



October 2017

OPIOID USE DISORDERS

HHS Needs Measures to Assess the Effectiveness of Efforts to Expand Access to Medication- Assisted Treatment

Accessible Version

GAO Highlights

Highlights of [GAO-18-44](#), a report to the Majority Leader, U.S. Senate

Why GAO Did This Study

The misuse of prescription opioid pain relievers and illicit opioids, such as heroin, has contributed to increases in overdose deaths. According to the most recent Centers for Disease Control and Prevention data, in 2015 over 52,000 people died of drug overdose deaths, and about 63 percent of them involved an opioid. For those who are addicted to or misuse opioids, MAT has been shown to be an effective treatment.

GAO was asked to review HHS and other efforts related to MAT for opioid use disorders. This report (1) describes HHS's key efforts to expand access to MAT, (2) examines HHS's evaluation, if any, of its efforts to expand access to MAT, and (3) describes efforts by selected stakeholders (states, private health insurers, and national associations) to expand access to MAT. GAO gathered information from HHS officials as well as a non-generalizable selection of 15 stakeholders selected based on their MAT expansion activities, among other factors. GAO also assessed HHS's evaluation plans using internal control standards for defining objectives and evaluating results.

What GAO Recommends

GAO recommends that HHS take two actions: (1) establish performance measures with targets related to expanding access to MAT, and (2) establish timeframes for its evaluation of its efforts to expand access to MAT. HHS concurred with both recommendations.

View [GAO-18-44](#). For more information, contact Elizabeth H. Curda at (202) 512-7114 or curdae@gao.gov.

October 2017

OPIOID USE DISORDERS

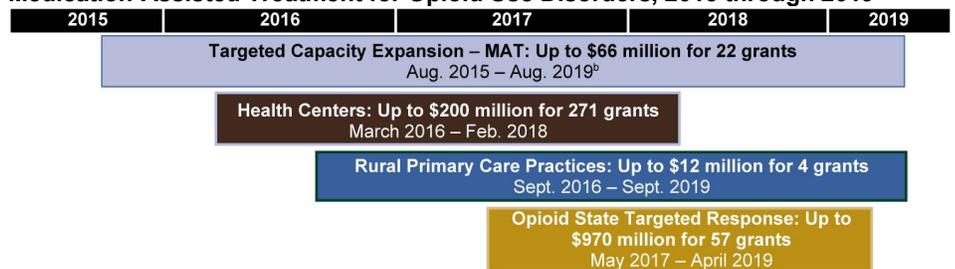
HHS Needs Measures to Assess the Effectiveness of Efforts to Expand Access to Medication-Assisted Treatment

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) established a goal to expand access to medication-assisted treatment (MAT). MAT is an approach that combines behavioral therapy and the use of certain medications, such as methadone and buprenorphine. HHS has implemented five key efforts since 2015 that focus on expanding access to MAT for opioid use disorders—four grant programs that focus on expanding access to MAT in various settings (including rural primary care practices and health centers) and regulatory changes that expand treatment capacity by increasing patient limits for buprenorphine prescribers and allowing nurse practitioners and physician assistants to prescribe buprenorphine.

Some of the grant awards were made in 2015, while others were made as recently as May 2017. (See figure.) As of August 2017, efforts under all the grant programs were ongoing. Grant recipients can use funding to undertake a range of activities, such as hiring and training providers and supporting treatments involving MAT. In addition, certain providers and grant recipients are required to develop plans for preventing MAT medications from being diverted for nonmedical purposes.

Figure: Implementation Timeframes of HHS Grants for Expanding Access to Medication-Assisted Treatment for Opioid Use Disorders, 2015 through 2019^a



Source: GAO analyses of HHS grant information. | GAO-18-44

^aThese grants were awarded between August 2015 and May 2017.

^bThere are two sets of these grants. The first cohort of 11 grants is for 2015 through 2018 and the second cohort of 11 grants is for 2016 through 2019.

HHS officials told GAO that as of August 2017, the department was in the process of finalizing its plans to evaluate its efforts to address the opioid epidemic. In September 2016, HHS awarded a contract to conduct the evaluation. HHS officials told GAO that they are still working with the contractor to finalize the evaluation approach and that it will focus on whether HHS's efforts to address the opioid epidemic have been implemented as intended. HHS officials said that in the future, HHS may also evaluate whether, or to what extent, its efforts have been effective in expanding access to MAT, in addition to evaluating implementation.

While HHS has some of the information that could be used in a future evaluation of the effectiveness of its efforts to expand access to MAT, it has not adopted specific performance measures with targets specifying the magnitude of the increases HHS hopes to achieve through its efforts to expand access to MAT, and by when. For example, HHS has not established a long-term target specifying the percentage increase in the number of prescriptions for buprenorphine HHS would like to achieve, which would help to show whether efforts by HHS and others are resulting in a sufficient number of prescriptions for MAT medications. HHS has also not chosen a specific method of measuring treatment capacity or established targets associated with it, which would help determine whether a sufficient number of providers are becoming available to evaluate and treat patients who may benefit from MAT.

Without specifying these performance measures and associated targets, HHS will not have an effective means to determine whether its efforts are helping to expand access to MAT or whether new approaches are needed. Gauging this progress is particularly important given the large gap identified nationwide between the total number of individuals who could benefit from MAT and the limited number who can currently access it based on provider availability.

In addition, GAO also found that as of August 2017, HHS had not finalized its approach for its planned evaluation activities, including timeframes. Without timeframes for the evaluation's activities, HHS increases the risk that the evaluation will not be completed as expeditiously as possible.

In addition to HHS efforts to expand access to MAT, officials from selected states, private health insurers, and national associations reported using several efforts to expand patients' access to MAT for opioid use disorders. For example, several stakeholders provided GAO with the following examples of their efforts:

- **States.** State health officials from all five selected states have implemented or are planning approaches that focus on integrating the use of MAT into primary care, such as by providing services for centralized intake and initial management of patients or through telehealth that connects patients in rural areas with addiction specialists in a different location.
- **Private health insurers.** Three private health insurers reported removing prior authorization requirements for MAT medications so patients can avoid a waiting period before receiving the medications.
- **National associations.** Officials told GAO that they are conducting outreach and training for their members and developing tools and resource guides. For example, one association developed a road map with strategies that state policymakers can use to address the opioid epidemic, including strategies for reducing the stigma associated with MAT through educating the public and potential providers.

Contents

Letter		1
	Background	5
	HHS Uses Grant Programs and Other Efforts to Expand Access to MAT for Opioid Use Disorders	8
	HHS is Finalizing Its Approach for Evaluating MAT Expansion Efforts but Lacks Performance Measures with Targets and Implementation Timeframes	14
	Selected Stakeholders Reported Using Outreach, Training, and Other Efforts to Help Expand Access to Medication-Assisted Treatment for Opioid Use Disorders	19
	Conclusions	22
	Recommendations for Executive Action	22
	Agency Comments	23
<hr/>		
Appendix I: Diversion Plan Requirements for Opioid Treatment Programs and Practitioners Who Prescribe Buprenorphine		25
Appendix II: Comments from the Department of Health and Human Services		28
Appendix III: GAO Contact and Staff Acknowledgments		32
Appendix IV: Accessible Data		32
	Agency Comment Letter	32
<hr/>		
Table		
	Table 1: Factors for Measuring Access to Medication-Assisted Treatment (MAT) for Opioid Use Disorders and Related Data Sources	17
<hr/>		
Figure		
	Figure 1: Implementation Timeframes of HHS Grants for Expanding Access to Medication-Assisted Treatment for Opioid Use Disorders, 2015 through 2019 ^a	11

Abbreviations

AHRQ	Agency for Healthcare Research and Quality
APG	agency priority goal
ASPE	Assistant Secretary for Planning and Evaluation
CARA	Comprehensive Addiction and Recovery Act of 2016
CSA	Controlled Substances Act
DATA 2000	Drug Addiction Treatment Act of 2000
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
HRSA	Health Resources and Services Administration
MAT	medication-assisted treatment
Opioid STR	State Targeted Response to the Opioid Crisis Grants
OTP	opioid treatment program
PDMP	prescription drug monitoring program
RTI	Research Triangle Institute International
SAMHSA	Substance Abuse and Mental Health Services Administration

This is a work of the U.S. government and is not subject to copyright protection in the United States. The published product may be reproduced and distributed in its entirety without further permission from GAO. However, because this work may contain copyrighted images or other material, permission from the copyright holder may be necessary if you wish to reproduce this material separately.



October 31, 2017

The Honorable Mitch McConnell
Majority Leader
United States Senate
Dear Senator McConnell:

The misuse of and addiction to prescription opioid pain relievers and illicit opioids, such as heroin, contributes to significant morbidity and mortality in the United States. Substance Abuse and Mental Health Services Administration (SAMHSA) data show that in 2014 almost 2.3 million people aged 12 years and older misused or were dependent on opioids, up from almost 1.7 million in 2005. According to the most recent Centers for Disease Control and Prevention data, in 2015 there were over 52,000 drug overdose deaths in the United States, and about 63 percent of these deaths involved an opioid.¹

For those who misuse or are addicted to opioids—a condition known as opioid use disorder—research shows that medication-assisted treatment (MAT)² is an effective treatment. MAT—which combines behavioral therapy and the use of certain medications (methadone, buprenorphine, and naltrexone)—has been shown to reduce opioid use and to increase treatment retention compared with other treatments.³ Treatment can occur as part of federally regulated opioid treatment programs (OTP) or in other settings, such as office-based settings, within certain restrictions.⁴

¹Centers for Disease Control and Prevention, “Increases in Drug and Opioid-Involved Overdose Deaths – United States, 2010-2015.” *Morbidity and Mortality Weekly Report*, vol. 65, no. 50-51 (December 30, 2016): 1445-1452.

²The term “MAT” can be used to refer to treatment for a number of different substance abuse disorders. For the purposes of this report, we use the term to refer to MAT for opioid use disorders, unless specified otherwise.

³Methadone 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.

⁴The 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.

While MAT has been shown to be effective, several reports have also highlighted that accessing MAT services may be challenging for many. For example, in a 2016 report we identified several factors that affect access to MAT, including lack of insurance coverage and an insufficient number of existing treatment programs or practicing physicians offering MAT.⁵ Similarly, a 2016 Surgeon General's report on Alcohol, Drugs, and Health noted barriers to accessing treatment, such as the cost of care and challenges accessing providers who offer treatment services.⁶ In part because of these challenges, it is likely that only a portion of the individuals who need MAT are receiving it. The 2016 Surgeon General's report and a 2015 study on MAT treatment capacity have both highlighted this "treatment gap." The 2015 study, for instance, found that the availability of MAT has not kept pace with the incidence of opioid use disorders in the United States, as more are in need of the treatment than can currently access it—a treatment gap estimated to be nearly 1 million people in 2012.⁷

In March 2015, the Department of Health and Human Services (HHS) established the HHS Opioid Initiative, which aimed to decrease (1) opioid overdoses and overall overdose mortality, and (2) the prevalence of opioid use disorders. Led by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) in coordination with the Immediate Office of the Secretary, the HHS Opioid Initiative had three priorities related to opioid use disorders, one of which was to expand access to MAT.⁸ Although the HHS Opioid Initiative ended in January 2017, HHS activities related to improving access to treatment for opioid use disorders have continued under the new administration's five-point Opioid Strategy,

⁵For more information, see GAO, *Opioid Addiction: Laws, Regulations, and Other Factors Can Affect Medication-Assisted Treatment Access*, [GAO-16-833](#) (Washington, D.C.: September 27, 2016).

⁶Department of Health and Human Services (HHS), Office of the Surgeon General, *Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health*. Washington, D.C.: HHS, November 2016.

⁷Jones et al., "National and State Treatment Need and Capacity for Opioid Agonist Medication-Assisted Treatment" *American Journal of Public Health* vol. 105, no. 8 (2015).

⁸The other two priority areas were to (1) provide training and educational resources, including updated prescriber guidelines, to assist health professionals in making informed prescribing decisions involving opioids, and (2) increase the use of naloxone, which is a medication that reduces opioid and heroin overdose deaths.

which was announced in April 2017.⁹ Several agencies within HHS, such as SAMHSA and the Health Resources and Services Administration (HRSA), are overseeing various efforts to expand access to MAT, with ASPE responsible for leading efforts to collectively evaluate the results of these efforts.

You requested that we provide information on HHS and other efforts to expand access to MAT for opioid use disorders. In this report, we

1. describe HHS's key efforts to expand access to MAT;
2. examine HHS's evaluation, if any, of its key efforts to expand access to MAT; and
3. describe efforts by selected stakeholders (states, private health insurers, and national associations) to expand access to MAT.

To describe HHS's key efforts to expand access to MAT, we reviewed HHS documents that describe the HHS Opioid Initiative and the activities associated with it, such as HHS press releases, the ASPE Issue Brief on the Opioid Initiative, and HHS funding announcements for grants to expand access to MAT. We also reviewed HHS's April 2017 announcement of the Opioid Strategy, as well as relevant federal laws and regulations relating to MAT. In addition, we interviewed officials at relevant federal agencies, such as ASPE, SAMHSA, HRSA, the Agency for Healthcare Research and Quality (AHRQ), and the Food and Drug Administration (FDA) with knowledge of MAT expansion efforts within HHS.¹⁰ We specifically asked the officials to identify their key efforts to expand access to MAT and to confirm the key efforts that we identified independently through our document reviews. Our review focused on those efforts implemented from fiscal year 2015 through August 2017. We also inquired about the extent to which diversion control plans—procedures that reduce the possibility that controlled substances will be transferred or used illicitly—are included in HHS's efforts to expand access to MAT, and we reviewed relevant documents.

⁹The 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.

¹⁰ASPE coordinates with several agencies across HHS that manage efforts to expand access to MAT.

To examine any HHS evaluation of its key efforts to expand access to MAT, we reviewed relevant documentation that describes HHS's evaluation plans to assess MAT expansion efforts. These documents included a 2016 report by Mathematica Policy Research that describes a proposed evaluation approach developed under contract with HHS and the solicitation for a contractor to conduct the evaluation. We assessed these plans using criteria for defining objectives and evaluating results in federal internal control standards.¹¹ We also interviewed ASPE officials about their evaluation approach and the status of the evaluation.

To describe efforts by selected stakeholders to expand access to MAT, we first identified relevant stakeholder organizations that represent states, private health insurance plans, and national associations. Through our interviews with HHS officials, background interviews with officials from organizations, such as the America's Health Insurance Plans and Blue Cross Blue Shield Association, and background research, we identified a non-generalizable selection of 15 stakeholders in the following groups—states, private health insurance plans, and national associations—to obtain information about their efforts to expand access to MAT. Specifically, we gathered information from officials at (1) state health departments and behavioral health services agencies in five states: Rhode Island, Maryland, Washington, West Virginia, and Indiana; (2) seven private health insurance plans; and (3) three national associations that represent providers, government officials, and public health officials: the American Society of Addiction Medicine, the National Governors Association, and the Association of State and Territorial Health Officials. In addition to identifying and selecting stakeholders with efforts to expand access to MAT for opioid use disorder based on background interviews and research, we considered (1) geographic diversity and Centers for Disease Control and Prevention data on states with high opioid death rates when selecting the five states; and (2) health insurers with large market share when selecting the seven private health insurers.¹² We also

¹¹Internal control is a process effected by an entity's oversight body, management, and other personnel that provides reasonable assurance that the objectives of an entity will be achieved. See GAO, *Standards for Control in the Federal Government*, [GAO-14-704G](#) (Washington, D.C.: Sept. 2014).

¹²Centers for Disease Control and Prevention, *Drug Overdose Death Data, US 2015*, accessed February 7, 2017, <https://www.cdc.gov/drugoverdose/data/statedeaths.html> and National Association of Insurance Commissioners "2014 Market Share Reports – For the Top 125 Accident and Health Insurance Groups and Companies by State and Countrywide." June 16, 2015.

asked several stakeholders about their views on the diversion of MAT medications as part of their efforts to expand access to MAT, and we reviewed relevant documents.

We conducted this performance audit from October 2016 to October 2017 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.

Background

Health care practitioners prescribe opioid medications to treat pain and sometimes for other health problems, such as severe coughing. 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. Opioids slow down some processes of the body, such as breathing and heartbeat, by binding with certain receptors in the body.

Opioid Use Disorders and MAT

Over time, the body becomes tolerant to opioids, which means that larger doses of opioid medications are needed to achieve the same effect. People may use opioids in a manner other than as prescribed—that is, they can be misused. Because opioids are highly addictive substances, they can pose serious risks when they are misused, which can lead to addiction and death. Symptoms of an opioid use disorder include a strong desire for opioids, the inability to control or reduce use, and continued use despite interference with major obligations or social functioning. Another concern associated with prescribed opioids is the potential for diversion for illegal purposes, such as nonmedical use or financial gain.¹³

Research has shown that MAT—which combines behavioral therapy and the use of certain medications (methadone, buprenorphine, and naltrexone)—can be more effective in reducing opioid use and increasing

¹³Diversion can include selling prescription drugs that were obtained legally, transferring a legitimately prescribed opioid to family or friends who may be trying to self-medicate, or pretending to be in pain to obtain a prescription opioid because of an addiction.

retention (i.e., reducing dropouts) compared to abstinence based treatment—that is when patients are treated without medication. Three medications are currently approved by FDA for use in MAT for opioid use disorders—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 cravings. It has a long history of use for the treatment of opioid dependence in adults. Methadone suppresses withdrawal symptoms during detoxification therapy, which involves stabilizing patients who are addicted to opioids by withdrawing them in a controlled manner. Methadone also controls the craving for opioids during maintenance therapy, which is ongoing therapy meant to prevent relapse and increase treatment retention. Methadone can be administered to patients as an oral solution or in tablet form.
- **Buprenorphine:** Buprenorphine is a partial opioid agonist, meaning it binds to opioid receptors and activates them, but not to the same degree as full opioid agonists. It reduces or eliminates opioid withdrawal symptoms, including drug cravings. It can be used for detoxification treatment and maintenance therapy. It is available for MAT for opioid use disorder in tablet form for sublingual (under the tongue) administration, in film form for sublingual or buccal (inside the cheek) administration, and as a subdermal (under the skin) implant.¹⁴
- **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. It also results in withdrawal symptoms if recent opioid use has occurred. It can be taken daily in an oral tablet form or as a once-monthly injection given in a doctor's office.

¹⁴Some tablets and films also include naloxone. 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.

Authorized Settings for MAT Medications

Two of the three medications used to treat opioid use disorders—methadone and buprenorphine—are drugs that carry a potential for misuse. Under the Controlled Substances Act (CSA), treatment involving these medications can take place in certain authorized settings: as part of federally regulated OTPs or in other settings, such as a physician’s office, within certain restrictions.¹⁵

- *OTPs.* OTPs provide MAT, including methadone and buprenorphine, for people diagnosed with an opioid use disorder. Methadone may generally only be administered or dispensed within an OTP, as prescriptions for methadone cannot be issued when used for opioid use disorder treatment.¹⁶ Buprenorphine may be administered or dispensed within an OTP, or may also be prescribed by a qualifying practitioner who has received a waiver from SAMHSA.¹⁷ Naltrexone is not a controlled substance and can be used in OTPs and other settings.
- *Office-Based and Other Settings.* Under a Drug Addiction Treatment Act of 2000 (DATA 2000) waiver, practitioners may prescribe buprenorphine to up to 30 patients in the first year of their waiver, 100

¹⁵Enacted 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.). In this report, references to the CSA include any applicable requirements set forth in implementing regulations. See 21 C.F.R. ch. 2 (2017) and 42 C.F.R. pt. 8 (2016). 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.

¹⁶Methadone may be administered outside of an OTP under certain regulatory exceptions. 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.

¹⁷SAMHSA is the agency within HHS that leads public health efforts to advance the behavioral health of the nation. SAMHSA’s mission is to reduce the impact of substance abuse and mental illness on America’s communities.

patients in the second year, and up to 275 patients in the third year.¹⁸ Practitioners at the 275-patient level must meet additional qualifications and requirements. Naltrexone does not have similar restrictions.¹⁹

HHS Uses Grant Programs and Other Efforts to Expand Access to MAT for Opioid Use Disorders

HHS has implemented five key efforts from 2015 through August 2017 that focus on expanding access to MAT for opioid use disorders. Four of these are grant programs, including programs focused on health centers or primary care practices in rural areas.

- **Targeted Capacity Expansion: Medication Assisted Treatment – Prescription Drug and Opioid Addiction (MAT-PDOA).** This grant program is administered by SAMHSA and provides funding to states to increase their capacity to provide MAT and recovery support services to individuals with opioid use disorders.²⁰ Grant recipients are expected to identify a minimum of two high-risk communities within the state and partner with local government or community-based organizations to address the MAT-related treatment needs in these communities. Among other things, recipients are to use outreach and other engagement activities to increase participation in and access to MAT for diverse populations at risk for opioid use disorders. In August 2015, SAMHSA awarded 3-year grants to 11 states, under which each of the states will receive up to \$1 million in each grant year. In September 2016, SAMHSA awarded 11 additional 3-year grants to other states. Total funding is expected to be up to \$66 million for all 22

¹⁸DATA 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.

¹⁹See [GAO-16-833](#) for additional CSA requirements for methadone and buprenorphine when they are used for pain management and opioid treatment.

²⁰Recovery support services are nonclinical services that assist individuals and families working toward recovery from substance use conditions. The services include social supports and services such as child care, employment services, housing, peer coaching, and drug-free social activities.

grants. SAMHSA announced the availability of up to 5 additional 3-year grants for fiscal year 2017. Applications for these grants of up to \$2 million per year were due in July 2017 and as of August 2017 they had not been awarded.

- **Substance Abuse Service Expansion Supplement to Health Centers.** This grant program is administered by HRSA and provides funds for existing health centers to improve and expand their delivery of substance abuse services, including services with a specific focus on MAT for opioid use disorders in underserved populations.²¹ Health centers that receive these grants are required to increase the number of patients with health center-funded access to MAT for opioid use or for other substance abuse disorders treatment by adding at least one full-time substance abuse provider and supporting new or enhanced existing substance abuse services. HRSA awarded 2-year grants in March 2016 to 271 health centers. According to HRSA documents, total funding could be up to \$200 million for all grants over 2 years. HRSA announced the availability of another set of grants to health centers for fiscal year 2017. Applications for these grants were due in July 2017, and as of August 2017 they had not been awarded.²²
- **Increasing Access to Medication-Assisted Treatment in Rural Primary Care Practices.** This grant program is administered by AHRQ and funds demonstration research projects that aim to expand access to MAT for opioid use disorders in primary care practices in rural areas of the United States.²³ Grant recipients are expected to recruit and engage primary care providers and their practices, provide training, and support physicians and their practices in initiating treatment. The program also identifies and tests strategies for

²¹HRSA is the primary federal agency for improving health care to people who are geographically isolated, or economically or medically vulnerable.

²²According to HRSA officials, in September 2017, HRSA plans to award approximately \$195 million to existing health centers to expand access to mental health and substance abuse services focusing on the treatment, prevention, and awareness of opioid abuse through the Access Increases in Mental Health and Substance Abuse Services supplemental funding opportunity. \$100 million of this funding will provide ongoing support for mental health and substance abuse services; the remaining \$95 million will be available as one-time funding for health information technology and/or training investments that support the expansion of these services and their integration into primary care.

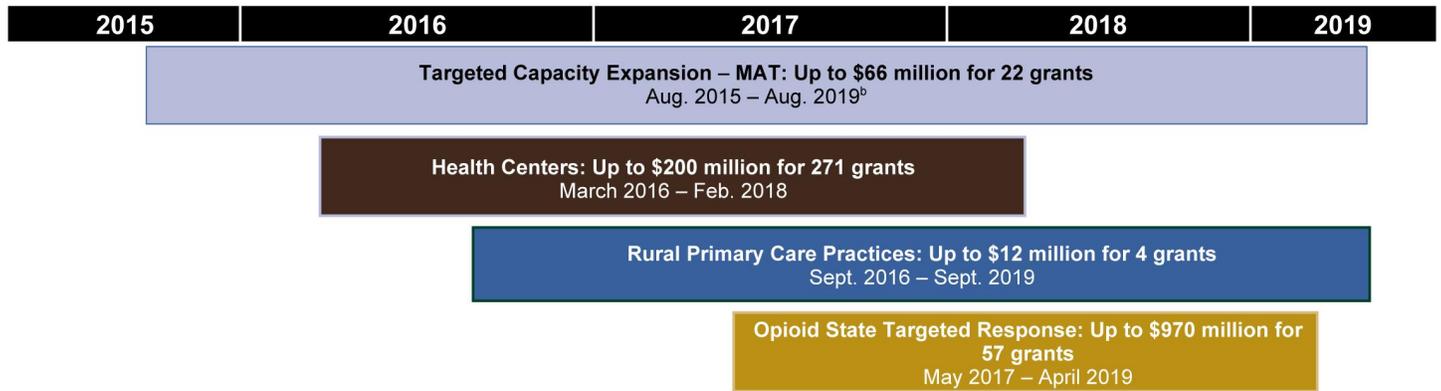
²³AHRQ is the lead federal agency charged with improving the safety and quality of America's health care system. AHRQ develops the knowledge, tools, and data needed to improve the health care system and help Americans, health care professionals, and policymakers make informed health decisions.

overcoming the challenges associated with implementing MAT in primary care settings and creates training and other resources for implementing MAT. AHRQ awarded these 3-year grants of up to \$1 million per year to four recipients—the recipients are teams of state health departments, academic health centers, local community organizations, physicians, and others—with project start dates of September 30, 2016. According to AHRQ documents, total funding is expected to be up to \$12 million for the four grants over 3 years.

- **State Targeted Response to the Opioid Crisis Grants (Opioid STR).** This grant program is administered by SAMHSA and provides funding to states and others to increase access to treatment services for opioid use disorders, including MAT; reduce unmet treatment needs; and reduce opioid overdose deaths. Grant recipients are expected to implement or expand access to evidence-based practices, particularly the use of MAT, and to report on the number of people who receive opioid use disorder treatment, the number of providers implementing MAT, and the number of providers trained to use MAT. SAMHSA awarded 2-year grants starting in May 2017 to 50 states, the District of Columbia, four U.S. territories and the free associated states of Micronesia and Palau. According to SAMHSA documents, total funding could be up to \$970 million for all grants over 2 years.

Figure 1 displays the implementation timeframes, the number of grants, and funding levels for the four HHS grant programs related to MAT. As the figure shows, some of these awards were made in fiscal year 2015, while others were made as recently as May 2017. As of August 2017, these efforts were ongoing.

Figure 1: Implementation Timeframes of HHS Grants for Expanding Access to Medication-Assisted Treatment for Opioid Use Disorders, 2015 through 2019^a



Source: GAO analyses of HHS grant information. | GAO-18-44

^aThese grants were awarded between August 2015 and May 2017.

^bThere are two sets of these grants. The first cohort of 11 grants is for 2015 through 2018 and the second cohort of 11 grants is for 2016 through 2019.

In addition to these four grant programs, HHS’s fifth key effort increases treatment capacity by expanding the waivers that practitioners may receive to prescribe buprenorphine. Specifically, SAMHSA issued a regulation that became effective August 8, 2016 increasing the number of patients that eligible practitioners can treat with buprenorphine outside of an OTP (e.g., in an office-based setting).²⁴ Previously, qualified practitioners could request approval to treat up to 30 patients at a time, and after 1 year the limit could increase to 100 patients at a time upon SAMHSA approval. The new regulation expanded access to MAT by allowing eligible practitioners who have had waivers to prescribe buprenorphine to 100 patients for at least 1 year to request approval to treat up to 275 patients thereafter. Similarly, SAMHSA has implemented provisions of the Comprehensive Addiction and Recovery Act of 2016 (CARA) that expanded the types of practitioners who can receive a waiver to prescribe buprenorphine in an office-based setting to include

²⁴Medication Assisted Treatment for Opioid Use Disorders, 81 Fed. Reg. 44,712 (July 8, 2016) (to be codified at 42 C.F.R. pt. 8). The final rule modified the requirements for 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). The waiver authority and related patients limits do not apply to methadone.

qualifying nurse practitioners and physician assistants.²⁵ CARA generally requires that these nurse practitioners and physician assistants complete 24 hours of training to be eligible for a waiver.²⁶ According to HHS documents, as of early 2017, nurse practitioners and physician assistants who have completed this training could request a waiver from SAMHSA to treat up to 30 patients at a time.

In addition to its five key efforts focused specifically on expanding access to MAT for opioid use disorders, HHS has other efforts with broader focuses, such as treating multiple types of substance abuse. While these efforts are not specifically focused on expanding access to MAT for opioid use disorders, they may result in expanded access to MAT. For example, CMS has approved section 1115 Medicaid demonstration projects to allow states to undertake comprehensive reforms of their delivery of substance abuse services, including provisions to enhance the use of MAT for opioid use disorders.²⁷ In July 2015, CMS issued a state Medicaid Director letter informing states that they may seek approval of section 1115 demonstrations to undertake comprehensive substance use service reforms. According to CMS, all participating states are using the demonstration authority to develop a full continuum of care for individuals with substance abuse disorders, including coverage of short-term residential treatment services not otherwise covered by Medicaid.

In addition, FDA has programs to help expedite development and to provide for faster review of marketing applications for certain drugs.²⁸

²⁵Specifically, CARA amends the CSA to expand the definition of “qualifying practitioner,” for the purposes of waiver eligibility, to include qualifying nurse practitioners and physician assistants from the date of CARA’s enactment until October 1, 2021. See Pub. L. No. 114-198, § 303(a)(1)(C)(v), 130 Stat. 695, 721 (July 22, 2016).

²⁶Alternatively, CARA allows the Secretary of HHS to determine that other training or experience demonstrates the ability of a nurse practitioner or physician assistant to treat and manage opiate-dependent patients. To be eligible for a waiver to prescribe buprenorphine in office-based settings, physicians must complete 8 hours of training.

²⁷Section 1115 of the Social Security Act allows the Secretary of HHS authority to waive certain traditional federal Medicaid requirements and allow costs that would not otherwise be eligible for federal payments for demonstrations that, in the Secretary’s view, are likely to promote Medicaid objectives.

²⁸FDA has four programs intended to facilitate and expedite development and review of certain new drug applications: fast track designation, breakthrough therapy designation, accelerated approval, and priority review designation. For additional information, see FDA’s May 2014 *Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics*.

According to FDA, it has conducted expedited reviews of Suboxone (buprenorphine and naloxone sublingual film), Vivitrol (extended release naltrexone injection) and Probuphine (buprenorphine subdermal implant).²⁹

According to some federal officials and other stakeholders that we interviewed, as part of efforts to expand access to MAT for opioid use disorder, steps are being taken to prevent the possibility that the MAT medications could, in some cases, be diverted for illicit use, misuse, or for purposes not intended by a prescriber. For example, OTPs and practitioners who request and receive a waiver to prescribe buprenorphine to treat up to 275 patients outside of an OTP setting are required under federal regulations to maintain a diversion control plan.³⁰ In addition, the MAT-PDOA grant program explicitly requires grant recipients to implement a diversion control plan, though the other grant programs do not have similar additional requirements. (See appendix I for an overview of the diversion control plan requirements for OTPs and the practitioners who prescribe buprenorphine outside of an OTP.) The 2016 Surgeon General's report on Alcohol, Drugs, and Health noted that decades of research have shown that the benefits of MAT greatly outweigh the risks associated with diversion, and that withholding these medications greatly increases the risk of relapse to illicit opioid use and overdose death.

²⁹In December 2015, we found that FDA review time was an average of 8.6 months for marketing applications for drugs when the agency used at least one expedited program compared with 12.1 months of review time for marketing applications for drugs when FDA did not use an expedited program. See GAO, *Drug Safety: FDA Expedites Many Applications, But Data for Postapproval Oversight Need Improvement*, [GAO-16-192](#) (Washington, D.C.: Dec. 15, 2015).

³⁰42 C.F.R. §§ 8.12(c)(2), 8.620(b)(5) (2016). Physicians who prescribe or dispense buprenorphine outside of an OTP at the 30- and 100-patient limit are not required to have a diversion control plan.

HHS is Finalizing Its Approach for Evaluating MAT Expansion Efforts but Lacks Performance Measures with Targets and Implementation Timeframes

HHS officials told us that as of August 2017, the department is in the process of finalizing its approach for evaluating the implementation of its agencies' collective efforts to address the opioid epidemic that were undertaken as part of the HHS Opioid Initiative and will continue under the new administration's Opioid Strategy. HHS officials provided a draft of the evaluation's schedule. According to the officials, the evaluation will include, but not be limited to, efforts to expand access to MAT. In September 2016, HHS awarded a 2-year contract to Research Triangle Institute International (RTI) to evaluate HHS agencies' collective efforts. HHS officials told us that they are still working with RTI to finalize the evaluation approach given new leadership priorities. Specifically, in April 2017, the new Secretary of HHS announced a revised strategy for addressing the opioid epidemic that will continue to address access to MAT for opioid use disorders but also include additional priority areas.³¹ According to HHS officials, to be responsive to the new priorities, the evaluation will focus initially on whether HHS's efforts have been implemented as intended, and officials expect the evaluation to also provide information on any challenges HHS has faced in implementing these efforts.

According to HHS officials, while the evaluation of MAT expansion efforts will use information from several sources, they have not yet determined exactly which information will be used or how it will be used.³² This information may include, for example, results from a separate, planned

³¹The HHS Secretary outlined a new five-pronged strategy in April 2017 that HHS will implement to fight the opioid epidemic. The 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.

³²In June 2016, Mathematica Policy Research, under contract with HHS, developed a proposed methodological approach for evaluating the implementation and impact of HHS agencies' efforts under the Opioid Initiative, including identification of program evaluations at the agency level that could be incorporated. This proposal also identified various HHS activities to be included in the evaluation, such as HHS's grant programs.

evaluation of one of the grant programs, Opioid STR, as well as other information HHS agencies collect as part of their ongoing monitoring efforts for each of their individual MAT grant programs.³³ While the reporting requirements vary across the four MAT grant programs, the grantees provide HHS with information related to expanding access to MAT. Specifically,

- **Targeted Capacity Expansion: Medication Assisted Treatment – Prescription Drug and Opioid Addiction (MAT-PDOA):** Every 6 months, grant recipients are expected to submit progress reports to SAMHSA on the planned and actual number of patients treated, as well as information on other performance measures.³⁴
- **Increasing Access to Medication-Assisted Treatment in Rural Primary Care Practices:** Grant recipients are expected to submit quarterly progress reports to AHRQ with various information, such as information on the number of physicians who have been certified to prescribe buprenorphine and the number of primary care practices successfully initiating the delivery of MAT services as a result of the grant project.
- **Substance Abuse Service Expansion Supplement to Health Centers:** Health centers that received these grants were expected to submit quarterly progress reports to HRSA through the second quarter of 2017 on the number of physicians who have obtained a DATA 2000 waiver and the number of patients who received MAT from these physicians. Health centers must now report these data elements in their annual performance reporting along with information on the number of certified nurse practitioners and physician assistants who have received a DATA 2000 waiver.
- **State Targeted Response to the Opioid Crisis Grants (Opioid STR):** Every 6 months, grant recipients are expected to submit progress reports to SAMHSA on the number of individuals who receive opioid use disorder treatment, the number who receive opioid

³³According to SAMHSA officials, the agency is planning to award a contract to evaluate the impact of the Opioid STR grant program.

³⁴In addition to the information in the biannual progress reports, according to SAMHSA, it requires grant recipients to submit additional information on a real-time basis, within 7 days of its collection, as part of SAMHSA's obligations under the Government Performance and Results Modernization Act of 2010. This includes information on abstinence from drug use, retention in services, housing status, and other information.

use disorder recovery services, and the number of providers implementing MAT, among other measures.

While HHS's evaluation will focus on whether HHS's efforts have been implemented as intended, officials told us that in the future an evaluation may also focus on the effectiveness of these efforts, including the effectiveness of efforts to expand access to MAT. Doing so would be consistent with federal standards for internal control, which call for agencies to evaluate results.³⁵ HHS has some of the information that could be used in a future evaluation of the effectiveness of its efforts to expand access to MAT. In particular, an HHS document describing the department's fiscal year 2016 – 2017 goals identifies expanding MAT access as an important strategy for the success of HHS's longer-term goal of reducing opioid use disorders and opioid overdoses. In addition, HHS has identified three potential ways to measure access to MAT:

- the number of prescriptions for MAT medications,³⁶
- the treatment capacity of practitioners who are authorized to prescribe buprenorphine for opioid use disorders through a DATA 2000 waiver, and
- the treatment capacity of OTPs certified to administer methadone and other medications.

In addition, HHS has data that could be useful for tracking progress in these areas (see table 1).

³⁵[GAO-14-704G](#).

³⁶Previously, HHS used a (now retired) performance measure with a target to increase by 10 percent the number of unique patients receiving prescriptions for buprenorphine and naltrexone during fiscal years 2016 and 2017. This performance measure was established as part of the Agency Priority Goal (APG) process, which is led by the Office of Management and Budget. HHS established an APG to reduce opioid-related morbidity and mortality, and one of its corresponding performance measures was to increase the number of unique patients receiving prescriptions for buprenorphine and naltrexone by September 30, 2017. According to HHS officials, the APGs and related measures have been retired and will be replaced after HHS receives guidance from the Office of Management and Budget. However, it is uncertain whether or to what extent the new APGs will include any measures related to MAT.

Table 1: Factors for Measuring Access to Medication-Assisted Treatment (MAT) for Opioid Use Disorders and Related Data Sources

Factor	Data source
The number of prescriptions for MAT medications	The Assistant Secretary of Planning and Evaluation obtains quarterly data from QuintilesIMS on the number of prescriptions for MAT medications. ^a
The treatment capacity of practitioners who are authorized to prescribe buprenorphine for opioid use disorders through a Drug Addiction Treatment Act of 2000 (DATA 2000) waiver	The Substance Abuse and Mental Health Services Administration tracks data on practitioners who can prescribe buprenorphine through a DATA 2000 waiver.
The treatment capacity of opioid treatment programs (OTPs) certified to administer methadone and other medications	The Substance Abuse and Mental Health Services Administration tracks data on OTPs through its National Survey of Substance Abuse Treatment Services. ^b

Source: GAO analysis of HHS data. | GAO-18-44

^aThese data include buprenorphine and naltrexone, but do not include data on methadone, which cannot be prescribed. QuintilesIMS, a merger of IMS Health and Quintiles, is a company that provides health plan claims and prescription data.

^bThe National Survey of Substance Abuse Treatment Services is an annual census of facilities providing substance abuse treatment, including treatment for opioid use disorder. Data are collected throughout the 50 states, the District of Columbia, and other U.S. jurisdictions. The survey collects data on the number of clients in treatment, but does not measure the potential capacity of facilities.

However, HHS has not adopted specific performance measures with targets specifying the magnitude of the increases HHS hopes to achieve through its efforts to expand access to MAT, and by when. For example, HHS has not established a long-term target specifying the percentage increase in the number of prescriptions for buprenorphine HHS would like to achieve, which would help to show whether efforts by HHS and others are resulting in sufficient progress in increasing prescriptions for this MAT medication. HHS has also not chosen a specific method of measuring treatment capacity or established targets associated with it, which would help to show whether a sufficient number of providers are becoming available to evaluate and treat patients who may benefit from MAT.

Without specifying these performance measures and associated targets, HHS will not have an effective means to determine whether its efforts are helping to expand access to MAT. The lack of such performance measures with associated targets is inconsistent with federal internal control standards that specify that management should define objectives and evaluate results.³⁷ According to these standards, using performance information such as performance measures can help agencies monitor results and determine progress in meeting program goals. In the context of HHS's efforts to expand access to MAT, establishing appropriate

³⁷[GAO-14-704G](#).

performance measures with associated targets would allow HHS to determine whether its efforts are making sufficient progress or whether they need to be improved. Gauging this progress is particularly important, given the large nationwide MAT treatment gap identified in 2015 between the total number of individuals who could benefit from MAT and the limited number who can access it based on provider availability. This gap was estimated at nearly 1 million people as of 2012, and according to HHS officials and other stakeholders, lack of providers continues to be a challenge.³⁸ Until HHS establishes performance measures with associated targets for the factors related to access to MAT, the department will be unable to evaluate its progress expanding access to MAT for opioid use disorders.

In addition, as of August 2017, HHS has not finalized its approach for the planned evaluation activities, including timeframes. ASPE officials said that timeframes for a finalized evaluation approach had not been established because they were still working with RTI to finalize the evaluation approach given the new leadership priorities. When we spoke with the officials, they provided us with a draft evaluation schedule that covered the contract period ending September 2018. As of October 2017, HHS had not provided a finalized evaluation approach or schedule. Federal internal controls call for management to establish and operate monitoring activities and evaluate results.³⁹ Without an implementation timeframe for the evaluation's activities, HHS increases the risk that its evaluation of its agencies' efforts will not be completed as expeditiously as possible, including an evaluation of HHS's efforts to expand access to MAT.

³⁸The maximum number of people who could access MAT was approximately 1.4 million in 2012, compared to the 2.3 million people who abused opioids or were dependent upon them. See C. M. Jones et al., "National and State Treatment Need and Capacity for Opioid Agonist Medication-Assisted Treatment" *American Journal of Public Health*, vol. 105, no. 8 (2015).

³⁹[GAO-14-704G](#).

Selected Stakeholders Reported Using Outreach, Training, and Other Efforts to Help Expand Access to Medication-Assisted Treatment for Opioid Use Disorders

Officials from selected state health departments and behavioral health agencies, private health insurers, and national associations reported using several different efforts to help expand patients' access to MAT for opioid use disorders. All of the stakeholders we interviewed reported conducting outreach efforts to communicate information about the importance of MAT and how to access it, or providing training to educate providers on prescribing MAT medications.

Efforts by states. State health officials we spoke to described several planned or ongoing efforts to expand access to MAT, some of which are supported by federal funding, including federal grant programs. Officials from all five selected states told us that they are offering outreach to and training for providers to help expand access to MAT. For example, several state officials told us that they are promoting training to (1) encourage physicians to obtain authorization (DATA 2000 waivers) to prescribe buprenorphine and (2) encourage physicians with waivers to treat patients up to their patient limit or to request a higher patient limit.

According to the stakeholders, all five selected states have implemented or are planning to implement a health care delivery model or approach that will expand access to MAT.⁴⁰ Specifically, these models or approaches focus on integrating the use of MAT into primary care settings. For example, health officials from three states described use of a hub-and-spoke model. This model generally involves centralized intake and initial management of patients at a "hub" (e.g., an OTP) and then connecting these patients to community providers at "spokes" (e.g., primary care clinics) for ongoing care, with ongoing support provided by the hub as needed. Additionally, officials from two states described offering remote MAT-related consultations through telehealth that

⁴⁰For more information that highlights examples of these models and approaches, see D. Korthuis et al., "Primary Care-Based Models for the Treatment of Opioid Use Disorder," *Annals of Internal Medicine*, vol.166, no.4 (2017).

connects patients in rural areas with addiction specialists.⁴¹ According to a 2017 Healthcare Fraud Prevention and Partnership whitepaper, telehealth expands the reach of the addiction professional workforce and the existing pool of MAT providers, and it supports remote forms of behavioral therapy to make trained professionals more accessible to those in underserved or isolated communities.⁴²

Officials from three states described focusing their MAT expansion efforts in various settings, such as in the criminal justice setting and emergency room departments. State health officials from four of the five states told us that programs in their states are using peer specialists (individuals who have successfully recovered from substance abuse disorders) in emergency rooms and other settings to engage with addicted patients and refer them to addiction specialists or behavioral health counselors.⁴³ Officials from the selected states said that some of these and other efforts are funded through federal sources, such as MAT expansion grants awarded by SAMHSA, or with state funds to the extent they are available.

Efforts by private health insurers. Officials from private health insurers reported that they are expanding access to MAT through outreach or training for providers and through the following three efforts:

- *Eliminating the need for prior authorization to prescribe MAT medications.* Officials from three insurers reported removing prior authorization requirements for MAT medications, thereby making it easier for patients to access needed MAT medications more readily, rather than undergoing a waiting period for approval to receive the medications. Other private health insurers told us that they continue to require prior authorization, intended for safety reasons and to reduce drug misuse, and officials from one insurer told us that they will allow a patient to access a limited amount of MAT medications for a period

⁴¹Telehealth services may use two-way video or other telecommunication technologies to enable health consultations between a patient and a physician in different locations. Such services can be particularly useful to address a lack of access in rural areas.

⁴²Healthcare Fraud Prevention Partnership, *Healthcare Payer Strategies to Reduce the Harms of Opioids*, January 2017.

⁴³21st Century Cures Act included a provision for GAO, within 2 years of the law's enactment, to review peer-support specialists programs in up to 10 states that receive funding from SAMHSA. The review is to include a review of best practices related to training and credential requirements for peer-support specialist programs. Pub. L. No. 114-255, § 9026(b), 130 Stat. 1033, 1256 (2016).

of 24 to 72 hours while making a determination about the appropriate treatment services for the patient.⁴⁴

- *Modifying health benefit coverage.* Officials from one private health insurance plan told us that the company is redesigning the benefit coverage for methadone and has removed member copays. This effort is intended to make MAT medications more affordable and allow members who are not able to use buprenorphine to have an alternative, such as methadone, that is not cost-prohibitive.
- *Incentivizing providers and health insurance plan members to use MAT.* Officials from four private health insurance plans described plans to offer incentives to providers or patients to use MAT. For example, officials from three health plans stated that they are offering alternative payment models or paying higher rates to providers that offer MAT, and another private health insurer is offering incentives to its members who are enrolled in behavioral health programs that provide access to MAT.

Efforts by national associations. Officials we interviewed from the national associations—including the American Society of Addiction Medicine, the National Governors Association, and the Association of State and Territorial Health Officials—told us that they are helping to expand access to MAT through outreach and training for their members and by developing tools and resource guides for their members. An official from one association told us that it shares federal grant announcements, including those that are focused on expanding access to MAT, with its members. Officials from another association said it provides training to providers on how to appropriately prescribe MAT medications. In addition, officials from one association told us that they developed an opioid-related road map that identifies examples of strategies—including MAT—that state policymakers can use in their ongoing efforts to address the opioid epidemic. Examples of strategies include reducing the stigma associated with MAT through educating the public and potential providers. Another strategy in the road map is changing payment policies to expand access to MAT services, such as ensuring that Medicaid and other state health programs adequately cover all MAT medications and behavioral interventions and encouraging or requiring commercial health plans to adopt similar policies.

⁴⁴According to an official from the private health insurer, reasons for denial of MAT can include a lack of commitment from the physician to treat the patient, the patient is still on opioids that he or she should not be taking, or the patient has not been diagnosed with an opioid use disorder.

Conclusions

HHS funds grant programs and has taken other steps to expand access to MAT, which has been shown to be effective in reducing the prevalence of opioid use disorders and with them, the likelihood of drug overdoses. HHS's Opioid Initiative began in 2015, and the grants that support it are ongoing, so it is likely too early to determine how effective HHS's efforts have been in expanding access to MAT and in meeting HHS's other priorities related to addressing the opioid epidemic. According to HHS, access to MAT can be measured in terms of the number of prescriptions for MAT and by the treatment capacities of OTPs and practitioners who are authorized to prescribe buprenorphine.

Our review suggests, however, that HHS may not be ready to perform this evaluation. While HHS told us that it may evaluate the effectiveness of its efforts in the future, the department has not established performance measures with targets that would specify the results that HHS hopes to achieve through its efforts, and by when. Furthermore, HHS has not established timeframes for the activities that will make up its planned evaluation of whether HHS's efforts have been implemented as intended. Without performance measures with targets and evaluation timeframes, HHS increases the risk that the evaluation will not be completed in a timely manner or that HHS will not know whether its MAT-related efforts are successful or whether new approaches are needed. The evaluation is particularly important, given the hundreds of millions of dollars HHS has invested in its MAT-related grant programs.

Recommendations for Executive Action

We are making the following two recommendations to HHS.

The Assistant Secretary for Planning and Evaluation should establish performance measures with targets related to expanding access to MAT for opioid use disorders. (Recommendation 1)

The Assistant Secretary for Planning and Evaluation should establish timeframes in its evaluation approach that specify when its evaluation of efforts to expand access to MAT will be implemented and completed. (Recommendation 2)

Agency Comments

We provided a draft of this report to HHS for review, and HHS provided written comments, which are reprinted in appendix II. HHS also provided technical comments, which we incorporated as appropriate. In its written comments, HHS concurred with both of our recommendations. Specifically, for our first recommendation to establish performance measures with targets related to expanding access to MAT for opioid use disorders, HHS stated that developing such measures is appropriate and that the department will continue to work to develop robust performance measures, including measures related to MAT, as part of its overall Opioid Strategy, which includes the department's most recent efforts to address the opioid epidemic. For our second recommendation to establish timeframes in its evaluation approach that specify when its evaluation of efforts to expand access to MAT will be implemented and completed, HHS agreed that timeframes are important to any evaluation. HHS noted that its evaluation is being conducted under a 2-year contract that is scheduled to end in September 2018. HHS has also provided us with a draft evaluation schedule. We clarified in our report, however, that HHS has not yet provided a finalized approach for the planned evaluation or a finalized schedule establishing timeframes for the activities that will make up the evaluation. Until it finalizes its evaluation approach and establishes related timeframes, HHS increases the risk that it will not complete its planned evaluation by September 2018.

We are sending copies of this report to the HHS, and appropriate congressional committees. In addition, the report will be available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staff have questions about this report, please contact me at (202) 512-7114 or 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,



Elizabeth H. Curda

Letter

Director, Health Care

Appendix I: Diversion Plan Requirements for Opioid Treatment Programs and Practitioners Who Prescribe Buprenorphine

According to the Department of Health and Human Services, a diversion control plan is a set of documented procedures intended to reduce the possibility that controlled substances will be transferred or used illicitly. Opioid treatment programs (OTPs) and practitioners who prescribe buprenorphine at the highest patient level through a Drug Addiction Treatment Act of 2000 (DATA 2000) waiver are required to have these plans. OTPs are programs that may administer or dispense medication-assisted treatment (MAT) for people diagnosed with an opioid use disorder, including the use of methadone and buprenorphine. In addition, under a DATA 2000 waiver, practitioners may prescribe buprenorphine for patients, up to a 30-, 100-, or 275 patient limit.

Diversion Control Plan Requirement for OTPs

An OTP must maintain a current diversion control plan that contains specific measures to reduce the possibility of diversion of controlled substances from legitimate treatment use.¹ Per federal guidelines, the goal of the diversion control plan is to reduce the scope and significance of diversion and its impact on communities.² The guidelines state that each OTP's diversion control plan should make every effort to balance diversion control against the therapeutic needs of the individual patient. They also state that diversion control plans should address at least four general areas of concern: program environment, dosing and take-home medication, prevention of multiple program enrollment, and prescription medication misuse. The guidelines include details about each of these areas:

¹This diversion control plan must also assign specific responsibility to the medical and administrative staff of the OTP for carrying out the diversion control measures and functions described in the diversion control plan. 42 C.F.R. § 8.12(c)(2) (2016).

²Substance Abuse and Mental Health Services Administration. *Federal Guidelines for Opioid Treatment Programs*. HHS Publication No. (SMA) PEP15-FEDGUIDEOTP. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2015.

- *Program environment:* Diversion in the program environment can be deterred and detected by regular surveillance and the monitoring of areas in and around the program, where opportunities for diversion may exist. A visible human presence at a program's location gives community members the opportunity to approach staff with concerns and communicates the program's commitment to assuring a safe environment and a positive impact on the surrounding community.
- *Dosing and take-home medication:* In the area of dosing and take-home medication, diversion control encompasses careful control of inventory, attentive patient dosing, and close supervision of take-home medication. Observing a patient take his or her dose and having each of them drink and speak after dosing are fundamental components of diversion control. Take-home dosing should be provided with careful attention to regulatory compliance and the therapeutic benefit and safety these regulations are meant to promote.
- *Prevention of multiple program enrollment:* Reasonable measures should be taken to prevent patients from enrolling in treatment provided by more than one clinic or individual practitioner. An OTP, after obtaining patient consent, may contact other OTPs within a reasonable geographic distance (100 miles) to verify that a patient is not enrolled in another OTP.
- *Misuse of prescription medication:* The misuse of prescription medication has become an area of great concern nationally and impacts diversion control planning at OTPs. All OTP physicians and other healthcare providers, as permitted, should register to use their respective state's prescription drug monitoring program (PDMP) and query it for each newly admitted patient prior to initiating dosing. The PDMP should be checked periodically (for example, quarterly) through the course of each individual's treatment and, in particular, before ordering take-home doses as well as at other important clinical decision points.

Diversion Control and Plans for Practitioners Prescribing Buprenorphine Outside of an OTP

SAMHSA's best-practice guidelines for using buprenorphine for treating opioid use disorders include multiple references to diversion, including monitoring for diversion, storage of this medication to minimize diversion, and use of formulations that may be less likely to be diverted. Specifically, the best practices state that, when possible, practitioners should use the combination buprenorphine/naloxone product, which increases safety and

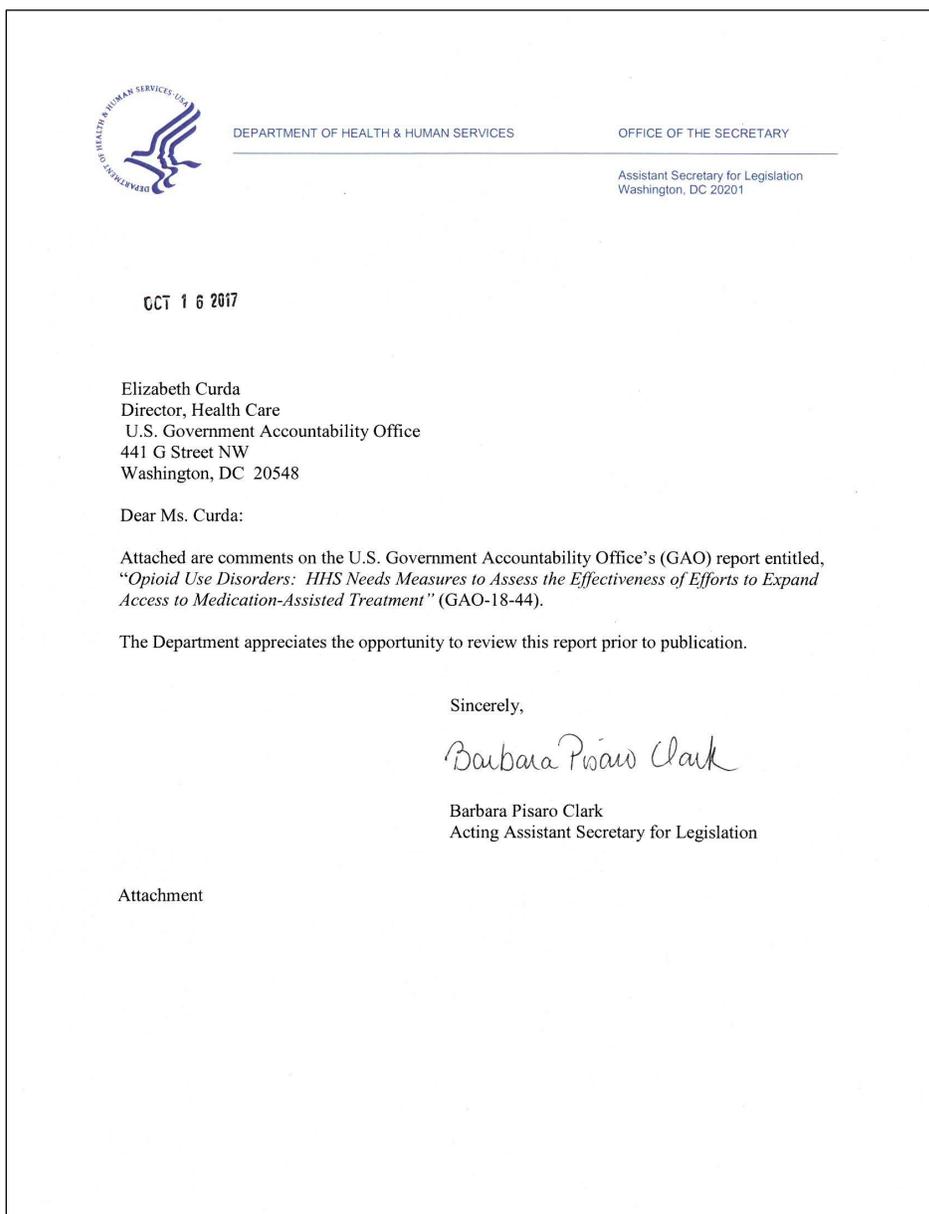
decreases the likelihood of diversion and misuse.³ Further, physicians who request and receive a waiver to prescribe buprenorphine to treat up to 275 patients outside of an OTP are required to have a diversion control plan. According to an HHS official, as of July 13, 2017, roughly 3,330 of the over 39,000 practitioners with a waiver had a 275-patient limit waiver. The majority of these practitioners, just over 27,000, have a 30-patient limit.

According to SAMHSA guidance, the diversion plan should contain specific measures to reduce the possibility of diversion of buprenorphine from legitimate treatment use and should assign specific responsibilities of the medical and administrative staff of the practice setting for carrying out these measures. Further, the guidance states that the plan should address how:

- the environment at the practice setting can prevent onsite diversion;
- to prevent diversion with regard to dosing and take-home medication; and
- to prevent patients from receiving a prescription from more than one practitioner and later diverting some of the prescribed medication.

³Center for Substance Abuse Treatment. *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction*. Treatment Improvement Protocol (TIP) Series 40. DHHS Publication No. (SMA) 04-3939. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2004.

Appendix II: Comments from the Department of Health and Human Services



GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: OPIOID USE DISORDERS: HHS NEEDS MEASURES TO ASSESS THE EFFECTIVENESS OF EFFORTS TO EXPAND ACCESS TO MEDICATION-ASSISTED TREATMENT (GAO-18-44)

The U.S. Department of Health and Human Services (HHS) appreciates the opportunity from the Government Accountability Office (GAO) to review and comment on this draft report.

Recommendation 1

The Assistant Secretary for Planning and Evaluation (ASPE) should establish performance measures with targets related to expanding access to medication-assisted treatment (MAT) for opioids use disorders.

HHS Response

HHS concurs with GAO's recommendation.

HHS agrees that it is appropriate to establish performance measures to assess the Department's efforts related to expanding access to MAT for opioid use disorders as part of its broader Opioid Strategy. Currently, there is a lack of health system and healthcare provider capacity to identify, engage, and provide individuals with high-quality, evidence-based opioid addiction treatment, in particular, the full spectrum of MAT. Further, research indicates that the majority of individuals who suffer from an opioid use disorder in the U.S. do not receive treatment; even among those who do receive treatment, many do not receive evidence-based care. Accounting for these factors is critical to the development of a successful strategy to combat the opioid crisis and to our ability to understand how our efforts are meeting current treatment needs, as we implement specific policies and programs. HHS continues to work through its internal processes to develop robust measures, including measures related to MAT, as part of our overall Opioid Strategy under the Trump Administration.

As we have stated during several discussions with GAO staff and in written response to GAO's questions and other documents, in fiscal year (FY) 2016, HHS established formal performance measures with targets related to expanding MAT access as part of the federal government-wide Agency Priority Goals (APGs) as required by the Government Performance and Results Act (GPR) of 1993 (P.L. 103-62) and the GPR Modernization Act of 2010 (P.L. 111-352). HHS's FY 2016-FY 2017 Agency Priority Goals (APGs) and accompanying metrics aligned with the three focus areas, one of which was expanding access to MAT, part of the previous Administration's Opioid Initiative and in place from March 2015 to January 2017. APGs represent targeted assessments of the near-term progress that will be essential for achieving the broader goals of overall reductions in morbidity and mortality associated with opioid abuse. OMB requires that progress on these goals are reported on a quarterly basis; therefore, HHS identified APGs for which quarterly data were available and timely.

Included in HHS's FY 2016-2017 APG for opioids were three measures related to reducing overall opioid-related morbidity and mortality. One of the measures explicitly addressed MAT:

- Increase by 10 percent the number of unique patients receiving prescriptions for buprenorphine and naltrexone in the U.S. outpatient retail pharmacy setting.

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: OPIOID USE DISORDERS: HHS NEEDS MEASURES TO ASSESS THE EFFECTIVENESS OF EFFORTS TO EXPAND ACCESS TO MEDICATION-ASSISTED TREATMENT (GAO-18-44)

HHS has far exceeded this goal. By the second quarter of calendar year 2016 (the last reporting period for the APG), 981,863 unique patients received a buprenorphine prescription compared to 807,527 at the baseline third quarter of calendar year 2014, a 22 percent increase. For naltrexone, in the second quarter of calendar year 2016, 151,515 patients received a naltrexone prescription compared to 85,494 in the third quarter of calendar year 2015, a 77 percent increase. While the FY 2016-FY 2017 APGs were retired with the new Administration, HHS has continued to monitor these data. HHS has not formally developed and/or adopted new APGs because it is awaiting guidance from OMB, which is responsible for leading APGs federal government wide. Opioids/MAT may or may not be included in the next round of HHS's APGs for FY 2018-FY 2019, but as stated previously, HHS continues to work internally to develop robust measures, including measures related to MAT, as part of our overall Opioid Strategy development and implementation.

In addition, as HHS has previously communicated to GAO, the Department continues to use a variety of measures to track opioid-related policy and programmatic activities including efforts to expand access to MAT. HHS also continues to collect and monitor outcome data such as overdose deaths, emergency department visits, rates of prescription opioid misuse and heroin use, and opioid use disorder, which are often publically reported through various Department publications and presentations.

Recommendation 2

ASPE should establish timeframes in its evaluation approach that specify when its evaluation of efforts to expand access to MAT will be implemented and completed.

HHS Response

HHS concurs with GAO's recommendation that timeframes are important to any evaluation activity.

HHS would like to clarify the assumptions under which this recommendation was made, as it does not appear to acknowledge information and materials that HHS has provided to GAO prior to this draft report. In both conversations with and in written response to GAO staff questions, HHS/ASPE has stated that the ASPE evaluation of the 2015 Initiative is a 2-year contract that was awarded to RTI International in September 2016 and will end in September 2018.

ASPE's evaluation of the 2015 Initiative is examining the implementation of activities across the Department collectively and within the three domains of the previous Administration's priority areas. MAT is just one of these three domains. HHS/ASPE previously provided GAO with a copy of the signed project contract, including the project's statement of work. Prior to the award of the evaluation contract, ASPE contracted with Mathematica Policy Research (MPR) to identify a potential framework for evaluating the Initiative. However, HHS/ASPE needed to prioritize its available resources for this contract (~\$375,000) and given the new Administration's opioid priorities, HHS/ASPE exercised the option to modify the original contract to now focus on a qualitative evaluation of the overall Initiative's implementation and revised the project's deliverables accordingly. The qualitative evaluation will provide HHS with

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: OPIOID USE DISORDERS: HHS NEEDS MEASURES TO ASSESS THE EFFECTIVENESS OF EFFORTS TO EXPAND ACCESS TO MEDICATION-ASSISTED TREATMENT (GAO-18-44)

insight on how agencies implemented activities under the previous Initiative. This information will help to identify any obstacles that may have been encountered in implementing these activities and achieving their objectives, and how such barriers or challenges can be addressed as HHS begins to implement its Opioid Strategy under the current Administration. HHS/ASPE has worked closely with the contractor (RTI) since the time of the award to make these changes to the contract and subsequently, to the analytic plan.

In addition, GAO's Statement of Facts for this engagement made a similar request for a timeline. In response, HHS/ASPE provided GAO staff with the updated schedule of deliverables/timeline for the evaluation project. Despite the contract modification and shifting timelines, the evaluation is still scheduled and on track for completion in September 2018.

HHS would also like to clarify two additional items. First, the "Opioid Initiative" as it is discussed in the draft report is the Initiative as it was implemented during the previous Administration and under the leadership of former Secretary Sylvia Burwell. This Initiative ended with the new Administration; however, some of its activities have continued and the current Administration has doubled-down on its commitment to improving access to prevention, treatment, and recovery services, including the full range of MAT, as part of its broader five-point Opioid Strategy.

Second, the Department would like to reiterate that HHS/ASPE's work to evaluate the implementation of the 2015 Initiative is not the sole evaluation or analytic activity underway within the Department pertaining to all HHS activities related to expanding access to MAT. For example, there is a planned evaluation of the State Targeted Response to the Opioid Crisis Grants administered by the Substance Abuse and Mental Health Services Administration, and additional information is regularly collected by individual HHS agencies as part of their ongoing monitoring efforts for their individual MAT-related programs.

Appendix III: GAO Contact and Staff Acknowledgments

GAO Contact

Elizabeth H. Curda, Director, (202) 512-7114 or curdae@gao.gov.

Staff Acknowledgments

In addition to the contact name above, Will Simerl, Assistant Director; Natalie Herzog, Analyst-in-Charge; La Sherri Bush; and Emily Wilson made key contributions to this report. Also contributing were Muriel Brown, Krister Friday, Sandra George, and Christina Ritchie.

Appendix IV: Accessible Data

Agency Comment Letter

Text of Appendix II: Comments from the Department of
Health and Human Services

Page 1

Elizabeth Curda Director, Health Care

U.S. Government Accountability Office 441 G Street NW

Washington, DC 20548 Dear Ms. Curda:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "Opioid Use Disorders: HHS Needs Measures to Assess the Effectiveness of Efforts to Expand Access to Medication-Assisted Treatment" (GAO-18-44).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Barbara Pisaro Clark

Acting Assistant Secretary for Legislation

Attachment

Page 2

The U.S. Department of Health and Human Services (HHS) appreciates the opportunity from the Government Accountability Office (GAO) to review and comment on this draft report.

Recommendation 1

The Assistant Secretary for Planning and Evaluation (ASPE) should establish performance measures with targets related to expanding access to medication-assisted treatment (MAT) for opioids use disorders.

HHS Response: HHS concurs with GAO's recommendation.

HHS agrees that it is appropriate to establish performance measures to assess the Department's efforts related to expanding access to MAT for opioid use disorders as part of its broader Opioid Strategy. Currently, there is a lack of health system and healthcare provider capacity to identify, engage, and provide individuals with high-quality, evidence-based opioid addiction treatment, in particular, the full spectrum of MAT. Further, research indicates that the majority of individuals who suffer from an opioid use disorder in the U.S. do not receive treatment; even among those who do receive treatment, many do not receive evidence-based care. Accounting for these factors is critical to the development of a successful strategy to combat the opioid crisis and to our ability to understand how our efforts are meeting current treatment needs, as we implement specific policies and programs. HHS continues to work through its internal processes to develop robust measures, including measures related to MAT, as part of our overall Opioid Strategy under the Trump Administration.

As we have stated during several discussions with GAO staff and in written response to GAO's questions and other documents, in fiscal year (FY) 2016, HHS established formal performance measures with targets related to expanding MAT access as part of the federal government-wide

Agency Priority Goals (APGs) as required by the Government Performance and Results Act (GPRA) of 1993 (P.L. 103-62) and the GPRA Modernization Act of 2010 (P.L. 111-352).

HHS's FY 2016-FY 2017 Agency Priority Goals (APGs) and accompanying metrics aligned with the three focus areas, one of which was expanding access to MAT, part of the previous Administration's Opioid Initiative and in place from March 2015 to January 2017. APGs represent targeted assessments of the near-term progress that will be essential for achieving the broader goals of overall reductions in morbidity and mortality associated with opioid abuse.

OMB requires that progress on these goals are reported on a quarterly basis; therefore, HHS identified APGs for which quarterly data were available and timely.

Included in HHS's FY 2016-2017 APG for opioids were three measures related to reducing overall opioid-related morbidity and mortality. One of the measures explicitly addressed MAT:

- Increase by 10 percent the number of unique patients receiving prescriptions for buprenorphine and naltrexone in the U.S. outpatient retail pharmacy setting.

Page 3

HHS has far exceeded this goal. By the second quarter of calendar year 2016 (the last reporting period for the APG), 981,863 unique patients received a buprenorphine prescription compared to 807,527 at the baseline third quarter of calendar year 2014, a 22 percent increase. For naltrexone, in the second quarter of calendar year 2016, 151,515 patients received a naltrexone prescription compared to 85,494 in the third quarter of calendar year 2015, a 77 percent increase. While the FY 2016-FY 2017 APGs were retired with the new Administration, HHS has continued to monitor these data. HHS has not formally developed and/or adopted new APGs because it is awaiting guidance from OMB, which is responsible for leading APGs federal government wide. Opioids/MAT may or may not be included in the next round of HHS' s APGs for FY 2018-FY 2019, but as stated previously, HHS continues to work internally to develop robust measures, including measures related to MAT, as part of our overall Opioid Strategy development and implementation.

In addition, as HHS has previously communicated to GAO, the Department continues to use a variety of measures to track opioid-related policy and programmatic activities including efforts to expand access to MAT. HHS also continues to collect and monitor outcome data such as overdose deaths, emergency department visits, rates of prescription opioid misuse and heroin use, and opioid use disorder, which are often publically reported through various Department publications and presentations.

Recommendation 2

ASPE should establish timeframes in its evaluation approach that specify when its evaluation of efforts to expand access to MAT will be implemented and completed.

HHS Response: HHS concurs with GAO's recommendation that timeframes are important to any evaluation activity.

HHS would like to clarify the assumptions under which this recommendation was made, as it does not appear to acknowledge information and materials that HHS has provided to GAO prior to this draft report. In both conversations with and in written response to GAO staff questions, HHS/ASPE has stated that the ASPE evaluation of the 2015 Initiative is a 2-year contract that was awarded to RTI International in September 2016 and will end in September 2018.

ASPE's evaluation of the 2015 Initiative is examining the implementation of activities across the Department collectively and within the three domains of the previous Administration's priority areas. MAT is just one of these three domains. HHS/ASPE previously provided GAO with a copy of the signed project contract, including the project's statement of work. Prior to the award of the evaluation contract, ASPE contracted with Mathematica Policy Research (MPR) to identify a potential framework for evaluating the Initiative. However, HHS/ASPE needed to prioritize its available resources for this contract (\$375 ,000) and given the new Administration's opioid priorities, HHS/ASPE exercised the option to modify the original contract to now focus on a qualitative evaluation of the overall Initiative's implementation and revised the project's deliverables accordingly. The qualitative evaluation will provide HHS with

Page 4

insight on how agencies implemented activities under the previous Initiative. This information will help to identify any obstacles that may have been encountered in implementing these activities and achieving their objectives, and how such barriers or challenges can be addressed as HHS begins to implement its Opioid Strategy under the current Administration. HHS/ASPE has worked closely with the contractor (RTI) since the time of the award to make these changes to the contract and subsequently, to the analytic plan.

In addition, GAO's Statement of Facts for this engagement made a similar request for a timeline. In response, HHS/ASPE provided GAO staff with the updated schedule of deliverables/timeline for the evaluation project. Despite the contract modification and shifting timelines, the evaluation is still scheduled and on track for completion in September 2018.

HHS would also like to clarify two additional items. First, the "Opioid Initiative" as it is discussed in the draft report is the Initiative as it was implemented during the previous Administration and under the leadership of former Secretary Sylvia Burwell. This Initiative ended with the new Administration; however, some of its activities have continued and the current Administration has doubled-down on its commitment to improving access to prevention, treatment, and recovery services, including the full range of MAT, as part of its broader five-point Opioid Strategy.

Second, the Department would like to reiterate that HHS/ASPE's work to evaluate the implementation of the 2015 Initiative is not the sole evaluation or analytic activity under way within the Department pertaining to all HHS activities related to expanding access to MAT. For example, there is a planned evaluation of the State Targeted Response to the Opioid Crisis Grants administered by the Substance Abuse and Mental Health Services Administration, and additional information is regularly collected by individual HHS agencies as part of their ongoing monitoring efforts for their individual MAT-related programs.

GAO's Mission

The Government Accountability Office, the audit, evaluation, and investigative arm of Congress, exists to support Congress in meeting its constitutional responsibilities and to help improve the performance and accountability of the federal government for the American people. GAO examines the use of public funds; evaluates federal programs and policies; and provides analyses, recommendations, and other assistance to help Congress make informed oversight, policy, and funding decisions. GAO's commitment to good government is reflected in its core values of accountability, integrity, and reliability.

Obtaining Copies of GAO Reports and Testimony

The fastest and easiest way to obtain copies of GAO documents at no cost is through GAO's website (<http://www.gao.gov>). Each weekday afternoon, GAO posts on its website newly released reports, testimony, and correspondence. To have GAO e-mail you a list of newly posted products, go to <http://www.gao.gov> and select "E-mail Updates."

Order by Phone

The price of each GAO publication reflects GAO's actual cost of production and distribution and depends on the number of pages in the publication and whether the publication is printed in color or black and white. Pricing and ordering information is posted on GAO's website, <http://www.gao.gov/ordering.htm>.

Place orders by calling (202) 512-6000, toll free (866) 801-7077, or TDD (202) 512-2537.

Orders may be paid for using American Express, Discover Card, MasterCard, Visa, check, or money order. Call for additional information.

Connect with GAO

Connect with GAO on [Facebook](#), [Flickr](#), [LinkedIn](#), [Twitter](#), and [YouTube](#).
Subscribe to our [RSS Feeds](#) or [E-mail Updates](#). Listen to our [Podcasts](#).
Visit GAO on the web at www.gao.gov and read [The Watchblog](#).

To Report Fraud, Waste, and Abuse in Federal Programs

Contact:

Website: <http://www.gao.gov/fraudnet/fraudnet.htm>
E-mail: fraudnet@gao.gov
Automated answering system: (800) 424-5454 or (202) 512-7470

Congressional Relations

Katherine Siggerud, Managing Director, siggerudk@gao.gov, (202) 512-4400,
U.S. Government Accountability Office, 441 G Street NW, Room 7125,
Washington, DC 20548

Public Affairs

Chuck Young, Managing Director, youngc1@gao.gov, (202) 512-4800
U.S. Government Accountability Office, 441 G Street NW, Room 7149
Washington, DC 20548

Strategic Planning and External Liaison

James-Christian Blockwood, Managing Director, spel@gao.gov, (202) 512-4707
U.S. Government Accountability Office, 441 G Street NW, Room 7814,
Washington, DC 20548