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September 2016

# OPIOID ADDICTION

## Laws, Regulations, and Other Factors Can Affect Medication-Assisted Treatment Access

Accessible Version

## Why GAO Did This Study

The abuse of prescription opioid pain relievers and illicit opioids, such as heroin, have contributed to increasing numbers of overdose deaths in the United States, and Centers for Disease Control and Prevention data show more than 28,000 opioid overdose deaths in 2014. Research has shown that MAT can more effectively reduce opioid use and increase treatment retention compared to treatment without medication.

GAO was asked to review issues related to patient and provider use of MAT for opioid addiction. GAO examined (1) how federal laws and regulations apply when using medications to treat opioid addiction compared to using the same medications for pain management and (2) key factors that can affect access to MAT for opioid addiction. GAO reviewed federal laws and regulations pertaining to MAT medications and reviewed key documents from HHS and other sources. GAO also identified 53 articles from peer-reviewed and scholarly journals related to MAT for opioid addiction for further examination. GAO interviewed stakeholders from patient and provider groups; experts on the issue of addiction treatment; and officials at relevant federal agencies.

GAO provided a draft of this report to the Office of National Drug Control Policy, HHS, and the Department of Justice. The Office of National Drug Control Policy agreed with the report's findings. The Office of National Drug Control Policy and HHS provided technical comments, which GAO incorporated as appropriate. The Department of Justice had no comments.

View [GAO-16-833](#). For more information, contact Elizabeth H. Curda at (202) 512-7114 or [curdae@gao.gov](mailto:curdae@gao.gov).

## OPIOID ADDICTION

### Laws, Regulations, and Other Factors Can Affect Medication-Assisted Treatment Access

## What GAO Found

The Department of Health and Human Services (HHS) has stated that addressing opioid abuse is a high priority and is promoting access to medication-assisted treatment (MAT)—an approach that combines behavioral therapy and the use of medications—to combat the problem. Three medications are currently approved for use in MAT for opioid addiction—methadone, buprenorphine, and naltrexone. Methadone and buprenorphine are regulated like other controlled substances under the Controlled Substances Act (CSA) when used to treat pain and have additional requirements that apply when used to treat opioid addiction. The third medication—naltrexone—is not a controlled substance and is therefore not subject to the CSA. Methadone is a Schedule II controlled substance, which indicates a higher risk of abuse. Buprenorphine is a Schedule III controlled substance, with lower risk, and so generally has fewer requirements. For example, when used to treat pain, methadone generally may not be dispensed without a written or electronic prescription. In contrast, buprenorphine may be dispensed based on a written, electronic, or oral (phone) prescription. When used for opioid addiction treatment, the CSA and implementing regulations impose additional requirements for methadone and buprenorphine:

- Methadone may generally only be administered or dispensed within an opioid treatment program (OTP), as prescriptions for methadone cannot be issued when used for opioid addiction treatment.
- Buprenorphine may be administered or dispensed within an OTP and may also be prescribed by a qualifying practitioner who has received a waiver from the Substance Abuse and Mental Health Services Administration. Practitioners who received this waiver are limited in the number of patients they may treat for opioid addiction.

In addition to laws and regulations, several key factors can affect patients' access to MAT for opioid addiction, according to articles from peer-reviewed and scholarly journals, documents GAO reviewed, and interviews with agency officials and experts. Specifically, through these sources GAO identified the following key factors:

- **The availability of qualified practitioners and their capacity to meet patient demand for MAT.** For example, there were approximately 1,400 OTPs in 2016. However, sources GAO reviewed stated that they are lacking in certain locations. Furthermore, some MAT practitioners may be operating at full capacity, leading to wait lists that can affect patients' access to MAT.
- **The perceptions of MAT and its value among patients, practitioners, and institutions.** Some practitioners do not believe that MAT is more effective than abstinence-based treatment—when patients are treated without medication—despite science-based evidence, and there are concerns that the medications will be misused.
- **The availability and limits of insurance coverage for MAT.** Patients with no insurance coverage for MAT may face prohibitive out-of-pocket costs that may limit their access to it, and coverage for MAT varies for those individuals with insurance. In some cases, state Medicaid programs limit the length of time that patients can use MAT medications.

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## Abbreviations

CSA	Controlled Substances Act
DATA 2000	Drug Addiction Treatment Act of 2000
DEA	Drug Enforcement Administration
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
MAT	medication-assisted treatment
OTP	opioid treatment program
SAMHSA	Substance Abuse and Mental Health Services Administration

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September 27, 2016

The Honorable Mitch McConnell  
Majority Leader  
United States Senate

Dear Senator McConnell:

The abuse of prescription opioid pain relievers and illicit opioids, such as heroin, contributes to significant morbidity and mortality in the United States. According to Centers for Disease Control and Prevention data, more than 28,000 people died of opioid overdoses in the United States in 2014—more than any previous year on record.<sup>1</sup> The number of overdose deaths from opioid pain relievers increased from roughly 4,000 in 1999 to almost 19,000 in 2014. The total number of overdose deaths also included those attributable to heroin, which increased from just under 2,000 to over 10,000 deaths in the same timeframe. In addition, Substance Abuse and Mental Health Services Administration (SAMHSA) data also show that in 2014 almost 2.3 million people aged 12 years and older abused or were dependent on opioids, up from almost 1.7 million in 2005.

The Department of Health and Human Services (HHS) has stated that addressing opioid abuse is a high priority and has identified increasing the use of medication-assisted treatment (MAT) as a means of reducing opioid addiction and preventing overdoses.<sup>2</sup> MAT for opioid addiction combines behavioral therapy and the use of medications—methadone,

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<sup>1</sup>Centers for Disease Control and Prevention, "Increases in Drug and Opioid Overdose Deaths — United States, 2000–2014." *Morbidity and Mortality Weekly Report*, 64 (2016). A small number of these deaths were attributed to both opioid pain relievers and heroin.

<sup>2</sup>For the purposes of our report, we use the term "opioid addiction" to include opioid use disorder. Opioid use disorder is defined as a problematic pattern of opioid use leading to clinically significant impairment or distress as indicated by at least 2 of 11 criteria occurring within a 12-month period. These criteria include opioids that are often taken in larger amounts or over a longer period than was intended; persistent desire or unsuccessful efforts to cut down or control opioid use; or craving, a strong desire or urge to use opioids. In addition to expanding MAT, HHS's other priority targets are to (1) encourage proper opioid prescribing practices and (2) expand the use and distribution of naloxone (a non-MAT medication) that reverses an opioid overdose.

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buprenorphine, or naltrexone—to treat this addiction. Methadone and buprenorphine are opioids that can be used for pain management, and also can be abused or subject to diversion for improper use, such as being resold illegally.<sup>3</sup>

Research has shown that MAT can be more effective in reducing opioid use and increasing treatment retention (i.e., reducing dropouts) compared to abstinence-based treatment, when patients are treated without medication. Despite the evidence that MAT can be an effective treatment for opioid addiction, other studies indicate that access to MAT has not kept pace with the increasing problem of opioid addiction in the United States. For example, a 2015 article indicated that the maximum number of people who could access MAT was approximately 1.4 million in 2012—indicating a gap of nearly 1 million people when compared to the 2.3 million people who abused opioids or were dependent upon them.

You requested that we provide information on issues related to patient and provider access to MAT for opioid addiction. In this report, we examine

1. how federal laws and regulations apply when using medications to treat opioid addiction compared to using the same medications for pain management and
2. key factors that can affect access to MAT for opioid addiction.

To identify and describe how federal laws and regulations apply when using medications to treat opioid addiction compared to using the same medications for pain management, we identified the medications approved for treating opioid addiction in the United States, which are methadone, buprenorphine, and naltrexone. We then reviewed any federal laws and regulations pertaining to the prescribing, administering, or dispensing of these medications for opioid addiction treatment and pain management. While these medications may also be subject to state laws and regulations, the laws and regulations were beyond the scope of this report. In addition, we interviewed officials at relevant federal agencies,

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<sup>3</sup>Methadone and buprenorphine suppress withdrawal symptoms and control the craving for opioids. Both medications are opioids that carry risks of abuse. Naltrexone is used for relapse prevention because it suppresses the effects of opioids, and it carries no known risk of abuse.

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such as the Drug Enforcement Administration (DEA) in the Department of Justice, and the Food and Drug Administration (FDA) and SAMHSA in HHS, about the relevant laws and implementing regulations.

To identify key factors that can affect access to MAT for opioid addiction, we conducted a literature review; reviewed documentation, such as reports; and conducted interviews. For the literature review, we searched for relevant articles published in peer-reviewed and scholarly journals from January 2011 through April 2016 and reviewed 50 articles.<sup>4</sup> We also independently identified three additional articles. We examined the methodologies for each of these articles and determined that they were sufficiently reliable for the purposes of our report. (For more details about the methodology of our literature review, see app. I.) We also interviewed federal officials from HHS, DEA, and the Office of National Drug Control Policy; researchers who authored articles identified in our literature review; and officials from relevant stakeholder organizations, including the American Society of Addiction Medicine, the National Association of State Alcohol and Drug Abuse Directors, Faces and Voices of Recovery, and Young People in Recovery. Finally, we obtained information related to individuals' use of opioids and the availability of opioid treatment programs (OTP) from the following SAMHSA resources: the National Survey on Drug Use and Health and the National Survey on Substance Abuse Treatment Services. We assessed the reliability of data from these sources based on information from SAMHSA officials about the procedures in place to ensure the data's quality and completeness. We determined that they were sufficiently reliable for the purposes of this report.

We conducted this performance audit from December 2015 to September 2016 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

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<sup>4</sup>We chose this period because injectable naltrexone—a medication used in MAT for opioid addiction—was approved by the FDA in 2010.



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## Background

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### Opioid Use

Opioids are drugs that slow down the actions of the body, such as breathing and heartbeat, by binding with certain receptors in the body. Some patients are prescribed opioids to treat pain. Opioid medications are available as immediate or extended release and in different forms, such as a pill, liquid, or a patch worn on the skin. Over time, the body becomes tolerant to them, which means that larger doses are needed to achieve the same effect. People may use opioids in a manner other than as prescribed—that is, they can be abused or misused. Because opioids are highly addictive substances, they can pose serious risks when they are abused or misused, which can lead to addiction and cause death. Symptoms of opioid addiction include a strong desire for opioids, inability to control or reduce use, and continued use despite interference with major obligations or social functioning, among others.

### Medications for Opioid Addiction and Their Role in MAT

Three medications are currently approved by the FDA for use in MAT for opioid addiction—methadone, buprenorphine, and naltrexone.

- **Methadone:** Methadone is a full opioid agonist, meaning it binds to and activates opioid receptors to help prevent withdrawal symptoms and reduce drug craving. It has a long history of use in treatment of opioid dependence in adults. It suppresses withdrawal symptoms in detoxification therapy, which involves stabilizing patients who are addicted by withdrawing them in a controlled manner. Methadone also controls the craving for opioids in maintenance therapy, which is ongoing therapy meant to prevent relapse and increase treatment retention. It can be administered to patients as an oral solution or in tablet form. Methadone also carries risk of abuse.
- **Buprenorphine:** Buprenorphine is a partial opioid agonist, meaning it binds to opioid receptors and activates them, but not as much as full opioid agonists. It reduces or eliminates opioid withdrawal symptoms, including drug cravings, and it may do so without producing the euphoria or dangerous side effects of heroin and other opioids. It can be used for detoxification treatment and maintenance therapy. It is available in tablet form or film for sublingual (under the tongue) administration both in a stand-alone formulation and in combination

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with another agent called naloxone, and as a subdermal (under the skin) implant.<sup>5</sup> Buprenorphine also carries risk of abuse.

- **Naltrexone:** Naltrexone is an opioid antagonist, meaning it binds to opioid receptors but does not activate them. It is used for relapse prevention following complete detoxification from opioids. Naltrexone prevents opioid drugs from binding to and activating opioid receptors, thus blocking the euphoria the user would normally feel and causing severe withdrawal symptoms if recent opioid use has occurred. It can be taken orally in tablets or as a once-monthly injection given in a doctor's office. Naltrexone carries no known risk of abuse.

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## Controlled Substances and the Controlled Substances Act

Two of the three medications used to treat opioid addiction—methadone and buprenorphine—are controlled substances and are governed at the federal level by the Controlled Substances Act (CSA).<sup>6</sup> Enacted in 1970, the CSA and its implementing regulations establish a framework through which the federal government regulates the use of these substances for legitimate medical, scientific, research, and industrial purposes, while preventing them from being diverted for illegal purposes. The CSA assigns controlled substances—including narcotics, stimulants, depressants, hallucinogens, and anabolic steroids—to one of five schedules based on the substance's medical use, potential for abuse, and risk of dependence.<sup>7</sup> Schedule I contains substances that have no currently accepted medical use and may not be manufactured, distributed, or dispensed under federal law. In contrast, Schedules II, III, IV, and V include substances that have recognized medical uses and may be manufactured, distributed, and dispensed in accordance with the CSA. The order of the schedules reflects substances that are progressively less dangerous and addictive, as shown in table 1 below.

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<sup>5</sup>The naloxone, in the combined formulation, is included to deter diversion or abuse of the medication by causing a withdrawal reaction if it is intravenously injected by individuals physically dependent on opioids.

<sup>6</sup>See Pub. L. No. 91-513, tit. II, 84 Stat. 1236, 1242-84 (1970) (codified, as amended, at 21 U.S.C. § 801 et seq.). In this report, references to the CSA include any applicable requirements set forth in implementing regulations. See 21 C.F.R. ch. 2 (2016) and 42 C.F.R. pt. 8 (2015).

<sup>7</sup>DEA exercises scheduling authority under the CSA. For a current list of scheduled substances, see 21 C.F.R. pt. 1308.

**Table 1: Controlled Substances Act (CSA) Schedules, Statutory Criteria, and Example Substances**

<b>Schedule</b>	<b>Statutory criteria for each schedule</b>	<b>Examples of substance under each schedule</b>
Schedule I	A substance is placed on Schedule I if the drug or other substance (1) has a high potential for abuse; (2) has no currently accepted medical use in treatment in the United States; and (3) there is a lack of accepted safety for use of the drug or other substance under medical supervision.	Heroin, lysergic acid diethylamide (LSD), methylenedioxymethamphetamine (Ecstasy), methaqualone (Quaalude)
Schedule II	A substance is placed on Schedule II if the drug or other substance (1) has a high potential for abuse; (2) has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions; and (3) abuse of the drug or other substance may lead to severe psychological or physical dependence.	Methadone, methamphetamine, methylphenidate (Ritalin), morphine, oxycodone (OxyContin), phencyclidine (PCP)
Schedule III	A substance is placed on Schedule III if the drug or other substance (1) has a potential for abuse less than the drugs or other substances in Schedules I and II; (2) has a currently accepted medical use in treatment in the United States; and (3) abuse of the drug may lead to moderate or low physical dependence or high psychological dependence.	Anabolic steroids and buprenorphine
Schedule IV	A substance is placed on Schedule IV if the drug or other substance (1) has a low potential for abuse relative to the drugs or other substances in Schedule III; (2) has a currently accepted medical use in treatment in the United States; and (3) abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule III.	Xanax, Valium, Equanil, Talwin
Schedule V	A substance is placed on Schedule V if the drug or other substance (1) has a low potential for abuse relative to the drugs or other substances in Schedule IV; (2) has a currently accepted medical use in treatment in the United States; and (3) abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule IV.	Certain cough medicines with codeine, and certain opium preparations

Source: GAO analysis of drug schedule definitions in the Controlled Substances Act, 8 U.S.C. § 812, the list of scheduled substances in 21 C.F.R. pt. 1308 (2016), and other public documents. | GAO-16-833

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## Methadone and Buprenorphine are Regulated Like Other Controlled Substances When Used to Treat Pain and Have Additional Requirements When Used to Treat Addiction

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### Methadone and Buprenorphine are Regulated Like Other Controlled Substances When Used to Treat Pain

When used for pain management, methadone and buprenorphine are regulated under federal laws and regulations that apply to controlled substances generally and do not impose requirements unique to methadone or buprenorphine.<sup>8</sup> However, certain requirements—such as restrictions on prescriptions—vary based on the schedule in which a controlled substance is classified. Methadone, like oxycodone (i.e., OxyContin), is a Schedule II controlled substance, which has the highest potential for abuse among scheduled drugs with an accepted medical use. Buprenorphine is a Schedule III controlled substance, which has currently accepted medical uses and a lower potential for abuse.

The CSA requires practitioners who dispense, administer, or prescribe methadone or buprenorphine and all other controlled substances in

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<sup>8</sup>Under the CSA, DEA has authority to regulate the use of methadone and buprenorphine for pain management as part of its oversight of controlled substances, and it has issued a policy statement that the legal standard for prescribing controlled substances to treat pain is the same as that for prescribing controlled substances generally. See Dispensing Controlled Substances for the Treatment of Pain, 71 Fed. Reg. 52,716 (Sept. 6, 2006). For purposes of this report, when we refer to DEA's regulation of the use of methadone or buprenorphine, we mean DEA's regulation of practitioners (such as physicians, pharmacies, or hospitals) who are authorized to prescribe, dispense, or administer these substances in the course of their professional practice.

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Schedules II-V to register with DEA.<sup>9</sup> In order to be registered, an applicant must meet certain criteria, including being licensed or otherwise authorized to dispense, administer, or prescribe controlled substances under the laws of the state in which they practice. Practitioners must reapply for this registration every three years.

The CSA also imposes certain requirements regarding the issuance of prescriptions for methadone and buprenorphine; these requirements vary depending on the controlled substance's schedule. For example, when used for pain management, methadone and other Schedule II controlled substances may typically only be dispensed by pharmacists based on a written or electronic prescription.<sup>10</sup> In contrast, buprenorphine and other Schedule III controlled substances may be dispensed based on a written, electronic, or oral prescription (i.e., a practitioner calls a pharmacist with the prescription). In addition, when used for pain management, prescriptions for Schedule II controlled substances may not be refilled, whereas prescriptions for Schedule III controlled substances may be refilled up to five times within six months after the date of the original prescription. All prescriptions for controlled substances—regardless of their schedule—must be issued for a legitimate medical purpose by a registered practitioner acting in the usual course of professional practice.

However, certain CSA requirements do not apply when Schedule II-IV controlled substances such as methadone and buprenorphine are used for pain management. For example, the CSA's inventory and recordkeeping requirement—which requires certain practitioners to

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<sup>9</sup>Practitioners may not prescribe, dispense, or administer Schedule I controlled substances to their patients under the CSA. Under the CSA, "administer" means for a practitioner to directly apply a controlled substance to the patient or for the practitioner's agent or the patient to do so in the practitioner's presence and at the practitioner's direction. "Dispense" means to deliver a controlled substance to a patient pursuant to the lawful order of a practitioner, including the prescribing and administering of a controlled substance. 21 U.S.C. § 802(2),(10).

<sup>10</sup>In emergency situations, pharmacists may dispense Schedule II controlled substances based on an oral prescription provided that the quantity prescribed and dispensed is limited to the amount needed during the emergency period. The pharmacist immediately writes down the prescription, including all required information, and the prescribing practitioner provides a written prescription to the pharmacist within seven days of authorizing the oral prescription. See 21 C.F.R. § 1306.11(d). When electronic prescriptions are issued for Schedule II-V controlled substances—including methadone and buprenorphine—certain conditions must be met. See 21 C.F.R. pt. 1311.

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maintain inventories of controlled substances and to make those inventories available for inspection for at least two years—generally does not apply when a practitioner prescribes or administers Schedule II-V controlled substances in the lawful course of professional practice for pain management purposes.<sup>11</sup>

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### Additional Requirements Apply to Methadone and Buprenorphine When Used for Opioid Addiction Treatment

When used for opioid addiction treatment, the CSA and implementing regulations issued by DEA and SAMHSA impose requirements in addition to those that generally apply when methadone and buprenorphine are used to treat pain.<sup>12</sup> See table 2 for a comparison of these requirements.

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<sup>11</sup>The CSA inventory and recordkeeping requirement does apply to (1) practitioners who dispense Schedule II-V controlled substances; (2) practitioners who administer Schedule II-V controlled substances if the practitioner regularly dispenses or administers controlled substances and charges patients for those controlled substances; and (3) practitioners who administer or prescribe Schedule II-V controlled substances for maintenance or detoxification treatment.

<sup>12</sup>Certain CSA requirements apply specifically to the use of medications for addiction treatment purposes. See 21 U.S.C. § 823(g). Within HHS, SAMSHA has responsibility for implementing some of these CSA requirements, and DEA is responsible for implementing others. SAMHSA's implementing regulations appear at 42 C.F.R. pt. 8, and DEA's appear in various provisions within title 21, chapter 2, of the C.F.R., including 21 C.F.R. §§ 1301.28, 1304.24, 1306.04(c), 1306.05(b), and 1306.07. The third medication that has been approved to treat opioid addiction—naltrexone—is not a controlled substance and is therefore not subject to the CSA. Naltrexone may be used to treat opioid use disorder by any practitioner with the authority to write prescriptions.

**Table 2: Comparison of Controlled Substances Act (CSA) Requirements for Methadone and Buprenorphine When Used for Pain Management and Opioid Addiction Treatment**

	Pain management		Opioid addiction treatment	
	Methadone	Buprenorphine	Methadone	Buprenorphine <sup>a</sup>
Allowable practitioner actions	Administer, dispense, and prescribe <sup>b</sup>	Administer, dispense, and prescribe	Administer and dispense	Dispense and prescribe
Limitations on location	None	None	Opioid treatment programs (OTPs) only <sup>c,d</sup>	Outpatient settings, such as a doctor's office or community health center
Restrictions on prescriptions	Written or electronic prescriptions only; <sup>e</sup> prescriptions may not be refilled.	Written, electronic, or oral (phone) prescriptions permitted; prescriptions may be refilled, subject to certain limitations. <sup>f</sup>	Prescriptions may not be issued	Prescriptions permitted with same limitations that apply when used for pain management
Registration requirements	Practitioners must register with the Drug Enforcement Administration (DEA)	Practitioners must register with DEA	OTPs are subject to an additional DEA registration requirement specific to OTPs, must be accredited, and must receive certification by the Substance Abuse and Mental Health Services Administration (SAMHSA)	Practitioners are exempt from the separate OTP registration requirement if they receive a waiver from SAMHSA <sup>g</sup>
Applicability of CSA inventory and recordkeeping requirements <sup>h</sup>	CSA inventory and recordkeeping requirements apply when dispensed but generally do not apply when administered or prescribed	CSA inventory and recordkeeping requirements apply when dispensed but generally do not apply when administered or prescribed	CSA inventory and recordkeeping requirements apply	CSA inventory and recordkeeping requirements apply
Who may prescribe, administer, or dispense (as permitted)	A DEA-registered practitioner	A DEA-registered practitioner	A practitioner or program that obtains a separate OTP registration or their agent <sup>i</sup>	Physicians with a waiver and, as of July 22, 2016, qualifying nurse practitioners and physicians' assistants with a waiver <sup>j</sup>
Limitations on number of patients	None	None	None	30 patients in a physician's first year with a waiver; 100 or 275 patients thereafter <sup>k</sup>

Source: GAO analysis of the Controlled Substances Act and implementing regulations. | GAO-16-833

<sup>a</sup>The requirements for buprenorphine refer to buprenorphine when dispensed or prescribed under a waiver authorized by amendments to the CSA enacted through the Drug Addiction Treatment Act of 2000 (DATA 2000). See 21 U.S.C. § 823(g)(2). In the absence of such a waiver, buprenorphine

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would be subject to the same limitations and requirements as methadone when used for opioid addiction treatment. See 21 C.F.R. § 1306.07.

<sup>b</sup>“Administer” means for a practitioner to directly apply a controlled substance to patient, or for the practitioner’s agent or the patient to do in the practitioner’s presence and at the practitioner’s direction. “Dispense” means to deliver a controlled substance to a patient pursuant to the lawful order of a practitioner.

<sup>c</sup>The term “OTP” refers both to a program or a practitioner engaged in opioid treatment of individuals. See 42 C.F.R. § 8.2.

<sup>d</sup>Methadone may be administered outside of an OTP under an exception known as the “3-day rule,” which permits a practitioner who is not separately registered as an OTP to administer—but not prescribe—narcotic drugs to a patient to relieve acute withdrawal symptoms while arranging for the patient’s referral to treatment. In addition, take-home doses of methadone may be given to patients for a day that an OTP is closed and, for certain patients, for longer periods of time subject to federal regulations and the discretion of the OTP’s medical director.

<sup>e</sup>Subject to certain limitations, pharmacists may dispense Schedule II controlled substances, including methadone, upon an oral prescription in emergency situations.

<sup>f</sup>Prescriptions may be refilled up to five times within 6 months after the date of the original prescription.

<sup>g</sup>SAMHSA is authorized to grant such waivers to qualifying physicians to treat opioid addiction with Schedule III-V medications approved by the Food and Drug Administration (FDA) for that purpose. Currently, the only Schedule III-V medication FDA has approved to treat opioid addiction is buprenorphine.

<sup>h</sup>The CSA requires certain practitioners to maintain inventories and records of controlled substances and to make those inventories and records available for inspection for at least two years. See 21 USC § 827; 21 C.F.R. pt. 1304.

<sup>i</sup>The agent must be supervised by and under the order of the licensed practitioner and is required to be a pharmacist, registered nurse, licensed practical nurse, or any other healthcare professional authorized by federal and state law to administer or dispense opioid drugs.

<sup>j</sup>To obtain a waiver, a physician must have a current state medical license; DEA registration number; expertise evidenced by certain certification, training, or experience; and the capacity to refer patients to appropriate counseling and other services. On July 22, 2016, the Comprehensive Addiction and Recovery Act of 2016 amended the CSA to also permit qualifying nurse practitioners and physicians assistants to receive a DATA 2000 waiver from the date of the act’s enactment until October 1, 2021. Pub. L. No. 114-198, § 303(a)(1).

<sup>k</sup>In July 2016, SAMHSA issued a final rule that increased the highest patient limit from 100 to 275 for certain physicians. 81 Fed. Reg. 44,711 (July 8, 2016). The effective date of this rule is August 8, 2016.

## Methadone

Prescriptions cannot be issued for methadone when used for opioid addiction treatment. Therefore, when used for that purpose, methadone may generally only be administered or dispensed within an OTP.<sup>13</sup>

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<sup>13</sup>The term OTP refers both to a program or a practitioner engaged in opioid treatment of individuals. See 42 C.F.R. § 8.2. OTPs are also called narcotic treatment programs or, often, methadone clinics. They may offer opioid medications, counseling, and other services for individuals addicted to heroin or other opioids.



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Under the CSA, OTPs must be certified by SAMSHA and registered by DEA. To be eligible for full certification, an OTP must first be accredited by a SAMHSA-approved accrediting organization. Accreditation is a peer-review process in which an accrediting organization evaluates an OTP by making site visits and reviewing policies, procedures, and practices. Once accredited, SAMHSA may certify an OTP if it determines that the OTP conforms with federal regulations governing opioid treatment standards. Among other things, federal opioid treatment standards set forth patient admission criteria, recordkeeping guidelines, and required services, such as counseling.

Once certified by SAMHSA, the OTP must apply for a separate registration from DEA—that is, a registration distinct from and in addition to the previously described DEA registration generally required of all practitioners who administer, dispense, or prescribe controlled substances. In order to register an OTP, DEA must determine that the OTP will comply with any applicable DEA requirements regarding the security of the stocks of controlled substances being used for treatment, as well as inventory and recordkeeping requirements. OTP registration from DEA must be renewed annually.

With limited exceptions, OTPs must administer methadone while patients are at the OTP facility. Federal opioid treatment standards permit patients to receive a single take-home dose for a day when an OTP is closed, including weekends and federal holidays. The medical director of an OTP may also allow certain patients to take home a specific number of doses based on the duration of the treatment the patient has completed.<sup>14</sup> OTPs are required to maintain current procedures adequate to identify the theft or diversion of take-home medications. Methadone could also be used outside of an OTP, such as in an emergency room, under an exception known as the “3-day rule,” which permits a practitioner who is not separately registered as an OTP to administer—but not prescribe—

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<sup>14</sup>In evaluating whether to permit a patient’s take-home use, medical directors are to consider recent abuse of drugs, including alcohol; regularity of clinic attendance; recent criminal activity; stability of the patient’s home environment and social relationships; length of time in treatment; assurance that take-home medication can be safely stored in the patient’s home; and whether the rehabilitative benefit the patient may derive from decreasing the frequency of clinic attendance outweighs the potential risks of diversion. 42 C.F.R. § 8.12(h)(4)(i)(2).

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narcotic drugs to a patient to relieve acute withdrawal symptoms while arranging for the patient's referral to treatment.<sup>15</sup>

## Buprenorphine

Like methadone, buprenorphine can be administered or dispensed in an OTP when used for addiction treatment. In addition, qualifying practitioners who receive a Drug Addiction Treatment Act of 2000 (DATA 2000) waiver may dispense or prescribe buprenorphine for opioid addiction treatment to a limited number of patients in an outpatient setting, such as a doctor's office.<sup>16</sup> Until recently, only physicians were eligible to receive a DATA 2000 waiver. On July 22, 2016, the Comprehensive Addiction and Recovery Act of 2016 amended the CSA to also permit qualifying nurse practitioners and physicians' assistants to receive a DATA 2000 waiver from the date of the act's enactment until October 1, 2021.<sup>17</sup> To qualify for a waiver, practitioners must be appropriately licensed under state law and have expertise as evidenced by certain certification, training, or experience. In addition, practitioners must have the capacity to refer patients for appropriate counseling and other services. Practitioners who receive a DATA 2000 waiver from SAMHSA may treat 30 patients in their first year under the waiver and may increase to 100 patients after one year upon submission of a notice to the Secretary of HHS. As of August 8, 2016, certain practitioners may be approved to treat up to 275 patients after one year.<sup>18</sup> Practitioners who

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<sup>15</sup>Under this exception, no more than 1 day's medication may be administered at one time, the treatment may not last for more than 72 hours, and the 72 hour period may not be renewed or extended. 21 C.F.R. § 1306.07(b).

<sup>16</sup>Specifically, DATA 2000 amended the CSA to authorize SAMHSA to grant qualifying practitioners a waiver of the separate registration requirement applicable to OTPs, for the purpose of treating opioid addiction with FDA-approved Schedule III-V opioid medications. Such medications may be prescribed or dispensed. 21 U.S.C. § 823(g)(2). Currently, the only Schedule III-V medication approved by FDA to treat opioid addiction is buprenorphine.

Although DATA 2000 authorized qualifying practitioners to receive a waiver of the separate OTP registration requirement, they must still have a valid DEA registration, as applicable to anyone who administers, dispenses, or prescribes controlled substances.

<sup>17</sup>Pub. L. No. 114-198, § 303(a)(1)(2016).

<sup>18</sup>SAMHSA has authority to change the statutory limits on the number of patients by regulation. 8 U.S.C. § 823(g)(2)(B)(iii). In July 2016, SAMHSA issued a final rule that increased the statutory limit of 100 patients to 275 patients for certain practitioners. 81 Fed. Reg. 44,711 (July 8, 2016).

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prescribe or dispense buprenorphine under a DATA 2000 waiver are subject to the CSA's inventory and recordkeeping requirement.

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## Practitioner Capacity, Perceived Value, and Insurance Coverage Can Affect Patients' Access to MAT for Opioid Addiction

In addition to laws and regulations, several key factors can affect patients' access to MAT for opioid addiction, according to articles and documents we reviewed and our interviews with stakeholders and agency officials. These factors include (1) the availability of qualified practitioners and their capacity to meet patient demand for MAT; (2) perceptions of MAT and its value among patients, practitioners, and in institutions; and (3) financing issues related to the availability and limits of insurance coverage for MAT.

**Practitioner availability and capacity.** According to literature we reviewed and some stakeholders we interviewed, the number of qualified practitioners—specifically OTPs and physicians with waivers who can prescribe buprenorphine—available to offer MAT services for opioid addiction may affect patients' access to this treatment. Further, some of these practitioners may be operating at full capacity, leading to wait lists that can affect patients' access to MAT. For example, in March 2016, SAMHSA reported that there were approximately 1,400 OTPs.<sup>19</sup> However, a 2014 SAMHSA brief and several stakeholders and articles stated that opioid-dependent individuals may not be able to access MAT due to lack of nearby OTPs, which are mostly concentrated in urban areas. As a result, some stakeholders told us that patients in rural areas have to travel several hours on a daily basis to seek treatment because they generally need to be at the OTP every day to take methadone. When OTPs are accessible, one article estimated that the majority of them are operating at 80 percent or more capacity, suggesting that they would not be able to handle a significant number of new patients, and another article noted that OTPs can have extensive waitlists. Some articles stated that OTP capacity is limited by factors such as funding limitations and a variety of state and local requirements.

In addition, several articles and a 2014 SAMHSA brief highlighted that the availability of buprenorphine, after FDA approval in 2002, helped to expand access to MAT for opioid addiction but also noted that patients' access is impeded by the availability of physicians and the limits on the

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<sup>19</sup>See 81 Fed. Reg. 17,639, 17,644 (March 30, 2016).

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number of patients that each physician can treat. In March 2016, SAMHSA reported that there were approximately 32,000 physicians with DATA 2000 waivers to prescribe buprenorphine.<sup>20</sup> According to one article, use of buprenorphine in OTPs has been limited, and another article noted that, in 2011, 43 percent of counties in the United States had no physicians with waivers who could prescribe buprenorphine as part of MAT. In March 2016, SAMHSA also reported that there is substantial geographic variation in the capacity to prescribe buprenorphine, including shortages of physicians, primarily in rural areas. Several articles and stakeholders noted that these patient limits can affect provider capacity and restrict access to MAT, even after the CSA was amended in 2006 to increase the maximum number of patients per physician from 30 patients to 100 patients after the first year.<sup>21</sup> For example, several stakeholders told us that patients experience waiting lists for treatment when physicians are treating their maximum number of patients. One article noted that because there are many areas of the country that have an insufficient number of physicians, the result is that many people needing treatment may remain on waitlists for weeks or months. It added that prolonged waitlists are associated with reduced likelihood of treatment entry.

**Perceptions of MAT and its value.** Several stakeholders, articles, and documents reported that perceptions of MAT, such as perceived stigma among patients and questions about its value among practitioners and institutions, can affect patients' access to MAT. Eight articles we reviewed noted that a perceived stigma about the use of MAT—especially methadone—among patients can make them reluctant to seek treatment, subsequently leading to social isolation and undermining the chances of long-term recovery. Another article noted that OTPs experience discrimination, such as community opposition, because they offer onsite medical care to people who are dependent on opioids. Another article stated that because of this perceived stigma, there is a desire among some patients to avoid OTPs to limit interactions with others who may be

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<sup>20</sup>See 81 Fed. Reg. 17,639, 17,644 (March 30, 2016).

<sup>21</sup>Office of National Drug Control Policy Reauthorization Act of 2006, Pub. L. No. 109-469, § 1102, 120 Stat. 3502, 3540 (2006). In July 2016, SAMHSA issued a final rule that increased the highest patient limit from 100 to 275 patients for certain physicians, effective August 8, 2016. 81 Fed. Reg. 44,711 (July 8, 2016).

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drug users and to avoid daily attendance requirements. This perception often makes buprenorphine—a MAT medication that can be prescribed in an office-based setting—a more attractive treatment option to many patients.

In addition, some practitioners may be reluctant to provide MAT based on beliefs about the value of using medications for treating addiction. For example, some articles and a 2014 SAMHSA report found that despite science-based evidence regarding the effective use of MAT, some practitioners do not believe there is a role for medications in the treatment of addiction disorders. Similarly, according to several articles we reviewed and stakeholders we interviewed, many practitioners believe in the efficacy of abstinence-based treatment—when patients are treated without medication—to treat addiction, even though research indicates that abstinence fails a large proportion of the time and is generally less effective than MAT.

Several documents and the literature we reviewed examined the reasons why MAT is not used more frequently within the criminal justice system. For example, a 2011 Legal Action Center report, a 2014 SAMHSA brief, and two articles cited various reasons why drug courts and other sentencing officials deny access to MAT. These included a lack of understanding about the nature of addiction and MAT, such as the belief that MAT is substituting one addiction for another. In addition, some judges may view opioid addiction as a social problem that is best addressed through abstinence. The 2014 SAMHSA brief and some reports and articles we reviewed show that institutions within the criminal justice system have policies that limit MAT, and these policies may be influenced by both negative perceptions of MAT and other factors, such as concerns over the risk of diversion. For example, some of these documents noted that some drug courts have policies that prohibit participants from using any controlled substances, which would include MAT.

Some stakeholders, documents, and an article we reviewed highlighted education as a key mechanism that can help reduce the perceived stigma of MAT and its value, including among those within the criminal justice system. For example, some stakeholders told us that they organize town hall meetings and workshops to educate their communities about the importance of MAT. The stakeholders explained that these efforts are opportunities to help educate patients and practitioners about MAT. Also, some documents and an article we reviewed on MAT and the criminal

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justice system noted that peoples' views about MAT can be addressed through education.

**Availability and limits of insurance coverage.** According to several stakeholders and articles we reviewed, financing of treatment is a key factor that can affect patients' access to MAT. Specifically, these sources show that the availability and limits of insurance coverage for MAT can create access challenges for patients who lack insurance, as well as for those with insurance. For example, patients with no insurance coverage for MAT may face prohibitive out-of-pocket costs that may limit their access to it. According to one article, a month's supply of a daily dose of sublingual buprenorphine may cost such patients between \$200 and \$450 per month. According to another article, access to injectable naltrexone among the uninsured is also limited due to costs that can range from \$750 to \$1,200 a month. A third article that reviewed available literature on MAT found that the monthly cost of injectable naltrexone is significantly higher than that of the other MAT medications—buprenorphine and methadone. Because of this, the article noted that cost is often a factor that practitioners consider when determining whether to prescribe naltrexone to a patient.

For individuals with insurance, the benefit coverage for MAT-related services can vary by insurance plan and by state. According to one article, some private health insurance plans do not cover buprenorphine treatment, or they impose limits on the length of treatment with buprenorphine. Some sources reported that lifetime coverage limits for buprenorphine can range from 12 months to 36 months, even though some patients may need access to the medications for the rest of their lives to prevent relapse. Similarly, a 2014 SAMHSA report found that although state Medicaid programs reimburse for at least one of the three MAT medications, most states did not reimburse for all three. In some cases, state Medicaid programs also limit the length of time that the medications can be used. Although Medicaid expansion allowed under the Patient Protection and Affordable Care Act could increase the number of individuals with coverage for substance abuse treatment, including MAT, the specific coverage can vary by state. We have previously examined access to behavioral health treatment—which can include MAT—in 10 states, and found that officials in 2 of the states that expanded Medicaid reported that the availability of behavioral health

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treatment has generally increased, although some concerns about access remain.<sup>22</sup> Specifically, officials in these states reported difficulties providing Medicaid enrollees with access to certain MAT medications due to lack of physicians willing to prescribe these drugs for Medicaid enrollees.

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## Agency Comments

We provided a draft of this report to the Office of National Drug Control Policy, HHS, and the Department of Justice. The Office of National Drug Control Policy agreed with the report's findings, and the office's comments are reprinted in appendix II. The Office of National Drug Control Policy and HHS provided technical comments, which we incorporated as appropriate. The Department of Justice had no comments.

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As agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the Department of Justice, HHS, the Office of National Drug Control Policy, and appropriate congressional committees. In addition, the report will be available at no charge on the GAO website at <http://www.gao.gov>.

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<sup>22</sup>GAO, *Behavioral Health: Options for Low-Income Adults to Receive Treatment in Selected States*, [GAO-15-449](#) (Washington, D.C.: June 19, 2015). Specifically, officials in these two states reported shortages of qualifying physicians with DATA 2000 waivers to prescribe buprenorphine to Medicaid-covered patients with opioid addiction. In addition, we have ongoing work related to the use of services and drugs to treat Medicaid beneficiaries with behavioral health conditions.

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If you or your staff have questions about this report, please contact me at (202) 512-7114 or [curdae@gao.gov](mailto:curdae@gao.gov). Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. Major contributors to this report are listed in appendix III.

Sincerely yours,

A handwritten signature in black ink, reading "Elizabeth H. Curda". The signature is written in a cursive style with a large, stylized "E" and "C".

Elizabeth H. Curda  
Acting Director, Health Care



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# Appendix I: Literature Review Methodology

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To identify and describe published research on key factors that affect access to medication-assisted treatment (MAT) for opioid addiction, we conducted a literature search for relevant articles published in peer-reviewed and scholarly journals from January 2011 through April 2016.<sup>1</sup> We searched the following databases for relevant articles in peer-reviewed and scholarly journals: ABI/Inform, PubMed, Biosis Databases, ProQuestDialog, PsychInfo, LexisNexis, and Law Reviews Combined. Key search terms included various combinations of “opioid addiction,” “opioid use,” “opioid dependence,” “medication assisted treatment,” “methadone,” “buprenorphine,” and “naltrexone.” From all database sources, 188 articles were identified. We first reviewed the abstracts for each of these articles for relevancy in determining key factors that affect access to MAT for opioid addiction.<sup>2</sup> For those abstracts we found relevant, we obtained and reviewed the full article and excluded those where the article was (1) published prior to 2011; (2) a duplicate of another article; (3) an editorial or commentary; (4) a dissertation; (5) not focused on the use of MAT within the United States; or (6) not focused on factors affecting patients’ use of MAT. After excluding these articles, 50 articles remained. We also independently identified three additional articles as we reviewed related documentation. For a complete list of the articles, see the bibliography at the end of this report. As part of our work, we examined the methodologies of all identified studies and determined that they were sufficiently reliable for the purposes of our report.

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<sup>1</sup>We chose this period because injectable naltrexone—the third medication used in MAT for opioid addiction—was approved by the FDA in 2010 for the prevention of relapse to opioid dependence following opioid detoxification.

<sup>2</sup>We reviewed the abstracts and did not obtain full articles if the article did not appear to address factors that affect patients’ use of MAT for opioid addiction; the article’s focus was on the use of MAT for opioid addiction outside of the United States; the article was an editorial or commentary or was a book; or if the article’s focus was about veterans who receive MAT within the Veterans Administration.

# Appendix II: Comments from the Office of National Drug Control Policy



EXECUTIVE OFFICE OF THE PRESIDENT  
OFFICE OF NATIONAL DRUG CONTROL POLICY  
Washington, D.C. 20503

August 31, 2016

Ms. Linda T. Kohn  
Director, Health Care  
U.S. Government Accountability Office  
441 G Street, NW  
Washington, DC 20548

Dear Ms. Kohn:

Thank you for the opportunity to review and comment on the report entitled, *Opioid Addiction: Laws, Regulations, and Other Factors Can Affect Medication-Assisted Treatment Access* (GAO-16-833). The report provides an excellent summary of the effectiveness of medicated-assisted treatment (MAT) for opioid use disorder, and the barriers to its adoption by practitioners, patients, policy makers and the public.

As noted by GAO, deaths involving opioids have reached record levels, with more than 28,000 such deaths reported by the Center for Disease Control and Prevention in 2014. Increased uptake of MAT by treatment programs and physicians can help reverse this trend. To further MAT's adoption the Administration has taken action in several areas to promote the use of MAT to treat opioid use disorder, as detailed at <http://www.hhs.gov/opioids/>. The Administration's actions include the following:

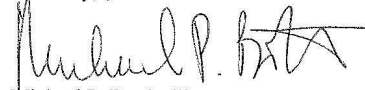
- Educating the public and policy makers of the effectiveness of MAT compared to treatment without medications;
- Encouraging treatment providers to incorporate MAT into their programs because data from the Substance Abuse and Mental Health Services Administration indicates that only about 10 percent of existing treatment programs currently offer MAT as a treatment option;
- Increasing the limit on the number of patients with opioid use disorder that a DATA-waived physician can treat with buprenorphine from 100 to 275;
- Promoting adoption of MAT in the criminal justice system, especially for persons with opioid use disorder in prison or jail;
- Convincing recovery support programs to accept persons with opioid use disorder and currently receiving MAT;

- Letting states know that they can use the Substance Abuse Prevention and Treatment Block grant to augment high co-pays or deductibles in covering the cost of treatment, including treatment with MAT; and
- Removing barriers from Federal health plans to providing MAT so that Federal employees and groups like Medicare recipients, Veterans and Tricare beneficiaries have improved access to MAT.

Improving access to MAT, the standard of care for opioid use disorders, is critically important to reducing opioid-involved deaths and other negative consequences of the current opioid epidemic.

ONDCP concurs with the findings of the report and appreciates the rigorous approach the GAO adopted in preparing it.

Sincerely,



Michael P. Botticelli  
Director

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# Appendix III: GAO Contact and Staff Acknowledgments

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## GAO contact

Elizabeth H. Curda, Acting Director, (202) 512-7114 or [curdae@gao.gov](mailto:curdae@gao.gov).

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## Staff Acknowledgments

In addition to the contact name above, Linda Kohn, Director; Will Simerl, Assistant Director; Natalie Herzog, Analyst-in-Charge; La Sherri Bush; and Emily Wilson made key contributions to this report. Also contributing were Joanna Berry, Christine Davis, Krister Friday, Cherie' Starck, and Eric Wedum.

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# Appendix IV: Accessible Data

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## Agency Comment Letter

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### Comments from the Office of National Drug Control Policy

Ms. Linda T. Kohn Director, Health Care

U.S. Government Accountability Office 441 G Street, NW

Washington, DC 20548 Dear Ms. Kohn:

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The Administration's actions include the following:

- Educating the public and policy makers of the effectiveness of MAT compared to treatment without medications;
- Encouraging treatment providers to incorporate MAT into their programs because data from the Substance Abuse and Mental Health Services Administration indicates that only about 10 percent of existing treatment programs currently offer MAT as a treatment option;
- Increasing the limit on the number of patients with opioid use disorder that a DATA-waived physician can treat with buprenorphine from 100 to 275;
- Promoting adoption of MAT in the criminal justice system, especially for persons with opioid use disorder in prison or jail;

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- Convincing recovery support programs to accept persons with opioid use disorder and currently receiving MAT;
  - Letting states know that they can use the Substance Abuse Prevention and Treatment Block grant to augment high co-pays or deductibles in covering the cost of treatment, including treatment with MAT; and
  - Removing barriers from Federal health plans to providing MAT so that Federal employees and groups like Medicare recipients, Veterans and Tricare beneficiaries have improved access to MAT.

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ONDCP concurs with the findings of the report and appreciates the rigorous approach the GAO adopted in preparing it.

Sincerely,

Michael P. Botticelli

Director

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