



## SAMHSA Is Missing Opportunities To Better Monitor Access to Medication-Assisted Treatment Through the Buprenorphine Waiver Program

### What OIG Did

Combating the opioid crisis by expanding treatment services is a key priority for the Substance Abuse and Mental Health Services Administration (SAMHSA).<sup>1</sup> The Buprenorphine Waiver Program—one of SAMHSA's primary initiatives to address this priority—authorizes 90,000 providers to provide medication-assisted treatment (MAT) to patients with opioid use disorder.<sup>2</sup> However, SAMHSA does not know how many total patients actually receive MAT through the program because it does not collect this information from all enrolled providers.

Instead, SAMHSA requires a subset of waived providers—those authorized to treat the maximum number of patients allowed by law (i.e., 275)—to annually report the number of patients to whom they provided MAT.<sup>3</sup> The primary purpose of this annual reporting requirement is to allow SAMHSA to monitor providers' compliance with additional requirements in place for providers authorized at this 275-patient limit. However, because these data constitute the only such information that SAMHSA collects from waived providers, OIG used the data to examine the waiver program's success in a broader goal—expanding access to treatment. Although they represent only a small percentage of waived providers, the 6,000 providers approved at the maximum patient level are important for access to MAT, because they are permitted to treat a much greater patient load and often specialize in addiction treatment.

In this data snapshot, we examined how many providers submitted the required annual report during 2019. For the latest month with complete data (June 2019), we examined the number of MAT patients whom providers reported treating and whether providers located in counties with a high need for MAT services treated more patients on average than providers located outside of these areas.<sup>4</sup>

### Key Takeaway

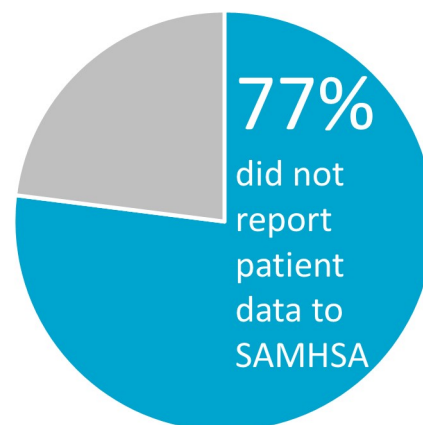
The data reported to SAMHSA indicated that providers who were waived at the highest patient level treated an average of 116 MAT patients each—far below the limit of 275 patients. However, less than a quarter of the providers who were required to submit data on their patient caseloads actually did so. Although SAMHSA collects these data to monitor provider compliance, the agency has exercised its discretion and not taken enforcement actions to improve reporting. OIG believes that these data have benefits beyond compliance and enforcement.

We recommend that SAMHSA develop methods to better measure access to MAT via waived providers. As policymakers consider changes to the waiver program, it will be critical to have valid data on the number of patients accessing MAT. With improved data, SAMHSA could better do the following: understand providers' MAT prescribing practices; monitor trends in the number of MAT patients being served; identify geographic areas where patients with opioid use disorder remain underserved; and target where to deploy its training and technical assistance resources. SAMHSA concurred with this recommendation.

## Results

In 2019, **77 percent of providers did not submit required data** to SAMHSA regarding the number of MAT patients they served

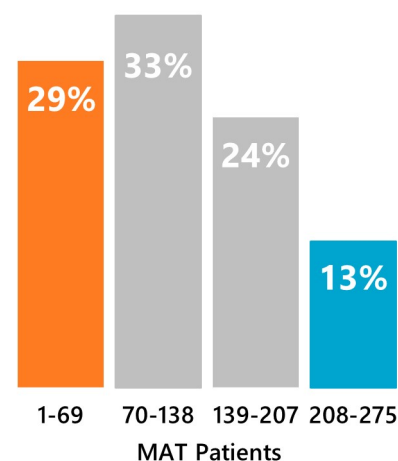
- Of the 4,546 providers subject to reporting requirements during 2019, 77 percent (3,512 providers) did not submit data to SAMHSA.<sup>5</sup>
- SAMHSA staff told us that SAMHSA uses the data it *does* receive to inform its MAT policies and to assess how localities are performing in the waiver program.
- Although SAMHSA sends reminders to providers when their annual reports are due, it has opted to exercise its enforcement discretion and not take any actions when providers do not comply with reporting requirements.
- SAMHSA says that it is electing not to enforce the reporting requirements because the opioid crisis is a public health emergency, and it does not want to disrupt patients' access to MAT services by rescinding the patient-limit authorization for providers who fail to meet administrative requirements.



Source: OIG analysis of data from the Buprenorphine Waiver Notification System (BWNS), 2020.

**Providers who reported data to SAMHSA treated an average of 116 MAT patients—far below the 275-patient limit**

- Nationwide, 66,217 patients received buprenorphine for MAT from the 568 providers who reported data to SAMHSA for June 2019 (the latest month for which complete data were available).<sup>6</sup>
- Although authorized to treat up to 275 MAT patients each, these providers each treated 116 patients, on average, during June 2019.
- **Twenty-nine percent of providers treated fewer than 70 patients.** In contrast, **only 13 percent (77 providers) treated at or near the 275-patient limit** (i.e., 208 or more patients).
- These results are consistent with prior studies indicating that providers waived to treat at the highest level were, on average, treating roughly 100 MAT patients each and that few were treating at or near the 275-patient limit.<sup>7, 8</sup>
- An individual provider who treats far less than 275 patients—possibly to focus on providing quality care to fewer patients—does not necessarily indicate a problem.
- However, the large proportion of providers doing so—especially in the midst of an opioid crisis—raises overall concerns about patients' access to MAT.



Source: OIG analysis of BWNS data, 2020.

Note: Total sums to less than 100 percent because of rounding.

**According to the limited data available, providers located in high-need counties treated more MAT patients than providers located elsewhere**

- In a prior study, we identified 1,119 counties (36 percent of U.S. counties) that had indicators of “high need” for MAT services, according to 2016 public health data.<sup>9</sup>
- Among the 568 providers who reported June 2019 data to SAMHSA, 46 percent were in high-need counties.
- **Providers in high-need counties reported treating more MAT patients** on average than providers in other counties—**127 patients** versus 107 patients, respectively.
- In high-need counties, 44 percent of providers treated in the upper half of the 275-patient limit (i.e., 139 to 275 patients), compared to 32 percent of providers in other counties.

## Why this Matters

Access to MAT is essential in addressing the high rates of opioid addiction and overdose mortality.<sup>10, 11</sup> However, many individuals seeking treatment face challenges in finding providers who prescribe MAT medications; in obtaining adequate insurance coverage for treatment services; and in accessing quality legitimate care.<sup>12</sup> Periodic independent studies have indicated that access to MAT via the Buprenorphine Waiver Program is limited by providers who treat substantially fewer patients than their waivers permit and also by geographic disparities in where these providers are located.<sup>13–16</sup> Providers reported a range of barriers that may limit their participation, including regulatory constraints (e.g., monitoring whether the patient limit has been exceeded); constraints from insurance payors (e.g., inadequate reimbursement rates, prior authorization requirements); lack of time for new patients; lack of training or experience working with patients with addiction; lack of patient access to mental health and psychosocial support services; and stigmas related to addiction and MAT.<sup>17–23</sup>

Over the 20-year history of the waiver program, SAMHSA and congressional policymakers have addressed the persistent problem of inadequate patient access to MAT by continually modifying the waiver program to encourage more provider participation. For example, Congress has twice raised the patient-limit levels for providers and also expanded the types of providers (e.g., nurse practitioners, physician assistants) who qualify for waivers.<sup>24–27</sup> During the COVID-19 public health emergency, SAMHSA and the Drug Enforcement Agency (DEA) eased restrictions so that patients could receive MAT via telemedicine.<sup>28, 29</sup> Further, in April 2021, SAMHSA exempted providers who treat up to 30 MAT patients from training requirements and from a mandate to offer MAT patients counseling and psychosocial services.<sup>30</sup> Additionally, members of Congress have reintroduced bipartisan proposals that would eliminate the waiver program altogether, so that any provider with prescribing privileges could provide MAT.<sup>31</sup>

Despite these ongoing efforts to increase patient access, SAMHSA remains hard-pressed to monitor how many patients are actually served by the waiver program and to identify unmet needs—much less address the more difficult issue of ensuring quality care. SAMHSA does not collect data on the number of patients served by most waived providers (i.e., those authorized at the 30- and 100-patient limit levels). Therefore, its only consistent source of patient access information is from the annual reports submitted by providers authorized to treat up to 275 patients. However, because three-quarters of these providers did not submit the required data, SAMHSA's ability to use this information for any purpose is extremely limited.

As the Department of Health and Human Services and policymakers consider additional changes to the waiver program, it will be critical—at a minimum—for any new proposals to address the need for valid data on the number of patients accessing MAT services. In the absence of such data, SAMHSA will not have reliable information to evaluate how changes in buprenorphine policy affect patient access to MAT. For example, telemedicine holds promise for addressing longstanding geographic disparities in the availability of waived providers, but without more valid data, SAMHSA will not know whether easing telemedicine restrictions succeeded in expanding patients' access.

## What OIG Recommends

To ensure access to MAT, SAMHSA should:

### **Develop comprehensive methods and measures to assess access to MAT via waived providers**

SAMHSA currently collects data from waived providers for compliance and enforcement purposes. We recommend that SAMHSA expand the way it uses data to also measure performance on an overarching agency goal—combating the opioid crisis through the expansion of treatment services. In the regulations implementing the reporting requirement, SAMHSA noted its need to balance program oversight with reducing the burden on providers participating in the program.<sup>32</sup> Minimizing burden is important because the buprenorphine waiver program is completely voluntary and does not directly reimburse providers for MAT services, meaning that SAMHSA has few incentives at its disposal to encourage providers' compliance with

program requirements. OIG recognizes that although SAMHSA would be permitted to revoke the 275-patient limit authorization for the three-quarters of providers who fail to report, doing so would undermine SAMHSA's goal of increasing patient access to MAT during the overdose epidemic.

Given the competing demands of ensuring compliance with reporting requirements and maintaining patient access, SAMHSA should consider alternative methods for assessing whether the agency is achieving its goal of increasing access to MAT. Rather than relying on individual providers to report data, SAMHSA could develop its own capacity to collect and analyze existing administrative data from other sources to monitor access to MAT. This approach aligns with the Foundations for Evidence-Based Policymaking Act of 2018, which requires Federal agencies to securely use data that the government already collects to better inform policy decisions and also encourages data-sharing between agencies.<sup>33</sup> In January 2021, SAMHSA announced it was "working with interagency partners to examine ways to increase access to buprenorphine, reduce overdose rates, and save lives."<sup>34</sup> In undertaking this effort, SAMHSA should also review available sources of data on patient access, identify ways to improve the quality of its data, and increase its use of relevant data in ongoing agency decision-making. For example, SAMHSA could partner with other stakeholders addressing the opioid crisis, such as the Centers for Disease Control and Prevention (CDC), the Centers for Medicare and Medicaid Services, and Prescription Drug Monitoring Programs (PDMPs), potentially linking its own data on waived providers to data collected by these others. Alternatively, instead of accessing data from the 54 State-specific PDMPs, SAMHSA could purchase commercial prescribing data to obtain nationwide data on trends in buprenorphine prescribing. With improved data, SAMHSA could better understand providers' buprenorphine prescribing practices; monitor trends in the number of MAT patients being served; identify geographic areas where patients with opioid use disorder remain underserved; and target where to deploy its training and technical assistance resources.

## Agency Comments and OIG Response

SAMHSA concurred with this recommendation and stated that data on patient access to MAT would be useful. However, SAMHSA stated that it has neither statutory obligation nor authority under the applicable waiver statutory scheme to collect waived provider information for the purpose of assessing access to MAT. While OIG agrees that SAMHSA has no statutory obligation to collect such information for this purpose, OIG disagrees that SAMHSA is precluded from doing so. SAMHSA's organic statute<sup>35</sup> gives it broad authority to analyze data to assess and improve access to waived MAT providers. Moreover, SAMHSA and congressional policymakers are considering further changes to the program to increase access (e.g., easing telehealth requirements, reducing training requirements for providers, eliminating the waiver altogether)—making the need for valid comprehensive data on patient access to MAT even more pressing.

SAMHSA stated that to fully understand access to buprenorphine, it is important to capture data on the prescribing practices of providers in regular primary care, community health, and emergency room settings, in addition to the addiction specialists with 275-patient limit waivers. OIG agrees and in our recommendation, we suggested several possible ways to gather such information. We recognize that SAMHSA may ultimately determine that some suggestions are not feasible (e.g., gathering data from multiple State-specific PDMPs) or are expensive (e.g., purchasing commercial data). Therefore, we recommended that SAMHSA should conduct a thorough review of the available sources of data on patient access and determine which sources provide relevant, feasibly obtainable, and high-quality information on patient access to MAT. Such a review could be part of SAMHSA's new interagency work group on increasing access to buprenorphine, so that the work group has reliable data both to inform its deliberations on additional program changes and to monitor the subsequent effects on patient access.

Our recommendation also provides a way for SAMHSA to decrease regulatory burdens for practitioners, which SAMHSA noted it has been under pressure to do. If SAMHSA developed its own capacity to collect and use existing administrative data to monitor access to MAT, it could reduce the need for individual providers to report such data. Lastly, although SAMHSA collects data on MAT access through its grant programs, it is unlikely that these data would fully capture the number of patients treated by waived providers, who work primarily in health care settings and do not receive SAMHSA grant funding.



# Methodology

## Scope

This analysis focused on 4,546 providers participating in SAMHSA's Buprenorphine Waiver Program who were authorized to treat up to 275 patients concurrently in 2019. Providers waived at lower patient-limit levels (i.e., 30 or 100 patients) were excluded from this review because SAMHSA does not collect comparable information from these providers. The study also excluded buprenorphine prescribed for other purposes (e.g., pain management) and in other settings (e.g., opioid treatment programs).

## Data Sources

*Buprenorphine Waiver Notification System (BWNS).* SAMHSA collects and stores buprenorphine waiver applicant information in the BWNS. This system includes data on each applicant's address, the patient-limit level at which the applicant was authorized, and the year of waiver approval. The BWNS also includes the information that providers at the 275-patient limit report annually to SAMHSA. Each provider reports the number of patients to whom the provider prescribed or dispensed MAT medications during each of the preceding 12 months (e.g., 71 patients in April, 103 in May, and 99 in June). SAMHSA receives these reports on a rolling basis throughout the year, because each provider's report is due within 30 days of the anniversary of when the provider was originally approved at the 275-patient level.

When we received BWNS data in June 2020, 6,137 total providers were waived at the 275-patient limit. Of these, 4,546 providers were required to report data to SAMHSA at some point during 2019. The remaining 1,591 providers had been more recently authorized at the 275-patient limit level and therefore had not yet reached their 1-year anniversary and thereby the deadline to send the annual report to SAMHSA.

Because providers report the aggregate number of MAT patients per month (rather than the annual total number of patients they treated), our patient-level analyses compared prescribing across providers during a single month—June 2019. We selected June 2019 because it was the most recent month for which complete data should have already been reported to SAMHSA. Of the 4,546 providers who reported data to SAMHSA at some point in 2019, 568 reported data about their MAT prescribing for the month of June 2019.

*High-Need Counties Identified by OIG.* In OIG's prior report, we identified a list of 1,119 counties (constituting 36 percent of U.S. counties) that had high needs for MAT services.<sup>36</sup> We used three public health data measures to identify these counties: 2016 drug overdose mortality data,<sup>37</sup> 2016 opioid prescribing rates from retail pharmacies,<sup>38</sup> and 2012–2014 prevalence rates of nonmedical use of pain relievers.<sup>39</sup> If a county had high rates (i.e., greater than the 60th percentile of the distribution) for at least two of the three measures of opioid misuse and abuse, we designated it as having a high need for MAT services.

*Interview With SAMHSA Staff.* We interviewed SAMHSA staff about how the agency currently uses the data from the annual reports submitted by providers at the 275-patient limit, and about whether SAMHSA uses any additional data to assess access to MAT through the Buprenorphine Waiver Program. We also asked how SAMHSA monitors providers' compliance with reporting requirements and whether it has taken enforcement actions against noncompliant providers.

## Data Analysis

*Providers' Compliance With Reporting Requirements.* We used BWNS data to calculate the number of providers who reported to SAMHSA within 30 days of their 1-year anniversary of being approved at the 275-patient limit, as required. We excluded providers who had been at the 275-patient limit for less than 1 year, because they were not yet required to report to SAMHSA.

*Patients Receiving MAT Medications.* For the latest month with complete data (i.e., June 2019), we calculated the nationwide total and average number of patients treated by providers at the 275-patient limit. We also

calculated the shares of providers who were treating the following proportions of the 275-patient limit: 25 percent or less (1–69 patients), 26–50 percent (70–138 patients), 51–75 percent (139–207 patients), and 76 percent or more (208–275 patients). We determined how many providers were at or near their patient-treating capacity (i.e., treating at least 250 patients, which is over 90 percent of the 275-patient limit).

*Waivered Providers' Location in High-Need Counties.* We compared each provider's county as listed in the BWNS to the list of high-need counties that we identified in our prior study. For those providers with multiple addresses listed in the BWNS, we selected the county associated with the most recent information that the provider had submitted to SAMHSA. We determined whether providers located in high-need counties reported treating more MAT patients than providers in other counties.

## Limitations

This study relied on self-reported data submitted by waived providers. We did not verify the accuracy of the information submitted. Additionally, to identify counties with high needs for MAT services, we used 2014 and 2016 public health data (the latest available data at the time of our prior report); these data may no longer reflect current county needs in all cases.

## Standards

We conducted this study in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

## Acknowledgments

Heather Barton, a Deputy Regional Inspector General, served as the team leader for this study, and Tori Lawson served as an analyst. Other OIG staff who provided support include Bahar Adili and Christine Moritz. This report was prepared under the direction of David Tawes, Regional Inspector General for Evaluation and Inspections in the Baltimore regional office, and Louise Schoggen, Assistant Regional Inspector General.

To obtain additional information concerning this report or to obtain copies, contact the Office of Public Affairs at [Public.Affairs@oig.hhs.gov](mailto:Public.Affairs@oig.hhs.gov).

## Endnotes

1. SAMHSA. *Strategic Plan FY2019 – FY2023*. Available at: <https://www.samhsa.gov/about-us/strategic-plan-fy2019-fy2023>.
2. The waiver program is intended to increase access to MAT by authorizing qualified providers to prescribe buprenorphine to patients in office settings (e.g., primary care practices, community health centers, treatment centers)—rather than limiting MAT services to specialized opioid treatment programs.
3. 42 CFR § 8.635. The purpose of the reporting requirements is to help the Department of Health and Human Services assess provider compliance with the additional responsibilities (i.e., ensuring that patients receive the full array of services that constitute evidenced-based MAT) of providers authorized to treat up to 275 patients. In addition to reporting their monthly caseloads of MAT patients, these waived providers also report the number of MAT patients who were referred to behavioral health services and describe the features of their diversion control plan.
4. OIG, *Geographic Disparities Affect Access to Buprenorphine Services for Opioid Use Disorder*, OEI-12-17-00240, January 2020. In this report, OIG classified a county as “high need” for MAT services if it had high rates (e.g., greater than the 60th percentile of the distribution) on at least two of the following measures: 2016 drug overdose mortality data, 2016 opioid prescribing rates from retail pharmacies, and 2012–2014 prevalence rates of nonmedical use of pain relievers.
5. Among the 6,137 total providers who were waived at the 275-patient limit, only 4,546 were subject to annual reporting requirements in 2019. The remaining 1,591 providers had received their waivers more recently and had not yet reached their 1-year anniversary dates, which were when their annual reports would be due to SAMHSA.
6. Among the 1,034 total providers who reported data to SAMHSA during 2019, only 568 reported the number of MAT patients they treated during June 2019 (the latest month with complete data).
7. Jones, Christopher and McCance-Katz, Elinore F. “Characteristics and Prescribing Practices of Clinicians Recently Waivered to Prescribe Buprenorphine for the Treatment of Opioid Use Disorder.” *Addiction*. 2018 Mar; 114: 471–482.
8. Duncan, Alexandra; Anderman, Jared; Deseran, Travis; Reynolds, Ian; and Stein, Bradley. “Monthly Patient Volumes of Buprenorphine-Waivered Clinicians in the US.” *JAMA Network Open*. 2020 Aug; 3(8):e2014045.
9. OIG, *Geographic Disparities Affect Access to Buprenorphine Services for Opioid Use Disorder*, OEI-12-17-00240, January 2020. In this report, OIG classified a county as “high need” for MAT services if it had high rates (e.g., greater than the 60th percentile of the distribution) on at least two of the following measures: 2016 drug overdose mortality data, 2016 opioid prescribing rates from retail pharmacies, and 2012–2014 prevalence rates of nonmedical use of pain relievers.
10. U.S. Department of Health and Human Services, *Facing Addiction in America: The Surgeon General’s Spotlight on Opioids*, September 2018. Available at <https://addiction.surgeongeneral.gov/sites/default/files/surgeon-generals-report.pdf>.
11. World Health Organization, *Guidelines for the Psychosocially Assisted Pharmacological Treatment of Opioid Dependence*, 2009. Available at [http://www.who.int/substance\\_abuse/activities/treatment\\_opioid\\_dependence/en/](http://www.who.int/substance_abuse/activities/treatment_opioid_dependence/en/).
12. U.S. Government Accountability Office, *Laws, Regulations, and Other Factors Can Affect Medication-Assisted Treatment Access*, September 2016.
13. Duncan, Alexandra; Anderman, Jared; Deseran, Travis; Reynolds, Ian; and Stein, Bradley. “Monthly Patient Volumes of Buprenorphine-Waivered Clinicians in the US.” *JAMA Network Open*. 2020 Aug; 3(8):e2014045.
14. Thomas, Cindy P.; Doyle, Erin; Kreiner, Peter W.; Jones, Christopher M.; Dubenitz, Joel; Horan, Alexis; and Stein, Bradley D. “Prescribing Patterns of Buprenorphine Waivered Physicians.” *Drug and Alcohol Dependence*, 2017 (181).
15. OIG, *Geographic Disparities Affect Access to Buprenorphine Services for Opioid Use Disorder*, OEI-12-17-00240, January 2020.

16. Andrilla, C. Holly A.; Moore, Tessa E.; Patterson, Davis G.; and Larson, Eric H. "Geographic Distribution of Providers with a DEA Waiver to Prescribe Buprenorphine for the Treatment of Opioid Use Disorder: A 5-Year Update." *The Journal of Rural Health*, 2018.
17. GAO, *Laws, Regulations, and Other Factors Can Affect Medication-Assisted Treatment Access*, September 2016.
18. Huhn, Andrew S. and Dunn, Kelly, E. "Why Aren't Physicians Prescribing More Buprenorphine?" *Journal of Substance Abuse Treatment*, 2017.
19. Kermack, Andrea; Flannery, Mara; Tofighi, Babak; McNeely, Jennifer; and Lee, Joshua D. "Buprenorphine Prescribing Practice Trends and Attitudes Among New York Providers." *Journal of Substance Abuse Treatment*, 2017.
20. Arfken, Cynthia L; Johanson, Chris-Ellen; di Menze, Salvatore; and Schuster, Charles R. "Expanding Treatment Capacity for Opioid Dependence with Office-Based Treatment with Buprenorphine: National Surveys of Physicians." *Journal of Substance Abuse Treatment*, 2010.
21. DeFlavio, JR; Rolin, SA; Nordstrom, BR; and Kazal, LA. "Analysis of Barriers to Adoption of Buprenorphine Maintenance Therapy by Family Physicians." *Rural and Remote Health*, 2015.
22. Hutchinson, Eliza; Catlin, Mary; Andrilla, C. Holly A.; Baldwin, Laura-Mae; and Rosenblatt, Roger A. "Barriers to Primary Care Physicians Prescribing Buprenorphine." *Annals of Family Medicine*, March/April 2014.
23. Suzuki, Joji; Connery, Hilary S.; Ellison, T. V.; and Renner, J. A. "Preliminary Survey of Office-Based Opioid Treatment Practices and Attitudes Among Psychiatrists Never Receiving Buprenorphine Training to Those Who Received Training During Residency." *The American Journal on Addictions*, 2014.
24. Section 1102 of the Office of National Drug Control Policy Reauthorization Act of 2006, P.L. No. 109-469 (Dec. 29, 2006)
25. 81 Fed. Reg. 44712 (July 8, 2016)
26. Section 303(a) of the Comprehensive Addiction and Recovery Act (CARA), amending section 303(g)(2) of the Controlled Substances Act
27. Section 303(g)(2)(G)(iii)(II) of the Controlled Substances Act, as amended by section 3201(c) of the SUPPORT for Patients and Communities Act.
28. SAMHSA, *Frequently Asked Questions: 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>.
29. DEA, *March 31, 2020 Letter to DEA Qualifying Practitioners*. Available at: [https://www.deadiversion.usdoj.gov/GDP/\(DEA-DC-022\)\(DEA068\)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20%20\(Final\)%20+Esign.pdf](https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-022)(DEA068)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20%20(Final)%20+Esign.pdf).
30. 86 Fed. Reg. 22439 (April 28, 2021).
31. Diamond, Dan. "Lawmakers urge Biden to back opioid-treatment measure." *Washington Post*, February 9, 2021. Available at: <https://www.washingtonpost.com/health/2021/02/09/lawmakers-urge-biden-back-opioid-treatment-measure/>.
32. 81 Fed. Reg. 66191, 66192 (September 2, 2016); 81 Fed. Reg. 44711, 44738 (July 8, 2016).
33. Foundations for Evidence-Based Policymaking Act of 2018, P.L. No. 115-435 (enacted Jan. 14, 2019).
34. SAMHSA, *Statement Regarding the X-Waiver* (January 25, 2021). Available at: <https://www.samhsa.gov/sites/default/files/statement-regarding-xwaiver.pdf>.
35. 42 U.S.C. § 290aa(d).
36. OIG, *Geographic Disparities Affect Access to Buprenorphine Services for Opioid Use Disorder*, OEI-12-17-00240, January 2020.



37. We used all drug overdose mortality in this report rather than opioid-specific overdose mortality. Drug-specific deaths (e.g., the type of opioid that caused the overdose) are not routinely reported across all U.S. jurisdictions, therefore, opioid-specific overdose mortality rates potentially underestimate the number of actual opioid overdose deaths. Instead, CDC staff recommended using the drug overdose mortality rates as an indicator of need for opioid use disorder treatment services. We obtained 2016 county-level data from CDC.
38. CDC, *U.S. Prescribing Maps*. Available at <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html>. IQVIA (formerly QuintilesIMS) Transactional Data Warehouse (TDW) 2006–2016 is the source for all prescribing data.
39. SAMHSA, *Substate Estimates of Substance Use and Mental Illness from the 2012–2014 NSDUH: Results and Detailed Tables*. Available at <https://www.samhsa.gov/samhsa-data-outcomes-quality/major-data-collections/state-reports-NSDUH/2012-2014-substate-reports>.



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April 22, 2021

TO: Suzanne Murrin  
Deputy Inspector General for Evaluation and Inspections  
Department of Health and Human Services Office of Inspector General

FROM: Tom Coderre  
Acting Assistant Secretary for Mental Health and Substance Use

SUBJECT: OIG Draft Data Snapshot: "*SAMHSA Lacks Adequate Data to Monitor Access to Medication Assisted Treatment Through the Buprenorphine Waiver Program*", OEI-BL-20-00260

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

Tom Coderre

Attachments

**GENERAL COMMENTS FROM THE SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION ON THE OFFICE OF INSPECTOR GENERAL'S DRAFT DATA SNAPSHOT REPORT ENTITLED SAMHSA LACKS ADEQUATE DATA TO MONITOR ACCESS TO MEDICATION ASSISTED TREATMENT THROUGH THE BUPRENORPHINE WAIVER PROGRAM, OEI-BL-20-00260**

**Overarching Comments:**

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 monitoring of controlled substances is part of the mission of the Drug Enforcement Administration (DEA). The DEA is mandated to enforce the controlled substances laws and regulations of the United States. The mission of the Center for Substance Abuse Treatment (CSAT) within SAMHSA is to promote community-based substance abuse treatment and recovery services for individuals and families in every community. SAMHSA in concert with the DEA already work collaboratively to grant practitioners the DATA 2000 waiver, but further data about prescribing practices is not readily available at either agency. Further, SAMHSA does not have the permission or authority to access the secure DEA databases.

The purpose of the Data Waiver program is to certify that the provider has proper licensing, training, and DEA registration. SAMHSA is not obligated to collect waived practitioner data for those with 30 and 100 patient limits. SAMHSA does not have the authority to require practitioners at these levels to provide this information. Providers with 275-level waivers are prescribing for the smallest proportion of clients, serving less than 800,000 clients (from OIG report), whereas providers with 30 or 100-level waivers have the capacity to serve over 4 million clients. To fully understand access to buprenorphine, it would be important to capture data on the prescribing practices of providers in regular primary care, community health, and emergency room settings, in addition to the addiction specialists with 275-waivers. This aggregated data would provide a complete picture of MAT prescribing in the United States.

The OIG report states that "SAMHSA could also partner with others addressing the opioid crisis, such as the Centers for Disease Control and Prevention (CDC) and Prescription Drug Monitoring Programs (PDMPs), potentially linking its own data on waived providers to data collected by these others". However, this may be problematic as provisions within the application for the SAMHSA's Buprenorphine Waiver Program waiver specify conditions where data can be disclosed. This activity would most likely not be a permissible disclosure. PDMP databases are state specific and patient centered, and with varied electronic platforms, making interfacing on a large scale not feasible. Also accessing PDMP records of individual patients or providers would be outside SAMHSA's regulatory authority and scope. The information SAMHSA collects as a result of the waiver process is protected by the Privacy Act, thus there are restrictions on how SAMHSA can disclose this information. For instance: SAMHSA can only check other data sources for the purposes of identifying prescribing over the patient limit as per 42 CFR 8.635 (d).

**GENERAL COMMENTS FROM THE SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION ON THE OFFICE OF INSPECTOR GENERAL'S DRAFT DATA SNAPSHOT REPORT ENTITLED SAMHSA LACKS ADEQUATE DATA TO MONITOR ACCESS TO MEDICATION ASSISTED TREATMENT THROUGH THE BUPRENORPHINE WAIVER PROGRAM, OEI-BL-20-00260**

The OIG report states that “SAMHSA requires providers authorized at the 275-patient limit to submit data explicitly for program integrity purposes—data that could also prove useful in gaining insights into the number of patients receiving MAT. However, because three-quarters of the providers did not provide the required data, SAMHSA’s ability to use this information for any purpose is extremely limited.” SAMHSA would contend that while the percentage of responders is low, the data is useful and that the response rate is similar to other physician surveys.

**Recommendation 1**

**SAMHSA should develop comprehensive methods and measures to assess access to MAT via office-based providers.**

SAMHSA concurs that comprehensive methods and measures to assess access to Medication Assisted Treatment (MAT) via office-based providers are needed. However, SAMHSA lacks authority and funding to implement some of the examples set forth in the recommendation. The Buprenorphine Waiver Program is not designed to do this. Although the data would be useful, SAMHSA has no statutory requirement to collect data on the number of individuals served. SAMHSA’s statutory obligations are limited to determining whether a practitioner is qualified for a waiver based on the information provided in an NOI, and to deliver that determination to the Attorney General. SAMHSA has no statutory obligation nor authority under the applicable waiver statutory scheme to collect waived provider information for the purpose of assessing access to MAT. SAMHSA will assess which recommendations and measures the agency currently has the authority and capacity to execute and monitor. Additionally, please note, the agency as a whole has been under pressure to further decrease regulatory burdens for practitioners as these are perceived as significant barriers to expanding access to MAT, and additional reporting requirements by practitioners would be contrary to the goal of expanding treatment access.

SAMHSA is committed to improving treatment access and retention to address the opioid crisis. The agency has been working with federal and state partners and grantees while also mounting efforts to encourage providers to engage in office-based opioid treatment. SAMHSA is also committed to reducing barriers and increasing access to all FDA-approved medications for MAT. These efforts are accomplished through outreach to recently waived providers, training and technical assistance programs, and direct support, such as:

- The Opioid Response Network (ORN), a large technical assistance (TA) and training effort
- Provider Clinical Support System – Medication Assisted Treatment (PCSS-MAT) and Provider Clinical Support System – Universities (PCSS-U), <https://pcssnow.org/>
- Addiction Technology Transfer Centers (ATTC)

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- Rural Opioid Technical Assistance (ROTA) Program, focusing on issues affecting rural communities.
- Grants to states in order to address access to MAT
- State Opioid Response (SOR) Grant Program
- Tribal Opioid Response (TOR) Grant Program
- Medication Assisted Treatment – Prescription Drug and Opioid Addiction (MAT-PDOA) Grant Program
- Substance Abuse Prevention and Treatment Block Grant (SABG)

Through these programs, SAMHSA identifies geographic areas where patients with OUD remain underserved and deploys training and technical assistance resources accordingly. SAMHSA is also able to document expansion of MAT treatment services.

In addition to state partners and grantees, SAMHSA will consider the recommendation that it might collect and analyze existing administrative data to monitor access to office-based treatment services through other sources. Used in combination with SAMHSA's current Opioid Use Disorder (OUD)-related grants and contracts, and knowledge of providers' buprenorphine prescribing practices, may enhance its understanding of access to MAT provided through office-based treatment services.