A Grassroots Toolkit for the DOJ Anticompetitive Regulations Task Force Request for Public Comment

DUE DATE: MAY 27, 2025

Background/Instructions

The Department of Justice (DOJ) Anticompetitive Regulations Task Force is seeking comment by May 27 on "laws and regulations that make it more difficult for businesses to compete effectively," particularly in high-impact sectors like health care. The DOJ notes that such rules often discourage low-cost, high-quality care and promote overbilling and consolidation.

Below are instructions on how advocates can submit a deregulatory idea related to the delivery of methadone for the treatment of opioid use disorder to the DOJ Anticompetitive Regulations Task Force.

1. **Personalize the form letter below; add your name at the bottom. Save the revised letter as a PDF on your Desktop, and upload it to the government webpage found here.**

2. **On that webpage, enter your email address where indicated.**

3. **On that webpage, if you are signing as an Individual, please select "Individual" and enter your information (i.e., do NOT select "Organization" or use any organization's information). Alternatively, you may choose "Anonymous." [Authorized signatories for an organization are also free to use/personalize the letter on their organization's behalf.]**

   Personally identifiable information (e.g., name, address, phone number) included in the comment form or in an attachment may be publicly disclosed in a docket or on the Internet.

4. **On that webpage, check the box for "I am not a robot."**

5. **On that webpage, press "Submit Comment."**

[FORM LETTER FOR DOJ Anticompetitive Regulations Task Force Request for Public Comment]

May __, 2025

Dear Attorney General Bondi:

[Personalize as you see fit: My name is _____./I am a board-certified physician in _____/pharmacist/healthcare professional/family member/person with lived/living experience./I take care of patients with addiction and co-occurring conditions in [City/County], [State][Zip Code] where I serve as _____./I am writing as a concerned resident in [City/County], [State][Zip Code] to express my deep concern about the addiction and overdose crisis in my community. Illicitly manufactured opioid overdose fatalities are alarming and heartbreaking. Urgent action is needed.] Thank you for this opportunity to submit input on regulations that make it more difficult for businesses to compete effectively, especially in markets like healthcare that have the greatest impact on American households and patients. To that end, I offer the following idea for consideration:

Eliminate DEA's Prohibition on the Prescribing of Methadone for Opioid Use Disorder

With limited exceptions, methadone for the treatment of opioid use disorder (OUD) may only be dispensed directly by federally regulated opioid treatment programs (OTPs). This ban on prescribing methadone for OUD through qualified practitioners prescribing it (and qualified pharmacies dispensing it) is due to 21 C.F.R. § 1306.07(a)), which is an incorrect interpretation of the underlying statute (21 U.S.C. 823(h)) and constitutes a significant regulatory action that materially harms competition in health care delivery.

Specifically, the underlying statute (21 U.S.C. 823(h)) does not prohibit qualified practitioners from prescribing methadone for opioid use disorder or pharmacies from administering or dispensing it under a prescription. Instead, the statutory language requires practitioners (including pharmacies) who dispense narcotic drugs for maintenance or detoxification to annually obtain a separate registration for that purpose. Federal statute defines "dispense" (21 U.S.C. 802 (10)) as "deliver[ing] a controlled substance to an ultimate user . . . by . . . a practitioner, including the prescribing and administering of a controlled substance." Since the DEA in the past has not correctly relied on the statute, the DEA has restricted methadone to OTPs that directly dispense it rather than qualified practitioners more broadly. This restriction limits the number of access points for methadone, thereby preventing competition.

21 C.F.R. § 1306.07(a) is inconsistent with the plain meaning of the underlying statute and its costs now outweigh its benefits. By largely restricting access to methadone for opioid use disorder (OUD) through OTPs that directly dispense it, rather than qualified practitioners more broadly, current regulations prevent competition in methadone treatment. The limited number of methadone treatment practitioners harms patients who do not live near OTPs, especially patients in rural areas. Additionally, the current system also raises concerns about the outsized influence of publicly traded and private equity interests in our nation's OTP infrastructure, which could distort healthy market dynamics for methadone and impact future patient care.

Furthermore, the DEA's current regulation prevents patient choice in treatment by only permitting access to two medications for OUD (i.e., buprenorphine and naltrexone) from practitioners outside of OTPs, rather than access to three medications for OUD (i.e., methadone, buprenorphine, and naltrexone) outside of OTPs. This limits patient choice, even though each medication works differently, and methadone may be the most effective option for some patients. Practitioners outside of OTPs have been similarly harmed by having their treatment options limited to buprenorphine and naltrexone, even when methadone would be more effective for some of their patients.

For further background, see:

- Dooling B, Stanley L. A Vast and Discretionary Regime Federal Regulation of Methadone as a Treatment for Opioid Use Disorder.; 2022. Pages 15-17. https://regulatorystudies.columbian.gwu.edu/federal-regulation-of-methadone; and

- ASAM, RSI, NCPA, ASHP, and NCCHC. Letter Re: Ensuring Lawful Governance and Implementing the President's "Department of Government Efficiency" Deregulatory Initiative , dated March 26, 2025. https://downloads.asam.org/sitefinity-production-blobs/docs/default-source/advocacy/letters-and-comments/final-asam-rsi-ncpa-ashp-ncchc---methadone-letter---executive-order-14219---3-26-25.pdf?sfvrsn=366c8da_3

While I understand that other federal agencies must also update their regulations/medication labels to allow all methadone products approved for OUD to be prescribed and dispensed outside of OTPs, it is crucial for the DEA to take the first step by eliminating its prescribing prohibition. Below is the pertinent text of the relevant C.F.R. provision as it will exist after the requested modifications:

§ 1306.07 Administering or dispensing (including prescribing) of narcotic drugs.

(a) A practitioner may ~~administer or~~ dispense ~~directly (but not prescribe)~~ a narcotic drug listed in any schedule to a narcotic dependent person for the purpose of maintenance or detoxification treatment if the practitioner meets both of the following conditions:

(1) The practitioner is separately registered with DEA under section 303(h) of the Controlled Substances Act (CSA) (21 U.S.C. 823(h)) as a narcotic treatment program or other qualified practitioner.

(2) The practitioner is in compliance with DEA regulations regarding treatment qualifications, security, records, and unsupervised use of the drugs pursuant to the Act.

…

Thank you for considering this request.

Sincerely,

[Insert Name/Credentials/Signature Block]