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1. Introduction

Opioid-involved overdose deaths and opioid use disorders (OUDs) continue to take a toll on America’s states and communities. As the nation continues to respond to this epidemic, it is critical to understand the current number of individuals that are accessing treatment in opioid treatment programs (OTPs) and the medications they are taking to support their recovery. To acquire this data, in April of 2021 the American Association for the Treatment of Opioid Dependence (AATOD) in partnership with the National Association of State Alcohol and Drug Abuse Directors (NASADAD) initiated a census of all patients currently receiving treatment in Substance Abuse and Mental Health Service Administration (SAMHSA) certified OTPs in the United States (U.S.). The purpose is to determine the number of patients receiving medications for opioid use disorders (MOUD) in OTPs, the types of federally approved medications used by patients in treatment, and the formulations of medication taken among the patient population. An annual census of OTPs is conducted as part of the National Survey of Substance Abuse Treatment Services (N-SSATS), a census of facilities providing substance use disorder (SUD) treatment. However, N-SSATS does not collect data on the formulations of medication used by patients in OTPs. This brief is the first effort to capture that data. It provides foundational information for future censuses.

The data on which this technical brief is based was collected from 1,547 OTPs between April and December of 2021. For the first time, the tables that follow will provide detailed information about the medications and formulations being used by patients in OTPs. This information will be invaluable to federal and state authorities and the entities that support OTP operations and provide a baseline to examine future trends. It will also help funders and policymakers to better understand treatment demand and the demand for particular medications.

2. Study Team & Overview of the Study

The partnership between the AATOD and NASADAD brings together two organizations with long histories of addressing substance use disorders. AATOD, a non-profit advocacy and policy organization founded in 1984, represents over 1,200 OTPs throughout the U.S. through its 29 state member chapters. NASADAD, a non-profit educational, scientific, and membership-based organization, represents the Single State Agencies (SSA) for alcohol and drugs that manage the publicly funded addiction treatment, prevention, and recovery systems throughout
the United States. A component of NASADAD’s structure is the Opioid Treatment Network (OTN) which includes the work of the State Opioid Treatment Authorities. The SOTAs serve as liaisons between OTPs SAMHSA, and the Drug Enforcement Administration (DEA) to ensure the quality and safety of OTPs. The census was supported by the Opioid Response Network (ORN), a group of diverse individuals and organizations working collaboratively to address the opioid and stimulant crisis. Funded by SAMHSA’s State Opioid Response (SOR) Technical Assistance (TA) grant, the ORN works with states, health professionals, community organizations, the justice system, and individuals in all 50 states and nine territories to provide education and training.

Between April and December of 2021, NASADAD in partnership with AATOD, collected census data from all OTPs across all states and U.S. territories. Using a brief web-based census, NASADAD, with the assistance of SOTAs in each state and/or territory, engaged OTPs and requested a current count of patients enrolled in treatment as of January 1, 2021. In total, of the 1,826 OTPs listed in the SAMHSA OTP directory, 1,547 OTPs across the country completed the census, reflecting an 85% response rate.

3. Methodology

3.1 Census

NASADAD and AATOD developed the web-based census collection instrument (Appendix A). The brief instrument collected treatment information concerning: 1) OTP reference information (e.g., name of person completing the form, contact information, name of agency, program address); 2) total number of patients enrolled in treatment as of January 1, 2021; 3) total number of patients provided buprenorphine and the formulations of the medication in use; 4) total number of patients provided methadone and the formulations in use; and 5) total number of patients provided
naltrexone and the formulations in use. The census was designed to be completed in approximately 10 minutes. Only aggregated patient numbers and medication information with no identifying information were collected as part of this effort.

3.2 Census Communications

Once the census design phase was complete, all SOTAs were contacted via email and informed of the purpose of the census, the information being requested, the voluntary nature of the census, and their role in the collection process. After the initial communication, separate messages were sent to each SOTA providing a link to share with OTPs in their state to access the electronic census, instructions for them to share with the OTPs to complete the census, and a PDF of the document to further familiarize respondents. Monthly reminders were sent to each SOTA providing census submission rates from the OTPs in their state to promote a robust response rate. With this information, SOTAs were able to maintain contact with OTPs to promote completion of the census.

In some cases, NASADAD staff reached out directly to OTPs to address specific data issues (e.g., data inconsistencies, incomplete submissions, respondent questions, duplicate submissions) to provide direct technical assistance to promote completion. More than 250 independent communications occurred to address the specific submissions provided by OTPs.

3.3 Sampling

The census targeted all OTPs listed in the SAMHSA OTP directory during the collection period. SOTAs were asked to review the SAMHSA OTP list and confirm the active status of all OTPs. In some cases, it was discovered that some OTPs listed in the SAMHSA directory had closed, or new OTPs not listed had opened. Closed OTPs were removed from the sampling list and the new OTPs, once confirmed as certified facilities, were added to the sampling frame. SOTAs then reached out to these facilities to complete the census.

3.4 Analysis

The census data analysis included developing descriptive information concerning the number of patients in treatment, types of medications in use, and the formulation of medications for each medication type used. A quantitative analysis was conducted tabulating the data in total and by regions. Numerical totals and percentages are provided for each medication type and formulation in total and by the four regions used as part of this analysis.
### 3.5 Study Limitations

This study has some important limitations that should be mentioned. First, the census is a first effort to collect the formulation of medications in use. Thus, there is not a prior study to compare changes that may have occurred with some medication formulations from one time period to another. Secondly, although the response rate was high (85%), some OTPs did not provide the formulations in use for reported medications. In addition, some OTPs provided a history of medications a patient may have used (and not solely the medication in use as of January 1, 2021); patients who had not yet received medications or obtained medications elsewhere; or patients who were using more than one form of a specific medication. These issues do not allow for a “one-for-one” match between all patients and their specific form of a medication. Despite these issues, we believe the information obtained from this census provides a unique snapshot of most patients in OTPs in terms of the type/formulations of medications they are receiving.

### 4. Findings

#### 4.1 Overall Medication Utilization

As shown in **Table 1**, there are three Federal Drug Administration (FDA) approved medications that are utilized by OTPs to treat OUDs: methadone, buprenorphine, and naltrexone. The table also includes information concerning the formulation of the medication currently available for use with SUD patients. A description of each medication is provided in **Appendix B** of this document.

<table>
<thead>
<tr>
<th>Medication</th>
<th>Mechanism of action</th>
<th>Route of administration</th>
<th>Dosing frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methadone</td>
<td>Full agonist</td>
<td>Available in pill, liquid, and wafer forms</td>
<td>Daily</td>
</tr>
<tr>
<td>Buprenorphine</td>
<td>Partial agonist</td>
<td>Pill or film (placed inside the cheek or under the tongue)</td>
<td>Daily</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Implant (inserted beneath the skin)</td>
<td>Every six months</td>
</tr>
<tr>
<td>Naltrexone</td>
<td>Antagonist</td>
<td>Oral formulations</td>
<td>Daily</td>
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<tr>
<td></td>
<td></td>
<td>Extended-release injectable formulation</td>
<td>Monthly</td>
</tr>
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</table>

**Table 1: FDA-Approved Medications to Treat OUD**
The census captured 512,224 patients receiving MOUD in the U.S. However, it should be noted that of the 512,224 patients for whom medication type was provided, formulation information is provided for only 510,557 of these patients. This brief will first provide a consolidated overview of the medications and formulations used in OTPs across the country. A complete summary of this data is provided in Appendix C of this report.

As shown in Exhibit 1, most patients captured in the census are using methadone to treat their OUD (476,763). Buprenorphine was the second most frequently reported medication used (33,473), with naltrexone reported as the least used medication (1,988).

Exhibit 1: Medications used by Patients in OTPs to Treat OUD

Exhibits 2, 3, and 4 illustrate the formulations used across the three FDA approved medications for the 510,557 patients for whom formulation was reported. Regarding the use of methadone hydrochloride products, Exhibit 2 shows that the most commonly used form of this medication was liquid. Of the 476,001 patients for whom methadone formulation information was provided, 436,429 (91.69%) were using the liquid form compared to 8,515 (1.79%) and 31,057 (6.25%) patients using tablet and
diskette forms, respectively. In comparison, the 2020 N-SSATS survey estimates that 311,531 patients were taking methadone for their OUD. This census shows a significant increase in the number of individuals taking methadone for their OUD.

Comparatively, **Exhibit 3** shows the use of buprenorphine products. Of the 32,652 total patients for whom formulation was reported, 20,586 (63.05%) were using the tablet formulation compared to 11,787 (36.10%) using film. Two hundred and seventy-four patients were reported as using Sublocade, while only five patients were reported as using Probuphine. In terms of the number of patients provided buprenorphine at OTPs, the 2020 N-SSATS reported 31,864 patients were receiving buprenorphine in facilities.
with OTPs, reflecting a similar but a minor increase in the use of the medication as compared to the 2021 census.iii

In terms naltrexone use, the smallest proportion of patients use this medication. The census found (Exhibit 4) that 1,904 patients received this medication, with the greatest number of patients provided Vivitrol (1,652 or 86.76% patients). Only 252 patients (13.24%) were reported as using the tablet form of this medication. As compared to data reported in the 2020 N-SSATS, 3,828 patients were receiving naltrexone in facilities with OTPs, reflecting a decrease in use of the medication.

4.2 Medication Formulations in Use Across the Regions

The exhibits below (Exhibits 5, 6, and 7) present data on medication formulations based on consolidated Federal Department of Health and Human Services (HHS) regions to simplify review of regional variations. For the purposes of this technical brief, the following regions are used: 1) Eastern Seaboard (HHS Regions 1, 2, and 3); 2) South/Southwest (HHS Regions 4 and 6); 3) Midwest (HHS Regions 5, 7, and 8); and Pacific Northwest/West (HHS Regions 9 and 10). The complete HHS Regional Map is in included in Appendix D of this report.

As shown in Exhibit 5, liquid methadone is the most used formulation of methadone across the regions. This form of methadone is used with between 82% to 96% of patients seeking MOUD across the regions. Methadone in diskette form is the second most popular formulation
used. Between 3% to 15% of patients across the regions use this version of methadone. Across the regions, the tablet formulation was the least used variant of methadone. Only 1% to 3% of patients across the region used this formulation.

Regarding the formulations for buprenorphine, with the exception of the Eastern Seaboard, the tablet form of buprenorphine is the most used across the regions. In the South/Southwest, Midwest, and Pacific Northwest/West regions, 87.03%, 70.74%, and 62.17% of patients, respectively, are prescribed this form of buprenorphine. In the Eastern Seaboard region, only 34.80% of patients use this formulation. The film formulation is the most provided version of buprenorphine in this region (64.27%). In contrast, this version of buprenorphine is the second most provided form in the South/Southwest (12.77%), Midwest, (27.72%), and Pacific Northwest/West (37.61%). Sublocade and Probuphine are the least provided forms of buprenorphine across all regions.
In contrast, naltrexone is the least provided medication used across all regions. As shown earlier in Exhibit 1, of the 512,224 patients for whom this census captures medication type used, only 1,988 of patients (or 0.39%), have been provided naltrexone for treatment. In terms of the formulations used across the regions, Vivitrol is most often provided, with this form comprising between 73.98% and 89.54% of naltrexone prescriptions. The tablet form of this medication is the least provided, encompassing between 10.46% and 26.32% of naltrexone prescriptions.
5. Discussion

The opioid epidemic has resulted in significant resources to confront the crisis. An area of investment over the last five years has been in opening new OTPs to treat more individuals with OUDs. In 2018, there were 1,519 OTPs with the number increasing to 1,963 OTPs in September 2022. The number of OTPs also grew during the COVID-19 pandemic when many policy officials believed the need for these services would decline.

As the country manages the third major wave of an opioid epidemic largely due to the use of synthetic opioids, particularly illicitly fentanyl, increased numbers of patients are accessing treatment through OTPs. In 2020, 347,223 patients received care through OTPs, which increased to 512,224 in 2021. This census also discovered that more patients were being treated with methadone in 2021 (476,001) compared to (311,531) to 2020. Patients receiving buprenorphine increased slightly in 2021 compared to 2020 (32,652 to 31,864, respectively, and patients receiving naltrexone decreased between 2021 and 2020 (1,904 to 3,828, respectively). These changes may reflect the potency of illicit fentanyl and that it is often mixed with other substances, making it both extremely dangerous and clinically challenging to treat. Initial indications are that methadone maybe preferable in treating fentanyl to relieve withdrawal symptoms and cravings and retaining patients in treatment. As clinicians and policymakers continue to respond to this wave of the opioid epidemic, future expansion of OTPs will likely be needed to treat those with OUDs, and new insights will be required on the most effective medication dosages, behavioral therapies, and recovery supports to manage OUD related to fentanyl use. Understanding how the current wave and other factors impact patient medication needs and demands for services will be critical to future systems planning.

6. Issues for Future Consideration

This census is a snapshot in time and provides an initial glimpse into issues that require more in-depth exploration. Additional investigation into the prescriber and patient selection of medications, including their forms, can yield valuable information for medical and clinical staff, researchers, funders, and pharmaceutical manufacturers. In conducting this baseline study, the following questions arose that require additional research: 1) Why patients use multiple forms of a medication; 2) Why and how frequently they switch medication types and/or formulations; and 3) Why certain formulations of medications are more often used in some regions compared to
others. These and other questions can produce information that informs treatment protocols, the development of policy, and the appropriate production levels of medications through the country.

A. Acknowledgement

    The AATOD and NASADAD team wish to express our appreciation to the SOTAs and OTPs that participated in the OTP Census. Without their assistance, compiling this important information would not have been possible. We also would like to thank the American Academy of Addiction Psychiatry, which provided funding for the project through the Substance Abuse and Mental Health Services Administration Technical Assistance Grant to AATOD and NASADAD as Opioid Response Network partners.
B. Appendices

Appendix A: Census Questionnaire
Appendix B: FDA-Approved Medications Descriptions
Appendix C: Medications Type/Form Data by Regions
Appendix D: HHS Regional Map
Appendix A: Census Questionnaire

<table>
<thead>
<tr>
<th><strong>Opioid Treatment Program (OTP)</strong></th>
<th><strong>Patient Census</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Respondent Information</strong></td>
<td></td>
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<tr>
<td>Name of person completing the form</td>
<td>Name:</td>
</tr>
<tr>
<td>Email Address</td>
<td>Email:</td>
</tr>
<tr>
<td>Phone Number</td>
<td>Phone Number:</td>
</tr>
<tr>
<td>Name of Agency</td>
<td>Agency Name:</td>
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<td>Program Address</td>
<td>Street Address:</td>
</tr>
<tr>
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<td>Street Address Line 2:</td>
</tr>
<tr>
<td></td>
<td>City:</td>
</tr>
<tr>
<td></td>
<td>State:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Questions</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>How many patients were enrolled at your OTP (s) on January 1, 2021?</td>
<td>Number of Patients: ________</td>
</tr>
</tbody>
</table>

**Types and Forms of Medications**

*Of the patients stated on this census, please identify the types of medication they are/were taking and the forms:*

**Buprenorphine Therapy**

- Of the patients treated, how many were dispensed buprenorphine therapy? Number of Patients: ________
- Of the patients dispensed buprenorphine therapy, identify the number that used each form of the medication.
  - 1. Film ________
  - 2. Tablets ________
  - 3. Sublocade (buprenorphine injections ) ________
  - 4. Probuphine* (buprenorphine implant) ________

**Methadone Therapy**

- Of the patients treated, how many were dispensed methadone therapy? Number of Patients: ________
- Of the patients dispensed methadone therapy, identify the number of patients that used each form of the medication.
  - 1. Liquid ________
  - 2. Tablets ________
  - 3. Diskettes ________

**Naltrexone Therapy**

- Of the patients treated, how many were dispensed naltrexone therapy? Number of Patients: ________
- Of the patients dispensed naltrexone therapy, identify the number of patients that used each form of the medication.
  - 1. Tablets ________
  - 2. Vivitrol® (naltrexone extended-release injectable suspension) ________
Appendix B: FDA-Approved Medication Descriptions

Introduction to Medications That Address OUD

Methadone

Methadone is the most used and most studied OUD medication in the world. The World Health Organization (WHO) considers it an essential medication. Many clinical trials and meta-analyses have shown that it effectively reduces illicit opioid use, treats OUD, and retains patients in treatment better than placebo or no medication. In the United States, roughly 1,500 federally certified opioid treatment programs (OTPs) offer methadone for OUD. Increasingly, they also offer buprenorphine, and some provide XR-NTX. Core OTP services include medical oversight of treatment, direct observation of dose administration, take-home dose dispensing under certain conditions, counseling, and drug testing.

Some OTPs provide other services, including mental health and primary care, HIV and hepatitis C virus care, and recovery support. Even so, significant demand remains for better integration and coordination of care among OTPs, primary care services, and mental health services to treat the range of needs common in people with OUD. Coordination is especially important for people with co-occurring medical, mental, and substance use disorders, who need multiple services and face challenges in treatment access and adherence.

Naltrexone

XR-NTX has demonstrated efficacy in reducing return to illicit opioid use, increasing treatment retention, and reducing opioid craving compared with placebo or no medication. Although only OTPs can administer or dispense methadone for OUD, all healthcare professionals and addiction and mental health counselors should be familiar with methadone. Their patients may be enrolled in or need referral to OTPs.

RESOURCE ALERT

Substance Abuse and Mental Health Services Administration (SAMHSA)
Federal Guidelines for OTPs

Federal Guidelines for Opioid Treatment Programs offers guidance on how to satisfy federal OTP regulations. (See Part 1 for more information on XR-NTX’s efficacy in OUD treatment.) Because the injectable form was approved more recently by FDA than methadone and buprenorphine, XR-NTX has been less studied than those medications. Physicians, NPs, and, PAs, and, until October 1, 2023, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives may prescribe or order XR-NTX for administration by qualified staff members without additional waiver requirements. XR-NTX initiated prior to release from controlled environments (e.g., jails, prisons, residential rehabilitation programs) may be useful in preventing return to opioid use after release. These settings are typically associated with extended periods of opioid abstinence, so maintaining abstinence for sufficient time to start naltrexone is less challenging than initiating it among outpatients in the community. Short-term pilot studies show that offering XR-NTX under these circumstances can increase treatment engagement after release. The oral formulation of naltrexone is not widely used to treat OUD because of low rates of patient acceptance and high rates of non-adherence leading to a lack of efficacy. However, consideration should be given to its use in situations where adherence can be ensured, such as with observed daily dosing. Naltrexone is also FDA approved for the treatment of alcohol use disorder and therefore may be useful for patients with both OUD and alcohol use disorder.
Buprenorphine

Buprenorphine is effective in retaining patients in treatment and reducing illicit opioid use, as demonstrated by many clinical trials comparing buprenorphine with placebo or no medication. Buprenorphine treatment is available throughout the world. WHO includes it in its list of essential medicines. (See Part 1 for more information on buprenorphine’s efficacy in OUD treatment.)

Buprenorphine is a partial agonist with a ceiling effect on opioid activity. Hence, it is less likely than methadone and other full agonists to cause respiratory depression in an accidental overdose. This property contributed to the decision permitting buprenorphine to be prescribed to treat opioid dependence outside OTPs. That being said, lethal overdose with buprenorphine is possible in opioid-naïve individuals or when it is taken in combination with central nervous system depressants such as benzodiazepines or alcohol.

Transmucosal buprenorphine is available by prescription through pharmacies, because the Drug Addiction Treatment Act of 2000 (DATA 2000) created an exception to the Controlled Substances Act to permit FDA schedule III, IV, and V medications approved to treat opioid dependence to be prescribed for that purpose outside OTPs. Buprenorphine, in various formulations, is the only medication to which DATA 2000 currently applies.

Qualifying physicians, NPs, and PAs can prescribe buprenorphine if they receive special training, obtain a SAMHSA waiver under DATA 2000, and get a unique Drug Enforcement Administration registration number. Until October 1, 2023, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives also are waiver-eligible to prescribe buprenorphine.

Additionally, providers who are state licensed and possess a valid Drug Enforcement Agency registration may be exempted from training requirements and the required attestation (about providing patients access to or referrals for psychosocial services) that are normally needed to obtain the X waiver. These providers are limited to treating no more than 30 patients. This has greatly increased the number and type of settings where medication for OUD is available and the number of patients in treatment. New settings include non-OTP outpatient addiction treatment programs, as well as general medical and mental health practices or clinics (office-based opioid treatment). OTPs can also provide buprenorphine.

In 2016, FDA approved buprenorphine implants (Probuphine) that last about 6 months for patients stabilized on sublingual or buccal formulations. Implants have been found to be more effective than placebo in reducing illicit opioid use among opioid-dependent patients receiving counseling. Implants are available in the same settings as other buprenorphine formulations but require waivered providers to receive specific training from the manufacturer on insertion and removal per the FDA-approved REMS (www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=IndyRemsDetails.page&REMS=356).

In 2017, FDA approved a monthly extended-release buprenorphine injectable formulation (Sublocade) for patients with moderate-to-severe OUD who had been initiated and treated with transmucosal buprenorphine for at least 7 days. The medication is for subcutaneous abdominal injection by a healthcare provider

DATA 2000 restrictions currently apply only to buprenorphine used to treat OUD. They do not apply to pain treatment using buprenorphine formulations approved to treat pain.
Appendix C: Medication Type/Form Data by Regions

<table>
<thead>
<tr>
<th>MEDICATION TYPE/FORM</th>
<th>EASTERN SEABOARD (REGIONS 1, 2, 3)</th>
<th>SOUTH/SOUTHWEST (REGIONS 4, 6)</th>
<th>MIDWEST (REGIONS 5, 7, 8)</th>
<th>NORTHWEST/WEST (REGIONS 9,10)</th>
<th>ALL REGIONS</th>
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</thead>
<tbody>
<tr>
<td>BUPRENORPHINE</td>
<td></td>
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<tr>
<td>FILM</td>
<td>5,779</td>
<td>930</td>
<td>3,030</td>
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<td>11,787</td>
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<tr>
<td>TABLETS</td>
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<td>7,731</td>
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<td>163</td>
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<td>PROBUPHINE</td>
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<td>TOTAL PATIENTS</td>
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<td>7,285</td>
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<tr>
<td>METHADONE</td>
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<td>LIQUID</td>
<td>187,512</td>
<td>95,827</td>
<td>71,712</td>
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<td>TABLET</td>
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<td>DISKETTE</td>
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Appendix D: HHS Regional Map
References


v Substance Abuse and Mental Health Services Administration Opioid Treatment Program Directory, 2022 https://dpt2.samhsa.gov/treatment/