November 15, 2022

The Honorable Patty Murray
Chair
U.S. Senate
Committee on Health, Education, Labor and Pensions (HELP)
428 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Richard Burr
Ranking Member
U.S. Senate
Committee on Health, Education, Labor and Pensions
428 Dirksen Senate Office Building
Washington, DC 20510

RE: Senate HELP Committee's Mental Health and Substance Use Disorder Legislative Package

Dear Chair Murray and Ranking Member Burr:

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 and co-occurring conditions, I applaud your committee for its ongoing efforts to ameliorate the nation's mental health (MH) and substance use disorder (SUD) crisis. ASAM's comments herein will focus on improvements that your committee can make to enhance HR 7666 – the Restoring Hope for Mental Health and Well-Being Act of 2022 (the "Restoring Hope Act"), which has already passed the U.S. House on a bipartisan basis.

The Restoring Hope Act would, among other things, reauthorize key Substance Abuse and Mental Health Services Administration (SAMHSA) and Health Resources and Services Administration (HRSA) programs to address the national MH and SUD crisis. Importantly, it also includes Sections 262 and 263, which, taken together, would ensure more controlled medication prescribers have completed at least eight hours of qualifying education (of their

choice) on treating patients with SUD and eliminate the requirement for a separate DEA waiver to prescribe buprenorphine for opioid use disorder (OUD). ASAM has previously sent a letter to you regarding the standalone bills reflected in these provisions.

The Centers for Disease Control and Prevention (CDC) has predicted more than 108,000 drug overdose deaths for the 12-month period ending May 2022.[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 affected access to addiction treatment for people in need. A wide gap exists between the number of individuals who have 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 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 Senate passage of key provisions in the Restoring Hope Act and offers the following recommendations for improvement:

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

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

Title II, Subtitle D of the Restoring Hope 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 that this portion of the Restoring Hope Act be strengthened with the inclusion of the following language in S. 4170 - the Mental Health Reform Reauthorization Act of 2022, introduced 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

ASAM supports Title II, Subtitle E of the Restoring Hope Act, which 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, as well as adjust time in treatment rules accordingly; (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.

However, ASAM notes that SAMHSA has already publicly indicated that it will propose revisions to 42 CFR Part 8 to make permanent some regulatory flexibilities for opioid treatment programs to provide extended take home doses of methadone. Thus, if Sections 251 and 252(c) of the Restoring Hope Act are also to be included in a Senate HELP MH/SUD legislative package, then ASAM recommends the following amendment to the first paragraph of Section 252(c)(2), so that it is not inadvertently overly restrictive and continues to provide SAMHSA with maximum regulatory authority:

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

In addition, considering the worsening racial disparities in, and rise in, overdose deaths outlined above, ASAM is deeply concerned that the Restoring Hope Act failed to include bipartisan provisions that would have allowed OTP clinicians and board-certified addiction specialist physicians to prescribe methadone for OUD to be dispensed from pharmacies for unsupervised use, subject to SAMHSA regulation and guidance. ASAM and NAMA-R, a patient advocacy group, previously sent a letter to House Energy and Commerce Committee leadership, detailing the importance of such a provision and responding to voiced concerns expressed by certain OTP advocates. **Thus, ASAM respectfully requests that Senate HELP include Section 4 of S.3629 - the Opioid Treatment Access Act of 2022 in any Senate HELP MH/SUD legislative package. In the absence of the inclusion of such Section 4, ASAM respectfully requests that Senate HELP,**

* An alternative way of capturing the meaning of "braiding" is to state "coordinating of funding sources to support similar objectives." See: https://bipartisanpolicy.org/download/?file=/wp-content/uploads/2022/04/FINAL-Combating-the-Opioid-Crisis-Smarter-Spending-to-Enhance-the-Federal-Response.pdf

at a minimum, clarify that nothing shall preclude the Attorney General from promulgating regulations specifying the circumstances in which a registration under 21 U.S.C. 823(g)[(1)] may be issued to a practitioner who is determined by the Secretary of Health and Human Services (HHS) to be qualified (under standards established by the HHS Secretary) to prescribe methadone to be dispensed through a pharmacy for individuals for unsupervised use and the procedures for obtaining such registration under that subsection.

A recent report by The George Washington University,[6] highlights that current Drug Enforcement Administration (DEA) regulations prohibit the prescribing of methadone to treat OUD outside of OTPs. While it is the opinion of the report's authors that the DEA may issue a rule to eliminate such restriction without Congressional authorization, the same report notes that the DEA's historical interpretation of 21 U.S.C. 823(g)(1) is that the registration under such subsection is restricted to practitioners who can administer or dispense directly (but not prescribe) methadone for OUD. Such DEA interpretation is likely due to concerns for diversion potential. A lesson from the COVID-19 public health emergency, however, is that such concern is unsubstantiated for "stable" and, to a certain extent, even "less stable" patients taking methadone for OUD.[7,8]

Further, as noted above, and as indicated in a March 2022 public statement issued by SAMSHA,[9] it appears that SAMHSA is in the process of issuing a proposed rule that will permanently allow for the dispensing of methadone for OUD for up to 28 days of take-home doses to stable patients if the OTP believes the patient can safely handle this amount of take-home medication. Science informs us that the lethality of take-home methadone does not depend on the physical place from where it is dispensed. With your leadership, now is the time for Congress to clarify that it is not standing in the way of the DEA and SAMHSA permitting the clinically appropriate prescribing, by OTP clinicians and addiction specialist physicians, of methadone for OUD to be dispensed from pharmacies.

Title III: Access to Mental Health Care and Coverage

Subtitle B—Helping Enable Access to Lifesaving Services

Title III, Subtitle B of the Restoring Hope Act would reauthorize multiple programs to support and strengthen the MH and SUD workforce. ASAM respectfully requests it be strengthened as follows:

- Section 311(d) of the Restoring Hope Act would reauthorize the "**Training Demonstration Program**" at $31.7 million for each of fiscal years 2023 through 2027. It is important to note that **42 U.S.C. 294k(a)(1)** of such training demonstration program 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, alone, 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 92 addiction medicine

fellowship programs accredited by the Accreditation Council for Graduate Medical Education (ACGME) in the nation.[10] This is 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.[11] For FY 2023, ASAM is asking Congress for $25 million for the AMF Program, alone, and to designate funding specifically for the AMF Program, as recommended in the President's budget request and as reflected on page 55 of Chairman Leahy's mark of the Labor, Health and Human Services, Education, and Related Agencies bill's explanatory statement; **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. Suggested language is as follows:**

(d) TRAINING DEMONSTRATION PROGRAM.—Section 760(g) of the Public Health Service Act (42 U.S.C. 294k(g)) is amended by inserting "and $25,000,000 for the program under subsection (a)(1) for fiscal year 2023, $30,000,000 for that program for each of fiscal years 2024 through 2027, and [at least $131,070,000] for the programs under subsections (a)(2) and (a)(3) for each of fiscal years 2023 through 2027" before the period at the end.

- Section 311(b) of the Restoring Hope Act would also update the Minority Fellowship Program to include those "in the fields of crisis care management." **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 co-occurring conditions, ASAM respectively requests that the Minority Fellowship Program also be updated to include those in "*addiction medicine*."** "Addiction medicine" was included in S. 4170 - the Mental Health Reform Reauthorization Act of 2022, introduced by Senators Murphy and Cassidy; **"addiction medicine" should be added to the Minority Fellowship Program provision in any Senate HELP MH/SUD legislative package to strengthen the program.**

Title IV—Children and Youth

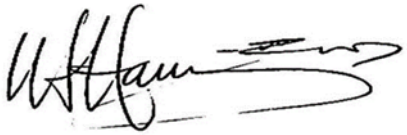
Subtitle A—Supporting Children's Mental Health Care Access

Section 401 of the Restoring Hope 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. **ASAM respectfully requests that Senate HELP provide that an "addiction specialist" may be part of this program and its teams, as supported by language found in Section 2 of S.3864 - Supporting Children's Mental Health Care Access Act of 2022**. Alternatively, the committee could consider a more general reference to a "licensed clinical substance use disorder professional." Any MH legislation must recognize that the workforce that treats SUD overlaps

with, but is also distinct from, MH professionals. Many states separately license or certify SUD professionals, and, thus, they must be explicitly included in MH legislation to ensure it meets the needs of patients with a primary diagnosis of SUD or no co-occurring MH condition. As emphasized 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."[12]

In conclusion, enactment of key provisions of the Restoring Hope Act, as further amended by the changes contained here, would be a tremendous step towards transforming addiction care during an unabated crisis. ASAM looks forward to working with you and your colleagues to strengthen the addiction medicine workforce and expand access to addiction care. 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,



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