursuant to section 253(b) ~~3(c)~~ of the Restoring Hope for Mental Health and Well-Being Act of 2022~~Opioid Treatment Access Act of 2022~~, or successor regulations or guidance.

``(D) The dispensing of methadone to an individual pursuant to subparagraph (A) shall be in addition to the other care which the individual continues to have access to through an opioid treatment program.

``(E) Persons registered in a State pursuant to subparagraph (A) shall--

``(i) ensure and document, with respect to each patient treated pursuant to subparagraph (A), informed consent to treatment; and

``(ii) include in such informed consent, specific informed consent regarding differences in confidentiality protections applicable when dispensing through an opioid treatment program versus dispensing through a pharmacy pursuant to subparagraph (A).

``(F) At the request of a State, the Attorney General, in consultation with the Secretary, shall--

``(i) cease registering persons in the State pursuant to subparagraph (A); and

``(ii) withdraw any such registration in effect for a person in the State.

``(G) Maintenance treatment or detoxification treatment provided pursuant to subparagraph (A), as well as other care provided in conjunction with such treatment, such as counseling and other ancillary services, may be provided by means of telehealth as determined jointly by the State and the Secretary to be feasible and appropriate.''.

(b) Annual Reporting.--Not later than 6 months after the date of enactment of this Act, and annually thereafter, the Assistant Secretary for Mental Health and Substance Use and the Administrator of the Drug Enforcement Agency, acting jointly, shall submit a report to the Congress including--

(1) the number of persons registered pursuant to section 303(g)(3) of the Controlled Substances Act, as added by subsection (a);

(2) the number of patients being prescribed methadone pursuant to such section 303(g)(3); and

(3) a list of the States in which persons are registered pursuant to such section 303(g)(3).