Congress of the United States

Washington, DC 20515

March 2, 2023

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Miriam Delphin-Rittmon
Assistant Secretary for Mental Health and Substance Use
Substance Abuse and Mental Health Services Administration
5600 Fishers Lane
Rockville, MD 20857

RE: RIN 0930-AA39

Dear Secretary Becerra and Assistant Secretary Delphin-Rittmon:

We write in support of proposed changes to 42 CFR Part 8,[1] which will make it easier for people to access opioid use disorder (OUD) medication treatment, and to highlight remaining barriers to accessing evidence-based treatment. The flexibilities included in the proposed regulations are a significant step forward in increasing access to evidence-based treatment as we continue to battle an epidemic that claims more than 100,000[2] lives annually and harms friends, families, and communities. But under the proposed changes, one important type of OUD medication, methadone, will still fall within an outdated regulatory structure that limits and impedes access to this key tool for recovery and overdose prevention.[3] Given the scope of this epidemic, we must ensure that all OUD medication treatment options are accessible to everyone, regardless of income or zip code.

Methadone is a medication that treats OUD and helps people maintain remission and recovery. Some clinicians have observed that it can be more effective against fentanyl than other medications.[4] To get methadone for OUD, people must go to an Opioid Treatment Program (OTP). In turn, an OTP must be accredited by a Substance Abuse and Mental Health Services Administration (SAMHSA) accreditor, certified by SAMHSA, and registered with the Drug Enforcement Administration (DEA).[5] States may also establish additional requirements for OTPs: Nineteen states and the District of Columbia require health care providers to demonstrate sufficient need before they can open a new OTP, and seven states and the District of Columbia impose zoning laws that prohibit OTPs from providing services in certain areas.[6]

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[1] Medications for the Treatment of Opioid Use Disorder, 87 Fed. Reg. 77330 (proposed Dec. 16, 2022) (to be codified at 442 C.F.R. pt. 8), https://www.federalregister.gov/documents/2022/12/16/2022-27193/medications-for-the-treatment-of-opioid-use-disorder.
[2] Press Release, Centers for Disease Control and Prevention, Drug Overdose Deaths in the U.S. Top 100,000 Annually (Nov. 17, 2021), https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2021/20211117.htm.
[3] *Study Highlights Effectiveness of Methadone and Buprenorphine*, National Institute on Drug Abuse (Feb. 28, 2020), https://nida.nih.gov/news-events/science-highlight/study-highlights-effectiveness-methadone-buprenorphine.
[4] Lev Facher, *Fentanyl isn't Just Causing Overdoses. It's Making it Harder to Start Addiction Treatment*, STAT News (Nov. 16, 2022), https://www.statnews.com/2022/11/16/fentanyl-isnt-just-causing-overdoses-its-making-it-harder-to-start-addiction-treatment/.
[5] 21 U.S.C. 832(g)(1) § 303(h); 42 C.F.R. pt. 8.
[6] Christine Vestal, *As Fentanyl Use Spikes, Feds Urge States to Ease Methadone Rules*, The Pew Charitable Trusts (Dec. 19, 2022), https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2018/10/31/long-stigmatized-methadone-clinics-multiply-in-some-

Restrictive rules on methadone access have led some to refer to methadone as "liquid handcuffs" that shackle those with OUD to OTPs.[7] Before March 2020, those rules required patients to go, in person, to an OTP at least four days per week until they had reached 270 days, or 9 months, of sobriety.[8] After that, a patient was required to go to an OTP at least monthly for the duration of their treatment.[9] As of 2019, 77 million people did not have an OTP in their county of residence. Travel is a unique barrier to methadone treatment compared to treatment for other chronic diseases,[10] and limited geographic accessibility and long travel times, especially for rural Americans,[11] result in people stopping OUD treatment prematurely.[12]

In March 2020, in response to the COVID-19 pandemic, SAMHSA took a wise step and issued exemptions to these restrictive access rules. During the public health emergency and for one year after, these flexibilities allow OTPs to "dispense up to 28 days of take-home doses" of methadone for stable patients and up to 14 days of take-home doses for patients who have been in treatment for 30 days.[13] As SAMHSA recognizes, these flexibilities also "[allow] those who reside far from an OTP or who lack access to reliable transportation to receive treatment, while also being able to gain or maintain employment, care for loved ones and engage in other required activities of daily living."[14]

We commend SAMHSA for recognizing the burdens placed on people trying to access methadone for OUD and proposing regulations that will make methadone for OUD more accessible. The proposed rules will allow more health care practitioners within OTPs to order methadone for OUD, including physician assistants, nurse practitioners, clinical nurse specialists, nurse midwives, and certified registered nurse anesthetists.[15] The rules will also reduce wait times before someone qualifies for treatment, allow more people to receive methadone without a daily, in-person OTP visit, and create options for telehealth and non-OTP provider physical evaluations.[16] Moreover, the proposed rules support mobile medication units, which will allow OTPs to deliver methadone for OUD to patients.[17]

But while the proposed rules increase individuals' autonomy, they still leave those with OUD tethered to OTPs, often miles away from where they need treatment the most. Under the proposed rules, some people will still be forced to travel to an OTP every day and face the stigma that comes with it.[18] And in states and

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[7] KHN Morning Briefing, *Methadone Clinics Become Liquid Handcuffs for those Who can't Afford Pricier Treatment Programs*, Kaiser Family Foundation (Jan. 12, 2018), https://khn.org/morning-breakout/methadone-clinics-become-liquid-handcuffs-for-those-who-cant-afford-pricier-treatment-programs/.

[8] Medication Assisted Treatment for Opioid Use Disorder Rule, 42 C.F.R. § 8.12 (2015).

[9] *Id*.

[10] Susan Iloglu et al., *Expanding Access to Methadone Treatment in Ohio through Federally Qualified Health Centers and a Chain Pharmacy: A Geospatial Modeling Analysis*, 220 Drug and Alcohol Dependence (2021), https://pubmed.ncbi.nlm.nih.gov/33497963/.

[11] Lindsay Allen et al., *Drive Times to Methadone Treatment among Medicaid Patients*, 33(3) J Health Care Poor Underserved 1169 (2022), https://pubmed.ncbi.nlm.nih.gov/36245155/.

[12] Robert A. Kleinman, *Comparison of Driving Times to Opioid Treatment Programs and Pharmacies in the US*, 77(11) JAMA Psychiatry 1163 (2020), https://pubmed.ncbi.nlm.nih.gov/32667648/.

[13] Methadone Take-Home Flexibilities Extension Guidance, SAMHSA (updated Jan. 25, 2023), https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines/methadone-guidance.

[14] Medications for the Treatment of Opioid Use Disorder, 87 Fed. Reg. 77,330 (Dec. 16, 2022) (to be codified at 42 C.F.R. pt. 8), https://www.federalregister.gov/documents/2022/12/16/2022-27193/medications-for-the-treatment-of-opioid-use-disorder.

[15] *Id*.

[16] *Id*.

[17] *Id*.

[18] Zoe Adams, et al., *To Save Lives from Opioid Overdose Deaths, Bring Methadone into Mainstream Medicine*, Health Affairs (May 27, 2022), https://www.healthaffairs.org/do/10.1377/forefront.20220524.911965.

territories with very few or no OTPs,[19] patients will still not be able to get methadone for OUD prescribed by their doctor and available to pick up at a pharmacy — even while a broader array of health care practitioners within an OTP can order methadone for OUD. Even in pilot programs that allow for pharmacy pick-up of methadone for OUD, commercial insurers often deny coverage because federal rules only permit dispensing at OTPs and not at pharmacies. As a result, commercial insurers do not include methadone for OUD as a pharmacy benefit, which can leave people facing prohibitive out-of-pocket costs for their medication.[20]

Allowing addiction specialist physicians outside of OTPs to prescribe methadone for OUD for pick-up at pharmacies would result in more people safely getting the medication they need where they can receive it—in their communities.[9] As of June 2022, there were about 1,920 OTPs in the United States[1] and comparatively, 53,203 established retail pharmacies.[21] In other words, for every OTP, there are 27 pharmacies that can provide medications for opioid use disorder. Other countries, such as the United Kingdom, Canada, and Australia, have demonstrated that physicians prescribing and community pharmacies dispensing methadone can expand access without harm.[4] Pharmacists in these countries have helped to provide methadone maintenance services for decades with procedures in place to prevent diversion.[22] Similarly, studies conducted in the United States have found that pharmacists are able to use prescription drug monitoring programs (PDMPs) to ensure that individuals who have been prescribed methadone for OUD are not also prescribed other opioids and medications that may interfere with methadone's effects.[13] Pharmacists also can provide education about high-risk behaviors and intervene when they occur.[23] In short, allowing addiction specialist physicians outside of OTPs to prescribe methadone for OUD to be picked up at a pharmacy is an evidence-based strategy that creates more paths to access to addiction care.

SAMHSA's proposed rules are a necessary and long-awaited step forward,[1] but we cannot tolerate any barriers to treatment, as more than 200 people die from overdoses each day.[24] The status quo of relegating methadone medication for opioid use disorder behind the walls of OTPs leaves this highly effective medication underutilized and stigmatized. Now is the time to do everything in our power to give people access to the medications they need to live healthy and productive lives.

Sincerely,

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[19] For example, there are no OTPs in Wyoming, Guam, North Marianas, the Federated States of Micronesia, and America Samoa, 1 in South Dakota and U.S. Virgin Islands, 3 in Nebraska, and 4 in Mississippi and Hawaii. Opioid Treatment Program Directory, SAMHSA, https://dpt2.samhsa.gov/treatment/directory.aspx.

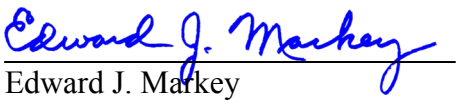
[20] Li-Tzy Wu et al., *Opioid Treatment Program and Community Pharmacy Collaboration for Methadone Maintenance Treatment: Results From A Feasibility Clinical Trial*, 117(2) Addiction 444 (2022), https://dukespace.lib.duke.edu/dspace/bitstream/handle/10161/23696/Wu%202021%20Opioid%20treatment%20program%20and%20community%20pharmacy%20collaboration%20for%20methadone%20maintenance%20treatment-feasibility%20clinical%20trial..pdf?sequence=2#:~:text=Background%20and%20aims%20Pharmacy%20administration%20and%20dispensing%20of,methadone%20maintenance%20treatment%20to%20be%20feasible%20and%20acceptable.

[21] Alex Petridis, *Pharmacies and Drug Stores in the U.S.*, IBIS World (2022).

[22] Gerald Cochran et al., *Medication Treatment for Opioid Use Disorder and Community Pharmacy: Expanding Care during a National Epidemic and Global Pandemic*, 41(3) Substance Abuse 269 (2020), https://pubmed.ncbi.nlm.nih.gov/32697171/.

[23] Insaf Mohammad et al., *Pharmacists and Opioid Use Disorder Care During COVID-19: Call for Action*, 5(2) J. of the Amer. College of Clin. Pharm. 203 (Feb. 2022), https://pubmed.ncbi.nlm.nih.gov/34909605/.

[24] Centers for Disease Control & Prevention, *Vital Statistics Rapid Release: Provisional Drug Overdose Death Counts*, (Feb. 2, 2022) https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm.



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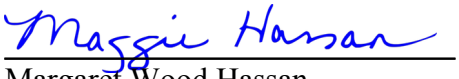

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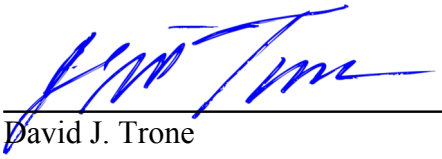

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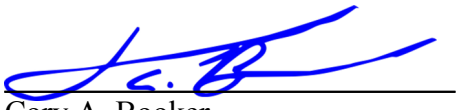

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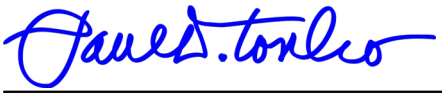

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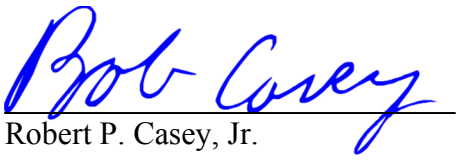

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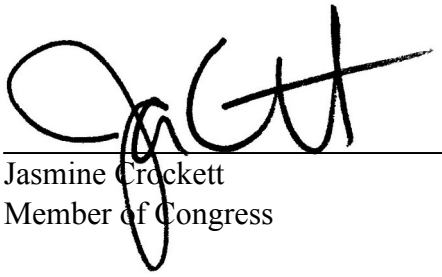

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