May 12, 2025

The Honorable Russell Vought
Director, US Office of Management and Budget
725 17th St, NW
Washington, DC 20503

Re: Request for Information (RFI) on Deregulatory Ideas

Dear Director Vought,

On behalf of the American Society of Addiction Medicine (ASAM), the nation's leading specialty medical society representing more than 8,000 physicians and other health professionals who specialize in the prevention and treatment of addiction, I welcome the opportunity to provide comments on the RFI regarding ideas for deregulation. While the nation has made considerable progress towards reducing the death and disease burden from addiction, the recent renewal of the public health emergency declaration of the opioid crisis underscores the urgent need for new ideas that expand access to addiction treatment and instill hope among more people that remission and long-term recovery are possible.

Below, ASAM offers the following two suggestions for consideration that align with President Trump's executive orders to streamline unduly burdensome regulations where costs exceed benefits or that are unsound or inconsistent with statute:

1. **Waive burdensome requirements that limit access to injectable buprenorphine for opioid use disorder (OUD); and**
2. **Reduce a criminal legal barrier to prescribing controlled addiction medications for legitimate medical purposes.**

<u>Waiving burdensome requirements that limit access to injectable buprenorphine for OUD</u>

Currently, prescribers must register and pay a fee for each principal place of business or professional practice where they administer injectable buprenorphine for OUD. This requirement can create financial burdens for some prescribers and can limit patient access to this critical medication.

To address this, **the Attorney General should waive this requirement under certain conditions.**

Relevant statutory and regulatory provisions include 21 U.S.C. § 822(e)(1) and 21 C.F.R. § 1301.12(a)), which require separate registration for each location where controlled substances are dispensed. However, under 21 U.S.C. § 822(d), the Attorney General may waive this requirement through regulation if consistent with public health and safety. In the past, this waiver authority has been delegated to the Administrator of the Drug Enforcement Administration (DEA).

To help close the addiction treatment gap in the United States, the DEA, under delegated authority from the Attorney General, should waive the separate registration requirement for each location where injectable buprenorphine approved by the Food and Drug Administration to treat OUD is administered. Doing so would better align with the administration's public health and safety objectives, as the current regulatory burden outweighs its benefits.

Long-acting injectable buprenorphine plays a critical role in OUD treatment, especially for individuals experiencing housing instability, or for whom storing a supply of daily medications or remembering to take daily medications can be more challenging. The risk of diversion or misuse of long-acting injectable buprenorphine is low, as the medication is stored and administered by registered practitioners.

Notably, a final rule waived the separate registration requirement at each principal place of business or professional practice for narcotic treatment programs with mobile components that fully comply with that rule's requirements. A similar waiver could be extended to other types of applicants who maintain at least one registration location in the same state.

Below is the text of 21 C.F.R. § 1301.12(b)(3) as it will exist after the waiver-related modifications:

> § 1301.12 Separate registrations for separate locations.
> …

(b)(3) An office used by a practitioner (who is registered at another location in the same State in which he or she practices) where controlled substances are prescribed — but neither administered (other than injectable buprenorphine approved by the Food and Drug Administration to treat opioid use disorder) nor otherwise dispensed as a regular part of the professional practice of the practitioner at such office, and where no supplies of controlled substances are maintained (other than injectable buprenorphine approved by the Food and Drug Administration to treat opioid use disorder).

Reducing a criminal legal barrier to prescribing controlled addiction medications for legitimate medical purposes

Regardless of whether buprenorphine prescribing actually increases the risk of federal investigation/prosecution, the perception that buprenorphine prescribing could increase risks of investigation/prosecution is a prescribing barrier. **To address this, the Attorney General/DEA**

should clarify that the regulation at 21 C.F.R. § 1306.04(a) - which requires prescriptions for controlled substances to be for "legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice" - means that a violation of such regulation requires proof of both a (1) lack of legitimate medical purposes and (2) deviation from the usual course of professional practice.

Addiction medications, such as medications for opioid use disorder (MOUD), are lifesaving treatments for addiction. In 2023, fewer than 20% of people with OUD in the US received MOUD. Several reasons exist for the underutilization of MOUD, including practitioners' fear of intrusion into clinical practice by the US Department of Justice (DOJ), including the Drug Enforcement Administration (DEA). Practitioners fear they will be investigated or prosecuted for well-intentioned prescribing of controlled medications that violate ambiguous federal law.

Federal regulations implementing the federal Controlled Substances Act (CSA) authorize the prescribing of controlled substances, like buprenorphine, for "a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." Federal circuit courts, however, are divided on whether a CSA violation requires proof of both a (1) lack of legitimate medical purpose and (2) deviation from the usual course of professional practice (i.e., a conjunctive standard), or whether proof of just one of these two conditions is sufficient (i.e., a disjunctive standard). Case law suggests "legitimate medical purpose" under the CSA means having the intention to improve a patient's health-related condition.

The regulation, as currently written, is sometimes being misconstrued in a way that is inconsistent with Congressional intent, creating bad policy. A disjunctive standard allows for prosecutions based solely on a violation of the "usual course of professional practice." Yet, the phrase "usual course of professional practice" is amorphous and ambiguous, with the meaning potentially varying among well-intentioned practitioners due to the heterogeneity of state regulations governing the practice of addiction medicine, as well as the heterogeneity of patients with substance use disorder (SUD), practitioners who treat SUD, and practice settings. DOJ personnel do not typically have the requisite medical expertise to accurately evaluate the totality of the circumstances that may explain differences in prescribing practices across practitioners. *DOJ's expertise would best be utilized by focusing on practitioners prescribing for improper reasons – that is, without a legitimate medical purpose.* It is important to consider Congressional intent in passing the Controlled Substances Act, which was to prevent the trafficking or dealing of drugs, not to ensure good quality medical treatment.

Below is the text of 21 C.F.R. § 1306.04(a) as it will exist after the requested modifications:

> **§ 1306.04 Purpose of issue of prescription.**
>
> (a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose — meaning for the purpose of preventing, treating, or managing a patient's health-related condition — by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing

practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances. A violation of this paragraph requires proof of both a lack of legitimate medical purpose and deviation from the usual course of professional practice.

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Thank you for the opportunity to outline these proposed deregulatory options. ASAM stands ready to work with the administration on new ideas to address the deadly overdose crisis and save more families from the pain and agony of losing a loved one. Please contact Corey Barton, Director of Advocacy at cbarton@ASAM.org for further engagement on these or other regulatory areas of interest.

Sincerely,

Stephen Taylor, MD

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President, American Society of Addiction Medicine