



Testimony

Before the Committee on Oversight and Reform, House of Representatives

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# DRUG POLICY

## Assessing Treatment Expansion Efforts and Drug Control Strategies and Programs

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and

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# GAO Highlights

Highlights of [GAO-19-535T](#), a testimony before the Committee on Oversight and Reform, House of Representatives

## Why GAO Did This Study

Over 70,000 people died from drug overdoses in 2017, according to the most recently available Centers for Disease Control and Prevention data. Opioids are currently the main driver of these deaths. For people who are addicted to or misuse opioids, MAT has been shown to be an effective treatment. GAO has a body of work on drug policy, including on treatment for opioid use disorder and on ONDCP's coordination and oversight of federal drug control efforts. GAO also identified federal efforts to prevent drug misuse as an emerging issue requiring close attention in its March 2019 High Risk report.

This statement includes information from GAO's 2016 and 2017 reports on access to MAT for opioid use disorder, including selected recommendation updates as of May 2019. It also includes information from GAO's March 2019 testimony with preliminary observations on the 2019 National Drug Control Strategy and on GAO's ongoing work regarding ONDCP's efforts. For recommendation updates, GAO reviewed HHS documents and spoke with HHS about its recent efforts.

## What GAO Recommends

GAO has previously recommended that HHS establish performance measures with targets to better gauge progress toward achieving agency goals for expanding access to MAT. HHS concurred and has taken some steps to address the recommendation.

View [GAO-19-535T](#). For more information, contact Triana McNeil at (202) 512-8777 or [McNeilT@gao.gov](mailto:McNeilT@gao.gov) or Mary Denigan-Macauley at (202) 512-7114 or [DeniganMacauleyM@gao.gov](mailto:DeniganMacauleyM@gao.gov).

May 9, 2019

## DRUG POLICY

### Assessing Treatment Expansion Efforts and Drug Control Strategies and Programs

## What GAO Found

In an effort to reduce the prevalence of opioid misuse and the fatalities associated with it, the Department of Health and Human Services (HHS) has made expanding access to medication-assisted treatment (MAT) for opioid use disorder a priority since 2015. MAT is an approach that combines behavioral therapy and the use of certain medications like methadone and buprenorphine. GAO reported in September 2016 that several factors could affect patients' access to MAT, such as availability of qualified practitioners and their capacity to meet patient demand. GAO also reported in October 2017 on HHS efforts to expand access to MAT for opioid use disorder and recommended, among other things, that HHS establish measures to better determine progress toward goals. While HHS established performance measures with targets to increase the number of prescriptions for certain MAT medications, it has not yet fully implemented this recommendation. Further action to measure the treatment capacity of providers would help HHS determine whether a sufficient number of providers are becoming available to evaluate and treat patients who could benefit from MAT.



Source: GAO. | GAO-19-535T

The Office of National Drug Control Policy (ONDCP)—responsible for coordinating and overseeing efforts by more than a dozen federal agencies to address illicit drug use—issued the 2019 National Drug Control Strategy on January 31, 2019. The Strategy encourages the use of evidence-based approaches to treatment and making MAT a standard of care for opioid addiction. However, as GAO testified in March 2019, the Strategy does not include certain information required by law, such as annual objectives that are quantifiable and measurable. Further, while the Strategy lists some items that it designates as measures of performance or effectiveness related to MAT, it lacks information on the current level of treatment access or any associated timeline by which ONDCP hopes to achieve desired results. Such information could help prioritize activities across federal agencies and measure progress over time, which previous GAO work has shown to be important for achieving results. ONDCP's responsibility to develop the National Drug Control Strategy and coordinate among federal agencies offers the agency an opportunity to guide activities to address the unprecedented number of drug overdose deaths. As part of its ongoing work, GAO will continue to assess ONDCP's efforts and consider recommendations as appropriate. GAO plans to issue a product by the end of the calendar year.

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Chairman Cummings, Ranking Member Jordan, and Members of the Committee:

We are pleased to be here today to discuss our prior work on access to medication-assisted treatment (MAT) for those who misuse or are addicted to opioids—a condition known as opioid use disorder—as well as our ongoing work on the Office of National Drug Control Policy’s (ONDCP) strategies and programs.<sup>1</sup> Over 70,000 people died from drug overdoses in 2017, and opioids are currently the main driver of these deaths, according to the Centers for Disease Control and Prevention.<sup>2</sup> The Acting Secretary of the Department of Health and Human Services (HHS) declared the opioid crisis a public health emergency on October 26, 2017.<sup>3</sup> Given the number of agencies engaged in federal drug control efforts and the range of activities that these efforts span—from prevention and treatment to interdiction, international operations, and law enforcement—these activities represent a considerable federal investment. According to the President’s fiscal year (FY) 2020 budget, federal drug control funding for FY 2018 was \$33 billion. In our March 2019 High-Risk report, we identified federal efforts to prevent drug misuse as an emerging issue requiring close attention.<sup>4</sup>

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<sup>1</sup>GAO, *Opioid Use Disorders: HHS Needs Measures to Assess the Effectiveness of Efforts to Expand Access to Medication-Assisted Treatment*, [GAO-18-44](#) (Washington, D.C.: Oct. 31, 2017) and GAO, *Opioid Addiction: Laws, Regulations, and Other Factors Can Affect Medication-Assisted Treatment Access*, [GAO-16-833](#) (Washington, D.C.: Sept. 27, 2016). We are also conducting ongoing work on ONDCP in response to a provision in 21 U.S.C. § 1708a(b) that GAO routinely examine ONDCP’s programs and operations, as well as in response to 2018 congressional requests.

<sup>2</sup>Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, *Drug Overdose Deaths in the United States, 1999-2017*, No. 329 (Washington, D.C.: November 2018).

<sup>3</sup>A public health emergency triggers the availability of certain authorities under federal law that enable federal agencies to take certain actions in response. See GAO, *Opioid Crisis: Status of Public Health Emergency Authorities*, [GAO-18-685R](#) (Washington, D.C.: Sep. 26, 2018).

<sup>4</sup>Every two years at the start of a new Congress, GAO calls attention to agencies and program areas that are high risk due to their vulnerabilities to fraud, waste, abuse, and mismanagement, or are most in need of transformation. See GAO, *High-Risk Series: Substantial Efforts Needed to Achieve Greater Progress on High-Risk Areas*, [GAO-19-157SP](#) (Washington, D.C.: Mar. 6, 2019).

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As federal agencies engage in drug control efforts, ONDCP is responsible for, among other things, overseeing and coordinating the implementation of national drug control policy across the federal government.<sup>5</sup> These responsibilities include the Director of ONDCP promulgating a National Drug Control Strategy, and assessing and certifying the adequacy of the National Drug Control Program agencies' budget submissions.<sup>6</sup>

In our testimony today, we will discuss findings from our 2016 and 2017 reports on access to MAT for opioid use disorder, as well as updates, as of May 2019, on actions HHS has taken in response to the key recommendation we made in our 2017 report. We will also discuss our ongoing examination of ONDCP's strategies and programs, including our scope and objectives. For our prior work, we reviewed federal laws and regulations pertaining to MAT medications, reviewed key documents from HHS and other sources, and interviewed stakeholders to identify factors that affect access to MAT. We applied internal control standards for defining objectives and evaluating results to assess HHS's evaluation plans for its efforts to expand access to MAT, and we interviewed HHS officials about their efforts. More detailed information on the scope and methodology can be found in the published reports. To update the status of our recommendation, we reviewed documents HHS provided and spoke with the agency about its recent, related efforts.

We conducted the work on which this statement is based 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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## Background

Research has shown that MAT for opioid use disorder reduces opioid use and increases treatment retention compared to abstinence-based treatment (where patients are treated without medication). MAT combines behavioral therapy and the use of certain medications (methadone, buprenorphine, and naltrexone). Methadone and buprenorphine suppress

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<sup>5</sup>21 U.S.C. § 1702(a)(2).

<sup>6</sup>21 U.S.C. § 1703(b)(2) and 21 U.S.C. § 1703(c)(3)(E).

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withdrawal symptoms and control the craving for opioids, while naltrexone suppresses the euphoric effects of opioids.<sup>7</sup> Treatment can occur as part of federally regulated opioid treatment programs or in other settings, such as health care providers' offices, within certain restrictions. HHS made expanding access to MAT a priority as part of its March 2015 Opioid Initiative, and has continued to do so under its five-point Opioid Strategy, announced in April 2017.<sup>8</sup>

Along with HHS, more than a dozen federal agencies—known as National Drug Control Program agencies—have responsibilities for drug treatment activities, as well as prevention and law enforcement activities.<sup>9</sup> For example, the Department of Justice has a lead role in limiting the availability of illicit drugs through criminal investigations and prosecutions. Since its creation under the Anti-Drug Abuse Act of 1988,<sup>10</sup> ONDCP has been responsible for (1) leading the national drug control effort, (2) coordinating and overseeing the implementation of national drug control policy, (3) assessing and certifying the adequacy of National Drug Control

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<sup>7</sup>Methadone and buprenorphine suppress withdrawal symptoms in detoxification therapy and control the craving for opioids in maintenance therapy. Both drugs are opioids that activate opioid receptors and carry risks of misuse. Both drugs can also be prescribed for pain. Naltrexone is used for relapse prevention because it suppresses the euphoric effects of opioids, and it carries no known risk of misuse.

<sup>8</sup>The Opioid Strategy's five priority areas are: (1) strengthening public health surveillance, (2) advancing the practice of pain management, (3) improving access to treatment and recovery services, (4) targeting the availability and distribution of overdose-reversing drugs, and (5) supporting cutting edge research.

<sup>9</sup>Currently under 21 U.S.C. § 1701(11), "the term 'National Drug Control Program Agency' means any agency (or bureau, office, independent agency, board, division, commission, subdivision, unit, or other component thereof) that is responsible for implementing any aspect of the National Drug Control Strategy, including any agency that receives Federal funds to implement any aspect of the National Drug Control Strategy, but does not include any agency that receives funds for drug control activity solely under the National Intelligence Program or the Joint Military Intelligence Program." In addition to ONDCP, these agencies include the departments of Agriculture, Defense, Education, Health and Human Services, Homeland Security, Housing and Urban Development, Interior, Justice, Labor, State, Transportation, Treasury, and Veterans Affairs, as well as the Court Services and Offender Supervision Agency for the District of Columbia, and the Federal Judiciary.

<sup>10</sup>Pub. L. No. 100-690, 102 Stat. 4181.

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Programs and the budget for those programs, and (4) evaluating the effectiveness of national drug control policy efforts.<sup>11</sup>

Under the October 2018 Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (the SUPPORT Act) and the previous ONDCP Reauthorization Act of 2006, the Director of ONDCP is required to promulgate the National Drug Control Strategy and work with National Drug Control Program agencies to develop an annual National Drug Control Program Budget.<sup>12</sup> ONDCP did not issue a National Drug Control Strategy for 2017 or 2018 despite the statutory requirement.<sup>13</sup> Under the SUPPORT Act and the ONDCP Reauthorization Act of 2006, the National Drug Control Strategy is to set forth a comprehensive plan to reduce illicit drug use and the consequences of such illicit drug use in the United States by limiting the availability of and reducing the demand for illegal drugs.<sup>14</sup> On January 31, 2019, ONDCP issued the 2019 National Drug Control Strategy.

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<sup>11</sup>21 U.S.C. § 1702(a). See also, 21 U.S.C. § 1702(a) (2017).

<sup>12</sup>21 U.S.C. § 1703(b)(2) and (c)(2). See also, 21 U.S.C. § 1703(b)(2) and (c)(2) (2017).

<sup>13</sup>Prior to ONDCP's 2018 reauthorization, ONDCP had most recently been reauthorized by the ONDCP Reauthorization Act of 2006, Pub. L. No. 109-469, 120 Stat. 3502, through fiscal year 2010. The ONDCP Reauthorization Act of 2006 "repealed" the provisions related to ONDCP effective September 30, 2010. However, ONDCP continued to operate under the provisions of that Act pursuant to its annual appropriations acts. See e.g., Consolidated Appropriations Act, 2017, Pub. L. No. 115-31, 131 Stat. 135, 340-41 (2017), Consolidated Appropriations Act, 2018, Pub. L. No. 115-141, 132 Stat. 348, 548-50 (2018).

<sup>14</sup>21 U.S.C. § 1705(b). See also, 21 U.S.C. § 1705(a)(1) (2017).

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## Factors that Can Affect Access to Opioid Use Disorder Treatment and Federal Efforts to Measure Expansion

In our September 2016 report, we identified key factors that can affect access to MAT for opioid use disorder.<sup>15</sup> These included:

- **Laws and Regulations:** Two MAT medications—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 use disorder.<sup>16</sup> For example, methadone is classified as a drug with a higher risk of abuse than buprenorphine and may generally only be administered or dispensed within an opioid treatment program. Buprenorphine may be administered or dispensed within an opioid treatment program and may also be prescribed by a qualifying practitioner who has received a waiver from HHS. The waivers place a limit on the number of patients a qualifying practitioner may treat for opioid use disorder.
- **Availability of qualified practitioners and their capacity to meet patient demand:** Qualified practitioners were lacking in certain locations, and some practitioners may have been operating at full capacity, leading to wait lists that can affect patients' access.
- **Perceptions of MAT and its value among patients, practitioners, and institutions:** Perceived stigma about the use of MAT—especially methadone—among patients could make them reluctant to seek treatment, subsequently leading to social isolation and undermining the chances of long-term recovery. In addition, some practitioners did not believe, despite evidence, that MAT is more effective than treatment without medication, and there were concerns that the medications would be misused.
- **Availability and limits of insurance coverage for MAT:** Patients with no insurance coverage for MAT could face prohibitive out-of-pocket costs that could limit their access to it, and coverage for MAT varied for those individuals with insurance. Insurance plans, including state Medicaid plans, did not always cover all the medications, and they sometimes imposed limits on the length of treatment.

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<sup>15</sup>[GAO-16-833](#).

<sup>16</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. 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.).

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In our October 2017 report, we found that HHS had implemented five key efforts to expand access to MAT for opioid use disorder but had not established performance measures with targets that would specify the results it hoped to achieve, and by when.<sup>17</sup> These five key efforts included four grant programs that focus on expanding access to MAT in various settings, including rural primary care practices and health centers. The fifth key effort was implementation of regulatory and statutory changes that expanded treatment capacity by increasing patient limits for a MAT medication—buprenorphine—and expanded the types of practitioners who can prescribe it in an office-based setting. We concluded that without performance measures and associated targets, HHS would not have an effective means to determine whether its efforts are helping to expand access to MAT or whether new approaches are needed.<sup>18</sup>

Among other things, we recommended in 2017 that HHS establish performance measures with targets related to expanding access to MAT for opioid use disorder. HHS concurred with the recommendation and in February 2019, provided information that the agency had established performance measures with targets to increase the number of prescriptions for certain MAT medications—one of the potential ways to measure access to MAT. However, the recommendation has not yet been fully addressed because these performance measures do not address the treatment capacity of providers who prescribe or administer MAT medications, which HHS had identified as another way to measure access. Measuring treatment capacity would help determine whether a sufficient number of providers are becoming available to evaluate and treat patients who may benefit from MAT. Fully implementing this recommendation will help ensure that invested resources in the program are yielding intended results.

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<sup>17</sup>[GAO-18-44](#).

<sup>18</sup>As we reported in [GAO-18-44](#), gauging this progress was particularly important given the large nationwide gap between the total number of individuals who could benefit from MAT and the limited number who could access it based on provider availability at the time of this report.



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## Ongoing Review of ONDCP Strategies and Programs

In March 2019, we testified before this committee about our ongoing work related to ONDCP's strategies and programs.<sup>19</sup> According to ONDCP, the 2019 National Drug Control Strategy provides a high-level vision of federal drug control efforts by focusing on prevention, treatment and recovery, and reducing the availability of illicit drugs. We testified that the 2019 National Drug Control Strategy designates one overarching objective to reduce the number of lives lost to drug addiction, and provides some description of federal agencies' activities, including steps to reduce the availability of illicit drugs. We also testified on our preliminary observation that the 2019 National Drug Control Strategy does not include certain information required by law, such as annual objectives that are quantifiable and measurable.

For example, the 2019 National Drug Control Strategy encourages the use of evidence-based approaches to treatment and making MAT a standard of care for opioid addiction, which is consistent with HHS's efforts to expand access to MAT. Further, it lists some items that it designates as measures of performance or effectiveness related to MAT. One of the measures of effectiveness is that evidence-based addiction treatment (particularly MAT for opioid addiction), is more accessible nationwide for those who need it. However, the 2019 National Drug Control Strategy lacks information on the current level of treatment access or any associated timeline by which ONDCP hopes to achieve desired results. As we previously testified, none of the measures has a baseline of current performance or annual targets, and four of the seven measures do not have associated timelines—which are important ways that results could be quantified. As we noted in March, annual objectives that are quantifiable and measurable could help prioritize activities across federal agencies and measure progress over time, which previous GAO work has shown to be important for achieving results.

As our prior work shows, using data—such as information collected by performance measures and findings from program evaluations and research studies—to drive decision-making can help federal agencies improve program implementation, identify and correct problems, and

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<sup>19</sup>GAO, *Drug Policy: Preliminary Observations on the 2019 National Drug Control Strategy*, [GAO-19-370T](#) (Washington, D.C.: Mar. 7, 2019).

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make other management decisions.<sup>20</sup> Although our work continues to show that agencies struggle to effectively use this approach, it has also found that regular performance reviews and evidence-based policy tools can help them incorporate performance information into federal decision-making. Without specific measures to track performance, federal agencies cannot fully assess whether taxpayer dollars are invested in ways that will achieve desired outcomes.

We are continuing our ongoing examination of ONDCP's strategies and programs, which will help us further assess ONDCP's coordination of federal drug control policy and the degree to which it is meeting statutory requirements. Specifically, we will provide additional information and analysis on:

1. the extent to which ONDCP met requirements to develop a National Drug Control Strategy in 2017, 2018, and 2019, and what challenges, if any, ONDCP reports as having affected its ability to do so;
2. the extent to which ONDCP had processes and procedures in 2017 and 2018 to oversee and coordinate select aspects of national drug control policy and what changes, if any, ONDCP reports due to the issuance of the 2019 National Drug Control Strategy; and
3. the requirements that ONDCP's 2018 reauthorizing statute imposed and the steps the agency is taking to meet these requirements.

We are continuing to assess documentation and interview officials from ONDCP. For example, we are in the process of reviewing statutory requirements for the development of the National Drug Control Strategy as well as the requirements of ONDCP's 2018 reauthorizing statute. We plan to review any processes and procedures that ONDCP followed as it conducted its work and implemented interagency collaborative efforts, and interview ONDCP officials to understand their planned approach for meeting its requirements. As part of this work, we are meeting with other

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<sup>20</sup>For example, see GAO, *Managing for Results: Government-wide Actions Needed to Improve Agencies' Use of Performance Information in Decision Making*, [GAO-18-609SP](#) (Washington, D.C.: Sep. 5, 2018). In addition, the Government Performance and Results Act of 1993 (GPRA), Pub. L. No. 103-62, 107 Stat. 285, sets out the performance planning and reporting framework. The GPRA Modernization Act of 2010, Pub. L. No. 111-352, 124 Stat. 3866 (2011), enhanced GPRA by providing important tools that can help decision makers address challenges facing the federal government, help resolve longstanding performance and management problems, and provide greater accountability for results.

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national drug control program agencies, such as HHS and the Department of Justice, as well as the Office of Management and Budget, to obtain their perspectives on ONDCP's oversight and coordination of national drug control policy in 2017 and 2018. We plan to publish the results of our study by the end of this calendar year.

ONDCP's responsibility to develop the National Drug Control Strategy and coordinate among federal agencies offers the agency an important opportunity to guide federal activities to address the unprecedented number of drug overdose deaths. As such, we will continue to assess ONDCP's efforts and make recommendations as warranted. Findings from our ongoing review of ONDCP's efforts will also help to inform our continuing body of work on the sufficiency of federal efforts to prevent drug misuse, including work on treatment for opioid use disorder.

Chairman Cummings, Ranking Member Jordan, and Members of the Committee, this concludes our prepared statement. We would be happy to respond to any questions you may have at this time.

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## GAO Contact and Staff Acknowledgments

If you or your staff has any questions concerning this testimony, please contact Triana D. McNeil at (202) 512-8777 ([McNeilT@gao.gov](mailto:McNeilT@gao.gov)) or Mary E. Denigan-Macauley at (202) 512-7114 ([DeniganMacauleyM@gao.gov](mailto:DeniganMacauleyM@gao.gov)). Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. Individuals who made key contributions to this testimony include Joy Booth, Will Simerl, Michelle Loutoo Wilson, Billy Commons, Wendy Dye, Jane Eyre, Kaitlin Farquharson, Natalie Herzog, and Jan Montgomery. Key contributors to the prior work discussed in this testimony are listed in each respective product.

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# Related GAO Products

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*Drug Policy: Preliminary Observations on the 2019 National Drug Control Strategy.* [GAO-19-370T](#). Washington, D.C.: March 7, 2019.

*Opioid Crisis: Status of Public Health Emergency Authorities.* [GAO-18-685R](#). Washington, D.C.: September 26, 2018.

*Prescription Opioids: Medicare Needs Better Information to Reduce the Risk of Harm to Beneficiaries.* [GAO-18-585T](#). Washington, D.C.: May 29, 2018.

*VA Health Care: Progress Made Towards Improving Opioid Safety, but Further Efforts to Assess Progress and Reduce Risk Are Needed.* [GAO-18-380](#). Washington, D.C.: May 29, 2018.

*Illicit Opioids: Office of National Drug Control Policy and Other Agencies Need to Better Assess Strategic Efforts.* [GAO-18-569T](#). Washington, D.C.: May 17, 2018.

*Illicit Opioids: While Greater Attention Given to Combating Synthetic Opioids, Agencies Need to Better Assess their Efforts.* [GAO-18-205](#). Washington, D.C.: March 29, 2018.

*Opioid Use Disorders: HHS Needs Measures to Assess the Effectiveness of Efforts to Expand Access to Medication-Assisted Treatment.* [GAO-18-44](#). Washington, D.C.: October 31, 2017.

*Preventing Drug Abuse: Low Participation by Pharmacies and Other Entities as Voluntary Collectors of Unused Prescription Drugs.* [GAO-18-25](#). Washington, D.C.: October 12, 2017.

*Prescription Opioids: Medicare Needs to Expand Oversight Efforts to Reduce the Risk of Harm.* [GAO-18-15](#). Washington, D.C.: October 6, 2017.

*Newborn Health: Federal Action Needed to Address Neonatal Abstinence Syndrome.* [GAO-18-32](#). Washington, D.C.: October 4, 2017.

*Drug Control Policy: Information on Status of Federal Efforts and Key Issues for Preventing Illicit Drug Use.* [GAO-17-766T](#). Washington, D.C.: July 26, 2017.

*Medicaid Expansion: Behavioral Health Treatment Use in Selected States in 2014.* [GAO-17-529](#). Washington, D.C.: June 22, 2017.

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*Highlights of a Forum: Preventing Illicit Drug Use.* [GAO-17-146SP](#). Washington, D.C.: November 14, 2016.

*Opioid Addiction: Laws, Regulations, and Other Factors Can Affect Medication-Assisted Treatment Access.* [GAO-16-833](#). Washington, D.C.: September 27, 2016.

*Behavioral Health: Options for Low-Income Adults to Receive Treatment in Selected States.* [GAO-15-449](#). Washington, D.C.: June 19, 2015.

*Office of National Drug Control Policy: Office Could Better Identify Opportunities to Increase Program Coordination.* [GAO-13-333](#). Washington, D.C.: March 26, 2013.

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