Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

OPIOID TREATMENT PROGRAMS REPORTED CHALLENGES ENCOUNTERED DURING THE COVID-19 PANDEMIC AND ACTIONS TAKEN TO ADDRESS THEM

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Report in Brief
Date: November 2020
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U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

Opioid Treatment Programs Reported Challenges Encountered During the COVID-19 Pandemic and Actions Taken To Address Them

Why OIG Did This Audit

The United States currently faces two nationwide public health emergencies: the opioid crisis and the COVID-19 pandemic. The COVID-19 pandemic has had an impact on the opioid crisis because individuals with an opioid use disorder may be at a higher risk for COVID-19 infection and serious consequences from that disease. In response to the pandemic, the Substance Abuse and Mental Health Services Administration (SAMHSA) granted opioid treatment programs (OTPs) and States increased flexibilities to ensure the delivery of OTP services and to protect patients and staff from COVID-19 to the greatest extent possible. To obtain information on the impact that the COVID-19 pandemic has had on OTPs, we conducted interviews with 142 OTPs.

Our objectives were to identify: (1) challenges that OTPs have encountered during the COVID-19 pandemic and (2) actions that OTPs have taken to address those challenges while ensuring the continuity of needed services and protecting the health and safety of their patients and staff.

How OIG Did This Audit

Of 1,746 OTPs nationwide, we randomly selected 150 OTPs, and after removing 7 of them for various reasons, we attempted to interview the remaining 143 OTPs from June 4 through June 22, 2020. We received responses from 142 OTPs, located in 37 States and the District of Columbia (137 urban areas and 5 rural areas).

What OIG Found

OTPs reported a variety of: (1) challenges they have encountered during the COVID-19 pandemic and (2) actions they have taken to address those challenges while ensuring the continuity of needed services and protecting the health and safety of their patients and staff.

OTPs reported challenges related to: (1) maintaining pre-pandemic service levels (124 OTPs); (2) managing impacts on facility operations (113 OTPs); (3) implementing and using telehealth (87 OTPs); (4) obtaining treatment medications, personal protective equipment, and cleaning supplies (83 OTPs); (5) maintaining patient participation in OTP activities (77 OTPs); (6) dealing with limitations posed by existing Federal guidance (65 OTPs); (7) providing take-home doses to patients (51 OTPs); and (8) implementing governmental guidance (34 OTPs).

OTPs reported actions taken, including: (1) encouraging or requiring various personal safety measures for patients and staff (141 OTPs), (2) implementing or expanding the use of telehealth to continue providing services (128 OTPs), (3) increasing the number of take-home doses to reduce the number of patients visiting facilities (127 OTPs), (4) making physical changes to facilities and increasing staffing flexibilities (121 OTPs), and (5) ensuring that patients received treatment medications (92 OTPs).

Conclusion and SAMHSA Comments

The information in this report was gathered to support HHS's goal of reducing opioid morbidity and mortality and to help SAMHSA by providing information on the impact that the COVID-19 pandemic has had on OTPs. This information was current when we conducted our interviews but may not represent all the challenges that OTPs have faced or the actions they have taken to address those challenges. We recognize that SAMHSA has taken actions to support OTPs as they work on the front lines to treat people diagnosed with opioid use disorders and to ensure the safety of the health care workforce. The information in this report provides SAMHSA and other decisionmakers (e.g., State and Tribal officials and other Federal agencies) with a national snapshot of OTPs' challenges and the actions they have taken to continue providing services during the pandemic. In written comments on our draft report, SAMHSA described actions that it had taken after becoming aware of COVID-19's impact on operations for its behavioral health stakeholders, such as providing technical assistance and training during the pandemic.

The full report can be found at https://oig.hhs.gov/oas/reports/region9/92001001.asp.

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INTRODUCTION

WHY WE DID THIS AUDIT

The United States currently faces two nationwide public health emergencies: the opioid crisis and the COVID-19 pandemic. Recent Centers for Disease Control and Prevention (CDC) data identified that nearly 47,000 people died in 2018 from opioid overdoses and more than 120,000 people had died as of June 22, 2020,[1] from complications related to COVID-19.

COVID-19 is a highly contagious disease that is thought to spread mainly from person to person through respiratory droplets.[2] Because of the widespread transmission of COVID-19, Federal, State, Tribal, and local government agencies recommended and implemented extensive community mitigation activities, including issuing orders to residents to stay at home and practice social distancing,[3] to help slow and contain the spread of COVID-19.

The COVID-19 pandemic has had an impact on the opioid crisis. Individuals with an opioid use disorder[4] may be at a higher risk for COVID-19 infection and serious consequences, including death, from that disease.[5, 6] In response to the COVID-19 pandemic, the Substance Abuse and Mental Health Services Administration (SAMHSA) granted opioid treatment programs (OTPs) and States increased flexibilities to ensure the delivery of OTP services and to protect patients and staff from COVID-19 to the greatest extent possible. (OTPs provide medications with counseling and behavioral therapies to treat substance use disorders and prevent opioid overdoses.) The extent to which OTPs have been able to implement these flexibilities and the effect they have had on maintaining services are unknown.

The information in this report was obtained primarily from interviews we conducted with executives and administrative officials at 142 OTPs from June 4 through June 22, 2020. The

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[1] The number of COVID-19 deaths as of June 22, 2020, reflected the number of deaths at the end of the data collection period for our audit. As of November 12, 2020, more than 240,000 people had died from complications related to COVID-19.

[2] CDC, "Coronavirus Disease 2019 (COVID-19) Frequently Asked Questions." Available at https://www.cdc.gov/coronavirus/2019-ncov/faq.html. Accessed on October 29, 2020.

[3] The purpose of social distancing, also called physical distancing, is to keep space between people outside of the home. It is recommended that a person stay at least 6 feet from others.

[4] Opioid use disorder is the chronic use of opioids, causing clinically significant distress or impairment.

[5] Bloomberg Law, *Pharmaceutical & Life Sciences News*, "Virus Pandemic, Opioid Epidemic Collide Around Social Distancing." Available at https://news.bloomberglaw.com/pharma-and-life-sciences/virus-pandemic-opioid-epidemic-collide-around-social-distancing. Accessed on June 30, 2020.

[6] Harvard Health Publishing, Harvard Medical School, "A tale of two epidemics: When COVID-19 and opioid addiction collide." Available at https://www.health.harvard.edu/blog/a-tale-of-two-epidemics-when-covid-19-and-opioid-addiction-collide-2020042019569. Accessed on June 30, 2020.

information was gathered to support the Department of Health and Human Services' (HHS's) goal of reducing opioid morbidity and mortality and to help SAMHSA by providing information on the impact that the COVID-19 pandemic has had on OTPs. Among other actions taken by the Federal Government, the HHS Office of Inspector General was appropriated a total of $12 million to conduct oversight of HHS's response to the pandemic.

This audit provides SAMHSA and other decisionmakers (e.g., State and Tribal officials and other Federal agencies) with a national snapshot of OTPs' challenges and the actions they have taken to continue providing services during the COVID-19 pandemic. In addition, OTPs may find the information about each other's strategies useful in their own efforts to address the challenges they are facing. This audit is not an assessment of HHS's or SAMHSA's response to the COVID-19 pandemic.

OBJECTIVES

Our objectives were to identify: (1) challenges that OTPs have encountered during the COVID-19 pandemic and (2) actions that OTPs have taken to address those challenges while ensuring the continuity of needed services and protecting the health and safety of their patients and staff.

BACKGROUND

The Opioid Crisis and the COVID-19 Pandemic

The United States has been faced with an opioid crisis since the late 1990s. Increased prescribing of opioid medications led to widespread misuse of both prescription and nonprescription opioids before it became clear that these medications could be highly addictive. This misuse resulted in an initial wave of opioid overdose deaths. There were two subsequent waves of opioid overdose deaths: the first wave included an increased number of deaths involving heroin, and the second wave involved increases in deaths caused by synthetic opioids, including illicitly manufactured fentanyl. From 1999 through 2018, almost 450,000 people died from opioid overdoses; there were nearly 47,000 deaths in 2018 alone. In October 2017, the opioid crisis was declared a national public health emergency, authorizing Federal agencies to use emergency authority to address the crisis.

In early 2020, a new health-related crisis emerged. On January 31, 2020, the Secretary of Health and Human Services declared a national public health emergency as a result of confirmed U.S. cases of COVID-19, a highly contagious disease caused by the SARS-CoV-2 coronavirus. On March 11, 2020, the World Health Organization characterized COVID-19 as a pandemic (an epidemic[7] that has spread over several countries or continents, usually affecting

[7] An epidemic refers to an increase, often sudden, in the number of cases of a disease above what is normally expected in that population in that area.

a large number of people). As of June 22, 2020, CDC had reported 2,302,288 confirmed cases in the United States and 120,333 deaths from COVID-19.

COVID-19 is thought to spread mainly from person to person through respiratory droplets produced when an infected person coughs, sneezes, talks, or breathes. These droplets can land in the mouths or noses of people who are nearby or possibly be inhaled into the lungs. Transmission is more likely to occur when people are in close contact with one another (within about 6 feet). Some infected individuals may exhibit symptoms (symptomatic), while others may exhibit no symptoms (asymptomatic). The risk for developing more serious complications from COVID-19 increases with age or having severe underlying medical conditions, such as heart or lung disease or diabetes.

The COVID-19 pandemic has had an impact on the opioid crisis. Individuals with an opioid use disorder may be at a higher risk for COVID-19 and serious consequences, including death, from that disease.[8] These individuals tend to be more vulnerable to contracting COVID-19 because they are more likely to: (1) be homeless, poor, smokers with lung or cardiovascular disease, or uninsured or underinsured or (2) have serious health and socioeconomic issues from drug addiction.[9] Many of these individuals also have mental health conditions that are exacerbated by the effects of the COVID-19 pandemic.[10, 11] For instance, these individuals may experience increased feelings of isolation and depression as the result of stay-at-home orders and the need for social distancing.[12, 13] Anecdotal evidence indicates that opioid overdoses may be increasing during the pandemic.[14]

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[8] Bloomberg Law, *Pharmaceutical & Life Sciences News*, "Virus Pandemic, Opioid Epidemic Collide Around Social Distancing." Available at https://news.bloomberglaw.com/pharma-and-life-sciences/virus-pandemic-opioid-epidemic-collide-around-social-distancing. Accessed on June 30, 2020.

[9] Harvard Health Publishing, Harvard Medical School, "A tale of two epidemics: When COVID-19 and opioid addiction collide." Available at https://www.health.harvard.edu/blog/a-tale-of-two-epidemics-when-covid-19-and-opioid-addiction-collide-2020042019569. Accessed on June 30, 2020.

[10] MedPage Today, "Addressing the Opioid Crisis During COVID-19." Available at https://www.medpagetoday.com/publichealthpolicy/opioids/86655. Accessed on May 28, 2020.

[11] Kaiser Family Foundation, "The Implications of COVID-19 for Mental Health and Substance Use." Available at https://www.kff.org/coronavirus-covid-19/issue-brief/the-implications-of-covid-19-for-mental-health-and-substance-use. Accessed on October 29, 2020.

[12] UCLA Health, "As Stay-at-Home Orders Increase, so do Feelings of Loneliness and Depression." Available at https://connect.uclahealth.org/2020/03/23/as-stay-at-home-orders-increase-so-do-feelings-of-loneliness-and-depression. Accessed on July 3, 2020.

[13] MedPage Today, "Addressing the Opioid Crisis During COVID-19." Available at https://www.medpagetoday.com/publichealthpolicy/opioids/86655. Accessed on May 28, 2020.

[14] American Medical Association, Advocacy Resource Center, "Issue brief: Reports of increases in opioid- and other drug-related overdose and other concerns during COVID pandemic." Available at https://www.ama-assn.org/system/files/2020-06/issue-brief-increases-in-opioid-related-overdose.pdf. Accessed on October 29, 2020.

Opioid Treatment Programs and Services

OTPs are on the front line in responding to the opioid crisis. They provide medication-assisted treatment (MAT)[15] for people diagnosed with an opioid use disorder.[16] OTPs tailor the treatment to meet each patient's needs. OTPs also focus on improving patients' quality of life through a range of services designed to reduce, eliminate, and prevent the use of illicit drugs, the spread of infectious disease, and potential criminal activity by providing medical, counseling, vocational, educational, and other assessment and treatment services. Collectively, all the services that OTPs provide are referred to as "OTP services" in this report.

MAT is primarily used to treat opioid dependence and addiction to short-acting opioids (e.g., heroin, morphine, and codeine) as well as semisynthetic and fully synthetic opioids (e.g., oxycodone, hydrocodone, and fentanyl). Medications approved by the Food and Drug Administration for use in MAT include methadone, buprenorphine, and naltrexone.[17] The oversight of treatment medications used in MAT is a coordinated effort involving States; HHS, including SAMHSA; the Department of Justice; and the Drug Enforcement Administration (DEA).

Patients who are prescribed MAT generally visit an OTP facility daily to receive their medication and necessary counseling or therapy. However, patients may receive take-home doses[18] of their medication for days on which an OTP facility is closed (e.g., Sundays and holidays) or if the OTP has determined that the patient has met certain requirements identified in Federal regulations.

SAMHSA's Oversight of Treatment for Opioid Use Disorders and Certification of Opioid Treatment Programs

SAMHSA, an agency within HHS, leads public health efforts focused on behavioral health and improving the lives of those with mental and substance use disorders. It provides guidance related to the treatment of opioid use disorders and administers grants aimed at combating the opioid crisis, including funding of prevention, treatment, and recovery services for opioid use disorders.

[15] MAT is the use of medications with counseling and behavioral therapies to treat substance use disorders and prevent opioid overdose.

[16] OTPs refer to the individuals who are enrolled in an OTP for MAT as "patients."

[17] Methadone and buprenorphine are medications that reduce opioid cravings and withdrawal and can blunt the effects of other opioids. Methadone is dispensed or administered only through OTPs. In addition to being dispensed at OTPs, buprenorphine can be prescribed or dispensed in physician offices by qualified practitioners. Naltrexone is a medication that blocks the euphoric and sedative effects of other opioids. It can be prescribed by any health care provider licensed to prescribe medications.

[18] Take-home doses refer to medications dispensed to patients for unsupervised use.

OTPs must be certified by SAMHSA and accredited by an independent, SAMHSA-approved accrediting body to dispense opioid treatment medications. In addition, OTPs must be licensed by the State in which they operate and must register with DEA.

Federal Opioid Treatment Standards for Opioid Treatment Programs

Federal regulations contain requirements for OTPs to provide adequate medical, counseling, vocational, educational, and other assessment and treatment services.[19] The regulations require each patient to undergo a complete, fully documented physical evaluation before admission to an OTP.[20] OTPs are allowed to use only those medications that the Food and Drug Administration has approved for use in the treatment of opioid addiction, and methadone must be dispensed in oral form.[21] Adequate drug testing must be conducted, including a minimum of eight random drug tests per year.[22] To determine whether a patient is responsible for handling MAT drugs for unsupervised (i.e., take-home) use, OTPs must consider eight requirements.[23] The maximum number of days of take-home doses is limited based on the length of time the patient has been in treatment.[24] SAMHSA may grant exemptions to some of these requirements.[25]

Flexibilities Granted to Opioid Treatment Programs for Delivery of Services During the COVID-19 Pandemic

In March 2020, SAMHSA and DEA granted OTPs and States increased flexibilities and temporary exemptions affecting the delivery of services during the COVID-19 pandemic. For example, SAMHSA allowed States to request exceptions to Federal requirements related to take-home doses. Specifically, SAMHSA granted States and OTPs the flexibility to provide patients with more take-home doses than Federal regulations allow: "stable" patients may receive 28 days of take-home doses and "less stable" patients may receive 14 days of take-home doses, as long as

[19] 42 CFR § 8.12(f)(1).

[20] 42 CFR § 8.12(f)(2).

[21] 42 CFR §§ 8.12(h)(2) and (h)(3)(i).

[22] 42 CFR § 8.12(f)(6).

[23] Federal regulations (42 CFR § 8.12(i)(2)) require that an OTP's medical director consider the following in determining whether a patient is responsible for handling take-home doses: (1) absence of recent abuse of drugs, including alcohol; (2) regularity of clinic attendance; (3) absence of serious behavioral problems at the clinic; (4) absence of known recent criminal activity; (5) stability of the patient's home environment and social relationships; (6) length of time in comprehensive maintenance treatment; (7) assurance that take-home medication can be safely stored within the patient's home; and (8) whether the rehabilitative benefit the patient derived from decreasing the frequency of clinic attendance outweighs the potential risks of diversion.

[24] 42 CFR § 8.12(i).

[25] 42 CFR § 8.11(h).

the OTP believes that the patient can safely handle it. In addition, SAMHSA and DEA granted a temporary exemption to OTPs from having to perform in-person physical evaluations of patients who will be treated with buprenorphine,[26] with intake of new patients and treatment permitted using telehealth.[27] SAMHSA and DEA also provided guidance on implementing flexibilities affecting the delivery of medications to patients who were quarantined at home with COVID-19.

CDC Guidance for Health Care Providers Related to Health and Safety of Patients and Staff During the COVID-19 Pandemic

In response to the COVID-19 pandemic, CDC issued guidance to health care providers, including OTPs, addressing the health and safety of patients and staff. The intent of the guidance is to reduce OTP facility risk (e.g., screening those entering a facility), isolate symptomatic patients as soon as possible, and protect health care personnel. Measures include having patients and staff wear face coverings while at a facility, limiting and monitoring points of entry to the facility, posting visual alerts to provide instructions on hand and respiratory hygiene, implementing alternatives to face-to-face visits (e.g., telehealth), and canceling or modifying in-person group health care activities.

HOW WE CONDUCTED THIS AUDIT

As of April 17, 2020, there were 1,746 OTPs nationwide (excluding U.S. territories) that SAMHSA had either certified or provisionally certified[28] to provide MAT. Of these OTPs, we randomly selected 150 OTPs from 49 States (excluding Wyoming, which had no operating OTPs) and the District of Columbia. From the sample, we removed seven OTPs for various reasons, including one OTP that was no longer in operation. We attempted to interview the remaining 143 OTPs.

We received responses from 142 of the 143 OTPs, for a response rate of 99.3 percent. The OTPs that responded were located in 37 States and the District of Columbia.[29] (The blue dots on the map in Figure 1 on the following page show the locations of the OTPs.)

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[26] New patients who will be prescribed methadone must still be evaluated in person. SAMHSA, "FAQs: provision of methadone and buprenorphine for the treatment of Opioid Use Disorder in the COVID-19 emergency." Available at https://www.samhsa.gov/sites/default/files/faqs-for-oud-prescribing-and-dispensing.pdf. Accessed on July 7, 2020.

[27] Telehealth is the use of electronic information and telecommunication technologies to support and promote long-distance clinical health care, patient and professional health-related education, public health, and health administration.

[28] Provisional certification is a temporary certification that SAMHSA grants to a new OTP for up to 1 year. During that period, the OTP must become accredited.

[29] Of the 142 OTPs that responded to our request for an interview, 137 were located in urban areas (i.e., areas with 2,500 or more people) and 5 were located in rural areas (i.e., areas with fewer than 2,500 people), based on 2010 census data from the U.S. Bureau of the Census.

Figure 1: Locations of the 142 OTPs (in 37 States and the District of Columbia)

The information in this report was obtained primarily from telephone interviews[30] of one or more OTP executives and administrative officials (e.g., the program director, medical director, or clinical director)[31] from June 4 through June 22, 2020, and reflects OTPs' responses at a specific point in time. During each interview, we obtained information related to challenges that the OTP stated that it had encountered during the COVID-19 pandemic and the actions that the OTP stated that it was taking or had taken to address those challenges.

We asked each OTP to answer four primary questions:[32]

- What challenges are you encountering in providing OTP services to patients during the COVID-19 pandemic?

[30] Two OTPs responded to our interview questions through email.

[31] Most interview responses were provided by OTP officials. However, in some cases, we spoke with officials from an OTP's parent company instead of or in addition to an OTP official. We considered the interviews with parent company officials to be formal responses from those OTPs owned by the parent company.

[32] In addition to these four questions, we asked each OTP about the impact that the COVID-19 pandemic has had on the number of patients who: (1) were enrolled in the OTP, (2) were visiting its facility for MAT, (3) were seeking enrollment in the OTP, (4) had experienced a relapse, or (5) had experienced an overdose.

- What strategies or actions has your facility employed to ensure the availability and delivery of OTP services to your patients during the COVID-19 pandemic?

- What strategies or actions have you taken to protect the health and safety of your patients and staff?

- What strategies or actions would you like to implement but are unable to and why are you not able to implement them?

The information in this report represents a range of challenges, actions, experiences, and perceptions that OTP officials conveyed to us, as of a point in time, during the interviews. This information may not represent all the challenges that OTPs have faced or the actions they have taken during the COVID-19 pandemic. Since our interviews, OTPs may have addressed some of the challenges and identified new challenges. Additionally, during our interviews, OTPs may not have shared with us all their challenges or all the actions they have taken. Although some OTPs may have faced the same challenges or taken the same actions that other OTPs reported, these OTPs did not describe them to us in response to our questions. We did not independently verify the information that the OTPs provided to us or determine the effectiveness of the actions that the OTPs identified.

The information in this report is provided for informational purposes only and, therefore, the report does not contain any recommendations. We gathered this information to support HHS's goal of reducing opioid morbidity and mortality and to help SAMHSA by providing information on the impact that the COVID-19 pandemic has had on OTPs. This report provides SAMHSA and other decisionmakers (e.g., State and Tribal officials and other Federal agencies) with a national snapshot of OTPs' challenges and the actions they have taken to continue providing services during the COVID-19 pandemic. In addition, OTPs may find the information about each other's strategies useful in their own efforts to address the challenges they are facing. This audit is not an assessment of HHS's or SAMHSA's response to the COVID-19 pandemic.

We conducted this performance audit 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.

Appendix A describes our audit scope and methodology.

RESULTS OF AUDIT

OTPs reported a variety of: (1) challenges they have encountered during the COVID-19 pandemic and (2) actions they have taken to address those challenges while ensuring the continuity of needed services and protecting the health and safety of their patients and staff.[33] (Figure 2 provides a summary of the challenges encountered and the actions taken.)

Figure 2: Challenges That Opioid Treatment Programs Encountered and Actions Taken To Address Challenges[34]

Challenges	Actions Taken
Maintaining pre-pandemic service levels	Encouraged or required various personal safety measures for patients and staff
Managing impacts on facility operations	Implemented or expanded the use of telehealth
Implementing and using telehealth	Increased the number of take-home doses
Obtaining treatment medications, personal protective equipment, and cleaning supplies	Made physical changes to facilities and increased staffing flexibilities
Maintaining patient participation in opioid treatment program activities	Ensured that patients received treatment medications
Dealing with limitations posed by existing Federal guidance	
Providing take-home doses to patients	
Implementing governmental guidance	

OPIOID TREATMENT PROGRAMS REPORTED A VARIETY OF CHALLENGES ENCOUNTERED DURING THE COVID-19 PANDEMIC

OTPs reported a variety of challenges they have encountered during the COVID-19 pandemic, including challenges related to: (1) maintaining pre-pandemic service levels (124 OTPs);

[33] At the beginning of the sections in which we describe the challenges that OTPs encountered and the actions they took, we show the number of OTPs who reported challenges in different categories. When we describe the specific challenges or actions that OTPs reported to us, we provide various examples of the challenges that OTPs faced or actions they took to address their challenges. The examples we provide do not represent a comprehensive list of all of the examples that OTPs reported to us. Additionally, because of the open-ended nature of our questions and the varied responses we received from OTPs, we do not report the number of OTPs that described any specific challenge encountered or action taken. We also are not representing that the majority of OTPs, or any specific number of OTPs (other than a single OTP), reported a specific challenge encountered or action taken.

[34] The order in which we list the categories of challenges that OTPs encountered and the actions they took is based on the number of OTPs that reported to us information related to each category and does not necessarily reflect the importance of the categories.

(2) managing impacts on facility operations (113 OTPs); (3) implementing and using telehealth (87 OTPs); (4) obtaining treatment medications, personal protective equipment (PPE),[35] and cleaning supplies (83 OTPs); (5) maintaining patient participation in OTP activities (77 OTPs); (6) dealing with limitations posed by existing Federal guidance (65 OTPs); (7) providing take-home doses to patients (51 OTPs); and (8) implementing governmental guidance (34 OTPs).

Maintaining Pre-pandemic Service Levels Was Challenging

Of the 142 OTPs that we interviewed, 124 reported challenges in maintaining the levels of service they provided before the COVID-19 pandemic and maintaining safe contact with patients.

Maintaining Service Levels

OTPs reported challenges in maintaining the level of services they normally provided because they were trying to find the appropriate balance between keeping patients and staff safe and providing quality care to patients. Before the COVID-19 pandemic, some OTPs provided a broad range of services,[36] mostly in their facilities. Since the beginning of the pandemic, however, OTPs have not been able to provide their normal range of services because of reductions in revenues, staffing, operating hours, and the number of patients visiting their facilities; as a result, OTPs have reduced the amount of services they provide to focus on providing MAT to their patients.

OTPs found it challenging to maintain services because staff were afraid to be in facilities. OTPs stated that it was challenging to perform services that required close personal contact (e.g., new admissions, examinations of patients requiring methadone treatment, and drug testing) and, at the same time, adhere to social distancing guidelines. Even after implementing social distancing practices, some OTPs discontinued or postponed all annual physical exams of patients for a period of time to limit close contact between patients and staff. In addition, OTPs stopped providing or delayed some services because they did not have PPE for patients and staff and discontinued providing group counseling sessions to eliminate the need for patients and staff to gather in large groups. One OTP stated that after implementing social-distancing measures in its facility, staff were not able to observe the collection of patients' urine samples for required drug tests.

> One OTP administrator commented: "[MAT] hinges on face-to-face interaction as it is personalized to each patient, so some of the effectiveness is lost from not being onsite and having [personal or face-to-face] interaction."

[35] As used in this report, PPE refers to protective clothing, helmets, gloves, face shields, goggles, face masks, respirators, or other equipment designed to protect the wearer from injury or the spread of infection or illness.

[36] In addition to providing MAT (i.e., medications and counseling services), some OTPs provided other services, such as primary care, psychiatric, and social services.

OTPs also reported that some patients have been afraid or unwilling to visit a facility for medication or counseling because of the increased risk of being exposed to COVID-19. OTPs stated that, in some cases, patients visited a facility for medication and counseling but did not stay long because they feared exposure to COVID-19. In other cases, patients skipped their scheduled appointments because they were symptomatic.

OTPs reported other challenges related to:

- determining how best to provide services to each of their patients, including those who had tested positive for COVID-19 or were in quarantine because of exposure to someone who had tested positive;

- admitting new patients because medical staff who performed physical examinations of patients were working limited schedules;

- obtaining physical examinations or blood tests from outside providers because the providers were no longer furnishing those services;

- scheduling patients for counseling sessions because OTPs did not always have accurate contact information for patients, OTPs were challenged by coordinating patient schedules with clinic counseling schedules, and some patients would not participate in telehealth; and

- following up with patients who were approved for take-home doses.

Maintaining Safe Contact With Patients

OTPs reported challenges in implementing CDC's guidance on protecting the health and safety of patients and staff. OTPs stated that they were not prepared for a situation like the COVID-19 pandemic. PPE was in short supply or not available, and social distancing measures had to be put in place.

Early in the COVID-19 pandemic, because OTPs were unable to purchase PPE, they struggled to implement their policies requiring the use of PPE. After PPE was available, OTPs stated that it was difficult to get patients to wear PPE that facilities provided (i.e., masks) and to follow other safety measures (e.g., frequent hand washing) that facilities put in place.

OTPs reported many challenges in implementing and enforcing social distancing (i.e., maintaining at least 6 feet of distance between people in a facility) to maintain safe contact with patients. OTPs stated that they had to determine how many patients could safely be in a facility; by limiting the number of patients, some OTP facilities had long lines of patients waiting outside to enter. OTPs stated that while patients were waiting in line, they did not follow social distancing guidelines, and OTPs were unable to enforce the guidelines.

> One OTP said that its patients were not taking the threat of contracting COVID-19 as seriously as they were at the beginning of the pandemic (i.e., treating COVID-19 as if it were the seasonal flu).

OTPs stated that many of their patients were considered to be at high risk for COVID-19 complications because they were older or had underlying health conditions. OTPs stated that it was challenging to schedule visits for those patients and other patients who had tested positive for COVID-19 and to ensure that they were isolated from others while at a facility.

OTPs also stated that they found it difficult to maintain social distancing within their facilities when telehealth was not an option for certain patients. OTPs stated that patients need to closely interact with OTP staff to complete paperwork and sign required forms. In addition, physical examinations of new patients who are prescribed methadone must be conducted in person. One OTP also expressed concerns with maintaining social distancing if there were to be a major weather event, such as a hurricane, during the COVID-19 pandemic. For example, patients would need to visit the facility to obtain take-home doses during a short period before evacuation.

Opioid Treatment Program Facility Operations Were Impacted

Of the 142 OTPs that we interviewed, 113 reported that the COVID-19 pandemic had an impact on their facilities' operations. For example, OTPs reported that their operating budgets, staffing, and hours of operation were impacted. In addition, OTPs reported that it was difficult to implement social distancing in their facilities.

Operating Budgets

OTPs reported that their operating expenditures increased while operating revenues decreased:

- Expenditures increased because of: (1) higher salary and compensation costs incurred (e.g., overtime pay, hazard pay, and sick leave costs); (2) hiring of additional staff to meet the changing needs of delivering OTP services (i.e., curbside dosing[37] or third-party

[37] Curbside dosing refers to providing medication outside of the OTP facility. For example, OTP staff administered or delivered treatment medication to patients outside the facility who were symptomatic, had tested positive for COVID-19, or had underlying health conditions.

transfers[38]), to offset staff absences or departures related to the COVID-19 pandemic and to perform additional tasks, such as screening patients for symptoms of COVID-19 (e.g., temperature checks); (3) acquisition of PPE (such as masks) for patients and staff; (4) acquisition of cleaning supplies and sanitizers; (5) procurement of additional janitorial services; (6) acquisition of larger than normal quantities of medication and related supplies to fulfill increased numbers of take-home doses; and (7) implementation of telework and telehealth.

- Revenues decreased because State reimbursements declined, patients visited facilities less often, and patients did not have the ability to pay for services themselves. OTPs reported that some State Medicaid agencies did not pay providers for some services (e.g., take-home doses and telehealth) or did not pay providers for telehealth services at the same rates they paid for in-person services. In addition, fewer patients visiting facilities resulted in fewer reimbursements from State Medicaid programs, private insurance companies, and patients. Further, some patients were unable to pay for services received because their work hours had been reduced, they had lost their jobs, or they had no insurance coverage. OTPs stated that they continued to treat patients irrespective of their ability to pay.

Staffing

OTPs reported that staffing was impacted, with some OTPs expressing that they needed more staff, while other OTPs needed to reduce the number of staff. OTPs also reported that existing staff were required to work more hours to comply with and implement COVID-19-related safety protocols (e.g., additional cleaning of facilities, screening of patients for COVID-19, and delivering curbside dosing or transferring medication to third parties).

Some OTPs reported that staff spent more time than they did before the COVID-19 pandemic doing the following:

- training patients to properly secure, manage, and account for their take-home doses and to use telehealth;

- helping teleworking colleagues with sending and receiving faxes and gathering information; and

[38] A third-party transfer is the delivery of medication to a designated individual on the patient's behalf, who then delivers it to the patient. The designated individual is verified by the OTP, and a chain-of-custody record documenting the transfer of the medication must be maintained.

- performing the work of colleagues who could not work because of personal situations. For example, staff may not have been able to work because they had underlying health conditions that put them in a high-risk category, may have tested positive for COVID-19, or may have been quarantined because of exposure to someone who tested positive. In addition, staff may have needed to care for family members or feared possible exposure to COVID-19 when working in the facility.

> One OTP stated that at one point, 50 percent of its staff was not working because of the COVID-19 pandemic. Staff tested positive, had relatives who had tested positive, were fearful of coming into the facility, or were immunocompromised. This same OTP reported that one staff member had died because of COVID-19.

Other OTPs reported that they: (1) had reduced the number of staff within their facilities to limit staff members' exposure to COVID-19 or (2) had to let go some of their administrative and part-time staff because of reductions in services and revenues.

In addition, OTPs reported that they were concerned with staff members' mental health because staff were working under stressful conditions. OTPs reported that some staff experienced fatigue and burnout and eventually resigned. The staffing problems were compounded by the difficulty of hiring new staff, because the entities that performed background checks and fingerprinting services were also working at reduced capacities.

Hours of Operation

OTPs reported that they had closed facilities temporarily or reduced facilities' hours of operation[39] because: (1) facilities had to be cleaned as a result of patients or staff testing positive for COVID-19 or being exposed to someone who had tested positive, (2) facilities were short-staffed because staff members who tested positive for COVID-19 or were exposed to someone who tested positive had to be quarantined, (3) staff were concerned about working in facilities without PPE and other safety measures in place, and (4) OTPs wanted to limit face-to-face interactions between patients and staff as much as possible.

Implementing Social Distancing in Facilities

OTPs reported that they had difficulties implementing social distancing in facilities because the facilities were small and were not designed or arranged to implement the recommended amount of space between people. Areas such as lobbies, reception and waiting areas, dosing areas, and counseling rooms did not provide for adequate distance between patients and staff

[39] Although OTPs may have reduced their hours of operation, some OTPs increased the number of hours in which they provided medication to patients to limit the number of patients in the facility at one time (i.e., for those patients who were not eligible for take-home doses).

and did not have physical barriers to limit or prevent transmission of COVID-19 among patients and staff.

Implementing and Using Telehealth Was Challenging

Of the 142 OTPs that we interviewed, 87 reported challenges in implementing telehealth for both staff and patients, as well as in using telehealth for counseling services and check-ins.

Technological and Other Barriers to Implementing Telehealth

Although most OTPs had implemented some form of telehealth to continue providing services to patients during the COVID-19 pandemic, implementing telehealth presented some challenges to both staff and patients because of technological and other barriers.

For those OTPs implementing telehealth, OTP staff encountered challenges in learning how to use telehealth software. Other OTPs encountered challenges because they did not have: (1) reliable internet or wireless internet connections in their facilities, (2) technology capable of using video to deliver telehealth services, (3) equipment (e.g., laptops and phones) that counselors who were teleworking could use to provide counseling services, or (4) the funds to purchase the necessary equipment. As a result, staff resorted to using their personal devices (i.e., computers, tablets, and cellphones) to contact and provide counseling to patients.

These limitations led to additional challenges related to:

- complying with State Medicaid rules that required OTPs to use video technology for group therapy sessions and to confirm that patients were ingesting prescribed take-home doses;

- providing counseling sessions and checking in with patients who were approved for take-home doses (e.g., for issues related to treatment medications, economic/financial burdens, stress, and fear); and

- securing patient information and maintaining the privacy of counselors and patients.

OTPs also reported challenges with telehealth and the security of patient information. Some OTPs expressed concern about using unsecure technology for counseling sessions and stated that they had not received guidance on this issue.

Patients experienced their own technology-related challenges with adopting telehealth. OTPs reported that patients did not always have access to necessary technologies required to participate in telehealth because they lacked internet access or reliable internet connectivity, a working phone or a phone with a data plan, or video equipment. In some cases, patients also lacked a private, safe place to participate in remote counseling sessions. In addition, OTPs

stated that some patients did not have enough minutes available on their phones to use for counseling sessions or may have been unable to replace a phone that was lost or stolen.

Using Telehealth for Counseling Sessions and Check-Ins

Those OTPs that had implemented telehealth stated that both staff and patients struggled to use telehealth for counseling sessions and check-ins and that staff and patients needed time to learn the technology. OTPs reported that both counselors and patients had difficulty transitioning from in-person counseling to counseling using telehealth. OTPs stated that patients preferred in-person counseling over telehealth, and some refused to use telehealth. As a result, OTPs suspended some counseling sessions or were not able to be provide them. Some OTPs found that group counseling was difficult to coordinate and that it was difficult to get patients to use telehealth for group sessions. Some OTPs also reported that some patients did not respond well to receiving counseling over the phone.

Treatment Medications, Personal Protective Equipment, and Cleaning Supplies Were More Difficult To Obtain and More Expensive Than Before the COVID-19 Pandemic

Of the 142 OTPs that we interviewed, 83 reported that treatment medications, PPE, and cleaning supplies were more difficult to obtain and more expensive than before the COVID-19 pandemic.

Treatment Medications and Related Supplies

OTPs stated that they were concerned initially with the impacts that the significant increase in the numbers of take-home doses being provided to patients would have on their supply chains and ability to obtain medications when needed. OTPs stated that, ultimately, they did not observe any disruptions in the medication supply chains; however, they experienced longer lead times on deliveries and higher costs for medications and the associated shipping and handling charges. OTPs also reported challenges in obtaining supplies (e.g., bottles and caps) used to package take-home doses because some supplies were on back-order and common carriers reduced their delivery services to some areas during the COVID-19 pandemic.

Personal Protective Equipment

OTPs stated that early in the COVID-19 pandemic, PPE was difficult to find and purchase because of supply shortages and high demand. OTPs commented that they did not normally have large supplies of PPE on hand. According to some OTPs, States and PPE distributors allocated their existing PPE supplies to hospitals and to COVID-19 hotspots on the east and west coasts, where

> One OTP administrator said: "Our first, biggest challenge was the absolute lack of adequate PPE in the industry. It created this feeling of 'Are we going to be able to provide services? What if we run out of masks?' "

there were existing outbreaks of COVID-19. In addition, some States distributed PPE supplies to providers based on a priority system, and OTPs were not considered to be a top priority.

Some OTPs reported that it took 2 to 3 weeks to obtain PPE and at much higher costs than before the COVID-19 pandemic. One OTP reported purchasing PPE, such as masks and gloves, at a cost that was 10 times higher than normal. OTPs also reported that they were not able to obtain PPE from their normal suppliers, so they changed suppliers, accepted donated items (e.g., masks that did not meet N95 standards[40]), or used other products, such as food service gloves, to provide some protection to patients and staff.

Cleaning Supplies and Sanitizers

OTPs reported that it was initially difficult to find and purchase supplies needed to clean and disinfect their facilities. Antibacterial soaps, bleach, hand sanitizer, and disinfectant wipes were all in low supply and high demand. OTPs reported obtaining some of these items through donations. Some OTPs reported that these items were available at the time we conducted our interviews but at higher prices than normal, while other OTPs stated that obtaining them was still a challenge.

Patient Participation in Opioid Treatment Program Activities Was Challenging To Maintain

Of the 142 OTPs that we interviewed, 77 reported challenges in maintaining patient participation in OTP activities. These challenges were related to the limited availability of transportation to facilities and maintaining patient engagement with OTP services.

Availability of Transportation to Facilities

OTPs reported that patients encountered difficulties in visiting facilities because transportation options were limited during the COVID-19 pandemic and, as a result, missed their scheduled appointments at the facility. OTPs commented that many patients do not have their own transportation and instead rely on public transportation, medical transportation companies under contract with Federal and State health care programs, ride services, and friends or relatives for transportation to and from an OTP facility. OTPs stated that public transportation services, transportation provided by medical transportation companies, and ride services were sometimes difficult to obtain or unavailable because of changes in routes and schedules, limits on the number of riders, and overall reductions in services during the COVID-19 pandemic.

In addition, OTPs stated that some patients no longer had a transportation benefit through their Federal health benefits because they had lost their Medicaid benefits during the COVID-19 pandemic or their veterans' health benefits no longer paid for transportation. Further, one OTP

[40] The N95 designation refers to a respirator or mask that, when subjected to careful testing, blocks at least 95 percent of small test particles. OTPs did not specifically indicate in their responses whether the masks they were able to obtain from suppliers met N95 standards.

stated that a nonemergency medical provider declined to transport patients unless the facility confirmed that the patient had been tested for COVID-19, which was information that the facility was prohibited from providing.

Maintaining Patient Engagement With Opioid Treatment Program Services

OTPs reported challenges in maintaining contact with patients and getting them to visit facilities to receive services during the COVID-19 pandemic. Although most OTPs stated that they were able to implement some form of telehealth to connect with patients, OTPs reported that it was difficult to: (1) check in or follow up with patients because some did not have phones or their phones had limited minutes available that were needed for other purposes, (2) maintain updated contact information for each of their patients, or (3) get patients to attend scheduled counseling sessions. As a result, certain services, such as annual reviews, could not be performed or had to be postponed.

OTPs reported that patients who were generally more resistant to treatment were less likely to engage in counseling sessions through telehealth than if the sessions were provided in person. OTPs also reported challenges in getting patients into support groups that had been successful in the past.

Dealing With Limitations Posed by Existing Federal Guidance Was Challenging, and Opioid Treatment Programs Would Like To Have Additional Flexibilities for Providing Services During the COVID-19 Pandemic

Of the 142 OTPs that we interviewed, 65 reported challenges posed by existing Federal guidance, which limited actions they wanted to take. OTPs stated that they would like to have additional flexibilities to better serve their patients. OTPs reported that the increased flexibilities SAMHSA provided to OTPs during the COVID-19 pandemic have generally produced positive results related to patient retention rates, patient engagement in counseling sessions, and patient no-shows for counseling sessions. However, OTPs stated that they think current Federal requirements limit their ability to provide care tailored to their patients' needs.

> One OTP reported that, with the increased number of take-home doses, patients who missed doses decreased by 50 percent during the COVID-19 pandemic.

OTPs provided the following examples of additional flexibilities they would like to have:

- OTPs stated that, to admit new patients who are being prescribed methadone, they would like to have the option to use telehealth as a replacement for in-person physical examinations. OTPs commented that the requirement for an in-person examination needlessly placed staff at risk. OTPs also stated that they were unsure why new patients being prescribed buprenorphine could be admitted via telephone, but new patients being prescribed methadone were required to be evaluated in person. OTPs stated that they believe that this is a barrier to treatment.

> Regarding the use of telehealth to replace in-person physical examinations when prescribing methadone, one OTP stated: "SAMHSA's ongoing refusal to make this accommodation made new methadone patient inductions more difficult and time-consuming than they needed to be, in addition to needlessly exposing our team members to a greater risk of COVID-19 infection."

- OTPs stated that they would like more flexibilities in providing telehealth services. Specifically, OTPs stated that they would like to have the ability to provide telehealth services without having to use video conferencing and have additional options available for communicating with patients. OTPs also stated that some patients better engage with counselors over the phone or even through text messaging. Additionally, because many patients do not have access to video technology, the additional options would allow patients who are feeling isolated to connect with a counselor at any time.

> One OTP administrator commented: "I have a concern that the gains that are being made in telehealth delivery are going to be taken away when things return to normal."

- OTPs stated that they would like the flexibilities for increased take-home doses to be extended after the COVID-19 pandemic. OTPs also stated that they would like more flexibility in deciding which patients are approved for take-home doses and how many doses can be prescribed.

- OTPs reported they would like to continue to deliver medication to their patients' homes after the COVID-19 pandemic.

Providing Take-Home Doses to Patients Posed Some Challenges

Of the 142 OTPs that we interviewed, 51 reported that providing take-home doses to patients posed challenges. Example of challenges included: (1) implementing controls and procedures for take-home doses, (2) evaluating patients' eligibility for take-home doses, (3) preventing patients' improper management of or diversion of take-home doses, (4) clarifying patients'

confusion with take-home doses, and (5) complying with recordkeeping requirements for take-home doses.

Implementing Controls and Procedures for Take-Home Doses

OTPs reported challenges in implementing controls and procedures related to the increased flexibilities that SAMHSA granted for take-home doses. Because OTPs were allowed to provide more take-home doses to patients than before the COVID-19 pandemic, OTPs stated that they had to establish new or additional procedures related to transferring take-home doses to patients who could not or were not willing to come into a facility for treatment. Different procedures had to be established for take-home doses that were delivered curbside, through verified third parties, and directly to a patient's residence.

Evaluating Patients' Eligibility for Take-Home Doses

OTPs reported challenges in determining which patients were "stable" and determining the number of take-home doses to prescribe each patient, taking into account, among other things, each patient's health status, medical history, and ability to independently and safely ingest their medication at the prescribed intervals. OTPs stated that they also found it challenging to determine whether patients could properly store and secure medication at home (e.g., OTPs required patients to store medication in a lockbox and to keep it locked and secured from others) and sufficiently account for the take-home doses they received.

> One OTP stated that it was not sure ". . . how to allow patients to have take-home doses."

Preventing Patients' Improper Management of or Diversion of Take-Home Doses

As stay-at-home orders and social distancing protocols were implemented and more services were provided outside of OTP facilities, OTPs encountered challenges with balancing the risk that patients could mismanage or divert (i.e., illegally share or sell) take-home doses against the risk that patients could visit the facility and possibly be exposed to COVID-19. Specifically, OTPs had concerns about patients' abilities to manage prescribed take-home doses. OTPs reported that some patients did not understand how much medication to take. Patients sometimes took more than their prescribed doses, which required OTPs to adjust the number of take-home doses. OTPs also noted that some patients may not take all their prescribed doses but instead share it with others or sell it. In some cases, OTPs revoked the take-home privileges of patients who had not properly managed or had diverted their take-home doses.

Clarifying Patients' Confusion With Take-Home Doses

One OTP stated that patients were confused about how to deal with take-home doses. For example, the OTP stated that patients: (1) did not know when they should return to a facility for more medication, (2) visited a facility on days that they were not scheduled to be there, (3) took more doses in a day than were prescribed, and (4) visited a facility multiple times a day.

The OTP stated that some patients had to be rescheduled from weekly or biweekly visits to daily visits because they were unable to take their medication without supervision. Another OTP stated that patients receiving take-home doses thought incorrectly that they would no longer be subjected to drug testing or diversion checks.[41]

Complying With Recordkeeping Requirements for Take-Home Doses

OTPs encountered challenges in complying with recordkeeping requirements for take-home doses and maintaining adequate documentation. OTPs stated that maintaining documentation was difficult because more patients were prescribed take-home doses and in larger quantities.

Implementing Governmental Guidance Was Not Always Easy

Of the 142 OTPs that we interviewed, 34 reported that it was not always easy to implement guidance from various governmental agencies. OTPs commented that, at the beginning of the COVID-19 pandemic, the guidance from Federal agencies (e.g., SAMHSA and CDC) and from State agencies was limited and slow to arrive; later, the guidance became difficult to implement because it changed frequently.

OTPs reported that it was difficult to plan or develop any strategies without timely guidance from oversight agencies. In addition, OTPs stated that it was difficult to implement State guidance because it was sometimes: (1) not coordinated with other oversight agencies, (2) in conflict with Federal guidance, and (3) contradicted infection control standards. One OTP commented that its State Medicaid agency provided guidance on which services Medicaid would pay for, only to retroactively disallow the same services later.

OPIOID TREATMENT PROGRAMS REPORTED A VARIETY OF ACTIONS TAKEN TO ADDRESS CHALLENGES WHILE ENSURING THE CONTINUITY OF NEEDED SERVICES AND PROTECTING THE HEALTH AND SAFETY OF PATIENTS AND STAFF

OTPs reported a variety of actions they have taken to address challenges during the COVID-19 pandemic, including actions related to: (1) personal safety measures for patients and staff (141 OTPs), (2) the implementation or expansion of telehealth (128 OTPs), (3) increased numbers of take-home doses (127 OTPs), (4) physical changes to facilities and increased staffing flexibilities (121 OTPs), and (5) patients' receipt of treatment medications (92 OTPs).

[41] Diversion checks are measures taken to reduce the possibility of diversion of controlled substances from legitimate treatment use. These measures include OTPs randomly calling patients to take inventories of their take-home doses.

Opioid Treatment Programs Encouraged or Required Various Personal Safety Measures for Patients and Staff

Of the 142 OTPs that we interviewed, 141 reported that they encouraged or required a variety of personal safety measures for patients and staff in their facilities, including the use of PPE, social distancing among patients and staff, proper hygiene, facility cleaning, and measures to reduce exposure to COVID-19.

Personal Protective Equipment

OTPs reported that they encouraged or required patients and staff to use PPE while in facilities. OTPs also reported that they posted signs around their facilities to remind patients and staff to wear PPE to protect themselves against possible exposure to COVID-19 and provided training to both patients and staff on the proper use of PPE.

OTPs reported that staff were generally required to wear masks, face shields, and gloves. Certain staff, such as those working in isolation units or delivering medications curbside, wore more PPE (e.g., goggles and gowns). OTPs also reported that patients were generally required to wear a mask or a face covering. If a patient did not have a mask, OTPs generally provided a mask if one was available.

Some OTPs reported that they were able to provide staff with N95 or similar masks. One OTP stated that it reserved these masks for staff who performed high-risk tasks, such as in-person examinations. Some OTPs reported that they have been able to purchase or obtain (e.g., through donations) PPE and have an adequate stock. Other OTPs reported that they used cloth or other handmade masks because of mask shortages.

> One OTP administrator said: "One lesson I've learned is to have supplies of PPE rather than wait until we have a low supply."

Social Distancing Among Patients and Staff

OTPs reported that they took specific actions to implement social distancing in and around their facilities. Specifically, OTPs stated that, among other things, they:

- increased the number of hours that counselors were available for counseling sessions through telehealth;
- extended dosing hours to limit contact among patients and allow for more time between patient visits (i.e., to limit the number of patients in the facility at one time);
- reduced the number of hours that staff had to be in the facility by increasing the use of telework and telehealth;

- limited the number of patients entering the facility by having patients schedule appointments for specific times or having them wait in their vehicles until there was room in the facility;

- created alternating or staggered schedules for patient visits (e.g., scheduling patients with last names starting with letters A through E on Mondays, patients with last names starting with letters F through J on Tuesdays, and so on);

- limited the number of patients who were allowed to be in certain areas of the facility (e.g., lobby or dosing areas) simultaneously;

- limited the amount of time that patients were in the facility by preparing pre-packed kits before dispensing take-home doses;

- prohibited or limited the number of patients' visitors and guests who could enter the facility;

- organized staff into teams and scheduled the teams to work together in the facility only on specific days;

- conducted staff meetings virtually or by phone from separate rooms within the facility; and

- used security guards to monitor and enforce social distancing among patients.

Proper Hygiene

OTPs reported that they encouraged proper hygiene by promoting frequent hand washing and the use of hand sanitizer. OTPs stated that they installed hand-washing stations and placed signage and posters around facilities to remind patients and staff to wash their hands. OTPs also made hand sanitizer available throughout their facilities.

Facility Cleaning

OTPs reported that they frequently cleaned high-touch surfaces (e.g., doorknobs), bathrooms, and other rooms used by patients. In addition, OTPs stated that they cleaned and sanitized entire facilities regularly (e.g., daily or twice daily). OTPs also stated that they made disinfectant spray or wipes available to patients and staff.

Other Measures To Reduce Exposure to COVID-19

OTPs reported that they educated patients and staff and provided literature on ways to reduce exposure to COVID-19 (e.g., through social distancing, proper mask use, and proper hand-

washing techniques). OTPs also reported that they tested and screened patients and staff for COVID-19. OTPs stated that they: (1) took the temperatures of patients and staff before they entered facilities and (2) screened patients by asking a series of questions to determine whether they had been diagnosed with COVID-19, were symptomatic, or had been exposed to someone who had been diagnosed positive. Some OTPs reported that they conducted COVID-19 testing in their own facilities rather than sending test samples to an independent laboratory. OTPs also stated that they required staff who tested positive for COVID-19 to have two negative test results before they were permitted to return to work.

OTPs reported that they stopped using breathalyzers to measure patients' blood alcohol levels because it involved too much risk for spreading aerosol droplets. One OTP stated that it purchased breathalyzers that did not blow air into nurses' faces.

Opioid Treatment Programs Implemented or Expanded the Use of Telehealth To Continue Providing Services

Of the 142 OTPs that we interviewed, 128 reported that they implemented or expanded the use of telehealth to continue providing services to patients and to reduce the number of patients who were required to visit facilities. OTPs stated that they used telehealth technologies for such things as individual and group counseling sessions, psychiatric services, support groups, and new patient admissions.

OTPs reported taking different actions to provide telehealth services:

- OTPs provided telehealth services using a variety of communication services and telemedicine applications (e.g., Google Voice, Zoom, BlueJeans, Doximity, and Doxy.me).

- OTPs set up rooms with technology in facilities to allow patients to contact counselors who were working remotely or in another room at a facility, which allowed patients who did not have access to telehealth technologies to participate in telehealth.

- OTPs called patients to check in with them and used video meetings to conduct diversion checks (i.e., to verify that the patient had the appropriate number of take-home doses on hand). OTPs that offered inpatient services used tablets to conduct meetings with patients who had tested positive for COVID-19 and were in isolation units.

- OTPs offered stipends to staff who were working remotely so that they could use personal devices to contact patients.

> One OTP found that patients were more willing to participate in an hour-long conversation over the phone than they were to come to the facility for an hour-long meeting.

OTPs also reported additional information on actions they took to ensure the successful implementation of telehealth:

- OTPs provided patients training on telehealth technologies and trained staff on how to better serve patients through telehealth.
- OTPs increased the number of phone calls with patients and spoke with them more often.
- OTPs remained flexible on when they would contact patients.

One OTP official stated: "Our no-show rate is non-existent because of telehealth. We have bus and transportation issues when weather is bad, but with telehealth it is not an issue. The verbal feedback from patients is 100-percent satisfaction."

Opioid Treatment Programs Increased the Number of Take-Home Doses To Reduce the Number of Patients Visiting Facilities

Of the 142 OTPs that we interviewed, 127 reported that they increased the number of take-home doses for some patients to reduce the number of patients who had to visit a facility each day. Some OTPs increased the number of take-home doses for patients up to the limits allowed by SAMHSA, while other OTPs increased the number of take-home doses but at lower levels than the SAMSHA limits because of State or OTP restrictions.

OTPs reported taking different actions to determine the number of take-home doses for some patients:

- In addition to applying the requirements outlined in Federal regulations (42 CFR § 8.12), OTPs evaluated whether a patient was responsible enough to handle his or her medication for opioid use disorder in an unsupervised environment (i.e., at home) based on the patient's:
    - risk level for relapse, overdose, or misuse;
    - history of managing the medication;
    - underlying health conditions;
    - demonstrated compliance with the treatment plan; and
    - past level of engagement with counselors.
- OTPs worked with opioid treatment trade associations and State agencies to implement rules to maximize the number of take-home doses for both stable and less stable patients.

OTPs reported taking different actions to ensure that patients were accountable for the increased number of take-home doses. Specifically, OTPs:

- required patients to sign antidiversion agreements,

- called patients to conduct diversion checks or wellness checks to ensure that patients were using their medications responsibly, and

- required patients to participate in phone calls as a condition of continuing to receive take-home-dose privileges.

One OTP also reported taking actions to ensure that patients were taking appropriate doses by using pill trays to help minimize the risk of overdoses.

Finally, OTPs reported taking additional actions to ensure implementation of increased take-home doses. Two examples follow:

- OTPs purchased and maintained larger quantities of medication to meet the increased demand of take-home doses for more patients and to prepare for possible supply disruptions.

- OTPs purchased lockboxes to store take-home doses for patients who did not have them. OTPs provided lockboxes to patients at no cost or sold them to patients at costs below what the OTPs purchased them for. (Some States also purchased lockboxes for patients who could not afford them.)

Opioid Treatment Programs Made Physical Changes to Facilities and Increased Staffing Flexibilities

Of the 142 OTPs that we interviewed, 121 reported that they took a variety of actions affecting business operations, including: (1) making physical changes to their facilities and (2) increasing staffing flexibilities and making changes in employee pay and benefits.

Physical Changes to Facilities

OTPs reported that they made various physical changes to their facilities to protect patients and staff. Specifically, OTPs stated that, among other things, they:

- installed physical barriers, such as plexiglass screens, in areas where patients and staff needed to be in close contact with one another (e.g., security stations, waiting rooms, reception areas, nursing stations, and dispensing and dosing areas);

- modified the layouts of their facilities to improve traffic flow by limiting the number of entry doors and designating separate entry and exit doors;

- repurposed some areas to allow for more social distancing, including using individual rooms, offices, and conference rooms to admit new patients and provide counseling sessions;

- created isolation areas for symptomatic patients;

- reduced the number of chairs in lobbies and waiting areas and spaced the chairs at least 6 feet apart;

- placed tape or markers in 6-foot intervals on the floors of facilities and the areas outside facilities;

- removed communal items (e.g., magazines and toys), water, and coffee from lobbies and waiting areas;

- opened doors to minimize contact with door handles and opened windows to improve airflow in facilities;

- purchased air purifiers and filters for waiting areas and other rooms; and

- placed posters and signs inside and outside facilities to remind both patients and staff to: (1) wear protective face coverings (such as masks), (2) wash their hands or use hand sanitizer frequently, (3) practice social distancing, and (4) not enter facilities if they were sick or were showing signs of having COVID-19.

Increased Staffing Flexibilities and Changes in Employee Pay and Benefits

OTPs reported that they reduced the number of staff in their facilities to protect staff from possible exposure to COVID-19. Some administrative staff, counselors, and staff members at risk of complications from COVID-19 were allowed to telework. OTPs also reported that they stopped meeting in large groups. For example, virtual staff meetings were held from telework locations or from separate rooms in the facility.

OTPs stated that they set up employee assistance programs for staff to help them manage their stress.

OTPs stated that they offered hazard pay to staff who continued working during the COVID-19 pandemic and extended emergency paid-time-off for staff who were unable to work in facilities because of personal situations (e.g., for staff who had no child care options).

Opioid Treatment Programs Took a Variety of Actions To Ensure That Patients Received Treatment Medications

Of the 142 OTPs that we interviewed, 92 reported that they took a variety of actions to ensure that patients received treatment medications. For example, OTPs offered curbside dosing and delivered treatment medications (i.e., take-home doses) to patients who were not able to visit facilities because patients: (1) were quarantined or had tested positive for COVID-19, (2) were immunocompromised (e.g., patients with HIV or hepatitis C), or (3) were at high-risk for serious complications from COVID-19 (e.g., older patients or patients with certain underlying medical conditions). OTPs also reported that they continued to provide services, including treatment medications, to patients who did not have the ability to pay or worked with another facility to ensure that all patients received treatment.

Curbside Dosing

OTPs reported that they took the following actions to administer curbside dosing:

- Patients were required to call a facility from the parking lot on arrival to the facility before medication was brought to them.
- Staff were stationed outside the facility and notified the dosing staff that a patient had arrived for curbside dosing.
- Security personnel escorted nurses who were delivering or administering the curbside doses.
- Every person who handled a medication for curbside dosing was required to sign a form to document the chain of custody of medication.
- One OTP that was part of a hospital moved its dosing services to a mobile unit in a parking lot near the OTP clinic to reduce possible exposure to COVID-19 for the hospital staff, clinic staff, and patients.
- One OTP left a patient's curbside dose outside a glass door and watched the patient take the medication.

One OTP official described the use of curbside dosing for symptomatic patients as a "game changer" in preventing others from being exposed to COVID-19.

Delivery of Take-Home Doses to Patients

OTPs reported that they delivered take-home doses to their patients and took the following actions to ensure that patients received the take-home doses:

- OTP staff who delivered medication to a patient's residence placed the take-home doses outside the patient's door and waited to leave until visually confirming that the patient had picked up the medication.

- OTPs provided patients prescribed take-home doses through third parties (e.g., family members, friends, caregivers, or home health aides).[42, 43] To verify that a person could deliver a patient's medication, one OTP required a family member to have a picture on file at the OTP, show an ID, and have the patient's permission before the family member could receive the patient's medication.

CONCLUSION

During the COVID-19 pandemic, OTPs have encountered a variety of challenges affecting the specific services they provide and how they provide them. Some of the challenges reported by OTPs related to: (1) maintaining pre-pandemic service levels (124 OTPs); (2) managing impacts on facility operations (113 OTPs); (3) implementing and using telehealth (87 OTPs); (4) obtaining treatment medications, PPE, and cleaning supplies (83 OTPs); (5) maintaining patient participation in OTP activities (77 OTPs); (6) dealing with limitations posed by existing Federal guidance (65 OTPs); (7) providing take-home doses to patients (51 OTPs); and (8) implementing governmental guidance (34 OTPs).

OTPs have taken a range of different actions to address all these challenges while ensuring continuity of needed services and protecting the health and safety of their patients and staff, including: (1) encouraging or requiring various personal safety measures for patients and staff (141 OTPs), (2) implementing or expanding the use of telehealth to continue providing services (128 OTPs), (3) increasing the number of take-home doses to reduce the number of patients visiting facilities (127 OTPs), (4) making physical changes to facilities and increasing staffing flexibilities (121 OTPs), and (5) ensuring that patients received treatment medications (92 OTPs).

The information in this report was gathered to support HHS's goal of reducing opioid morbidity and mortality and to help SAMHSA by providing information on the impact that the COVID-19 pandemic has had on OTPs. This information was current when we conducted our interviews, from June 4 through June 22, 2020, but may not represent all the challenges that OTPs have faced or the actions they have taken to address those challenges. Since our interviews, OTPs may have addressed some of the challenges and identified new challenges. Additionally, during the interviews, OTPs may not have shared with us all their challenges or all the actions they have taken.

[42] In its guidance dated March 30, 2020, "OTP Guidance for Patients Quarantined at Home with the Coronavirus," SAMHSA stated that a member of a patient's household could deliver take-home doses to a patient.

[43] One OTP reported that it received a waiver from DEA to allow deliveries by a person who was not a nurse or a qualified professional.

We recognize that SAMHSA has taken actions to support OTPs as they work on the front lines to treat people diagnosed with opioid use disorders and to ensure the safety of the health care workforce. The information in this report provides SAMHSA and other decisionmakers (e.g., State and Tribal officials and other Federal agencies) with a national snapshot of OTPs' challenges and the actions they have taken to continue providing services during the COVID-19 pandemic. In addition, OTPs may find the information about each other's strategies useful in their own efforts to address the challenges they are facing.

SAMHSA COMMENTS

In written comments on our draft report, SAMHSA described actions that it had taken after becoming aware of COVID-19's impact on operations for its behavioral health stakeholders, including OTPs. SAMHSA stated that it had promoted its *Disaster Planning Handbook for Behavioral Health Treatment Programs,* which included continuity-of-clinical-care instructions during a pandemic. SAMHSA also stated that it had worked closely with State Opioid Treatment Authorities to authorize extended take-home medications for those with opioid use disorder. Further, SAMHSA stated that it had worked with DEA to waive the requirement for an in-person physical exam for new patients receiving buprenorphine and to permit the use of telehealth for established patients with opioid use disorder. Finally, SAMHSA stated that it has provided technical assistance and training during the pandemic, including telehealth training for mental health providers.

Regarding the flexibilities that OTPs requested to admit new methadone patients using telehealth as a replacement for in-person physical examinations, SAMHSA said that eliminating the in-person physical examination requirement could present a significant safety issue for a patient with opioid use disorder because methadone, when compared with buprenorphine, has greater potency, and adverse effects (such as sedation and overdose) can occur more commonly.

SAMHSA's comments are included in their entirety as Appendix B.

OTHER MATTERS

During our interviews with OTPs, we attempted to get a sense of COVID-19's impact on the population the OTPs served. Specifically, we asked each OTP whether the COVID-19 pandemic has had any impact on the number of patients who: (1) were enrolled in the OTP, (2) were visiting its facility for MAT, (3) were seeking enrollment in the OTP, (4) had experienced a relapse, or (5) had experienced an overdose. OTPs reported the following:[44]

[44] The totals in this section do not add up to the total number of OTPs interviewed because some OTPs did not indicate the impact that the COVID-19 pandemic has had on the patient population.

- Regarding the number of patients enrolled in their OTPs for MAT, 32 OTPs reported an increase in enrollment, 28 OTPs reported a decrease in enrollment, and 76 OTPs reported no change in their enrollment.

- Regarding the number of patients visiting their facilities for MAT, 6 OTPs reported an increase, 75 OTPs reported a decrease, and 30 OTPs reported that there was no change. OTPs that reported a decrease in patients visiting facilities attributed the decrease to the increase in the number of patients who received take-home doses and to the increased use of telehealth for counseling sessions.

- Regarding the number of patients seeking enrollment in their OTPs, 33 OTPs reported an increase, 53 OTPs reported a decrease, and 49 OTPs reported no change.

- Regarding the number of patients who had experienced a relapse during the COVID-19 pandemic, 41 OTPs reported an increase, 8 OTPs reported a decrease, and 50 OTPs reported no change. OTPs stated that because they were performing fewer drug tests during the COVID-19 pandemic, they did not have information on relapses other than what was disclosed by the patients themselves. OTPs attributed the increase in relapses to the following reasons: (1) patients were experiencing stress, anxiety, depression, loneliness, isolation, and boredom with staying at home; (2) patients were out of work; and (3) patients lacked support because support groups (e.g., Alcoholics Anonymous) were unavailable, they had limited contact with family and friends, and they were not receiving face-to-face therapy.

  Of the OTPs interviewed, 29 percent reported an increase in the number of patients who had experienced a relapse, and 6 percent reported an increase in the number of patients who had experienced an overdose.

- Regarding the number of patients who had experienced an overdose during the COVID-19 pandemic, 9 OTPs reported an increase, 4 OTPs reported a decrease, and 90 OTPs reported no change.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

As of April 17, 2020, there were 1,746 OTPs nationwide (excluding U.S. territories) that SAMHSA had either certified or provisionally certified to provide MAT. Of these OTPs, we randomly selected 150 OTPs from 49 States (excluding Wyoming, which had no operating OTPs) and the District of Columbia. From the sample, we removed seven OTPs for various reasons, including one OTP that was no longer in operation. We attempted to interview the remaining 143 OTPs. Of these, we received responses from 142 OTPs, for a response rate of 99.3 percent.[45] The OTPs that responded were located in 37 States and the District of Columbia.

We conducted our interviews primarily by telephone with one or more OTP executives and administrative officials (e.g., the program director, medical director, or clinical director) in the same interview from June 4 through June 22, 2020. (Two OTPs responded to our interview questions through email.) In some cases, we spoke with officials from an OTP's parent company instead of or in addition to an OTP official.[46] We considered the interviews with parent company officials to be formal responses for those OTPs owned by the parent company.

During each interview, we obtained information related to challenges that the OTP stated it had encountered during the COVID-19 pandemic and the actions that the OTP stated it was taking or had taken to address those challenges. We asked each OTP to answer four primary questions:

- What challenges are you encountering in providing OTP services to patients during the COVID-19 pandemic?

- What strategies or actions has your facility employed to ensure the availability and delivery of OTP services to your patients during the COVID-19 pandemic?

- What strategies or actions have you taken to protect the health and safety of your patients and staff?

- What strategies or actions would you like to implement but are unable to and why are you not able to implement them?

In addition to these four questions, we asked each OTP about the impact that the COVID-19 pandemic has had on the number of patients who: (1) were enrolled in the OTP, (2) were

[45] We attempted to contact the one remaining OTP to request an interview nine times during the period June 4 through June 22, 2020, but the OTP did not respond to our requests.

[46] We conducted 9 interviews in which parent company officials spoke on behalf of 18 OTPs in our sample.

visiting its facility for MAT, (3) were seeking enrollment in the OTP, (4) had experienced a relapse, or (5) had experienced an overdose.

The information in this report represents a range of challenges, actions, experiences, and perceptions that OTP officials conveyed to us, as of a point in time, during our interviews. It may not represent all the challenges that OTPs have faced or the actions they have taken during the COVID-19 pandemic. Since our interviews, OTPs may have addressed some of the challenges and identified new challenges. Additionally, during our interviews, OTPs may not have shared with us all their challenges or all the actions they have taken. Although some OTPs may have faced the same challenges or taken the same actions that other OTPs reported, these OTPs did not describe them to us in response to our questions. We did not independently verify the information that the OTPs provided to us or determine the effectiveness of the actions that the OTPs identified.

We did not assess SAMHSA's or the OTPs' internal controls because they were not significant to our audit objectives. The objectives did not require us to assess HHS's or SAMHSA's: (1) internal controls related to oversight of OTPs or (2) response to the COVID-19 pandemic. Additionally, we did not evaluate whether OTPs complied with applicable Federal and State requirements, including opioid treatment standards.

The information in this report is provided for informational purposes only and, therefore, the report does not contain any recommendations. We gathered this information to support HHS's goal of reducing opioid morbidity and mortality and to help SAMHSA by providing information on the impact that the COVID-19 pandemic has had on OTPs. This report provides SAMHSA and other decisionmakers (e.g., State and Tribal officials, and other Federal agencies) with a national snapshot of OTPs' challenges and the actions they have taken to continue providing services during the COVID-19 pandemic. In addition, OTPs may find the information about each other's strategies useful in their own efforts to address the challenges they are facing. This audit is not an assessment of HHS's or SAMHSA's response to the COVID-19 pandemic.

METHODOLOGY

To accomplish our objectives, we:

- reviewed Federal opioid treatment standards at 42 CFR part 8 and Federal guidance describing the flexibilities that States and OTPs were granted during the COVID-19 pandemic;

- obtained from the SAMSHA website the list of 1,746 OTPs that SAMHSA had certified and provisionally certified to provide MAT as of April 17, 2020;

- developed a survey questionnaire and tested it with 2 OTPs;

- selected a simple random sample of 150 OTPs across 49 States and the District of Columbia;

- removed 7 OTPs from our sample for various reasons, including 1 OTP that was no longer in operation;

- attempted to interview officials at the 143 remaining OTPs and received responses from 142 OTPs;

- compiled a list of the challenges the 142 OTPs have encountered during the COVID-19 pandemic and the actions they have taken to address them; and

- discussed the results of our audit with SAMHSA officials.

We conducted this performance audit 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.

APPENDIX B: SAMHSA COMMENTS

SAMHSA
Substance Abuse and Mental Health Services Administration
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November 10, 2020

TO: Amy J. Frontz
Deputy Inspector General for Audit Services
Department of Health and Human Services Office of Inspector General

FROM: Assistant Secretary for Mental Health and Substance Use

SUBJECT: OIG Draft Report "*Opioid Treatment Programs Reported Challenges Encountered During the COVID-19 Pandemic and Actions Taken To Address Them*", A-09-20-01001

The Substance Abuse and Mental Health Services Administration has reviewed the subject document and concurs with the recommendations.* SAMHSA offers the attached comments for consideration.

Elinore F. McCance-Katz, M.D., Ph.D.

* **Office of Inspector General Note:** This report contains no recommendations.

GENERAL COMMENTS FROM THE SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION ON THE OFFICE OF INSPECTOR GENERAL'S DRAFT REPORT ENTITLED –OPIOID TREATMENT PROGRAMS REPORTED CHALLENGES ENCOUNTERED DURING THE COVID-19 PANDEMIC AND ACTIONS TAKEN TO ADDRESS THEM A-09-20-01001

The Substance Abuse and Mental Health Services Administration (SAMHSA) appreciates the opportunity from the Office of Inspector General (OIG) to review and comment on this report.

SAMHSA would like to note that as we became aware of COVID-19's impact on operations for our behavioral health stakeholders we began rapid dissemination of guidance and support. First SAMHSA promoted the existing Technical Assistance publication "Disaster Planning Handbook for Behavioral Health Treatment Programs" which included continuity of clinical care instructions during a pandemic. For those with opioid use disorder (OUD) SAMHSA worked closely with State Opioid Treatment Authorities to authorize extended take home medications which are currently still in effect. For the safety of providers and patients, in concert with the DEA, SAMHSA has waived the in-person physical exam for those receiving buprenorphine while also permitting the use of telehealth for established patients with OUD. These provisions balanced patient and community safety. SAMHSAs Technology Transfer Centers have been working tirelessly to provide technical assistance and training during the pandemic. Most importantly as we realized that many providers were not poised or prepared to implement telemedicine, our technical assistance has been mobilized for telehealth training among mental health providers.

SAMHSA would also like to address the issue raised in the report concerning methadone inductions during this health emergency. SAMHSA has collaborated with the DEA and other federal partners, specifically allowing for greater flexibilities for both OTPs and individual practitioners to continue providing care in the midst of a pandemic. Our work in this area continues and we have been gathering information from stakeholders across many settings. When admitting a new patient to an OTP via telehealth, 42 Code of Federal Regulations (CFR) § 8.12(f)(2) requires a patient to undergo a complete physical evaluation by a program physician or primary care physician before admission to the OTP. Because 42 CFR § 8.11(h) allows SAMHSA to grant exemptions to OTPs from certain requirements, as of April 21, 2020, during the national emergency declared for COVID-19, patients treated by the OTP with buprenorphine do not need an in-person examination if an adequate evaluation can be done via telehealth. SAMHSA has made this determination on the basis that eliminating the in-person physical examination requirement for new methadone patients could present significant safety issue for a patient with OUD. Buprenorphine as a partial agonist retains a ceiling on its effects and possesses a much lower overdose risk while methadone as a full agonist has greater potency and adverse effects like sedation and overdose can occur more commonly. Leadership at HHS understands that the circumstances of this public health emergency may change and we rely on stakeholders to inform our policy.