STATEMENT

of

Stephen M. Taylor, MD, MPH, DFAPA, DFASAM

President-Elect

American Society of Addiction Medicine

U.S. Senate Committee on Health, Education, Labor, and Pensions (HELP)
Subcommittee on Primary Health & Retirement Security

Re: A Crisis in Mental Health and Substance Use Disorder Care: Closing Gaps in Access by Bringing Care and Prevention to Communities

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Chairman Markey, Ranking Member Marshall, and esteemed Members of this Subcommittee, thank you for inviting me to participate in today's critically important hearing on closing gaps in access to mental health and substance use disorder (SUD) care by bringing that care into communities across this nation. My name is Dr. Stephen Taylor. I am board-certified in addiction medicine, addiction psychiatry, child and adolescent psychiatry, and general psychiatry. I take care of patients with addiction and co-occurring conditions in Birmingham, Alabama where I serve as the Chief Medical Officer of Pathway Healthcare - a company operating seventeen outpatient mental health and addiction treatment offices in five southern states. I am also the Medical Director of the Player Assistance and Anti-Drug Program of the National Basketball Association (NBA) and the National Basketball Players Association (NBPA) . Today, I am testifying in my capacity as President-Elect of the American Society of Addiction Medicine, known as ASAM. ASAM is a national medical society representing over 7,000 physicians and other clinicians who specialize in the prevention and treatment of addiction and co-occurring conditions.

I would like to begin by recognizing the bipartisan work that Congress has done over the years to help address - what is turning out to be - the deadliest addiction and overdose crisis in American history. Your efforts have made a positive difference. Thank you.

Still, at a time of elevated death rates and medical complications associated with synthetic opioids like fentanyl, psychostimulants like methamphetamine, and the non-opioid veterinary tranquilizer xylazine, **much more work needs to be done to create a sustainable and robust addiction care infrastructure – one that addresses *addiction as* a *preventable and treatable chronic medical disease.***

Accordingly, ASAM asks this Subcommittee to focus on the following three areas that are ripe for policy intervention:

1. Prioritization of the recruitment, training, and retention of addiction specialist physicians – defined as physicians who are board certified in addiction medicine or addiction psychiatry;[1]

2. Decriminalization of the prescribing of methadone for the treatment of opioid use disorder (OUD) by addiction specialist physicians (and OTP (defined below) clinicians) for dispensing at pharmacies; methadone is the only full opioid agonist medication that is approved by the Food and Drug Administration (FDA) for the treatment of OUD; and
3. Enforcement of federal mental health and addiction parity law that is already on the books.

Prioritization of the Addiction Specialist Physician Workforce

Addiction is a chronic medical disease involving complex interactions among brain circuits, genetics, the environment, and an individual's life experiences. People with addiction use substances or engage in behaviors that become compulsive and often continue despite harmful consequences. A lack of knowledge and misinformation about addiction within the medical community has been a longstanding problem. Therefore, the fact that there remains far too few physicians and other clinicians who specialize in the assessment of substance use disorder (SUD) and the prevention and treatment of the disease of addiction is of grave concern. According to the Substance Abuse and Mental Health Services Administration (SAMHSA), in 2021, well over 40 million Americans had SUD in the past year.[2] For purposes of comparison, the state of California has nearly 40 million residents. At the same time, deaths continue to persist at record levels from drug overdoses, according to the Centers for Disease Control and Prevention.[3]

Shortfalls exist at all levels of the addiction care workforce, but one of the most grievous is among addiction specialist physicians. ASAM estimates that there are only about 7,000[4] of said physicians in this country - defined as physicians holding board certification in the medical subspecialty of addiction medicine or addiction psychiatry. As of March 2023, there were only 96 ACGME-accredited addiction medicine fellowship programs in the nation[5] – far below the recommended goal of 125 fellowships by 2022 set by the President's Commission on Combating Drug Abuse and the Opioid Epidemic over five years ago.[6] Our failure to meet this goal should be unacceptable.

While addiction treatment in the U.S. is often delivered to patients by multidisciplinary healthcare teams that work to address patients' biopsychosocial needs,[7] the distinct clinical knowledge and skill set of addiction specialist physicians best situate them to lead those teams. Addiction specialist physicians can increase a healthcare team's capacity to prevent and treat more complex medical cases involving substance use disorder. Addiction specialist-led care teams can also lead to the greater integration of addiction care into general medical and mental health treatment settings. Even more importantly, such care models can enable our healthcare system to increase its capacity to provide addiction treatment in primary care settings - which is especially important in areas where there is a dearth of specialty addiction treatment facilities.

Indeed, Congress acknowledged just how severe the overall SUD workforce shortage is – including its addiction specialist shortage – when it created a groundbreaking loan repayment program, known as the Substance Use Disorder Treatment and Recovery Loan Repayment Program, or STAR-LRP, in the SUPPORT for Patients and Communities Act of 2018. When individuals pursue a full-time job to provide SUD treatment in high-need geographic areas, the Health Resources and Services Administration (HRSA)'s STAR-LRP can help them repay up to $250,000 in their student loans. Unsurprisingly, demand for this program has been overwhelming. In Fiscal Year 2021, alone, over 3,000 people applied for the program, but HRSA

only had enough funding to serve 8 percent – or 255 of them – at an average award amount of a little over $100,000, which is far below the maximum award amount allowed. Reauthorizing and strengthening STAR-LRP this year, while retaining its laser focus on the SUD workforce, is a top priority for ASAM. **That is why ASAM strongly supports passage of the Substance Use Disorder Treatment and Recovery Loan Repayment Program Reauthorization Act of 2023, which is bipartisan legislation in the House that would further strengthen the program while preserving its focus on the addiction care workforce**.

In addition, while **ASAM urges Congress to ensure that addiction specialist physicians are included across all HRSA Behavioral Health Workforce Development Programs**, I also want to highlight that addiction specialist physicians often hold primary board certifications in the primary care specialties recognized by HRSA's Teaching Health Center Graduate Medical Education (THCGME) program. Those primary care specialties include family medicine, internal medicine, pediatrics, and general psychiatry. **This multispecialty characteristic of addiction medicine is, therefore, why ASAM recommends that Congress pass legislation that would prioritize (or otherwise incentivize) THCGME program applicants that sponsor addiction medicine fellowship programs. ASAM also strongly supports the President's Budget proposals to (1) make additional investments in addiction and mental health services at health centers and (2) amend section 330 of the Public Health Service Act to require all HRSA-funded health centers to offer addiction and mental health services.**[8]

Decriminalization of the Prescribing of Methadone for OUD by Addiction Specialist Physicians for Pharmacy Dispensing

Secondly, we all know that the long U.S. history of treating addiction in siloed settings separate from the rest of medicine exacerbates the addiction care workforce shortage. SAMHSA estimates that less than four in ten patients with OUD - who are primarily admitted for OUD to publicly-funded SUD treatment - receive treatment with medications for OUD.[9] Other studies have shown even worse rates of appropriate medication usage for alcohol use disorder.[10,11] We no longer accept this in other parts of American medicine, and it is not acceptable for caring individuals with addiction.

In 2019, a national report noted that the fragmentation that has occurred as a result of separating OUD treatment settings from other medical care not only creates significant access barriers, but is not supported by evidence.[12] More specifically, while models of integrated methadone treatment of OUD with primary and other medical care sometimes exist in the U.S., they are much more common internationally. A 2017 international meta-analysis showed a significant reduction in all-cause mortality among people treated with methadone for OUD, both by general practitioners and specialty clinics.[13,14] Randomized controlled trials – the gold standard – have demonstrated the safety and efficacy of methadone treatment of stable patients in primary care.[15,16] Safety has also been shown in multiple non-randomized studies, some with 9 to 15 years of follow-up.[17,18,19] Methadone has been available by prescription in Australia since 1970, and in Great Britain since 1968.[20] Moreover, office-based prescribing and pharmacy dispensing of methadone increase the number of individuals with OUD with access to methadone treatment, as occurred in Canada following its 1996 implementation of such practices.[21]

Here, in the U.S., methadone was first used for OUD treatment in the 1960s under Investigational New Drug applications issued by the FDA, at a time when providing opioid medications for OUD remained illegal otherwise.[22] In 1972, the FDA determined and approved methadone as safe and effective for treatment of OUD.[23] At the same time, erroneous beliefs that methadone replaced one addiction for another, reports of methadone-related deaths and diversion,[24] and concerns over increasing crime rates[25] created a climate of skepticism and hostility toward methadone-based OUD care. In 1974, Congress granted additional jurisdiction over methadone to the Drug Enforcement Administration (DEA).[26] Both FDA, and subsequently SAMHSA, replaced the usual practice of physician autonomy with strict rules governing the provision of methadone for OUD treatment that – to this day- do not apply when methadone is prescribed for pain and dispensed from a community pharmacy.

These exceptional federal regulations specified criteria on eligibility, initial methadone dosages, required counseling services, supervised dosing, and restricted methadone treatment to provision within a closed system of regulated clinics, then known as narcotic treatment programs, now known as opioid treatment programs or OTPs.[27] Such detailed regulations surrounding a specific medical practice have led into an orientation toward regulatory compliance, to the detriment of incentivizing innovation, quality, or individualized patient care. The detailed regulations also have carried along with them a misguided conception of abstinence defined as cessation of methadone pharmacotherapy.[28] Experts have written about how such a highly regulated system of methadone-specific clinics in the U.S. reflects structural racism and contributes to health disparities among people with OUD.[29]

It is progress and good news that outdated federal OTP regulations will be updated soon to address OUD treatment standards in that setting. Drawing on research, evidence, and experience from the past two decades, thankfully, SAMHSA has indicated forthcoming regulatory updates when it issued a notice of proposed rulemaking in December 2022.[30] However, by continuing to largely restrict access to methadone for OUD to OTPs, the potential for expanded access to methadone treatment for OUD remains severely limited. Despite an expansion of OTPs in the U.S. in certain sectors in recent years, the prevalence of OUD has grown more quickly.[31] Most U.S. counties do not even have an OTP.[32] OTPs have established only a limited number of "mobile components," known as medication vans,[33] and a limited number of satellite medication units in locations such as pharmacies, jails, prisons, federally qualified health centers (FQHCs), and residential treatment facilities, resulting in limited geographic reach,[34] and complex demographic inequities in access to treatment.[35]

For these reasons, ASAM strongly supports passage of the bipartisan and bicameral Modernizing Opioid Treatment Access Act (M-OTAA) (S. 644/H.R. 1359). M-OTAA would responsibly expand the capacity for lifesaving methadone treatment for individuals with OUD through our existing medical infrastructure. Specifically, it would decriminalize[36] OTP clinicians and addiction specialist physicians — the latter representing some of the most educated and experienced physicians using pharmacotherapies for OUD in the nation[37] - who prescribe methadone for OUD that can be dispensed from a community pharmacy. Among other safeguards contained in M-OTAA, these separately registered prescribers would remain subject to SAMHSA's continued regulation and guidance on supply of methadone for unsupervised use.

While it is true there is widespread stakeholder support for SAMHSA's proposals for greater OTP clinician discretion in determining take-home methadone doses for OUD,[38] certain OTP

stakeholders have expressed concerns with M-OTAA's provisions that would allow addiction specialist physicians practicing outside of OTPs to prescribe methadone for OUD. These critics often cite the risks of methadone overdose and diversion as the primary reasons for this concern. However, when more closely examined, the totality of that opposition puts more patients with OUD at risk for overdose in a time of an alarming death toll.

For starters, any analysis of M-OTAA must be situated in a contemporary framework for the current crisis. The adulteration of the illegal drug supply with illicitly manufactured fentanyl, fentanyl analogs, and xylazine has created an unprecedented and catastrophic moment in U.S. history. Today, it is a more dangerous time than it has ever been to be an American with OUD. However, patients with OUD who are engaged in addiction treatment are less likely to die than those who remain untreated, and for some patients, methadone is essential to a successful recovery.[39] Methadone can facilitate abstinence from illegal substance use, support recovery, and prevent overdose deaths.[40] Thus, restrictions that continue to limit methadone treatment for OUD to OTPs are a well-recognized vulnerability in the response to the nation's addiction and overdose crisis.[41]

Furthermore, there are underlying complexities in the early trends of diversion of methadone and related overdoses, which were, in large part, associated with historical trends in the acceleration of prescribing opioids for chronic, non-cancer pain.[42, 43, 44] Methadone is unusual among opioid agonists in that the slow accumulation of serum levels during initial dose adjustment may contribute to the risk of fatal methadone overdose,[45] especially if healthcare professionals overestimate a patient's degree of opioid tolerance.[46] And, when methadone is used to treat chronic pain—especially by prescribers lacking training in pain medicine, the frequent dosing regimens tend to play into methadone's pharmacological risks.[47] M-OTAA, however, does <u>not</u> increase methadone prescribing for chronic pain (which happens to remain available through prescription and pharmacy dispensing today). Indeed, historical and contemporary research support a responsible expansion in access to methadone treatment for OUD, including through office-based practices.[48, 49, 50]

To be clear, M-OTAA is not methadone for everyone, prescribed by anyone. It represents a responsible expansion in methadone access for OUD, including through a highly trained, modern-day workforce of expert physicians who can manage this essential treatment for Americans who need it. Inaction on M-OTAA is the risk that this country cannot continue to take.

Enforcement of Existing Federal Mental Health and Addiction Parity Law

Lastly, despite over a decade since the passage of the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008, such parity of coverage for care remains elusive for millions of Americans suffering with mental health and substance use disorders. A wide disparity in network use and provider payment rates between mental health and addiction treatment, on the one hand, and general medical care on the other, have been well-documented.[51] A recent report to Congress, issued by the U.S. Departments of Labor, Health and Human Services, and the Treasury, suggests that health plans and issuers are not always delivering parity for mental health and substance use disorder benefits to their beneficiaries.[52]

While the reasons for parity elusiveness are many, one sits squarely within your jurisdiction. Under current law, the U.S. Department of Labor (DOL) lacks the authority to assess civil monetary penalties for violations of federal parity law already on the books. Without this power, DOL cannot effectively end parity violations with respect to group health plans. **That is why ASAM strongly supports passage of the Parity Enforcement Act,[53] which would finally add civil monetary penalty authority to the DOL's oversight, by amending the Employee Retirement Income Security Act (ERISA) to allow the DOL to levy federal parity violation penalties against covered health insurance issuers, plan sponsors, and plan administrators.** According to the same report to Congress noted above, the Employee Benefits Security Administration (EBSA) *"believes that authority for DOL to assess civil monetary penalties for parity violations has the potential to greatly strengthen the protections of MHPAEA* [the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008]."[54]

Conclusion

In conclusion, ASAM is actively designing, implementing, and advocating for the policies and resources that will secure a stronger foundation for addiction prevention, treatment, harm reduction, and recovery in this country. The policies and resources I have mentioned today are not inconsequential; they are imperative to saving lives.

We know what to do to treat addiction. We also know that systemic change – a disruption of the status quo, which is currently falling short of our country's full potential – is exceptionally difficult. But, working together, we must effect change, nonetheless. It is a matter of life or death.

Thank you, and I look forward to answering your questions.

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[2] Substance Abuse and Mental Health Administration. "Key Substance Use and Mental Health Indicators in the United States: Results from the 2021 National Survey on Drug Use and Health." U.S. Department of Health and Human Services Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality, Populations Survey Branch, no. PEP22-07-01-005 (December 2022). https://www.samhsa.gov/data/sites/default/files/reports/rpt39443/2021NSDUHFFRRev010323.pdf.
[3] Ahmad FB, Cisewski JA, Rossen LM, Sutton P. Provisional drug overdose death counts. National Center for Health Statistics. 2023. Designed by LM Rossen, A Lipphardt, FB Ahmad, JM Keralis, and Y Chong: National Center for Health Statistics.

[4] According to an email that ASAM received from the Executive Director of the American Board of Preventive Medicine (ABPM), as of January 2023, there were 4,347 Addiction Medicine Diplomates through ABPM with active status. According to an email that ASAM received from the Executive Director of the American College of Academic Addiction Medicine (ACAAM), as of January 2023, there were 1,312 addiction medicine physicians through the American Board of Addiction Medicine (ABAM). (According to ACAAM's Executive Director, there may be small overlap of people who remain both certified by ABAM and ABPM, but it would not be a significant number.) According to the *2021–2022 ABMS Board Certification Report*, as of June 30, 2022, there were 1,398 board-certified addiction psychiatrists in the U.S (some of whom may be retired). ASAM was unable to confirm the number of AOA board-certified addiction medicine physicians as of the date of this hearing, but estimates a few hundred physicians holding such board certification.

[5] American College of Academic Addiction Medicine. https://www.acaam.org/fellowship-training

[6] THE PRESIDENT'S COMMISSION ON COMBATING DRUG ADDICTION AND THE OPIOID CRISIS. https://trumpwhitehouse.archives.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-15-2017.pdf

[7] Examples of multidisciplinary team models include specialized addiction treatment programs, the Patient Centered Medical Home (PCMH), the "hub-and-spoke" model, the nurse care management model, and the Collaborative Care Model, which exist on a spectrum of integration with general medical treatment.

[8] Johnson, Carole. HRSA Administrator. Testimony before the United States House of Representatives Committee on Energy and Commerce Subcommittee on Health on "Examining Existing Federal Programs to Build a Stronger Health Workforce and Improve Primary Care." https://d1dth6e84htgma.cloudfront.net/Witness_Testimony_Carole_Johnson_HE_Hearing_04_19_23_e3abe98943.pdf?updated_at=2023-04-17T20:18:01.021Z. Published April 19, 2023. Accessed April 24, 2023.

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[36] Lampe, J.R. (2023). The Controlled Substances Act (CSA): A legal overview for the 118th Congress (CRS Report No. R45948). Congressional Research Service, 9. https://crsreports.congress.gov/product/pdf/R/R45948 (stating that a violation of the Controlled Substances Act's registration requirements is a criminal offense if the violation is committed knowingly, and the Department of Justice may bring criminal charges against individual registrants; for example, a first criminal violation of the registration requirements by an individual is punishable by a fine or up to a year in prison).
[37] 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)).
https://www.acgme.org/globalassets/pfassets/programrequirements/404_addictionmedicine_2022_tcc.pdf
[38] Two studies published in January 2023 raise questions about the role of federal regulatory OTP flexibilities during the COVID public health emergency in increases in methadone-involved overdoses deaths. However, both studies' authors identify significant limitations of their study in demonstrating direct causality. While there remains no direct evidence of causality, ASAM recognizes that granting more flexibilities *within the OTP setting* must be carried out with caution and with federal agencies' continual, longitudinal regulations and monitoring for unintended consequences, notwithstanding the widespread support of making such federal take home policy changes permanent, including among OTP stakeholders. OTP medical directors are not required to be addiction specialist physicians, and not all OTP clinicians are physicians. See Kleinman, Robert A., and Marcos Sanches. "Methadone-Involved Overdose Deaths in the United States before and during the COVID-19 Pandemic." Drug and Alcohol Dependence 242 (January 1, 2023): 109703. https://doi.org/10.1016/j.drugalcdep.2022.109703. See also Kaufman, Daniel E., Amy L. Kennalley, Kenneth L. McCall, and Brian J. Piper. "Examination of Methadone Involved Overdoses during the COVID-19 Pandemic." Forensic Science International 344 (January 31, 2023): 111579. https://doi.org/10.1016/j.forsciint.2023.111579.
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