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May 10, 2022

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

The Honorable Cathy McMorris Rodgers
Chairwoman
U.S. House 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 20510

The Honorable Brett Guthrie
Ranking Member
U.S. House of Representatives
Health Subcommittee of the Committee
on Energy and Commerce
Washington, DC 20510

RE: H.R. 7666 - Restoring Hope for Mental Health and Well-Being Act of 2022

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

On behalf of the American Society of Addiction Medicine (ASAM), a national medical specialty society representing more than 7,000 physicians and associated health professionals who specialize in the prevention and treatment of addiction, I am thankful for the introduction of the Restoring Hope for Mental Health and Well-Being Act of 2022 (the "Act"). Among other things, the Act would reauthorize key Substance Abuse and Mental Health Services Administration (SAMHSA) and Health Resources and Services

Administration (HRSA) programs to address the national mental health and substance use disorder crises. ASAM greatly appreciates your leadership on this matter.

The Centers for Disease Control and Prevention (CDC) has predicted a record 106,854 drug overdose deaths from November 2020 to November 2021.[1] What's more, alarming trends of disparities in worsening overdose mortality rates, particularly for Black Americans and other people of color, have been accelerated during the COVID-19 pandemic.[2] The pandemic clearly complicated access to addiction treatment for people in need. A wide gap exists between the number of individuals who have a substance use disorder (SUD) and those who receive treatment. In general, about 10 percent of those diagnosed with SUD receive any SUD treatment,[3] and the latest national survey results show 6.5 percent of individuals diagnosed with a SUD received specialty treatment.[4] Multiple, complex barriers create this treatment gap, including persons' difficulties locating addiction clinicians and accessing treatment.[5]

Given these daunting statistics, ASAM is eager to support the Act and provides the below input for your consideration.

Title II: Substance Use Disorder Prevention, Treatment, and Recovery Services

Subtitle D—Substance Use Prevention, Treatment, and Recovery Services Block Grant

This portion of the Act would, among other things: (1) reauthorize and rename SAMHSA's Substance Abuse Prevention and Treatment Block Grant as the "Substance Use Prevention, Treatment, and Recovery Services Block Grant;" (2) require states receiving block grant funds to provide viral hepatitis screening and referrals to providers whose practice includes viral hepatitis vaccination and treatment, and (3) replace "substance abuse" with "substance use," and update statutory language to recognize Tribes and Tribal organizations as proper nouns.

To better coordinate efforts between SAMHSA and the Centers for Medicare & Medicaid Services, ASAM respectfully requests amending this portion of the Act to include the following language, which is included in the bipartisan Mental Health Reform Reauthorization Act of 2022 introduced today by Senators Murphy and Cassidy:

Section 501(d) of the Public Health Service Act (42 U.S.C. 290aa(d)) is amended—

(1) in paragraph (5), by inserting "coordination between programs and Centers of Excellence regarding promising and best practices and dissemination to the field and" after ", including";

(2) in paragraph (24)(E), by striking "; and" and inserting a semicolon;

(3) in paragraph (25), by striking the period and inserting "; and"; and

(4) by adding at the end the following:

"(26) coordinate with the Centers for Medicare & Medicaid Services to promote coverage of evidence-based services, improve quality of care, and identify opportunities for State Medicaid agencies and State mental health and substance use disorder agencies to collaborate, including through the braiding of funds, demonstration programs, waivers, amendments to State plans under section 1912, other State flexibilities, and agency guidance.".

Subtitle E—Timely Treatment for Opioid Use Disorder

This portion of the Act would: (1) eliminate the requirement that an individual be addicted to opioids for at least one year before being admitted for treatment by an Opioid Treatment Program (OTP); (2) require the Assistant Secretary for Mental Health and Substance Use to conduct a study and report on the impact of treatment exemptions (also known as flexibilities) allowed during the pandemic on OTP effectiveness and safety; (3) codify changes to federal opioid treatment standards to allow an OTP to operate one or more mobile units to dispense medications at locations other than the registrant's principal place of business or professional practice under the same registration, and (4) require the establishment of new criteria to allow certain patients to receive take-home methadone.

ASAM generally applauds these provisions.

First, limiting treatment admission to individuals who have been addicted to opioids for at least one year creates an arbitrary and unnecessary barrier to persons with OUD trying to take the notable step of accessing treatment at an OTP. Less than 20 percent of persons with OUD receive addiction medications, despite their demonstrated efficacy[6], in an environment where the drug supply has been contaminated by fentanyl. Fentanyl has made it more dangerous than it has ever been to be a person with an OUD,[7] and it creates an increased susceptibility for addiction. Patients with OUD who receive medical treatment are less likely to die than persons with OUD who do not receive such treatment; therefore, this barrier should be eliminated.[8]

Second, there was significant variability in states' and OTPs' implementation of SAMHSA's "flexibilities" for methadone "take-home doses" during the COVID-19 pandemic.[9] State regulations do not always align with federal standards, neither are they always based on evidence, nor are they necessarily associated with improvements to patient outcomes.[10] While an abundant research base has been produced on the impact of the SAMHSA flexibilities,[11–23] a national synthesis of this research would help inform adapting federal standards to improve patient outcomes.

Third, mobile units to dispense methadone are critical to expanding access to treatment for OUD with methadone, and federal regulations that allow for mobile units under the same federal registration as an OTP should be codified in law. In 2020, while 2.7 million had an OUD, less than 12 percent, or about 312,000 persons, received methadone from an OTP.[24] In addition, mobile units are particularly important to expand methadone treatment to jails and prisons, where OUD is prevalent, and at least half of individuals meet the criteria for a SUD.[25] Correctional institutions are obligated by the U.S. Constitution to provide adequate medical care

for those that have been incarcerated,[*] and methadone treatment should be available for individuals with OUD.[26] Yet, less than 1% of more than 5,000 prisons and jails that incarcerate over two million individuals in the U.S. allow them access to all three FDA-approved addiction medications for OUD.[27] This has contributed to the disastrous consequence of heightened overdose mortality rates when persons who have been incarcerated re-enter society.[28]

Finally, ASAM applauds the Act's language "to establish relevant criteria for the medical director of an OTP *or a medical practitioner appropriately licensed by the State to prescribe or dispense controlled medications* (emphasis added) to determine whether a patient is stable and may qualify for unsupervised use."

ASAM, however, respectfully requests the following, redlined changes to Section 253 of the Act:

(2) CRITERIA.—The regulation under paragraph (1) shall establish relevant criteria for the medical director of an opioid treatment program, or a medical practitioner appropriately licensed by the State to prescribe or dispense controlled medications, to determine whether a patient is stable and may qualify for unsupervised use, which criteria may ~~shall~~ include each of the following:

(A) Whether the benefits of providing unsupervised doses to a patient outweigh the risks.

(B) The patient's demonstrated adherence to their treatment plan.

~~**(C) The patient's history of negative toxicology tests.**~~

ASAM supports greater discretion of clinicians in methadone dosing for OUD. Further, while negative toxicology tests can be an important component in decision-making around take-home privileges, treatment decisions should not solely be based on toxicology results.[29] Unfortunately, some states continue to require many such tests per year. For example, Massachusetts requires a minimum of 15 tests per year, and Arkansas mandates weekly testing for the first three months of treatment.[29] Moreover, screening tests are not definitive, and necessitate confirmatory tests that OTPs may not provide to patients.[30] While listing such tests as one criterion may seem reasonable at first blush, it may also perpetuate onerous state requirements that do not always serve patients well.

ASAM also respectfully requests that the Act be amended to include Sections 4 of H.R.6279- the Opioid Treatment Access Act of 2022, as more fully explained in the letter attached as <u>Exhibit A</u>.

[*] Estelle v. Gamble, 429 U.S. 97, 103, 97 S. Ct. 285, 290, 50 L. Ed. 2d 251, 256 (1976) ("These elementary principles establish the government's obligation to provide medical care for those whom it is punishing by incarceration.").

Title III: Access to Mental Health Care and Coverage

Subtitle B—Helping Enable Access to Lifesaving Services

This portion of the Act would reauthorize multiple programs to support and strengthen the healthcare workforce. ASAM respectfully requests the following adjustments to this portion of the Act:

- With respect to the proposed reauthorization of the "**Training Demonstration Program**" at $10 million annually for FY 2023 through FY 2027, **such a reauthorization level would represent a significant and unfortunate cut in funding for this program**. **42 U.S.C. 294k(a)(1)** created the **Addiction Medicine Fellowship (AMF) Program**, which awards grants to certain institutions to expand the number of fellows trained as addiction medicine physicians and addiction psychiatrists who work in underserved, community-based settings that integrate primary care with mental health disorder and SUD prevention and treatment services. In FY 2022, Congress funded the AMF Program at $24 million as one component of this Mental and Substance Use Disorder Workforce Training Demonstration Program. As of March 2022, there were still only 86 addiction medicine fellowship programs accredited by the Accreditation Council for Graduate Medical Education (ACGME) in the nation—far below the recommended goal of 125 fellowships by 2022 set by the President's Commission on Combating Drug Abuse and the Opioid Epidemic five years ago. **In FY 2023, ASAM has asked Congress for $25 million for the AMF Program and to designate funding specifically for the AMF Program, as recommended in the President's budget request**; **therefore, ASAM respectfully requests that the reauthorization for 42 U.S.C. 294k(a)(1) for the "Training Demonstration Program" be revised to authorize $25,000,000 for fiscal year 2023 and $30,000,000 for each of FY 2024 through FY 2027.**

- This portion of the Act would also update the Minority Fellowship Program to include those "in the fields of crisis care management." ASAM respectively requests that the Minority Fellowship Program also be updated to include those in "*addiction medicine*," as it is imperative that the nation increase the number of addiction medicine physicians who are from racial and ethnic minority populations that provide high-quality care to patients who have SUD and/or co-occurring mental health disorders. ASAM also supports increasing funding levels to $25,000,000 per fiscal year. **To that end, ASAM recommends the following language, which is included in the bipartisan Mental Health Reform Reauthorization Act of 2022 introduced today by Senators Murphy and Cassidy:**

  SEC. 9. MINORITY FELLOWSHIP PROGRAM.

  Section 597 of the Public Health Service Act (42 U.S.C. 290ll) is amended—

  (1) in subsection (b), by inserting "addiction medicine," after "mental health counseling,"; and

(2) in subsection (c), by striking "$12,669,000 for each of fiscal years 2018 through 2022" and inserting "$25,000,000 for each of fiscal years 2023 through 2027".

Title IV—Children and Youth

Subtitle A—Supporting Children's Mental Health Care Access

This portion of the Act would, among other things, reauthorize HRSA's **Pediatric Mental Health Care Access grant program** that promotes behavioral health integration into pediatric primary care by supporting pediatric mental health care telehealth access programs in states at $14 million annually for FY 2023 through FY 2025 and $30 million annually for FY 2026 through FY 2027. **ASAM applauds these reauthorization levels and respectfully requests amending this portion of the Act to provide that "addiction specialists" may be part of this program and its teams, as reflected by language found in Section 2 of S.3864 - Supporting Children's Mental Health Care Access Act of 2022**. As highlighted in the Office of National Drug Control Policy's strategy for 2022, "adolescents are at the highest risk compared to any other age group for experiencing health issues related to substance use, and that the potential benefits of identifying substance use and intervening to reduce or prevent use are substantial."[31]

New Provisions: the MATE and MAT Acts

Finally, ASAM strongly urges you to include both the bipartisan, bicameral H.R. 2067 – the Medication Access and Training Expansion (MATE) Act of 2021 and the H.R. 1384 – the Mainstreaming Addiction Treatment (MAT) Act of 2021 in the Act. Lack of standardization in the treatment and management of patients with SUD has undermined our national response to the addiction and overdose crisis. Only a fraction of clinicians receives appropriate education on treating SUD or has a license to prescribe buprenorphine for the treatment of OUD. Further, the DATA 2000-waiver is a barrier that is preventing the uptake of treatment with buprenorphine, a life-saving medication for individuals with OUD, during a national opioid public health emergency.[32] As the previous chair of the American Medical Association's (AMA) Opioid Task Force has said, "*Patients are struggling to find physicians who are authorized to prescribe buprenorphine; the onerous regulations discourage physicians from being certified to prescribe it.*"[33] By including both critical pieces of legislation in the Act, we can make significant progress in combating the nation's addiction and overdose crisis.

The MATE Act

The MATE Act would require most controlled medication prescribers that are registered with the Drug Enforcement Administration (DEA) to have a baseline knowledge of how to identify, treat, and manage patients with SUD. Specifically, it would:

- Require most controlled medication prescribers to attest—on either one initial or renewal DEA application—that they are an addiction specialist physician, or have completed at least eight hours of education on treating and managing patients with SUD from one or more accredited organizations, or an accredited health professional school or residency program;

- Not prevent the use of this education both for purposes of satisfying the one-time DEA registration requirement and for other purposes, such as satisfying state licensing requirements;
- Allow accredited health professional schools and residency programs to deliver the education through comprehensive SUD curricula. This would normalize and mainstream addiction medicine education and phase out the need to complete federally mandated educational hours after graduation/residency training; and
- Authorize federal grants to professional associations, universities, and other schools to develop and implement high-quality, comprehensive curricula on identifying and treating SUD.

Critically, the MATE Act's flexible education requirement is not a condition of state medical licensure and does not interfere with state licensing responsibilities. The requirement of the MATE Act would be a condition on the *federal DEA registration* to prescribe controlled medications. While there is a lack of adequate education in the treatment and management of patients with SUD across the medical profession, it is particularly troublesome to find it lacking among prescribers of DEA-controlled medications. Across different clinical settings, these healthcare professionals often interact with individuals with SUD and have opportunities to provide effective interventions for individuals with SUD – opportunities to help that are often missed.

Further, while most states now have continuing education requirements related to safer opioid prescribing or pain management, only about 20 percent of state education requirements for physicians mention they have educational content on the disease of addiction or SUD.[34] Compounding this problem, some of these states mention this content as merely one option of many. Therefore, it is unsurprising that such state-level continuing education requirements - alone - have not proved helpful in expanding access to evidence-based SUD treatment.

Importantly, in a letter about the MATE Act of 2019 to U.S. Representative Lori Trahan, on February 20, 2020, ACGME states, "*. . . the ACGME recognizes that alone it is inadequate to rapidly increase the number of physicians who are able to address the current addiction and overdose crisis. The need to prepare practicing physicians and other clinicians for the treatment of addiction, for this and the next generation, is a shared responsibility of the medical school, GME, and continuing medical education communities. While GME has an important role to play, it will take many years for sufficient numbers of those physicians to bring these skills into practice.*" And ASAM agrees with our colleagues at the American Medical Association (AMA) that a one-time, mandated education requirement on SUD treatment may not be as impactful as a more robust, recurring, continuing medical education requirement. However, ASAM also notes that federal legislative efforts to implement recurring, continuing medical education requirements have been met with strong opposition. ASAM stands ready to work with the AMA to strengthen the MATE Act's SUD education requirement if the AMA is receptive.

The MAT Act

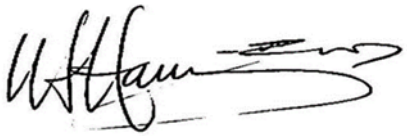
With enactment of the MATE Act, the MAT Act would then eliminate a clearly redundant requirement that practitioners apply for a separate DEA waiver to prescribe buprenorphine for

OUD and would eliminate the DATA 2000-waiver's patient limits and other regulatory burdens on buprenorphine treatment for OUD.

Passage of these critical pieces of legislation, which address both (1) the elimination of the DATA 2000-waiver for buprenorphine for OUD and (2) prescriber education on SUD treatment, are critical and recognized by a growing number of lawmakers sponsoring federal bills that address both.[†] For far too long, stigma, discrimination, and lack of understanding about SUD, especially within the health care system itself, have contributed to many Americans' difficulties with accessing timely, evidence-based care for addiction. Only one in four healthcare professionals received any training about the disease of addiction during their medical education in one state survey, and a substantial number of those surveyed incorrectly believed that OUD cannot be treated at all.[35] We must better equip healthcare professionals across the healthcare continuum to treat the disease of addiction.

In conclusion, enactment of this Act, as further amended by the changes contained here, would represent a tremendous step towards transforming addiction care during a national opioid public health emergency. ASAM looks forward to working with you and your colleagues to strengthen the addiction medicine workforce and expand access to addiction medicine. Thank you for this opportunity to share ASAM's perspective. If you have any questions or concerns, please contact Kelly Corredor, ASAM's Chief Advocacy Officer, at kcorredor@asam.org.

Sincerely,



William F. Haning, III, MD, DLFAPA, DFASAM
President, American Society of Addiction Medicine

[†] See overlapping bill sponsorship of (1) the MAT Act and either the MATE Act or the bipartisan Safer Prescribing of Controlled Substances Act and (2) the CARA 3.0 Act of 2021, the latter of which includes provisions addressing both the elimination of the x-waiver and prescriber education on SUD.

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Exhibit A

See attached.