



U.S. Department of Health and Human Services
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**Geographic
Disparities Affect
Access to
Buprenorphine
Services for Opioid
Use Disorder**

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Geographic Disparities Affect Access to Buprenorphine Services for Opioid Use Disorder

What OIG Found

The number of providers who have obtained waivers through the Substance Abuse and Mental Health Services Administration's (SAMHSA's) Buprenorphine Waiver Program has increased significantly since 2002, with close to 47,000 permitted to prescribe the drug in the office setting as part of medication-assisted treatment (MAT) as of April 2018. However, this figure likely overstates the availability of buprenorphine treatment in these settings, as (1) studies show that many waived providers do not treat up to their approved patient-limit capacity (i.e., up to 30, 100, or 275 patients), and (2) our analysis indicates that access to buprenorphine services through waived providers is not distributed evenly across the nation. Specifically, 40 percent of counties in the United States did not have a single waived provider in 2018. Even more concerning, waived providers were not necessarily found in the areas where access to MAT is most critical. Among the approximately 1,100 counties identified by OIG as having the greatest need for buprenorphine services, 56 percent likely had inadequate capacity to treat patients with buprenorphine in an office setting.

Key Takeaway

Access to buprenorphine services remains challenging in many localities, despite substantial increases in the number of waived providers and the total patient capacity nation-wide. Specifically, among the 1,000-plus counties in the United States that OIG identified as being at the greatest risk from the opioid crisis, more than half did not have adequate capacity to treat patients in need with buprenorphine in office-based settings.

What OIG Recommends and How the Agency Responded

OIG recommends that SAMHSA geographically target its efforts to increase the participation of waived providers in high-need counties. In high-need counties with few or no waived providers, the best strategy may be for SAMHSA and its grantees to encourage existing local providers to obtain buprenorphine waivers and/or to address overall local shortages of providers in general. In high-need counties that already have higher numbers of waived providers, it may be more effective for SAMHSA and its grantees to encourage and support existing waived providers to treat more patients in need of buprenorphine services. SAMHSA concurred with our recommendation.

Why OIG Did This Review

Adequate access to treatment is vital in addressing the escalating rates of addiction and mortality related to opioid misuse and abuse. MAT couples medication (such as buprenorphine, methadone, or naltrexone) with counseling and behavioral therapies to treat opioid use disorder. Since 2000, Congress has enacted several measures to increase the availability of MAT, including the creation and expansion of the Buprenorphine Waiver Program. The waiver program allows physicians and certain other qualified providers to prescribe buprenorphine to patients in office settings (e.g., primary care practices, community health centers, treatment centers) rather than limiting this service to specialized opioid treatment programs, which primarily dispense methadone. Despite these efforts, studies still show that only a small percentage of Americans who need treatment actually receive it.

How OIG Did This Review

OIG used data from SAMHSA to determine the number and nationwide patient capacity of providers who had received waivers to prescribe buprenorphine for MAT as of April 2018. We also used these data to identify U.S. counties with low patient capacity rates. We used three public health data sources to identify counties with high indicators of opioid misuse and abuse (i.e., counties with high need). We then examined the patient capacity rates for these high-need counties and identified those with low-to-no capacity to provide buprenorphine services.

TABLE OF CONTENTS

BACKGROUND	1
Methodology	3
FINDINGS	
The number of providers obtaining waivers for buprenorphine has increased substantially since 2015; most providers were limited to the lowest patient-limit level	7
Although total patient capacity under the waiver program has increased significantly, the number of patients actually receiving treatment likely falls well below this potential figure	8
Despite increases in the number of waived providers and total patient capacity nation-wide, access to buprenorphine services remains challenging in many localities	9
CONCLUSION AND RECOMMENDATION	
SAMHSA geographically target its efforts to increase the participation of waived providers in high-need counties	15
AGENCY COMMENTS AND OIG RESPONSE	17
APPENDICES	
A: Detailed Methodology	18
B: Substance Abuse and Mental Health Services Administration Comments	26
ACKNOWLEDGMENTS	31

BACKGROUND

Objectives

1. Determine the number and nation-wide patient capacity of providers who received waivers to prescribe buprenorphine to treat opioid use disorder.
2. Determine the extent to which waived providers are in areas with high indicators of opioid misuse and abuse (i.e., areas likely to have large numbers of residents in need of treatment services).

The growth of opioid misuse and abuse among Americans combined with inadequate access to quality, specialized substance abuse treatment continues to fuel the opioid crisis. According to the Substance Abuse and Mental Health Services Administration (SAMHSA), an estimated 2.1 million people have an opioid use disorder (OUD) related to prescription pain relievers and/or heroin.¹ Further, between 1999 and 2017, the number of opioid overdose deaths (including prescription pain relievers and illegal opioids, such as, heroin and fentanyl) increased 6-fold,² with an estimated 130 Americans dying every day.³ Access to substance abuse treatment, including medication-assisted treatment (MAT), is vital in addressing the alarming rates of addiction and mortality. MAT is widely recognized as a key component of effective treatment for OUD.^{4, 5} Despite the increasing need for services, SAMHSA estimates that only 19 percent of Americans who need substance abuse treatment receive it.⁶ Among individuals seeking substance abuse treatment, many experience difficulties finding providers who prescribe one of the three FDA-approved medications associated with MAT, obtaining adequate insurance coverage for treatment services, and accessing quality, legitimate care.^{7, 8}

For this study, OIG examined access to one drug that is often prescribed as part of MAT—buprenorphine. SAMHSA's Buprenorphine Waiver Program permits physicians and certain other qualified providers to prescribe buprenorphine to patients in office settings rather than limiting this service to specialized opioid treatment programs. Although expanding buprenorphine to office settings increased overall access to MAT,⁹ concerns persist that patient access remains limited in many communities.^{10, 11, 12}

Medication-Assisted Treatment

MAT couples medication with counseling and behavioral therapies to treat OUD.¹³ According to the National Institute on Drug Abuse, effective substance abuse treatment aims to assist individuals with stopping drug use, remaining drug-free, and regaining productivity in family, work, and

society.¹⁴ Extensive evidence supports the effectiveness of MAT in meeting these goals.¹⁵ There is no recommended length of treatment with MAT, and it can continue safely for months, years, or indefinitely.¹⁶

Buprenorphine is one drug commonly used in MAT.¹⁷ As a partial opioid agonist, buprenorphine suppresses withdrawal symptoms and relieves cravings because it targets the brain in the same way as heroin and prescription opioids, but its effects and risks, such as respiratory depression and overdose, are weaker than full opioid agonists, such as heroin and oxycodone.^{18, 19} Buprenorphine, when used for MAT, is frequently formulated with naloxone to prevent high levels of euphoria and other dangerous side effects, resulting in a lower risk of abuse.²⁰ The U.S. Drug Enforcement Administration (DEA) has classified buprenorphine as a Schedule III controlled substance in recognition of its moderate or low potential for abuse and physical dependence.²¹

Historically, prescribing buprenorphine for MAT was limited to opioid treatment programs (OTPs)—often referred to as methadone clinics. According to SAMHSA data, the vast majority of clients who receive MAT through an OTP are treated with methadone—in 2017, more than 380,000 OTP clients received methadone at an OTP, compared to 28,000 receiving buprenorphine.²² Because OTPs were not available in many communities, the Drug Addiction Treatment Act of 2000 expanded access to buprenorphine by allowing providers to prescribe Schedule III, IV, and V drugs for substance abuse treatment in office settings.^{23, 24, 25} Unlike methadone, a Schedule II drug used in MAT, buprenorphine can now be prescribed to patients in office settings.²⁶ To prescribe buprenorphine for MAT in an office setting, providers must apply to SAMHSA for a waiver.^{27, 28}

Buprenorphine Waiver Program

SAMHSA oversees the enrollment and certification of office-based buprenorphine providers (i.e., waived providers) through the Buprenorphine Waiver Program (i.e., waiver program). In 2001, SAMHSA began issuing waivers for providers who wanted to prescribe buprenorphine for MAT in the office setting (i.e., buprenorphine services).²⁹ All providers practicing in a broad spectrum of outpatient settings (e.g., primary care practices, community health centers, treatment centers) must obtain a waiver to prescribe buprenorphine for MAT.³⁰ Exceptions apply only to those providers dispensing medications through OTPs and providers in hospitals who are treating patients with preexisting opioid dependency.³¹ The waiver program is intended to increase access to quality buprenorphine treatment from trained providers while also preventing drug diversion.³²

To qualify for a waiver, providers must have a valid DEA registration number, a State license number, and a minimum of 8 hours of approved addiction training.³³ Typically, waived providers may not treat more than 30 patients at any one time with buprenorphine during their first year in the program.³⁴ Waivered providers may then apply to increase this limit to 100 patients at any one time beginning in their second waiver year.³⁵ After at

least 1 year at the 100-patient level, waived providers may apply to increase their limit to 275 patients.³⁶

SAMHSA's oversight requirements vary according to patient-limit levels. Providers with waivers to treat 30 or 100 patients are not required to report to SAMHSA the number of patients who were prescribed buprenorphine for MAT. Additionally, as long as waived providers at these patient-limit levels maintain a valid DEA registration, they also maintain their buprenorphine waiver; there is no expiration date. In contrast, providers with waivers to treat up to 275 patients must renew their waivers every 3 years and are required to report annually to SAMHSA the number of buprenorphine patients they served.³⁷

Concerns Regarding Access to Buprenorphine Services

According to numerous studies, the expansion of buprenorphine services to office settings through SAMHSA's waiver program decreased provider shortages in many areas and increased access to MAT overall.³⁸ However, concerns regarding the limited number of patients receiving buprenorphine treatment persist.³⁹ Only a small percentage of providers in the United States have a waiver to prescribe buprenorphine⁴⁰ and, among those with waivers, evidence suggests that a majority are either not prescribing buprenorphine at all or not treating up to their potential patient capacity (i.e., 30, 100, or 275 patients).⁴¹ Waivered providers cite a lack of patient demand for buprenorphine services, professional time constraints, and insurance restrictions (e.g., prior authorizations and insurance reimbursement rates) as the primary barriers restricting their ability to treat up to their capacity.⁴² Furthermore, GAO found that the regulatory restrictions placed on waived providers, such as patient limits, and the stigmas related to drug addiction and MAT, are additional barriers that may inhibit waived providers' participation in the program.⁴³

In an effort to address access concerns, Congress has repeatedly taken steps to expand the reach of the waiver program. For example, the patient-limit threshold for buprenorphine waivers has been increased twice since the program's inception in 2001—once in 2006 to 100 patients and again in 2016 to 275 patients.^{44, 45} Furthermore, in July 2016, the enactment of the Comprehensive Addiction and Recovery Act (CARA), expanded buprenorphine prescribing privileges to nurse practitioners (NPs) and physician assistants (PAs).^{46, 47}

Methodology

This study determined the number and nation-wide patient capacity of providers who had received waivers to prescribe buprenorphine for MAT and determined the extent to which these providers were located in counties with high indicators of opioid misuse and abuse (i.e., areas likely to have large numbers of residents in need of treatment services). Patient capacity is the number of patients that could potentially receive buprenorphine services through the program given the number of providers that have received waivers and the maximum number of patients

these providers are permitted to treat at any one time. See Appendix A for a detailed description of our data sources and analysis, including the criteria used to identify counties with high indicators of opioid misuse and abuse and counties with high and low patient capacity.

Scope

This report is national in scope. We included data on waived providers located in the 50 States and the District of Columbia. We collected data on waived providers from SAMHSA as of April 2018. We did not analyze access to buprenorphine through OTPs, as they primarily dispense methadone (rather than buprenorphine) to patients with OUD.

Data Sources

We obtained waived provider application data from SAMHSA's Buprenorphine Waiver Notification System (BWNS) for May 2002–April 2018. These data included information on each waived provider's address, patient-limit level, and year of waiver approval. Based on consultation with Centers for Disease Control and Prevention (CDC) and SAMHSA staff, we relied on three public health data sources to identify counties with high indicators of opioid misuse and abuse: drug overdose mortality data,⁴⁸ opioid prescribing rates from retail pharmacies,⁴⁹ and prevalence rates of nonmedical use of pain relievers.⁵⁰

Data Analysis

We analyzed the BWNS data to determine the number of waived providers nation-wide and in each county as of April 2018. We also analyzed these data to identify the proportion of waived providers: (1) approved at each patient-limit level (i.e., 30, 100, or 275) and (2) with different provider types (i.e., NPs, PAs, or physicians). To determine whether policy changes (i.e., increased patient limits and expanded types of waived providers) were associated with increased patient capacity, we examined annual trends in the number of new providers entering the waiver program and waived providers who increased their patient limits. We also used these data to determine the county-level patient capacity rates (i.e., patient capacity per 100,000 residents). We classified counties as either having low-to-no patient capacity (i.e., rates equal to or less than the 40th percentile of the patient capacity distribution) or average-to-high patient capacity (i.e., rates greater than the 40th percentile of the patient capacity distribution). Finally, we used CDC's National Center for Health Statistics' (NCHS) Urban-Rural Classification Scheme to classify, then calculate the proportion of waived providers located in metropolitan and rural areas.

For each measure of opioid misuse and abuse (i.e., drug overdose mortality data, opioid prescribing rates from retail pharmacies, and prevalence rates of nonmedical use of pain relievers), we identified counties as having high rates if their rates were greater than the 60th percentile of the relevant distribution.⁵¹ (See Appendix A for each measure's distribution and OIG's

classification scheme for identifying high-need counties.) If a county had high rates for at least two of the three opioid misuse and abuse measures, we designated it as having a high need for buprenorphine services. We then examined the patient capacity rates for these high-need counties and identified which had low-to-no capacity to provide buprenorphine services.

Limitations

This study did not estimate the actual number of patients receiving buprenorphine services in office settings because SAMHSA does not collect this information from the majority of waived providers. Instead, we determined the maximum number of patients that could potentially be served through the program (i.e., patient capacity). The number of patients actually receiving buprenorphine services is likely to be lower than the estimated national and county-level patient capacities because many waived providers are not treating up to their maximum capacity.⁵²

Additionally, there is no established benchmark for what patient capacity rate is considered adequate to meet the need for buprenorphine services. Therefore, we used the 40th percentile of the patient capacity rate distribution as the threshold for classifying counties as either average-to-high (i.e., those greater than the 40th percentile) or low (i.e., those equal to or less than the 40th percentile). As noted earlier, the patient capacity rates in this report may overestimate actual access. Therefore, even patients in counties with average-to-high patient capacity may still encounter challenges accessing buprenorphine services.

This study identified counties with high indicators of opioid misuse and abuse and used them as a proxy for identifying counties with high needs for treatment services. We used the most recent data available for each measure. Rates may have changed since the date of our analysis. (See Appendix A for a detailed description of the data we used for each of the opioid misuse and abuse measures.) Although we used a distribution of U.S. rates for each selected measure to identify counties as having comparatively higher needs for treatment services, there is no published information indicating “acceptable” rates of pain reliever misuse, opioid prescribing, or drug overdose mortality. According to multiple sources comparing U.S. rates of opioid use, overdose, and prescribing to their international counterparts, U.S. rates are significantly higher for each measure.^{53, 54, 55} Therefore, counties not falling into the “high need” category may still have rates that are well above acceptable levels. Such counties may still require government oversight and assistance with regard to opioid use disorder.

Finally, this study used counties as the unit of analysis for examining treatment need and waived provider access. We acknowledge, however, that patients may also seek treatment services outside their counties of residence. Therefore, even in counties with low patient capacity rates, some patients may be able to obtain care by traveling to a neighboring county. In

addition, patients may access all three FDA-approved medications for the treatment of OUD (i.e., methadone, buprenorphine, naltrexone) at OTPs. We did not analyze access to buprenorphine through OTPs, as they primarily dispense methadone (rather than buprenorphine) to patients with OUD. Finally, patients may receive MAT drugs other than buprenorphine (i.e., methadone or naltrexone) for OUD treatment. We did not review access to other MAT drugs in this report.

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.

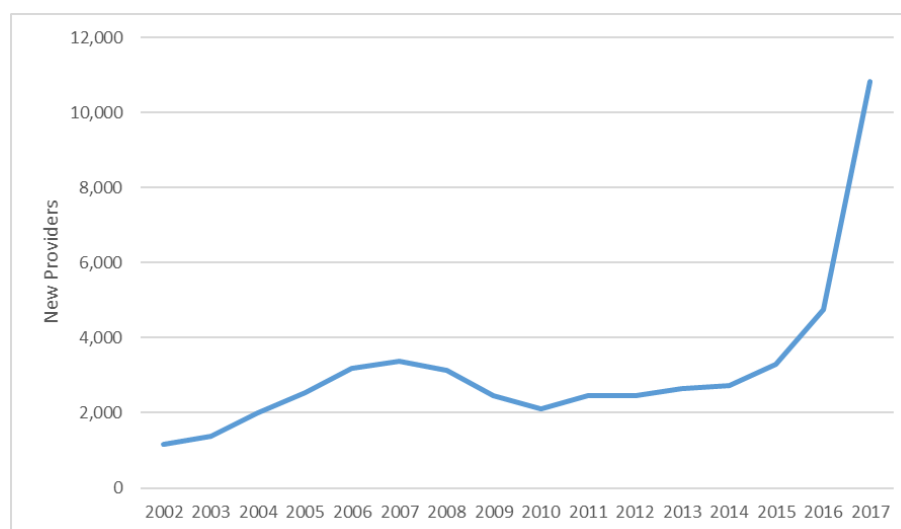
FINDINGS

The number of providers obtaining waivers for buprenorphine has increased substantially since 2015; most providers were limited to the lowest patient-limit level

Between January 2016 and April 2018, almost 19,000 new providers obtained waivers for buprenorphine

As of April 2018, a total of 46,857 providers had current waivers to prescribe buprenorphine, reflecting a rapid influx of new providers entering the program since 2015. As depicted in Exhibit 1, between 2002 and 2015, the waiver program added an average of 2,498 waived providers each year.⁵⁶ Since 2015, the rate of growth increased significantly with 4,754 waived providers added in 2016, followed by 10,841 in 2017, and 3,448 in just the first 3 months of 2018. The large increase in 2017 coincided with a new Federal policy expanding buprenorphine prescribing privileges to NPs and PAs, with almost half (5,212) of the new waived providers added that year belonging to those two groups.

Exhibit 1: The Number of New Providers Obtaining Waivers Each Year Has Risen Substantially Since 2015



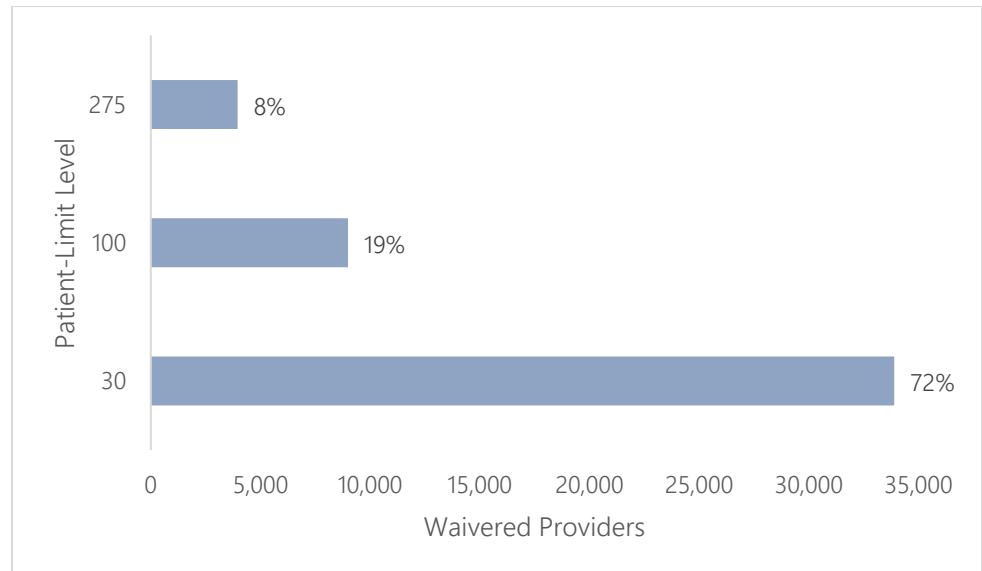
Source: OIG analysis of SAMHSA Buprenorphine Waiver Notification System data, April 2018.

Although patient-limit caps have increased, almost three-quarters of waived providers remain at the lowest patient-limit level

Key policy changes implemented in 2007⁵⁷ (i.e., increasing the patient-limit level to 100 for qualified providers) and again in 2016 (i.e., increasing the patient-limit level to 275) led some waived providers to expand their treatment capacity. As of April 2018, 8 percent of waived providers were permitted to treat the maximum number of patients (i.e., 275) and 19 percent were at the middle level (i.e., 100). However, as depicted in Exhibit 2, almost three-quarters of waived providers (72 percent) were limited to treating no more than 30 patients at one time. The number of waived providers increasing their patient-limit levels slowed over time; indicating

that only a subset of waived providers were seeking to treat more patients.

Exhibit 2: Most Waivered Providers May Only Treat Up to 30 Patients



Source: OIG analysis of SAMHSA Buprenorphine Waiver Notification System data, April 2018.
Note: The rows do not total to 100 percent due to rounding.

Although total patient capacity under the waiver program has increased significantly, the number of patients actually receiving treatment likely falls well below this potential figure

As both the number of waived providers and the allowed patient-limit levels have increased (see Exhibits 1 and 2), the program's potential capacity to serve more patients has grown substantially. For example, although only 8 percent of waived providers have increased their patient limit to 275 pursuant to the 2016 policy change, these providers are now waived to treat more than 1 million potential patients. As of April 2018, if every waived provider treated up to his or her capacity, approximately 3 million patients at any one time could receive buprenorphine for MAT through the Buprenorphine Waiver Program.

However, there is substantial evidence that "real-world" access to buprenorphine services lags well behind the potential patient capacity. Recent studies by SAMHSA and others found that the majority of waived providers are not prescribing at or near their patient-limit capacity.^{58, 59} For example, one study of buprenorphine prescribing patterns between 2010 and 2015 found that waived providers at the 30-patient limit level were treating relatively few—and sometimes zero—patients.⁶⁰ Specifically, the study determined that waived providers at the 30-patient limit level treated an average of 14 patients per month and those at the 100-patient limit level treated an average of 43 patients a month.⁶¹ Waivered providers who responded to a different survey from SAMHSA in 2018 indicated that the main barriers to prescribing buprenorphine to more patients were lack of patient demand, time constraints, and insurance reimbursement and requirements.⁶²

Despite increases in the number of waived providers and total patient capacity nationwide, access to buprenorphine services remains challenging in many localities

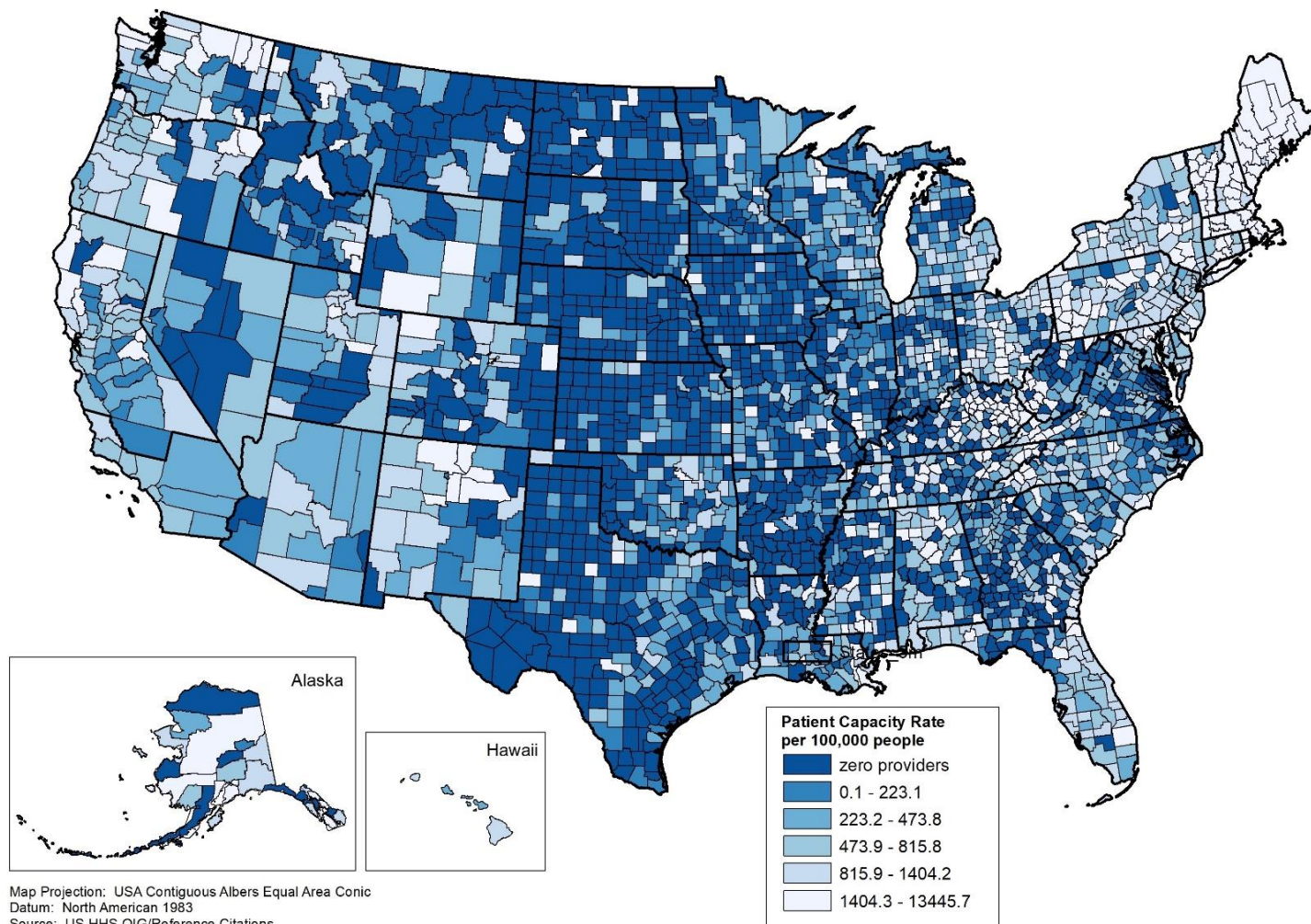
Approximately two-thirds of U.S. counties either have low or no patient capacity to provide buprenorphine services to patients in the office setting

Forty percent of counties nation-wide do not have any waived providers and another 24 percent have low patient capacity (defined as a rate less than or equal to 473.8 per 100,000 people). Depicted in Exhibit 3 as the dark blue counties, a swath of the United States from the Upper Midwest region and Great Plains to Texas and the Southeast have large areas of low to no capacity to provide buprenorphine services. For example, 77 percent of Oklahoma counties (59 of 77) have low-to-no patient capacity. Among these low-patient capacity counties in Oklahoma, 81 percent have no waived providers at all or only one per county. There are also large numbers of counties within other States, such as Nevada and Indiana, with similarly low patient capacity.

In total, 72 percent of counties with low-to-no patient capacity are in rural areas (for comparison purposes, 63 percent of counties nation-wide are rural). The lack of waived providers in rural areas may reflect a wider problem with shortages and maldistribution of primary care and other providers.⁶³

In contrast, 36 percent of counties have average-to-high patient capacity (defined as a rate greater than or equal to 473.9 per 100,000 people). Depicted in Exhibit 3 as the lightest blue counties, the Pacific Northwest, Northeast, and parts of Appalachia have average or better capacity to provide buprenorphine services to patients. Forty-six percent of counties with average-to-high patient capacity are in rural areas.

Exhibit 3: Rates of Patient Capacity in the United States by County, 2018



Source: OIG analysis of SAMHSA Buprenorphine Waiver Notification System data, 2018

Note: All counties with patient capacity rates less than or equal to 473.8 are considered to have low-to-no patient capacity

More than half of counties with high treatment needs may not have adequate patient capacity to provide buprenorphine services to patients in the office setting

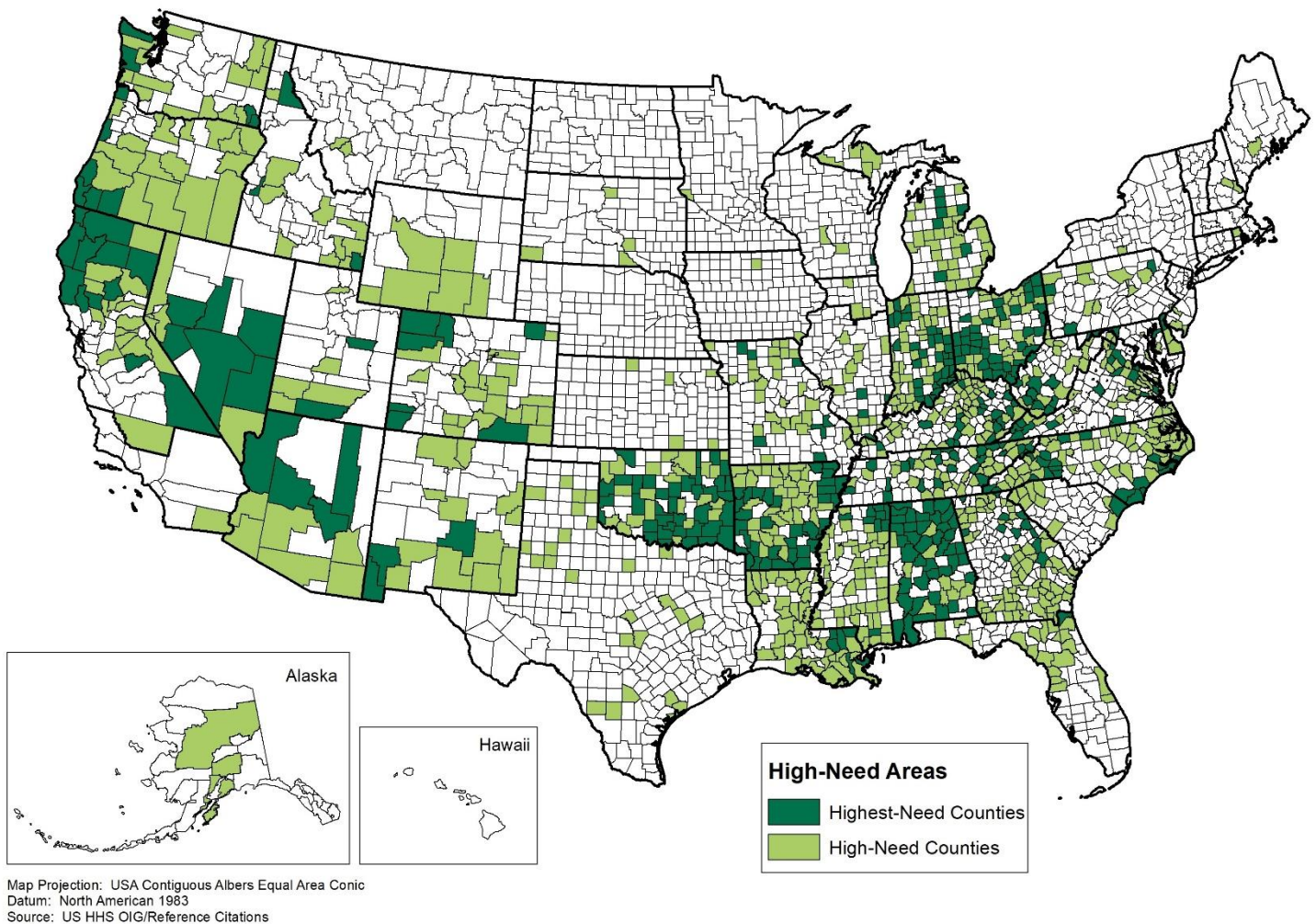
When considering geographic distribution of waived providers, the most important consideration is whether waived providers are located where the need for buprenorphine services is the greatest.

36 percent of counties in the United States have a high need for treatment services. In total, 1,119 counties had high indicators for at least two of the three opioid misuse and abuse measures (i.e., drug overdose mortality, nonmedical use of pain relievers, and opioid prescribing) included in our analysis, thereby meeting OIG's definition of "high need." For example, in Exhibit 4, high-need counties are clustered throughout the Appalachian region,⁶⁴ parts of the Southeast (including Arkansas and Alabama), and the Southwest (including Nevada and New Mexico). Other high-need areas include the Pacific Northwest and along the South-Atlantic coast, including

Virginia and North Carolina. More than half (61 percent) of these high-need counties are in rural areas.

In total, 381 high-need counties (the darkest green in Exhibit 4) have the highest indicators of opioid misuse and abuse (i.e., rates greater than the 80th percentile of the distribution for two of the three measures). These counties, which represent 12 percent of all counties nation-wide, are likely to be the areas facing the most critical need for treatment services. More than half (62 percent) of these highest-need counties are in rural areas.

Exhibit 4: Counties With High Need for Treatment Services, 2018

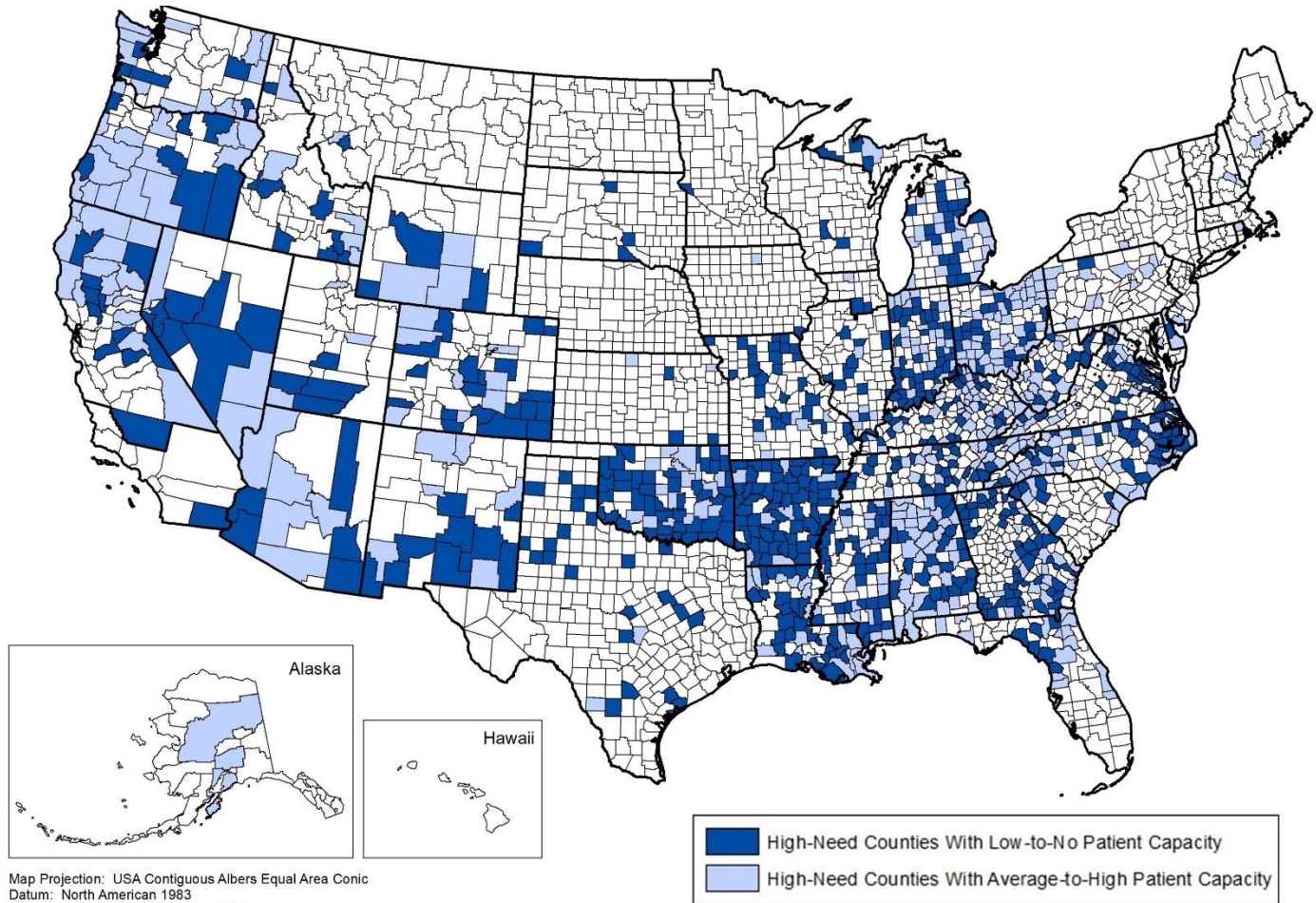


Source: OIG analysis of CDC and SAMHSA data, 2018

56 percent of the high-need counties may lack adequate patient capacity to provide buprenorphine services to patients. Exhibit 5 below overlays the earlier map of patient capacity rates (Exhibit 3) with the map depicting high-need counties (Exhibit 4). Among the high-need counties, 56 percent (623 of 1,119) have low-to-no capacity to provide buprenorphine services (depicted in Exhibit 5 as the darkest blue counties). These counties are

clustered in areas such as, the Southeast (including Arkansas, Louisiana, and Mississippi), the Southwest (including Nevada and New Mexico), and along the South-Atlantic coast (including Virginia and North Carolina). Seventy-two percent of the high-need counties with low-to-no patient capacity were in rural areas. Among these high-need-with-low-capacity counties, half (320) did not have a single waived provider.

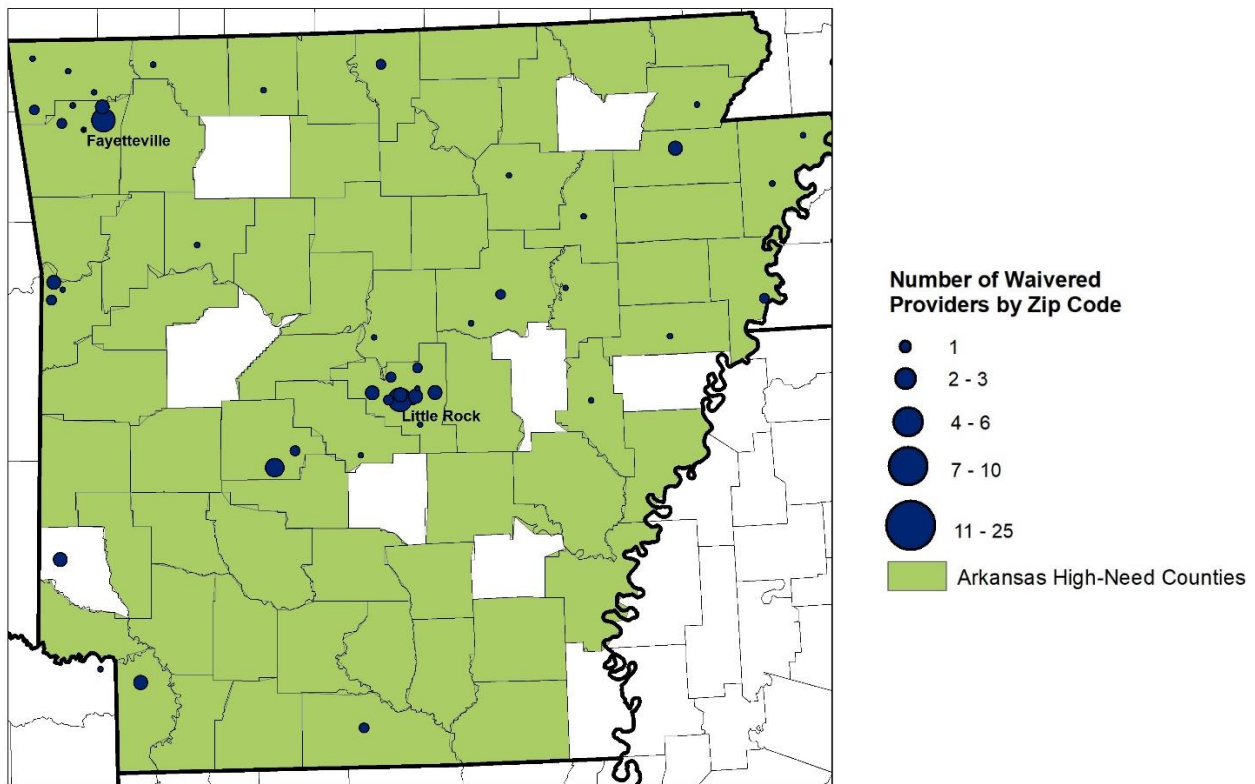
Exhibit 5: High-Need Counties and their Patient Capacity, 2018



Source: OIG analysis of CDC and SAMHSA data, 2018

For example, 66 of 75 Arkansas counties were classified as high-need, with most waived providers clustered around two of the State's largest cities (Fayetteville and Little Rock). Furthermore, two-thirds (43) of high-need counties in Arkansas did not have a single waived provider, potentially indicating the existence of a serious waived provider shortage in much of the State (Exhibit 6). Similar trends of low-to-no patient capacity are occurring in high-need counties in other States, such as, Oklahoma and Nevada.

Exhibit 6: Example of Waivered Provider Distribution in High-Need Counties With Low-to-No Patient Capacity—Arkansas



Map Projection: USA Contiguous Albers Equal Area Conic

Datum: North American 1983

Source: HHS-OIG/Reference Citations

Source: OIG analysis of CDC and SAMHSA data, 2018

Although 44 percent of counties with high treatment needs have average-to-high patient capacity, patients may still experience difficulties accessing treatment in those areas

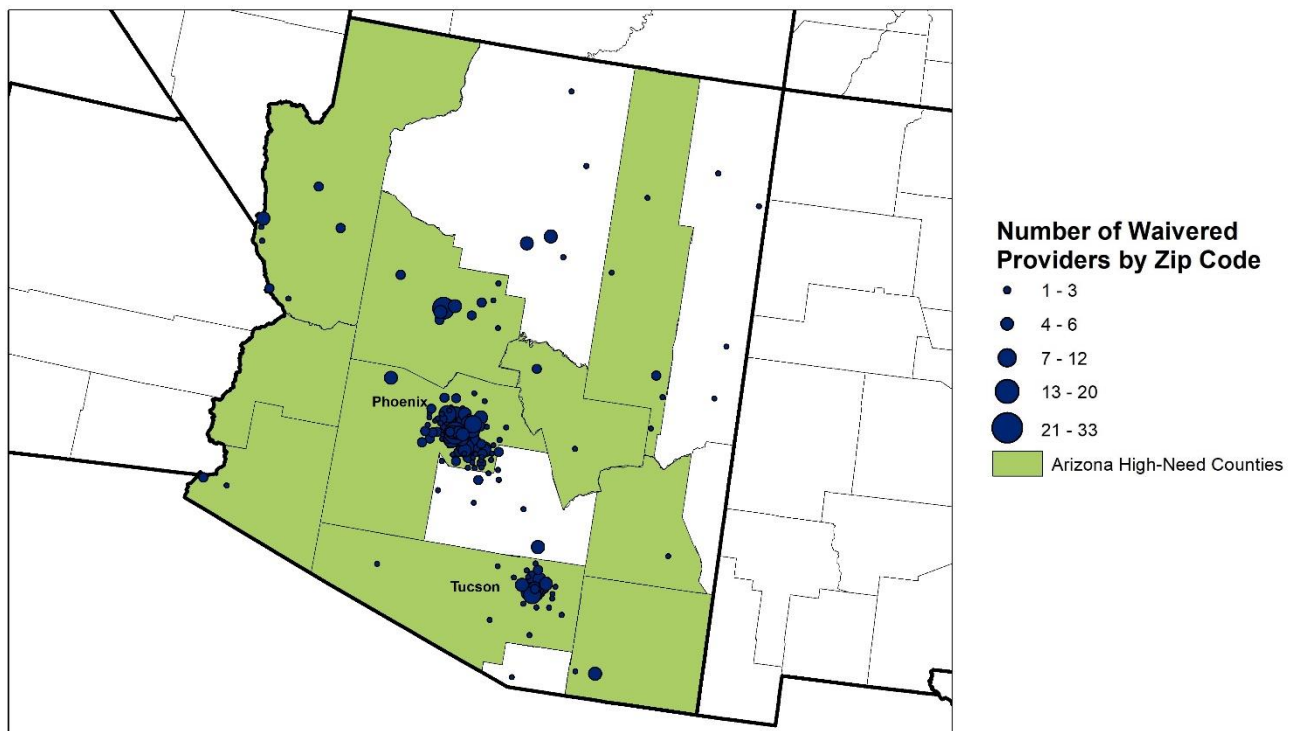
Depicted in Exhibit 5 as light blue, 44 percent of high-need counties have average-to-high patient capacity to provide buprenorphine services. Examples include parts of the Appalachian region, the Pacific Northwest, and Arizona. Forty-eight percent of high-need counties with average-to-high patient capacity are in rural areas.

Average-to-high patient capacity, however, may not always reflect actual geographic accessibility to buprenorphine services—especially in counties and States that encompass a large physical area. In other words, although these counties may appear to have adequate capacity to treat patients in need of buprenorphine services, individuals who live there may still experience difficulties accessing waived providers.

For example, two high-need counties in Arizona (Maricopa and Pima) also met our criteria of having average-to-high patient capacity (777.7 and 846.8 per 100,000 people, respectively). However, nearly all waived providers

were clustered around the major population centers of Phoenix (in Maricopa County) and Tucson (in Pima County), meaning that individuals located in the furthest reaches of these large counties may not have adequate access to waived providers (see Exhibit 7). For example, an individual residing in southwest Maricopa County, where zero waived providers are located, would have to drive an estimated 115 miles to access buprenorphine services in the Phoenix area (the closest cluster of waived providers in the county). This same individual would experience similar access issues if attempting to see a waived provider in neighboring counties. Even greater geographic disparities likely exist in Pima County and across the State as a whole.

Exhibit 7: Example of Disparities in Waivered Provider Distribution in High-Need Counties With Average-to-High Patient Capacity—Arizona



Map Projection: USA Contiguous Albers Equal Area Conic
Datum: North American 1983
Source: HHS-OIG/Reference Citations

Source: OIG analysis of CDC and SAMHSA data, 2018

CONCLUSION AND RECOMMENDATION

As the opioid crisis and public health emergency continue to affect many communities, this study raises concerns about access to MAT across the country. Congress created the buprenorphine waiver program to increase access to MAT—access that was previously restricted to specialized clinics (i.e., OTPs)—by making it available to patients in doctors’ offices. Despite significant increases in the number of new providers obtaining waivers and a substantial expansion of potential office-based treatment capacity nationwide, access to buprenorphine services remains challenging in many localities. Roughly a third (36 percent) of counties nationwide have high needs for buprenorphine services. However, patients in more than half (56 percent) of these high-need counties are hampered by a scarcity of local providers who have obtained waivers to provide MAT in office settings. The need is especially critical in the 320 high-need counties that lacked even a single waived provider.

One of HHS’s goals in addressing the opioid crisis is to “increase the number of providers, including nurse practitioners, physicians, and physician assistants who are able and willing to provide MAT.”⁶⁵ Increasing the number of providers with buprenorphine waivers is undoubtedly a vital step towards expanded access. However, as our findings illustrate, any increase on its own is not enough to ensure that all patients who need treatment have access to it. To expand the availability of buprenorphine services in counties where they may be needed the most, we recommend:

SAMHSA geographically target its efforts to increase the participation of waived providers in high-need counties

In its efforts to expand access to buprenorphine services, SAMHSA should work with its State partners and grantees to specifically target the high-need counties with low-to-no patient capacity. Particular attention should be given to high-need areas with clusters of counties that do not have any waived providers. Patients in these areas may have little to no access to buprenorphine services.

SAMHSA should work with its State partners and grantees to determine the best strategy for increasing each high-need county’s patient capacity. For example, in high-need counties with few or no waived providers, the best strategy may be for SAMHSA and its grantees to encourage the existing local providers to obtain buprenorphine waivers. If these high-need counties have few existing primary care or behavioral health providers, SAMHSA should continue partnering with other agencies, such as the Health Resources and Services Administration, in ongoing efforts to address health professional shortage areas. In high-need counties that already have waived providers, it may be more effective for SAMHSA and its grantees

to encourage and support existing waived providers to treat more patients in need of buprenorphine services, which might include applying to increase their patient-limit level, leveraging telehealth services, and addressing barriers to providing this service (e.g., time constraints; insurance coverage and requirements).

Even among the high-need counties with average-to-high patient capacity, SAMHSA should work with its State partners and grantees to ensure that there is adequate access to buprenorphine services. Although these high-need counties may appear to have enough waived providers to treat the need, patients may still lack access. Waivered providers may be clustered around major population centers and/or treating relatively few to no patients. In States that have buprenorphine access problems but are not fully utilizing telehealth services, SAMHSA could work with States and grantees to develop effective telehealth programs.

AGENCY COMMENTS AND OIG RESPONSE

SAMHSA concurred with our recommendation to target its efforts to increase the participation of waived providers in high-need counties. SAMHSA stated that it is committed to improving treatment access to address the opioid crisis, and has been working with Federal and State partners and grantees on efforts that are authorized by Congress to (1) encourage providers to obtain waivers and treat more patients; (2) reduce barriers and increase access to MAT medications, including buprenorphine; and (3) support increasing access to MAT for those in rural, underserved, and/or high-need counties. SAMHSA noted that through training and technical assistance opportunities, grants, and other efforts, the agency has infused millions of dollars into communities to address the issues raised in OIG's report and recommendation.

OIG appreciates SAMHSA's efforts to address this important issue, and urges SAMHSA to continue their work in this area to ensure access to MAT. More attention should be given to high-need counties with low-to-no patient capacity and those high-need areas with clusters of counties that do not have any waived providers, as patients in these areas may have little to no access to buprenorphine services.

For the full text of SAMHSA's comments, see Appendix B.

APPENDIX A: Detailed Methodology

Data Sources

Buprenorphine Waiver Notification System (BWNS). SAMHSA collects and stores buprenorphine waiver applicant information in the BWNS. The BWNS includes data on each applicant's address,⁶⁶ DEA registration number, patient-limit level, provider specialty, and year of waiver approval. We used these data to identify the number of waived providers nationwide and in each county. We also used these data to identify how many waived providers were approved at each of the three patient-limit levels. We reviewed BWNS data collected by SAMHSA between May 2002 and April 2018, which represented all waiver applications received by SAMHSA within this time period.

DEA Active Controlled Substances Act (CSA) Registrants Database. This database contains all active DEA registrants and their associated registration numbers. OIG regularly receives these data from the DEA. We reviewed January 2018 DEA registrant's data, the most recent data available to OIG at the time of our analysis, to verify that each waived provider's DEA number listed in the BWNS data was currently active.

U.S. Census Bureau Topologically Integrated Geographic Encoding and Referencing (TIGER) shapefiles. TIGER shapefiles are designed to be used with ArcGIS. These files include data on spatial boundaries, roads, address information, and water features. We used publicly available TIGER shapefiles with ZIP Code, State, and county data.⁶⁷ These shapefiles were used in our geocoding analyses in this review.

U.S. Census Bureau Cartographic Boundary shapefiles. Cartographic shapefiles are designed to be used with ArcGIS. They contain less detail than TIGER shapefiles and are used for small scale thematic mapping. They display accurate shoreline boundaries, especially in areas where shorelines and county lines overlap. We used publicly available cartographic county and State shapefiles in our ArcGIS mapping throughout this review.⁶⁸

U.S. Census Bureau resident population estimates data. Population estimates for each county are provided by the U.S. Census Bureau. We used the publicly available population estimates from 2016 to determine the county patient capacity rates.⁶⁹

National Center for Health Statistics (NCHS) Urban-Rural Classification Scheme for counties. CDC's NCHS developed this classification scheme for counties to demonstrate urban-rural health differences.⁷⁰ All counties and county-equivalent entities are grouped in either the metropolitan or nonmetropolitan categories.⁷¹ We labeled metropolitan counties as metropolitan and nonmetropolitan counties as rural in the report. We used

these publicly available data to determine the proportion of waived providers located in metropolitan and rural areas.⁷²

Centers for Disease Control and Prevention (CDC) drug overdose data.

CDC's National Vital Statistics System collects information on births, deaths, and fetal deaths from U.S. States and jurisdictions. Age-adjusted drug overdose mortality rates are calculated based on the underlying cause-of-death codes from the International Classification of Diseases, Tenth Revision (ICD-10), that detail drug poisoning.⁷³ We used all drug overdose mortality rates in this report. Drug-specific deaths (e.g., the type of opioid that caused the overdose) are not routinely reported across all U.S. jurisdictions, therefore, using only opioid-specific overdose mortality rates would have underestimated the number of actual opioid overdose deaths. In addition, because rising mortality rates are being driven by opioids, CDC staff recommended using the drug overdose mortality rates as an indicator of need for OUD treatment services. We obtained 2016 county-level mortality data from CDC. We used these data to calculate the age-adjusted drug overdose mortality rates for each county.^{74, 75} We used these data as one of three measures to identify counties with high indicators of opioid misuse and abuse.

U.S. Census Bureau 2016 Bridged-Race Postcensal Population Estimates.

The Bridged-Race Postcensal Population Estimates contains population estimates for age groups and race at the county level. These publicly available population estimates were used to calculate the age-adjusted drug overdose mortality rates for each county.⁷⁶

Opioid prescribing rates from retail pharmacies. The CDC published its analysis of IQVIA data on the geographic distribution in the United States of retail opioid prescriptions dispensed per 100 persons for the years 2006–2017.⁷⁷ We used publicly available county-level data from 2016 located on CDC's website as one of three measures to identify counties with high indicators of opioid misuse and abuse.

SAMHSA National Survey on Drug Use and Health (NSDUH) prevalence rates of nonmedical use of pain relievers. NSDUH is a national population survey and serves as the primary source of statistical information on illicit drug use, alcohol use, substance use disorders and mental health issues in the United States. We used prevalence estimates of nonmedical use of pain relievers⁷⁸ in the past year (nonmedical use of pain relievers) for the years 2012–2014 (the most recent available). The NSDUH provides national-, State-, and substate-level⁷⁹ prevalence estimates on this measure. Because county-level estimates were not available, we assigned each county to its associated substate region's prevalence estimate.⁸⁰ We used these publicly available data⁸¹ as one of three measures to identify counties with high indicators of opioid misuse and abuse.

Data Analysis

Waivered provider list. To determine the number of waivered providers nation-wide, we created a national list of current waivered providers from SAMHSA's BWNS data. Providers meeting the following characteristics were removed from our analysis:

- *Providers without current waivers.* SAMHSA's BWNS data include application information on both "certified" (i.e., providers with currently valid waivers) and "non-certified" providers (i.e., providers whose waivers are no longer valid, have not yet been approved, or whose applications were not processed/deemed incomplete). For these analyses, we only included certified providers and removed non-certified providers.
- *Providers with multiple and duplicate entries.* Providers who applied for a patient-limit increase(s) had a record for each application in the BWNS data. Therefore, we retained the most recent patient-limit application (i.e., the provider's current waiver level) data. Earlier application data were combined into this one observation, resulting in the removal of all additional multiple entries. Additionally, there were numerous providers with duplicate entries (i.e., a provider with potentially two waivers at the same patient-limit level). This list of duplicate provider entries was sent to SAMHSA for review.
- *Providers with missing DEA registration data.* DEA registration numbers are required to verify that waivered providers hold valid DEA registrations and are legally allowed to prescribe buprenorphine for MAT. All providers with missing DEA registration numbers were removed. This list of providers with missing DEA registration numbers was sent to SAMHSA for review in August 2018.
- *Providers with inactive DEA registration numbers.* To ensure that all current waivered providers hold a valid DEA registration, we compared the DEA registration numbers in the BWNS data to the DEA registration numbers listed in the DEA Active CSA Registrants database. All waivered providers that did not have an active DEA registration number were removed. This list of 1,415 providers with inactive DEA registration numbers was sent to SAMHSA for review.
- *Providers located in U.S. territories.* Data about U.S. territories (e.g., Puerto Rico, Guam, U.S. Virgin Islands) were not available for some key data sources used in this review (e.g., opioid prescribing rates from retail pharmacies, nonmedical use of pain relievers data). Therefore, we removed providers located in the U.S. territories from our analyses. We included data on providers located in the 50 States and District of Columbia.

To determine the number of waivered providers in each county, we grouped the waivered providers by county. First, we assigned each waivered provider to a county using the address data included in the BWNS

data. We used the Geographic Information System ArcGIS 10.5 software to geocode⁸² the ZIP Codes listed for each waived provider. Then, to obtain each waived provider's county, we matched each geocoded ZIP Code to a county through ArcGIS. For the approximately 3 percent of waived providers that we were unable to geocode through ArcGIS, we used the U.S. Census Bureau's manual geocoder⁸³ as an alternative. We used waived providers' street, city, and State address information listed in the BWNS data to assign counties to the remaining waived providers. We were unable to assign a county to 703 waived providers—most likely due to typographical errors in the address information in BWNS. These waived providers were removed from our county-level analyses. Please see Exhibit 8 for a detailed list of the waived providers that were excluded from our analyses.

Please note that the national-level analyses in this review are based on the total subpopulation of 46,857 waived providers (which includes the 703 waived providers lacking sufficient address information to geocode). However, all metropolitan/rural and county-level analyses are based on a subpopulation of 46,154 waived providers, which excludes the 703 waived providers lacking county location information.

Exhibit 8: Waivered Provider List Removals

Criteria for Removal	Number of Provider Records Removed	Number of Providers Remaining
Original number of waived provider entries in BWNS	N/A	76,403
Removed providers without current waivers (non-certified)	9,775	66,628
Removed providers without current waivers (non-processed applications)	90	66,538
Removed multiple entries for same waived provider (providers with multiple applications for patient-limit level increases)	17,746	48,792
Removed providers with missing DEA registration numbers	7	48,785
Removed duplicate provider entries (providers with potential duplicate waivers)	48	48,737
Removed providers with non-active DEA registration numbers	1,415	47,322
Removed waived providers located in U.S. territories	465	National waived provider total 46,857
Removed waived providers that could not be geocoded	703	County waived provider total 46,154

Source: OIG analysis of SAMHSA's BWNS data.

Analysis of national waived provider data. To determine the total number of waived providers nation-wide (i.e., 50 States and the District of Columbia), we counted the total number of waived providers on the national waived provider list. We then calculated the national proportion of waived providers approved at each patient-limit level (i.e., 30, 100, or 275). Finally, we summed the maximum number of patients each waived provider may treat (i.e., patient-limit level) to determine the national patient capacity.

We also conducted analyses to describe the national population of waived providers. We examined the provider type by calculating the proportion of waived providers that were NPs, PAs, and physicians.⁸⁴

To examine the historical trend in the number of new waived providers who entered the waiver program since its inception in 2002, we calculated the number of waived providers who received an initial 30-patient limit level waiver for each year from 2002 to 2017.⁸⁵ To determine the number of waived providers who increased their patient limits, we calculated the number of current waived providers who received a patient-limit increase (i.e., 100 or 275) each year from 2006 (the first-year patient limits were statutorily permitted to be increased) to 2017.

To determine the national proportion of waived providers located in metropolitan and rural areas, we first assigned each waived provider's location a metropolitan or rural classification using the NCHS Urban-Rural Classification Scheme. Then, we calculated the proportion of waived providers located in metropolitan and rural areas. We could assign a metropolitan or rural classification only to waived providers with sufficient address information (i.e., geocoded ZIP Codes). Therefore, the national proportion of waived providers located in metropolitan and rural areas does not include the 703 waived providers with insufficient address information.

Analysis of county-level waived provider data. We first calculated the number of waived providers in each county. Then, we summed the number of counties without any waived providers. To calculate each county's patient capacity, we summed the maximum number of patients each waived provider in the county may serve based on each waived provider's patient-limit level (i.e., 30, 100, or 275). Additionally, we compared each county's total patient capacity to its 2016 population size to calculate the county patient capacity rates (e.g., county patient capacity per 100,000 people).

To determine the counties with average-to-high and low-to-no patient capacity rates, we first determined counties with zero patient capacity rates (i.e., counties with zero waived providers). All counties with zero waived providers were included in the subsequent low-to-no patient capacity analyses. For counties with greater than zero patient capacity rates, we distributed the county patient capacity rates into five quintiles. Then, we

identified all counties equal to or less than the 40th percentile of the distribution (i.e., all counties with patient capacity rates less than or equal to 473.8 per 100,000 people) as having low patient capacity.⁸⁶ We identified those counties with patient capacity rates greater than the 40th percentile of the distribution (i.e., all counties with patient capacity rates greater than or equal to 473.9 per 100,000 people) as having average-to-high patient capacity. Then, we calculated the proportion of counties with low-to-no patient capacity rates and the proportion of counties with average-to-high patient capacity rates. Finally, we calculated the proportion of counties with low-to-no patient capacity rates that were in rural areas.

Exhibit 9: Distribution of County Patient Capacity Rates per 100,000

Patient Capacity Rates	Percentile	OIG Classification
0	-	No patient capacity
18.9–223.1	0–20th	Low patient capacity
223.2–473.8	21st–40th	Low patient capacity
473.9–815.8	41st–60th	Average patient capacity
815.9–1404.2	61st–80th	High patient capacity
1404.3–13445.7	81st–100th	High patient capacity

Source: OIG analysis of SAMHSA and CDC data, 2018.

Identification of counties with high indicators of opioid misuse and abuse.

To identify counties with a high need for buprenorphine services, we consulted with CDC. Based on CDC’s recommendation, we used three measures to identify counties with high indicators of opioid misuse and abuse:

- (1) CDC county-level drug overdose mortality data,
- (2) Opioid prescribing rates from retail pharmacies, and
- (3) SAMHSA NSDUH prevalence rates of nonmedical use of pain relievers.

We determined the median rate for each measure, then distributed each of the three measures into five quintiles.⁸⁷ Then, for each measure, we identified the counties that were greater than the 60th percentile of the distribution. All counties with rates greater than the 60th percentile of the distribution were considered to have a high indicator for opioid misuse and abuse for that measure.⁸⁸ We also identified counties with indicators in the highest quintile (i.e., greater than the 80th percentile of the distribution) for each opioid misuse and abuse measure and were considered to have the highest indicators for that measure. We identified those counties with opioid misuse and abuse indicators less than or equal to the 60th percentile

of the distribution as having average-to-low opioid misuse and abuse indicators.

Exhibit 10: Opioid Misuse and Abuse Measure Distributions by County

Drug Overdose Age-Adjusted Mortality Rate per 100,000 people	Percentile	OIG Classification of High Need
0–3.5	0–20th	
3.6–11.5	21st–40th	
11.6–17.7	41st–60th	
17.8–27.6	61st–80th	✓
27.7–223.5	81st–100th	✓

Percentage of Nonmedical Use of Pain Relievers in the Past Year	Percentile	OIG Classification of High Need
2.95%–3.74%	0–20th	
3.75%–4.15%	21st–40th	
4.16%–4.49%	41st–60th	
4.50%–4.83%	61st–80th	✓
4.84%–5.89%	81st–100th	✓

Opioid Prescribing Rate per 100 people	Percentile	OIG Classification of High Need
0–43.6	0–20th	
43.7–64.7	21st–40th	
64.8–82.4	41st–60th	
82.5–105.6	61st–80th	✓
105.7–470.3	81st–100th	✓

Source: OIG analysis of SAMHSA and CDC data, 2018.

Then, we identified the counties that had high indicators (i.e., greater than the 60th percentile of the distribution) for at least two of the three measures. These counties were designated as the counties in high-need areas for buprenorphine services. We then identified the counties that had

the highest indicators (i.e., greater than the 80th percentile of the distribution) for at least two of the three measures. These counties were designated as the counties with the highest need for buprenorphine services. Then, we calculated the proportion of counties nation-wide that were in high-need areas. We also calculated the proportion of counties in high-need areas that had the highest indicators of opioid misuse and abuse. Finally, we calculated the proportion of counties in high-need areas that were in rural areas.

Geographic comparison and analysis of county-level patient capacity and areas of high need. Among the counties in high-need areas, we identified the counties with low-to-no or average-to-high patient capacity. Then, we calculated the proportion of counties in high-need areas with average-to-high and low-to-no patient capacity. Finally, we calculated the proportion of counties in high-need areas without any waived providers.

We chose to further examine waived provider characteristics in high-need counties in select States to obtain a more in-depth understanding of the dynamics between need and patient capacity. First, we identified 14 States where at least 50 percent of their counties were identified as high need. Then, among those 14 States, we calculated the percent of their high-need counties that had low-to-no patient capacity and the percent of their high-need counties that were rural.

Ultimately, we chose to examine high-need counties in Arizona, Ohio, Oregon, Arkansas, Alabama, Oklahoma, and Indiana. We calculated the proportion of high-need counties in each of these States without any waived providers. Next, we calculated the proportion of waived providers in high-need counties approved at each patient-limit level (i.e., 30, 100, or 275) in each of these States. To determine whether waived providers were clustered within a few high-need counties within each State, we calculated the proportion of waived providers located in each high-need county and identified where the major cities were located.

Using ArcGIS mapping software, we mapped the patient capacity rates for each county. Next, we mapped the counties in high-need areas and highlighted those counties with the highest opioid misuse and abuse indicators. Then, we mapped the counties in high-need areas and marked them as having low-to-no or average-to-high patient capacity rates. Finally, we chose to include maps of the high-need counties and the States' waived provider distribution in Arkansas and Arizona in this report.

APPENDIX B: Substance Abuse and Mental Health Services Administration Comments



Substance Abuse and Mental Health
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DEC 04 2019

TO: Joanne M. Chiedi
Acting Inspector General
Department of Health and Human Services Office of Inspector General

FROM: Assistant Secretary for Mental Health and Substance Use

SUBJECT: OIG Draft Report "*Geographic Disparities Affect Access to Buprenorphine Services for Opioid Use Disorder*" (OEI-12-17-00240)

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

A handwritten signature in black ink, appearing to read "Elinore F. McCance-Katz".

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

Behavioral Health is Essential To Health • Prevention Works • Treatment is Effective • People Recover

GENERAL COMMENTS FROM THE SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION ON THE OFFICE OF INSPECTOR GENERAL'S DRAFT REPORT ENTITLED – GEOGRAPHIC DISPARITIES AFFECT ACCESS TO BUPRENORPHINE SERVICES FOR OPIOID USE DISORDER OEI-12-17-00240

The Substance Abuse and Mental Health Services Administration appreciates the opportunity from the Office of Inspector General (OIG) to review and comment on this draft report and looks forward to continuing to work with the Department and Congress on efforts to address the opioid crisis.

Recommendation 1

SAMHSA should geographically target its efforts to increase the participation of waived providers in high-need counties. In high-need counties with few or no waived providers, the best strategy may be for SAMHSA and its grantees to encourage existing local providers to obtain buprenorphine waivers and/or to address overall local shortages of providers in general. In high-need counties that already have higher numbers of waived providers, it may be more effective for SAMHSA and its grantees to encourage and support existing waived providers to treat more patients in need of buprenorphine services.

SAMHSA Response

SAMHSA's efforts and its focus are directed in either appropriation or other statute. When permissible, SAMHSA may target such efforts; but often the target of our efforts are specified in statute. SAMHSA is committed to improving treatment access and retention to address the opioid crisis, which is why we have already worked with federal and state partners and grantees to take action and have efforts in place to:

- Encourage providers to obtain the DATA waiver and treat more patients;
- Reduce barriers and increase access to all FDA approved medications for MAT, including buprenorphine; and
- Support means of increasing access to MAT for those in rural, underserved, and/or high needs counties.

Through training and technical assistance opportunities, grants, and other efforts, SAMHSA has infused millions of dollars into communities to address the issues raised in OIG's report and recommendations. Some examples of these actions and efforts are outlined below.

Training and Technical Assistance Grants

As discussed by the OIG, SAMHSA funds a large TA and training effort, the Opioid Response Network, whose primary focus is locally based. The premise of this approach is that local expertise is needed to ensure jurisdictions get the service access they need. SAMHSA has placed local teams of experts on the ground in every state which are available to individuals, communicates, practitioners and anyone else seeking training/education on addressing the opioid crisis. These efforts are tailored to local needs specified by the recipient of the training.

Additionally, SAMHSA is working to increase education, interest, and expansion of Buprenorphine to practitioners through our Provider Clinical Support System (PCSS) programs and Training and Technical Assistance Centers (TTCs).

GENERAL COMMENTS FROM THE SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION ON THE OFFICE OF INSPECTOR GENERAL'S DRAFT REPORT ENTITLED – GEOGRAPHIC DISPARITIES AFFECT ACCESS TO BUPRENORPHINE SERVICES FOR OPIOID USE DISORDER OEI-12-17-00240

- *Provider Clinical Support System – Medication Assisted Treatment (PCSS-MAT) and Provider Clinical Support System – Universities (PCSS-U), <https://pcssnow.org/>*
 - PCSS was created in response to the opioid overdose epidemic to train primary care providers in the evidence-based prevention and treatment of OUD and treatment of chronic pain. The project is geared toward primary care providers who wish to treat OUD. PCSS is made up of a coalition major healthcare organizations, led by the American Academy of Addiction Psychiatry, to address this healthcare crisis. Through a variety of trainings and a clinical mentoring program, PCSS's mission is to increase healthcare providers' knowledge and skills in the prevention, identification, and treatment of substance use disorders (SUD) with a focus on opioid use disorders (OUD).
 - PCSS-MAT trains health professionals to provide effective, evidence-based, MAT to patients with OUD in primary care, psychiatric care, substance use disorder treatment, and pain management settings. The program is not only intended to expand MAT training, but also encourage eligible providers to update their waivers.
 - PCSS-U is also intended to expand and enhance MAT services for individuals with OUD through ensuring the education and trainings of students in the medical, physician assistant and nurse practitioner fields. This program's focus is to ensure students fulfill the training requirements needed to obtain a DATA waiver to prescribe MAT in office-based settings.

These programs are steadily expanding training through the provision of education to additional providers eligible to receive the DATA Waiver as specified in the SUPPORT Act. The inclusion of these additional providers will expand capacity particularly in hard to reach regions where a physician, PA or NP may not always be available.

- *Addiction Technology Transfer Centers (ATTC)*
 - SAMHSA also continues to support all levels of providers in the addiction field with education, training, and resources through its ATTC Network. The Network has locations nationwide that provide general and tailored education and training on a variety of topics to develop, strengthen, and overall increase the capacity of specialized behavioral and primary healthcare providers to provide high quality, effective services for individuals with SUD, including OUD.

Grants

SAMHSA has also provided various grants to states in order to address access to MAT. These grants not only allow, but often require grantees (whether states or communities) to assess their needs, which includes targeting areas with highest need and low access; increase access to providers that use evidence-based practices, including MAT; and encourage leveraging innovative means, such as telehealth, to address barriers to accessing services. Some of these grants are described briefly below:

- *State Opioid Response (SOR) Grant Program*

GENERAL COMMENTS FROM THE SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION ON THE OFFICE OF INSPECTOR GENERAL'S DRAFT REPORT ENTITLED – GEOGRAPHIC DISPARITIES AFFECT ACCESS TO BUPRENORPHINE SERVICES FOR OPIOID USE DISORDER OEI-12-17-00240

- The SOR Program aims to address the opioid crisis by increasing access to MAT using the three FDA-approved medications for the treatment of OUD, reducing unmet treatment needs, and reducing opioid overdose-related deaths through the provision of prevention, treatment and recovery activities for OUD. This program includes a 15 percent set-aside for the ten states with the highest mortality rate related to drug overdoses. In addition to other requirements, but particularly relevant to the OIG recommendations in this report, all grantees are required to use epidemiological data to demonstrate critical gaps in availability of treatment for OUDs in geographic, demographic, and service level terms. Grantees also use SOR funds to support telehealth strategies in rural and underserved areas, another recommendation suggested by OIG in this report.
- *Tribal Opioid Response (TOR) Grant Program*
 - The TOR program aims to address the opioid crisis in tribal communities by increasing access to culturally appropriate and evidence-based treatment, including MAT using one of the three FDA-approved medications for the treatment of OUD. The intent is to reduce unmet treatment need and opioid overdose-related deaths through the provision of prevention, treatment and/or recovery activities for OUD.
- *Medication Assisted Treatment – Prescription Drug and Opioid Addiction (MAT-PDOA) Grant Program*
 - MAT-PDOA provides funding to enhance and expand treatment service systems to increase capacity and provide accessible, effective, comprehensive, coordinated care, and evidence-based MAT and recovery support services to individuals with OUD seeking or receiving MAT. Grantees are states with high rates of primary treatment admissions for heroin and opioids per capita. The population of focus includes individuals at risk for or with OUD seeking or receiving MAT including racial, ethnic, sexual and gender identity minority subpopulations.
- *Substance Use Prevention and Treatment Block Grant (SABG)*
 - States are able to utilize block grant funding to support access to and expansion of MAT, consistent with biennial or annual plans submitted to and approved by SAMHSA.

Other Efforts Already Underway to Increase Waivered Providers and Enhance Access to MAT

- SAMHSA implemented the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT Act) requirement to extend eligibility of prescribing buprenorphine in office-based settings to Clinical Nurse Specialists, Certified Registered Nurse Anesthetists, and Certified Nurse Midwives (CNSs, CRNAs, and CNMs).
- SAMHSA continues its partnerships with other federal agencies to increase workforce capacity and access to treatment. For example, SAMHSA has collaborated with the Health Resources and Services Administration (HRSA) on its National Health Service Corps (NHSC) Loan Repayment Program, which provides three opportunities for NHSC providers to receive monetary incentives if they possess a DATA waiver. SAMHSA also worked closely with the Centers for Medicare & Medicaid Services to

GENERAL COMMENTS FROM THE SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION ON THE OFFICE OF INSPECTOR GENERAL'S DRAFT REPORT ENTITLED – GEOGRAPHIC DISPARITIES AFFECT ACCESS TO BUPRENORPHINE SERVICES FOR OPIOID USE DISORDER OEI-12-17-00240

implement a new Medicare Part B benefit which expands access to OUD treatment through OTPs.

- SAMHSA and HHS launched FindTreatment.gov, <https://findtreatment.gov/>. This website provides an easy way for anyone across the nation to find treatment, including buprenorphine providers, for themselves or a loved one.

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This report was prepared under the direction of David Tawes, Regional Inspector General for Evaluation and Inspections in the Baltimore regional office, and Heather Barton, Deputy 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.

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ENDNOTES

¹ SAMHSA, *Key Substance Use and Mental Health Indicators in the United States: Results from the 2017 National Survey on Drug Use and Health*, September 2018.

² CDC, *Understanding the Epidemic*, December 2018. Available at <https://www.cdc.gov/drugoverdose/epidemic/index.html>. Accessed on December 28, 2018.

³ Ibid.

⁴ U.S. Department of Health and Human Services, *Facing Addiction in America: The Surgeon General's Spotlight on Opioids*, September 2018.

⁵ 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/.

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⁷ U.S. Government Accountability Office, *Laws, Regulations, and Other Factors Can Affect Medication-Assisted Treatment Access*, September 2016.

⁸ The Palm Beach County Grand Jury, *Report on The Proliferation of Fraud and Abuse in Florida's Addiction Treatment Industry*, December 8, 2016. Available at <http://www.sa15.state.fl.us/stateattorney/SoberHomes/content/GrandJuryReport2.pdf>. Accessed on December 19, 2017.

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¹⁰ Jones, Christopher M., et.al. National and State Treatment Need and Capacity for Opioid Agonist Medication-Assisted Treatment. *Am J Public Health*; 2015 Aug; 105(8): 55–64.

¹¹ Rosenblatt, Roger A, et.al. Geographic and Specialty Distribution of US Physicians Trained to Treat Opioid Use Disorder. *Ann Fam Med*. 2015 Jan-Feb; 13(1): 23–26.

¹² U.S. Department of Health and Human Services, *Facing Addiction in America: The Surgeon General's Spotlight on Opioids*, September 2018.

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¹⁴ National Institute on Drug Abuse, *Drug Facts: Treatment Approaches for Drug Addiction*, January 2018. Accessed at: <https://www.drugabuse.gov/publications/drugfacts/treatment-approaches-drug-addiction> on December 28, 2018.

¹⁵ U.S. Department of Health and Human Services, *Facing Addiction in America: The Surgeon General's Spotlight on Opioids*, September 2018.

¹⁶ American Society of Addiction Medicine (ASAM), *The ASAM National Practice Guideline*, June 2015.

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¹⁸ National Institute on Drug Abuse, *Drug Facts: Treatment Approaches for Drug Addiction*, January 2018. Available at <https://www.drugabuse.gov/publications/drugfacts/treatment-approaches-drug-addiction>.

¹⁹ SAMHSA, *Buprenorphine*, May 2019. Available at <https://www.samhsa.gov/medication-assisted-treatment/treatment/buprenorphine>. Accessed on September 25, 2019.

²⁰ ASAM, *The ASAM National Practice Guideline for the Use of Medication in the Treatment of Addiction Involving Opioid Use*, June 2015.

²¹ Drugs are classified in five distinct categories or schedules (Schedule I through V) depending on the drug's medical use and abuse and dependency potential. Schedule III drugs are defined as drugs with a potential for abuse that is lower compared to Schedule I and II substances and that may lead to moderate or low physical dependence or high psychological dependence. Section 202 of the Controlled Substances Act. The Controlled Substances Act was enacted under Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, P. L. No 91-513 (Oct. 27, 1970).

²² SAMHSA, *National Survey of Substance Abuse Treatment Services (N-SSATS): 2017—Data on Substance Abuse Treatment Facilities*, July 2018.

²³ ASAM, *The ASAM National Practice Guideline For the Use of Medications in the Treatment of Addiction Involving Opioid Use*, June 2015.

²⁴ Schedule IV and V drugs are defined to have low and lower potentials for abuse, respectively. Section 202 of the Controlled Substances Act.

²⁵ The Drug Addiction Treatment Act of 2000 (DATA 2000) was enacted under Title XXXV of the Children's Health Act of 2000, P.L. No. 106-310 (Oct. 17, 2000). DATA amended section 303(g) of the Controlled Substances Act. DATA 2000 was signed into law in 2000, but the first schedule III narcotics used for MAT, Suboxone and Subutex (two formulations of buprenorphine), were approved by the U.S. Food and Drug Administration in 2002.

²⁶ Section 303(g) of the Controlled Substances Act.

²⁷ Section 303(g)(2) of the Controlled Substances Act.

²⁸ 42 CFR part 8. Providers can prescribe buprenorphine for pain management without a waiver. These providers must comply with the Controlled Substances Act.

²⁹ 66 Fed. Reg. 4076 (Jan. 17, 2001).

³⁰ 70 Fed. Reg. 36339 (June 23, 2005).

³¹ 21 CFR § 1306.07.

³² 81 Fed. Reg. 44713 (July 8, 2016).

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- ³³ Section 303(g)(2)(B) of the Controlled Substances Act. Applicants must meet one of the following training requirements and submit proof of completion with their application: (1) board certification in addiction psychiatry, (2) board certification in addiction medicine, (3) 8-hour (24 hours if NP, PA, Clinical Nursing Specialist, Certified Registered Nurse Anesthetist, or Certified Nurse Midwife) training provided by an approved organization, (4) participated as an investigator in one or more clinical trial leading to the approval of an MAT drug, or (5) completed other training that is approved by a State licensing board/HHS.
- ³⁴ Section 303(g)(2)(B)(iii)(II) of the Controlled Substances Act, as amended by section 3201(a) of the Substance Use—Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, P.L. No. 115-271 (enacted Oct. 24, 2018), allows providers with a board certification in addiction medicine or psychiatry and/or provide MAT services in a qualified practice setting may treat up to 100 patients in their first year. The Substance Use—Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act is known as the SUPPORT for Patients and Communities Act.
- ³⁵ Section 303(g)(2)(B)(iii)(II) of the Controlled Substances Act.
- ³⁶ Section 303(g)(2)(B)(iii)(II)(dd) of the Controlled Substances Act and 42 CFR part 8, Subpart F.
- ³⁷ 42 CFR § 8.630, 8.635, and 8.640.
- ³⁸ Dick, Andrew W., et.al. Increasing Potential Access to Opioid Agonist Treatment in U.S. Treatment Shortage Areas. *Health Aff.* 2015 Jun; 34 (6): 1028–1034.
- ³⁹ Jones, Christopher M., et.al. National and State Treatment Need and Capacity for Opioid Agonist Medication-Assisted Treatment. *Am J Public Health.* 2015 Aug; 105(8): 55–64.
- ⁴⁰ Rosenblatt, Roger A, et.al. Geographic and Specialty Distribution of US Physicians Trained to Treat Opioid Use Disorder. *Ann Fam Med.* 2015 Jan-Feb; 13(1): 23–26.
- ⁴¹ Jones, Christopher, et. al. Characteristics and Prescribing Practices of Clinicians Recently Waivered to Prescribe Buprenorphine for the Treatment of Opioid Use Disorder. *Addiction.* 2019 Mar; 114(3): 1–12.
- ⁴² Ibid.
- ⁴³ GAO, *Laws, Regulations, and Other Factors Can Affect Medication-Assisted Treatment Access*, September 2016.
- ⁴⁴ Section 1102 of the Office of National Drug Control Policy Reauthorization Act of 2006, P.L. No. 109-469 (Dec. 29, 2006).
- ⁴⁵ 81 Fed. Reg. 44712 (July 8, 2016).
- ⁴⁶ Section 303(a) of CARA, amending section 303(g)(2) of the Controlled Substances Act.
- ⁴⁷ 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. In SUPPORT for Patients and Communities Act made the NP and PA expansion permanent and in addition, temporarily expanded buprenorphine prescribing privileges to Clinical Nursing Specialists, Certified Registered Nurse Anesthetists, and Certified Nurse Midwives. These providers are not included in our analyses because they were not yet eligible for waivers during the period of our review (April 2018).
- ⁴⁸ 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 OUD treatment services.
- ⁴⁹ 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.
- ⁵⁰ 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>.
- ⁵¹ Counties were distributed into five quintiles for each measure. Counties in quintiles below or above the 60th percentile for each measure were classified as having low or average-to-high indicators (i.e., rates) for that measure, respectively. The 2016 national median drug overdose mortality rate was 14.4 per 100,000 people. The 2016 national median opioid prescribing rate from retail pharmacies was 72.9 per 100 people. The 2012–2014 national median nonmedical use of pain relievers rate was 4.32 percent.
- ⁵² Jones, Christopher, et. al. Characteristics and Prescribing Practices of Clinicians Recently Waivered To Prescribe Buprenorphine for the Treatment of Opioid Use Disorder. *Addiction.* 2019 Mar; 114(3): 1–12.
- ⁵³ United Nations Office on Drugs and Crimes, *World Drug Report 2018: Global Overview of Drug Demand and Supply, Latest Trends, Cross-cutting Issues*, June 2018.
- ⁵⁴ Chen, Pingxi, et. al. Premature Mortality From Drug Overdoses: A Comparative Analysis of 13 Organisation of Economic Co-Operation and Development Member Countries with High-Quality Death Certificate Data, 2001 to 2015. *Ann Internal Med.* 2019 March; 170(5): 352–354.
- ⁵⁵ Council on Foreign Relations, *The U.S. Opioid Epidemic*, January 2019. Available at <https://www.cfr.org/backgrounders/us-opioid-epidemic>. Accessed on April 3, 2019.
- ⁵⁶ OIG estimated the number of providers that entered the program each year (i.e., those that obtained their initial 30 patient-limit waiver), beginning in 2002. A number of providers left the program since they initially obtained their waivers and these providers are not reflected in the list of the 46,857 providers with current waivers in April 2018. OIG used the list of providers with current waivers for all subsequent analyses.
- ⁵⁷ 81 Fed. Reg. 44729 (July 8, 2016).
- ⁵⁸ Jones, Christopher, et. al. Characteristics and Prescribing Practices of Clinicians Recently Waivered to Prescribe Buprenorphine for the Treatment of Opioid Use Disorder. *Addiction.* 2019 Mar; 114(3): 1–12.
- ⁵⁹ Thomas, Cindy Parks, et.al. “Prescribing patterns of buprenorphine waived physicians.” *Drug and Alcohol Dependence* 181.1 (December 2017): 213–218.
- ⁶⁰ Ibid.

⁶¹ Ibid.

⁶² Jones, Christopher, et. al. Characteristics and Prescribing Practices of Clinicians Recently Waivered to Prescribe Buprenorphine for the Treatment of Opioid Use Disorder. *Addiction*. 2019 Mar; 114(3): 1–12.

⁶³ Rural Health Information Hub, *Rural Healthcare Workforce*, July 2018. Available at <https://www.ruralhealthinfo.org/topics/health-care-workforce>. Accessed on June 24, 2019.

⁶⁴ The Appalachian region includes counties in the 13 States of Mississippi, Alabama, Georgia, Tennessee, South Carolina, North Carolina, Kentucky, West Virginia, Virginia, Ohio, Pennsylvania, Maryland, and New York.

⁶⁵ HHS, *Strategy to Combat Opioid Abuse, Misuse, and Overdose: A Framework Based on the Five Point Strategy*. Available at <https://www.hhs.gov/opioids/sites/default/files/2018-09/opioid-fivepoint-strategy-20180917-508compliant.pdf>. Accessed on July 2, 2019.

⁶⁶ OIG did not verify the accuracy of waived provider addresses in the BWNS. The addresses included in the BWNS data may be outdated.

⁶⁷ U.S. Census Bureau, *Geographies—TIGER/Line Shapefiles*. Available at <https://www.census.gov/geographies/mapping-files/time-series/geo/tiger-line-file.2016.html>.

⁶⁸ U.S. Census Bureau, *Geographies - Cartographic Boundary—Shapefile*, Available at <https://www.census.gov/geographies/mapping-files/time-series/geo/carto-boundary-file.2016.html>.

⁶⁹ U.S. Census Bureau, *American Fact Finder—2016 Population Estimates*, Available at <https://factfinder.census.gov/faces/nav/jsf/pages/searchresults.xhtml?>.

⁷⁰ CDC, *2013 NCHS Urban-Rural Classification Scheme for Counties*, April 2014.

⁷¹ Ibid. Metropolitan levels include: Large metro (population 1 million or more)—Large central metro; Large metro (population 1 million or more)—Large fringe metro; Medium metro (population 250,000–999,999); and Small metro (population less than 250,000). Nonmetropolitan levels include: Micropolitan (Urban cluster population 10,000–49,999) and Noncore.

⁷² CDC, *NCHS Urban-Rural Classification Scheme for Counties*, Available at https://www.cdc.gov/nchs/data_access/urban_rural.htm.

⁷³ CDC Morbidity and Mortality Weekly Report, *Drug and Opioid-Involved Overdose Deaths—United States, 2013–2017*, Vol. 67, Nos. 51 and 52, January 4, 2019. To identify opioid overdoses, NCHS uses a selection of external causes of morbidity and mortality ICD-10 codes that include X40–X44, X60–X64, X85, and Y10–Y14.

⁷⁴ CDC NCHS staff provided technical assistance and OIG performed quality assurance checks against CDC published rates to ensure accuracy.

⁷⁵ CDC flags all counties with less than 20 drug overdose deaths as “unreliable,” because the mortality rate based on fewer than 20 deaths has a relative standard error of 23 percent or more. A relative standard error greater than 23 percent is considered statistically unreliable. Therefore, they do not publicly publish the drug overdose age-adjusted mortality rates for these counties. Following CDC policy, we have not published the rates for each county but chose to continue to use the drug overdose age-adjusted mortality rates as a relative proxy of need for all counties.

⁷⁶ CDC, *Bridged-Race Population Estimates—Data Files and Documentation: Vintage 2016 Bridged-Race Postcensal Population Estimates*, Available at https://www.cdc.gov/nchs/nvss/bridged_race/data_documentation.htm#vintage2016.

⁷⁷ 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.

⁷⁸ SAMHSA, *Behavioral Health Trends in the United States: Results from the 2014 National Survey on Drug Use and Health*, September 2015.

Nonmedical use refers to the use of prescription drugs without a prescription of the individual's own or simply for the experience or feeling the drugs cause.

⁷⁹ SAMHSA, *2012–2014 National Surveys on Drug Use and Health: Guide to Substate Tables and Summary of Small Area Estimation Methodology*, July 2016. Prevalence estimates were generated on 25 measures for 384 substate regions to show the geographic distribution of substance use prevalence within and across States. SAMHSA uses the substate regions defined by each State. Most States defined regions in terms of counties or groups of counties. Substate estimates are calculated by aggregating 3 years of NSDUH population data. The most recent substate estimates of nonmedical use of pain relievers are for the years 2012–2014.

⁸⁰ Ibid. Fourteen counties spanned multiple substate areas. For those counties that were in multiple substate areas, we calculated a weighted average of the substate areas' prevalence estimates located in each county. We weighted each prevalence estimate based on each substate area's population estimate published by SAMHSA.

⁸¹ 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>.

⁸² ESRI, *What is geocoding?* Available at <http://desktop.arcgis.com/en/arcmap/10.3/guide-books/geocoding/what-is-geocoding.htm>. Geocoding is the process of transforming a description of a location—such as an address—to a location on the earth's surface. The resulting locations are output as geographic features with attributes, which can be used for mapping or spatial analysis.

⁸³ U.S. Census Bureau, *Welcome to Geocoder*. Available at <https://geocoding.geo.census.gov/>.

⁸⁴ Our analyses only include data on physicians, NPs and PAs. 2018 legislation expanding waiver participation to additional advanced practice nursing specialties (CNSs, CRNAs, and CNMs) occurred after our period of analysis and those new waived providers are not included in our analyses.

⁸⁵ A number of providers left the program since they initially obtained their waivers and these providers are not reflected in the list of the 46,857 providers with current waivers in April 2018. OIG used the list of providers with current waivers for all subsequent analyses.

⁸⁶ Based on the distribution of county patient capacity rates in the United States, we considered counties that were within the same percentile ranges that contained the median (i.e., between the 40th and 60th percentiles) of the distribution as having “typical” or “average” rates. Any counties with rates equal to or below the 40th percentile were classified as having low patient capacity rates. Please note that the 25th percentile typically categorizes the lower range of the distribution, but based on additional analysis of the waived provider counts in counties below the

25th percentile, we felt that this threshold would greatly underestimate the number of counties with low patient capacity, so we chose to use the 40th percentile as a conservative threshold for low patient capacity.

⁸⁷ The 2016 drug overdose mortality median rate was 14.4 per 100,000 people. The 2016 opioid prescribing median rate from retail pharmacies was 72.9 per 100 people. The 2012–2014 national nonmedical use of pain relievers median was 4.32 percent.

⁸⁸ Based on the distributions of the county rates for each measure, we considered counties between the 40th and 60th percentiles (percentile ranges which include the median) of the distribution as having “typical” or “average” rates. Therefore, any counties with rates greater than the 60th percentile were classified as having high indicators of opioid misuse and abuse. Please note that the 75th percentile and above typically categorizes the higher range of the distribution. However, because U.S. drug mortality and opioid nonmedical use and prescribing rates are very high, we felt that the 75th percentile threshold as an indicator of high need would greatly underestimate the number of counties with high indicators that require response. So, we chose to use the 60th percentile as a conservative threshold for high indicators of opioid misuse and abuse.