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## FOUNDING PRESIDENT

Ruth Fox, MD 1895-1989 June 20, 2025

Mr. Jon E. Rice Senior Official, Office of National Drug Control Policy (ONDCP) Executive Office of the President 1800 G Street, NW Washington, DC 20503

Re: ONDCP Request for Input on the 2026 National Drug Control Strategy

Dear Mr. Rice,

On behalf of the American Society of Addiction Medicine (ASAM), a national specialty society representing more than 8,000 physicians and other clinicians who specialize in the prevention and treatment of addiction and co-occurring conditions, thank you for your invitation to provide comments to the biennial National Drug Control Strategy.

Our nation is at a critical juncture as overdose deaths are beginning to decline, and illicit fentanyl seizures at the Mexican border are showing promising reductions. Yet, a sizeable portion of people who need substance use disorder (SUD) treatment still face considerable obstacles in obtaining it. As ONDCP finalizes its 2026 National Drug Control Strategy, ASAM encourages ONDCP to consider the following recommendations to dent the deadly impact of the addiction and overdose crisis:

- Promote the financial sustainability of addiction treatment services;
- Increase access to methadone for the treatment of opioid use disorder (OUD) by modernizing Drug Enforcement Administration (DEA) and Health and Human Services (HHS) regulations to allow qualified practitioners to prescribe it for pharmacy administration/dispensing helping to expand access in federally qualified health centers and certified community behavioral health clinics;

- Work with the US Department of Justice to increase access to buprenorphine for the treatment of OUD by establishing a non-punitive approach for related suspicious order reporting requirements outlined under §21 USC 832; and
- Close residential addiction treatment gaps in Medicare by working with Congress to pass the bipartisan Residential Recovery for Seniors Act, and in Medicaid by working with HHS to update section 1115 demonstration guidance.

### **Promote the Financial Sustainability of Addiction Treatment**

While crucial steps to address the addiction crisis in the US have been taken, additional actions are urgently needed to secure the long-term financial sustainability of addiction treatment services across the full continuum of care as defined by nationally recognized standards. Otherwise, treatment programs for substance-related and behavioral addiction will be unable to meet today's demand for their services or survive arbitrary and nonevidence based regulatory and reimbursement environments.

ASAM recommends that ONDCP coordinate a comprehensive federal review of public/private health insurance SUD payment rates to:

- ensure that public and private health insurers create appropriate reimbursement methodologies for addiction treatment programs that support evidence-based comprehensive care;
- emphasize quality or performance measures for addiction treatment outcomes that are
  patient-centered and align with addiction as a chronic disease, remission as a treatment
  goal, and recovery as an ongoing process, and refrain from using as the desired or
  measured outcome, "completion of treatment" or cessation of professional services; and
- promote reimbursement-based reward programs for adherence to nationally recognized, evidence-based, SUD-specific standards.

Furthermore, ASAM urges ONDCP to consider opportunities to encourage states to replicate Medicare's opioid treatment program (OTP) and office-based SUD care management<sup>1</sup> benefits in their Medicaid programs to support expanded access to addiction treatment.

# Make Methadone Treatment Accessible in More Medical Settings

Although there are three FDA-approved medications to treat OUD, methadone may be the best option for certain patients due to it being the only full-agonist opioid, and therefore uniquely positioned to treat individuals with high-potency synthetic opioid use. Despite limited exceptions, outdated regulations restrict outpatient access to just over 2,000 federally certified OTPs. In fact, over 70% of US counties, especially in rural areas, do not have a single OTP, making it difficult, if not impossible, for patients to access methadone for OUD.<sup>2</sup>

ASAM encourages ONDCP to work with the DEA and HHS to update regulations to allow qualified practitioners to prescribe methadone for OUD for pharmacy administration/dispensing so that this lifesaving treatment can be accessed through more medical settings, and support individuals on their pathway toward recovery and wellness. These

**settings include primary care, as well as Federally Qualified Health Centers and Certified Community Behavioral Health Clinics.** At a minimum, qualified practitioners should include board certified addiction psychiatrists and addiction medicine physicians; uniquely, addiction medicine is a multispecialty subspeciality, meaning these physicians may be certified by any primary board recognized by the American Board of Medical Specialties, including family medicine or internal medicine.<sup>3</sup> A recent ASAM-led coalition letter,<sup>4</sup> describes how this can be achieved through regulation and how such action is consistent with President Trump's executive order, "Ensuring Lawful Governance and Implementing the President's 'Department of Government Efficiency' (DOGE) Deregulatory Initiative," <sup>5</sup> which directs the rescission or modification of regulations that are not based on the best reading of the underlying statute.

# Establish a Non-Punitive Approach for Suspicious Orders Reporting Requirements for Buprenorphine Products Approved for OUD

Despite the proven efficacy of FDA-approved medications for OUD, ASAM has received numerous reports from clinicians regarding patients unable to fill prescriptions for buprenorphine. While some clinicians have reported that pharmacies cite "DEA quotas," ASAM appreciates <a href="DEA">DEA's clarification</a>6 that neither DEA nor the Controlled Substances Act (CSA) have regulations that dictate quantitative thresholds or place limits on the volume of controlled substances that DEA-registered manufacturers or distributors can order and dispense. Yet, problems with medication access, particularly buprenorphine, persist as pharmacies and distributors remain weary of triggering a suspicious order report (SOR) under §21 USC 832.

Although the DEA has clarified that neither the DEA, nor the CSA as amended in 2018, regulates the volume of controlled substances with quantitative thresholds that limit registrants' ordering or dispensing, ASAM believes that additional action is necessary, especially following the recent FDA <u>label changes</u><sup>7</sup> for buprenorphine/naloxone that notes that higher dosages above 24 mg/6 mg may be necessary for some patients. Therefore, ASAM encourages ONDCP to work with the US Department of Justice to consider a non-punitive approach to SORs submitted for buprenorphine. Such an approach would not change the reporting obligations of manufacturers and distributors under the law but would allow distribution of buprenorphine products approved for OUD pursuant to suspicious orders if manufacturers and distributors maintained a record of related suspicious orders and any related due diligence – that is, unless and until the DEA specifically instructs halted distribution. Such a non-punitive approach could help signal that the Administration is focused on ensuring that pharmacies have access to the supply of medications that patients need to sustain their recovery.

# Close Residential Treatment Coverage Gaps

While some Medicaid and Medicare beneficiaries may benefit from residential addiction treatment, current laws and regulations impede their access to it. In Medicaid, federal funding is largely barred for facilities that have more than 16 beds. While section 1115 demonstration guidance from the Centers for Medicare and Medicaid Services (CMS) has opened an avenue for states to work around this restriction, ASAM recommends updates. Specifically, we encourage ONDCP to coordinate with CMS to update SMD #17-0032 (Strategies to Address the Opioid Epidemic)<sup>8</sup> section 1115 demonstration guidance to eliminate the restrictive 30-day statewide

average lengths of stay (LOS) for residential treatment, and add an implementation milestone requiring residential treatment provider qualifications to fully align with the ASAM Levels 3.1, 3.5, and/or 3.7 program standards identified in HR 9232/S 4860 - the Residential Recovery for Seniors Act<sup>9</sup> (118th Congress), in licensure requirements, policy manuals, managed care contracts, or other guidance. Accordingly, ASAM also welcomes the Administration's support of HR 9232/S 4860, which would close the residential addiction treatment gap in Medicare.

ASAM appreciates the invitation to submit input on the 2026 National Drug Control Strategy. If you have any questions or would like to discuss these recommendations in further detail, please do not hesitate to contact Corey Barton, Director of Advocacy at <a href="mailto:cbarton@asam.org">cbarton@asam.org</a>.

Sincerely,

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

President, American Society of Addiction Medicine

<sup>&</sup>lt;sup>1</sup> Medicare pays for a monthly bundle of services for the treatment of SUD, including: overall management, care coordination, individual and group psychotherapy, and substance use counseling.

<sup>&</sup>lt;sup>2</sup> Brian Corry, Natasha Underwood, Laura J. Cremer, Cherie R. Rooks-Peck, Christopher Jones, County-level sociodemographic differences in availability of two medications for opioid use disorder: United States, 2019, Drug and Alcohol Dependence, Volume 236, 2022, 109495, ISSN 0376-8716, https://doi.org/10.1016/j.drugalcdep.2022.109495.

<sup>&</sup>lt;sup>3</sup> ABMS Officially Recognizes Addiction Medicine as a Subspecialty. American Board of Medical Specialties. Published March 14, 2016. <a href="https://www.abms.org/newsroom/abms-officially-recognizes-addiction-medicine-as-a-subspecialty/">https://www.abms.org/newsroom/abms-officially-recognizes-addiction-medicine-as-a-subspecialty/</a>

<sup>&</sup>lt;sup>4</sup> Trump Executive Order Opens Door to Fix Methadone for OUD Regulation. Default. Published March 31, 2025. Accessed April 5, 2025. <a href="https://www.asam.org/news/detail/2025/03/31/cut-recovery-red-tape">https://www.asam.org/news/detail/2025/03/31/cut-recovery-red-tape</a>

<sup>&</sup>lt;sup>5</sup> Ensuring Lawful Governance and Implementing the President's "Department of Government Efficiency" Regulatory Initiative. The White House. Published February 20, 2025. <a href="https://www.whitehouse.gov/presidential-actions/2025/02/ensuring-lawful-governance-and-implementing-the-presidents-department-of-government-efficiency-regulatory-initiative/">https://www.whitehouse.gov/presidential-actions/2025/02/ensuring-lawful-governance-and-implementing-the-presidents-department-of-government-efficiency-regulatory-initiative/</a>

<sup>&</sup>lt;sup>6</sup> US Government. Drug Enforcement Administration. (2023). *DEA-Registered Manufacturer and Distributor Established Controlled Substance Quantitative Thresholds and the Requirement to Report Suspicious Orders* (EO-DEA258, DEA-DC-065).

<sup>&</sup>lt;sup>7</sup> ASAM. New Buprenorphine for OUD Labels Clarify Higher Doses Appropriate for Some Patients. Published June 9, 2025. Accessed June 12, 2025. https://www.asam.org/news/detail/2025/06/09/new-buprenorphine-for-oud-labels-clarify-higher-doses-appropriate-for-some-patients

<sup>&</sup>lt;sup>8</sup> US Government. Centers for Medicare and Medicaid Services. (2017). Strategies to Address the Opioid Epidemic (SMD #17-0032).

<sup>&</sup>lt;sup>9</sup> Residential Recovery for Seniors Act, H.R. 9232/S. 4860, 118<sup>th</sup> Cong. (2024). <a href="https://www.congress.gov/bill/118th-congress/house-bill/9232/all-info">https://www.congress.gov/bill/118th-congress/house-bill/9232/all-info</a>.