

Barriers to Opioid Addiction Treatment

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POLICY QUESTION

What are the barriers facing care providers to becoming OBOT and OTP associated providers?
What are barriers to treating insured and uninsured patients in OBOTs and OTPs?

BACKGROUND

The opioid epidemic in the United States is defined as the rapid increase in the use of prescription and illicit opioid drugs in the 2010s. Opioids are an assorted class of moderate to strong painkillers and illicit drugs including: oxycodone (OxyContin and Percocet), hydrocodone (Vicodin), heroin, and Fentanyl, (synthesized to resemble other opiates such as opium-derived morphine and heroin).¹

Nearly half of all United States opioid overdose deaths in 2016 involved prescription opioids.² Prescription opioids serve as a gateway to addiction: as many as 80% of those who are currently addicted to opioids are estimated to have begun their addiction with prescription opioids.³ From 1999 to 2008, overdose death rates, sales, and substance abuse treatment admissions related to opioid pain relievers all increased substantially.⁴ In 2017, drug overdoses have since become the leading cause of death of Americans under 50, with two-thirds of those deaths from opioids.⁵ In the United States, opioid addiction spurred the increase from 52,404 Americans in 2015 to 64,000 drug overdoses in 2016. The sharpest increase of opioid use occurred among deaths related to fentanyl and fentanyl analogs (synthetic opioids) with over 20,000 overdose deaths.⁶ In 2015 in the United States, about 63% of all 52,404 overdose deaths were related to opioids.⁷

Opiates other than heroin represented 16 percent of all opiate admissions in 2003 and 33 percent in 2013. Opiate-related hospitalizations have increased between 2003 and 2013. The opioid epidemic affects primarily white and working-class individuals living in rural areas of the United States.

The Center for Disease Control provided data on counties experiencing above average drug overdose death rates in 2015. 67% of these counties were classified as rural, 16% counted as

¹ Bradford, Alina. "Facts About Opioids - Hydrocodone, Oxycodone, Codeine & Others." LiveScience, Purch, 26 Feb. 2016, www.livescience.com/53856-opioid-facts.html

² "Opioid Overdose." Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, 18 July 2017, www.cdc.gov/drugoverdose/data/index.html

³ Muhuri PK, Gfroerer JC, Davies MC. Associations of nonmedical pain reliever use and initiation of heroin use in the United States. CBHSQ Data Review. 2013.

⁴ "Morbidity and Mortality Weekly Report (MMWR)." Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, 23 Feb. 2012, www.cdc.gov/mmwr/index2011.html

⁵ Katz, Josh. "Drug Deaths in America Are Rising Faster Than Ever." The New York Times, The New York Times, 5 June 2017, www.nytimes.com/interactive/2017/06/05/upshot/opioid-epidemic-drug-overdose-deaths-are-rising-faster-than-ever.html?_r=0

⁶ National Institute on Drug Abuse. Overdose Death Rates. 15 Sept. 2017, www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates.

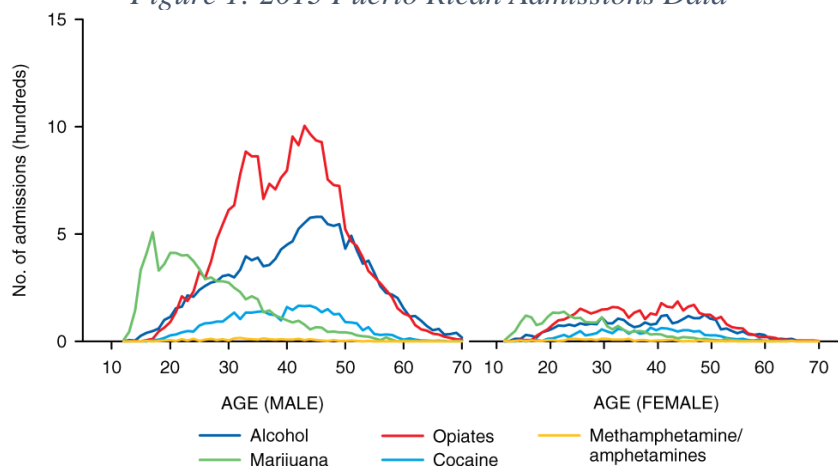
⁷ I.i.d

small metro areas, 13% of these counties were classified as suburban counties, and 6 percent were categorized as urban counties.⁸

The Brookings Institution found that the distribution of counties with above average drug overdose death rates roughly mirrors the overall allocation of counties across America: 65% rural, 17% small metro areas, 15%, and 4% urban.⁹ However, urban counties were the most likely to report overdose death rates: overdose statistics could be underreported. With opioids as the force behind this trend, opioid overdose statistics can be underreported and impacted by such county practices.

Americans who fall within the age demographic of 25-34 years old have the highest percentage of opioid-related overdoses as of 2015.¹⁰ Presently, the majority of the opioid-related hospitalizations in the United States are for non-Hispanic white males and females (31% and 38%, respectively). Non-Hispanic whites made up approximately 85 percent of admissions for opiates other than heroin (45 percent were males and 40 percent were females). However, among admissions of Puerto Rican origin, opiates were the most common primary substance at treatment admission for both men and women (46 and 38 percent, respectively).¹¹

Figure 1: 2013 Puerto Rican Admissions Data



SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 01.23.15.

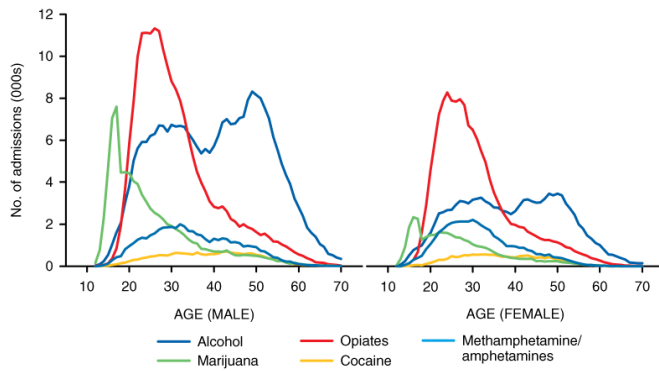
⁸ Kneebone, Elizabeth, and Scott W. Allard. “A Nation in Overdose Peril: Pinpointing the Most Impacted Communities and the Local Gaps in Care.” Brookings, Brookings, 26 Sept. 2017, www.brookings.edu/research/pinpointing-opioid-in-most-impacted-communities/.

⁹ I.i.d

¹⁰ “Opioid Overdose Deaths by Age Group.” The Henry J. Kaiser Family Foundation, 3 Aug. 2017, www.kff.org/other/state-indicator/opioid-overdose-deaths-by-age-group

¹¹ Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. Treatment Episode Data Set (TEDS): 2003-2013. National Admissions to Substance Abuse Treatment Services. BHSIS Series X-XX, HHS Publication No. (SMA) XX-XXXX. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2015.

Figure 2: 2013 White (non-Hispanic) Admissions Data



SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 01.23.15.

Figure 3

Drug Overdose Deaths (per 100,000) by Drug Type and Race/Ethnicity in the U.S. in 2016

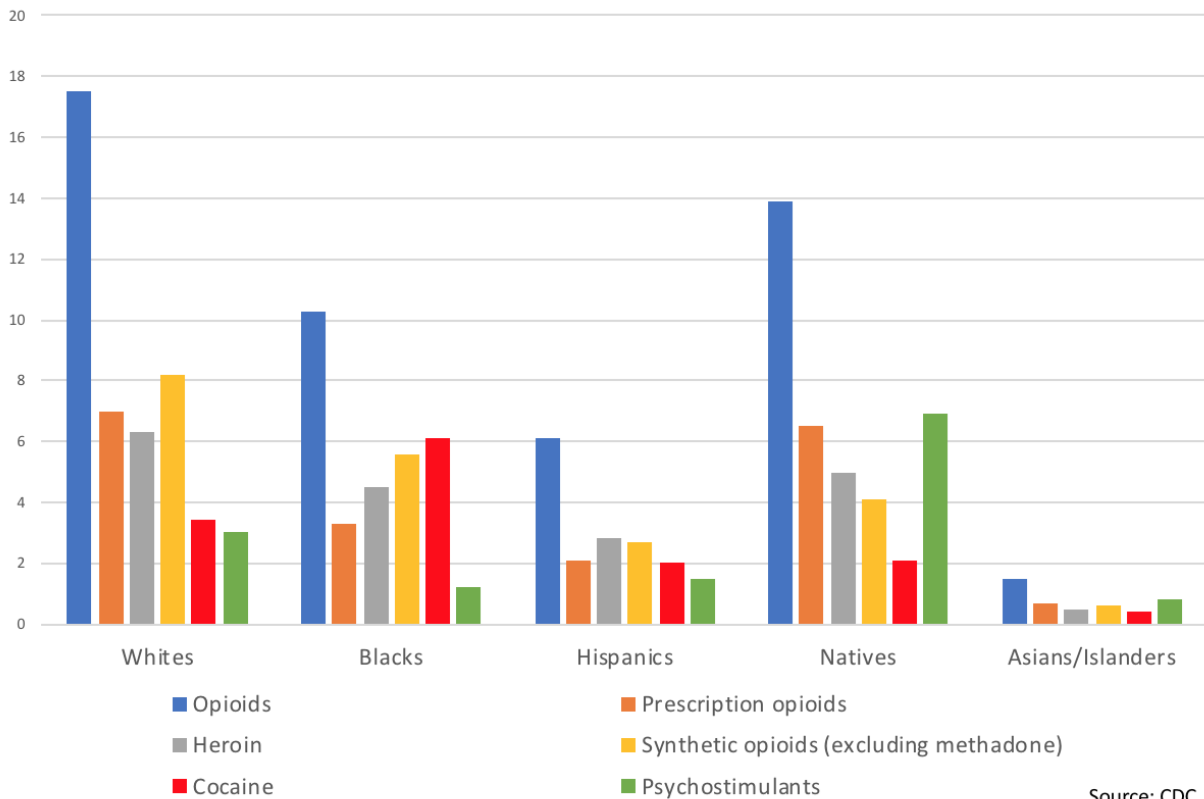


Figure 4: 2016 Opioid Overdose Deaths by Race/Ethnicity United States versus North Carolina

2016 Opioid Overdose Deaths by Race/Ethnicity The Henry J. Kaiser Family Foundation			
Location	White, Non-Hispanic	Black, Non-Hispanic	Hispanic
United States	33,450	4,374	3,440
North Carolina	1,313	132	31

Majority of the 2016 opioid overdose deaths in the United States and North Carolina were non-Hispanic whites, notable in Figure 4. North Carolina racial and ethnic deaths roughly reflect the proportions of the racial and ethnic deaths in the United States.

Further data provided by the North Carolina Treatment and Outcomes Program Performance System (NC TOPPS) reveals projected 2017 data indicating a similar pattern: racial and ethnic diversity in whom is impacted by the opioid epidemic.

North Carolina is expected to treat majority non-Hispanic, white males. However, while about 61% of North Carolina adults projected to be treated are white, 33% are black, and 45% are female. 19% of individuals with opioid addiction projected to be treated based on 2016 NC TOPPS data are uninsured and 68% are unemployed. 51.4% of the 2017 North Carolina population, projected by the Census Bureau, are female, 22.2% are black, and 71% are white.¹² There are more females and African-Americans projected to be affected by opioid addiction relative to the 2017 state demographics data. North Carolina’s opioid overdose amongst African-Americans has increased from 3.1 per 100,000 population in 2013 to 5.9 per 100,000 population in 2016.¹³ The United States reflects a similar pattern: an increase in opioid overdoses amongst communities of color between 2013 and 2016. As of June 2017, North Carolina has an average of 4 deaths a day,¹⁴ contributing to the US statistic of more than 115 opioid-related deaths per day.¹⁵

More than 900,000 U.S. physicians can write prescriptions for painkillers but fewer than 32,000 doctors opt to prescribe buprenorphine treatment, a treatment setting for opioid addiction patients.¹⁶ In the United States, only 49% of people with an opioid dependence can receive treatment with buprenorphine because too few doctors prescribe the medicine.¹⁷ With a lack of

¹² “U.S. Census Bureau QuickFacts: North Carolina.” Census Bureau QuickFacts, www.census.gov/quickfacts/NC.

¹³ “Opioid Overdose Deaths by Race/Ethnicity.” The Henry J. Kaiser Family Foundation, <https://www.kff.org/other/state-indicator/opioid-overdose-deaths-by-raceethnicity/>

¹⁴ Proposal to Address: Substance Abuse and Mental Health Services Administration Funding Opportunity Announcement No. TI-17-014 CFDA No. 93.788 State Targeted Response to the Opioid Crisis Grants. NC Department of Health and Human Services Division of Mental Health, Developmental Disabilities and Substance Abuse Services, 17 Feb. 2017, [ncdhhs.s3.amazonaws.com/s3fs-public/NC Opioid STR Final Narrative.pdf](https://ncdhhs.s3.amazonaws.com/s3fs-public/NC%20Opioid%20STR%20Final%20Narrative.pdf).

¹⁵ National Institute on Drug Abuse. “Opioid Overdose Crisis.” NIDA, 6 Mar. 2018, www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis.

¹⁶ “Few Doctors Are Willing, Able to Prescribe Powerful Anti-Addiction Drugs.” The Pew Charitable Trusts, www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2016/01/15/few-doctors-are-willing-able-to-prescribe-powerful-anti-addiction-drugs.

¹⁷ I.i.d

alternative treatment, opioids became overprescribed. The US consumed approximately 80 percent of the global opioid supply in 2014.

Today, from 2000 to 2015 more than half a million people died from drug overdoses. Ninety-one Americans die every day from an opioid overdose.¹⁸ This is approximately half of the annual 64,000 total drug overdoses in 2016 referenced on page 1.

Given the magnitude of the opioid epidemic, several actions have been taken to curb its effects ranging from policy changes, policy restatements, to innovative treatment models. One effective treatment of opioid addicts used in the past are medication-assisted treatments (MAT¹⁹). MAT, specifically treating opioid addiction, comes in two variations: Office-Based Opioid Treatment Programs (OBOT) and Opioid Treatment Programs (OTP).

OFFICE-BASED OPIOID TREATMENT PROGRAMS AND OPIOID TREATMENT PROGRAMS AS TREATMENT OPTIONS

The OBOT and OTP treatment settings are designed to help the body wean itself off the drug while the patient works on recovering from the psychological effects of the addiction. The National Institute of Health's National Institute on Drug Abuse and the Food and Drug Administration (FDA) deem medications, including buprenorphine (Suboxone, Subutex), methadone, and extended release naltrexone (Vivitrol), [as] effective for the treatment of opioid use disorders.²⁰²¹

The treatment settings utilize specially-metered doses of these medications to help the body through opioid withdrawal. Both are provided in inpatient and outpatient treatment settings. A combination of medications and psychological treatment is provided to address the root of the addiction with emphasis on finding alternative ways to cope and learning the tools needed to avoid relapse in the future. Patients who opt for intensive outpatient rehabilitation can still receive medication to prevent withdrawal symptoms and to aid in recovery.

In both treatment programs, which utilize medication as buprenorphine or methadone, the prescribed opiates activate the same receptors in the brain but are absorbed into the blood over a longer period of time. The function is to break the psychological want between taking a drug and the following euphoric effects while weaning the individual off opioids. Unlike methadone and buprenorphine, naltrexone binds and blocks opioid receptors.²² Methadone is a complete agonist and buprenorphine is a partial agonist. Naltrexone is not an opioid; thus, it is not decreasing patient withdrawal effects. One study found that patients have an increasingly difficult time

¹⁸ Opioid Overdose." Centers for Disease Control and Prevention. August 30, 2017. Accessed September 23, 2017. <https://www.cdc.gov/drugoverdose/epidemic/index.html>.

¹⁹ Medication-assisted treatment (MAT) is the use of medications with counseling and behavioral therapies to treat substance use disorders and prevent opioid overdose. MAT is primarily used for the treatment of addiction to opioids such as heroin and prescription pain relievers that contain opiates

²⁰ Abuse, National Institute on Drug. "Effective Treatments for Opioid Addiction." NIDA, www.drugabuse.gov/publications/effective-treatments-opioid-addiction/effective-treatments-opioid-addiction.

²¹ Alderks, C.E., Trends in the Use of Methadone, Buprenorphine, and Extended-release Naltrexone at Substance Abuse Treatment Facilities: 2003-2015 (Update). The CBHSQ Report: August 22, 2017. Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Rockville, MD.

²² "Naltrexone." Naltrexone | SAMHSA - Substance Abuse and Mental Health Services Administration, 16 June 2015, www.samhsa.gov/medication-assisted-treatment/treatment/naltrexone.

successfully initiating MAT with naltrexone (72% of a sample of 283 patients) than an opioid, buprenorphine (94% of a sample of 287 patients).²³ Methadone and buprenorphine are two commonly used agonists to treat opioid treatment patients. Because of the innate difference between methadone and buprenorphine, the usage of methadone and buprenorphine vary. Methadone, a full agonist and stronger medication than the partial buprenorphine, is provided to patients once a day to prevent withdrawal symptoms. Methadone has a longer half-life and remains in the human body longer than buprenorphine. Buprenorphine is subject to less stringent federal regulations because of its ceiling effect: patients can reach a stable dose more quickly than with methadone and it is more difficult to overdose from buprenorphine alone due to its ceiling effect. This makes those who are utilizing methadone more susceptible to overdose. Each medication appears on a different FDA schedule: a ranking of medication strength and addictiveness. The FDA Schedule was implemented by the Controlled Substances Act, passed in 1970 to set standards on importation, manufacture, distribution, and possession of potentially addictive drugs. All drugs were divided into five categories: schedule I through V. Schedule I drugs have no medical use and cannot be prescribed. As the Roman numerals decrease, the more stringent the regulations attached. Methadone is a schedule II drug/medication. Buprenorphine is a schedule III medication. Differences in drug schedules results in the two differing treatment settings.

Treatment settings for opioid addiction, with methadone and buprenorphine, will be within the scope of this paper; naloxone will not be expanded upon in this paper. Methadone and buprenorphine are regulated, controlled substances. Naltrexone hasn't been focused on in recent regulations, having it fall outside of the scope. Methadone and buprenorphine can be prescribed for pain and addiction treatment. Methadone and buprenorphine for pain will not be expanded upon in this paper.

A differentiating factor between the OBOT and OTP treatment settings lays within medications dispensed (methadone and/or buprenorphine). The author would like to emphasize the difference between prescribing medications for addiction treatment versus pain. Only prescribing and dispensing methadone and buprenorphine for addiction treatment are within the scope of this paper. This difference in medications prescribed and dispensed results in different state and federal policies impacting the number of patients to the ability to dispense certain opioid agonists, methadone and buprenorphine.

OPIOID TREATMENT PROGRAMS

An OTP is a treatment program federally certified by the Substance Abuse and Mental Health Services Administration (SAMHSA) according to 42 CFR § 8, to provide supervised assessment and medication assisted treatment for beneficiaries who have an opioid use disorder diagnosis.

²³ Comparative effectiveness of extended-release naltrexone versus buprenorphine-naloxone for opioid relapse prevention (X:BOT): a multicentre, open-label, randomised controlled trial. Lee, Joshua D et al. The Lancet , Volume 391 , Issue 10118 , 309 - 318

OTPs require registration with the DEA and licensure by the Division of Health Service Regulation (DHSR).²⁴

Under current federal and state policies, it is legal for practitioners, registered by the DEA²⁵ to prescribe methadone for addiction treatment only within a licensed OTP setting.^{26,27} Methadone can only be dispensed by practitioners within the OTP settings. Practitioners within the OTP setting can also prescribe buprenorphine, by using the DEA number of the OTP, rather than the required waiver, to prescribe buprenorphine. Buprenorphine can be dispensed by practitioners within the OTP and OBOT settings.

The number of OTPs has increased from approximately 1,100 in 2003 to almost 1,500 by the end of 2016; the number of clients receiving methadone on the National Survey of Substance Abuse Treatment Services (N-SSATS) survey reference date increased from about 227,000 in 2003 to over 350,000 in 2015.²⁸ The number of OTPs offering buprenorphine in the United States increased from 11 percent of OTPs in 2003 (121 OTPs) to 58 percent of OTPs in 2015 (779 OTPs).²⁹ In 2016, North Carolina had 53 OTPs with over 17,000 patients dosing daily that use medication, in combination with counseling and behavioral therapies, to provide a whole-patient approach to the treatment of substance use disorders. Approximately half of the OTPs in North Carolina receive state and federal dollars; however, most are cash pay.³⁰ As of December 2017, the United States has 1,482 OTPs.³¹

Oversight of treatment medications remains a tripartite system involving states, DHHS/SAMHSA, and the U.S. Department of Justice/DEA. Once a program is accredited, the

²⁴NC Division of Medical Assistance Medicaid and Health Choice Office-Based Opioid Treatment: Clinical Coverage Policy No: 1A-41 Use of Buprenorphine and Buprenorphine-Naloxone. NC Division of Medical Assistance, 1 Jan. 2018, www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=8&cad=rja&uact=8&ved=0ahUKEwi_qK6nk9jaAhXKdN8KHQCnD1oQFghnMAc&url=https://files.nc.gov/ncdma/documents/files/1A-41_4.pdf&usg=AOvVaw1x7r_OUgGk3hnOtiy9j69M.

²⁵NCBOP - Pharmacist FAQs, North Carolina Board of Pharmacy, www.ncbop.org/faqs/pharmacist/faq_MethadoneSuboxoneSubutex.htm.

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²⁷Kampman, Kyle. ASAM National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use. American Society of Addiction Medicine, 1 June 2015, www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=3&cad=rja&uact=8&ved=0ahUKEwjz5ebuOfaAhWGuVMKHQwnCwEQFggzMAI&url=https://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf&usg=AOvVaw1yZuxpJ099mRNzsvOf_7tl.

²⁸Trends in the Use of Methadone, Buprenorphine, and Extended-Release Naltrexone at Substance Abuse Treatment Facilities: 2003-2015 (Update), www.samhsa.gov/data/sites/default/files/report_3192/ShortReport-3192.html.

²⁹Alderks, C.E., Trends in the Use of Methadone, Buprenorphine, and Extended-release Naltrexone at Substance Abuse Treatment Facilities: 2003-2015 (Update). The CBHSQ Report: August 22, 2017. Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Rockville, MD.

³⁰NC Division of Medical Assistance Medicaid and Health Choice Office-Based Opioid Treatment: Clinical Coverage Policy No: 1A-41 Use of Buprenorphine and Buprenorphine-Naloxone. NC Division of Medical Assistance, 1 Jan. 2018, www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=8&cad=rja&uact=8&ved=0ahUKEwi_qK6nk9jaAhXKdN8KHQCnD1oQFghnMAc&url=https://files.nc.gov/ncdma/documents/files/1A-41_4.pdf&usg=AOvVaw1x7r_OUgGk3hnOtiy9j69M.

³¹"Home." Addiction Treatment Forum, 13 Feb. 2017, atforum.com/2017/02/aatods-goal-doubling-number-otps-strong-samhsa-support/.

SAMSHA uses the accreditation results and additional data to deem the program as ‘qualified’ to treat individuals with opioid addiction. OTPs, because of federal and state regulations, must provide structure for their patients, including counseling and a pay-as-you-go system.³² OTPs do not face a patient limit under an OTP license.

Unless the patient has been on an established maintenance program for a certain time, the patient must take the medication at the clinic where the medication is dispensed daily. Otherwise, the patient is permitted to take home dosages via recent 2013 changes in federal regulations. Clinic policies determine the established maintenance program time. However, state regulations may state an established maintenance program time. Potential methadone patients must have been physically addicted to opioids for at least one year; evaluated by physical examinations, urine drug tests, the Prescription Drug Monitoring Program database (PDMP) spanning inter and intra state; and evaluated with additional information from friends and family.

As of January 2013, federal policies permit OTP patients to receive take-home buprenorphine. However, OTPs are still subject to state policies and guidelines. North Carolina has produced guidelines for buprenorphine OTP patients regarding take home medication. As of January 2013, OTPs have freedom to deviate from past guidelines for take home medication for buprenorphine. However, OTPs must adhere to other criteria for take home doses of methadone.³³ The North Carolina guidelines do not mimic those provided by SAMSHA. The North Carolina guidelines provide more flexibility in the number of take homes with buprenorphine.

States can monitor the same areas as federal agencies, but state rules do not always echo federal regulations. Some states have established medical recertification requirements for continuation of comprehensive, long-term OTP after a specified period. Other state and local requirements, such as certificates of need, zoning, and licensure, can affect the number, size, and location of OTPs. These state regulations are not affected by the change in federal regulations.

Federal legislation specifically impacting OTPs includes DATA 2000, 21st Century Cures Act, the 2007 and 2015 SAMHSA Federal Guidelines, and the Federal Opioid Treatment Standards (42 CFR 8.12). OTP policies are created at the federal level and are largely implemented by the states.

OTPs can provide both methadone and buprenorphine, but face more barriers to providing buprenorphine products. OTPs providing approved buprenorphine products for opioid maintenance or detoxification treatment must conform to the Federal Opioid Treatment Standards, 42 CFR 8.12. Under these standards, in order to offer buprenorphine, OTPs must

³²Burson, Jana. Medications in the Opioid Treatment Program: Methadone, Buprenorphine, and Naltrexone. www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=0ahUKEwjRt47k1YPaAhVppVvKHXcXDxAQFggsMAA&url=http://www.ncatod.org/wp-content/uploads/Medications-in-the-OTP-Methadone-Buprenorphine-and-Naltrexone.pdf&usg=AOvVaw2aGF6pl-z7F0gGeqQ8m6ur.

³³ “Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction, Final Rule.” Federal Register, vol. 77, no. 235, 6 Dec. 2012, pp. 72752–72761., www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=3&cad=rja&uact=8&ved=0ahUKEwia0Kzw6NjaAhXCmOAKHSBIBvAQFgg2MAI&url=https://www.samhsa.gov/sites/default/files/programs_campaigns/medicati_on_assisted/dear_colleague_letters/2012-colleague-letter-final-rule-42-cfr-part-8.pdf&usg=AOvVaw3GQDrihO96mfEGuHKpSLxb.

modify their registration with the DEA to add schedule III narcotics to their registration certificates. Furthermore, under the standards OTPs must be certified by the federal SAMHSA's Division of Pharmacologic Therapies (DPT) and accredited by an independent, SAMSHA-approved accrediting body to dispense opioid medications.

The SAMSHA's DPT oversees certification of opioid treatment programs and provides guidance to nonprofit organizations and state governmental entities that want to become a SAMSHA-approved accrediting body. The DEA must approve the program level of the OTP.

Under 42 CFR 8, all OTPs are required to have a license in the states in which OTPs operate. To conduct treatment, all OTPs must register with the DEA, through a local DEA office. OTPs face time constraints if certification, but not accreditation, has been achieved. An OTP must become accredited during a one-year timeframe if the OTP has applied for initial certification with SAMHSA. After an OTP receives accreditation, SAMHSA determines if the program can be certified to provide treatment under 42 CFR 8. This work is carried out by SAMHSA's regional OTP Compliance Officers, a level closer to state. Certification and accreditation processes are parallel and can occur at the same time or with one before the other. For example, an OTP remains certified from one to three years, depending on the accreditation process timeline. If an OTP appears to be past a certain point in the accreditation process, the OTP can still remain certified.

OTPs become accredited if a SAMSHA-approved independent body deems the OTP eligible. The accreditation process includes site visits by specialists with experience in opioid treatment medications and related treatment activities.

The 2007 and 2015 Federal Guidelines expand upon the Federal Opioid Treatment Standards, 42 CFR 8.12, but are not required to be adopted by OTPs.

On December 13, 2016, President Obama signed the 21st Century Cures Act. The Act implements \$1 billion in funding to combat the opioid crisis through the State Targeted Response to the Opioid Crisis Grants. The Cures grant will provide up to \$970 million to states and territories over the next two years, beginning in fiscal year 2017.³⁴ In fiscal year 2017, the Trump Administration began to award the first fiscal year, of the two years, of the Cures grant, \$485 million dollars, to all fifty states through SAMSHA.³⁵ The Cures grant provides a two-year allocation to each state. After the first year, the grant must be reauthorized for the second year at the federal level. The Cures grant funding applies to patients at both the OBOT and OTP treatment settings below an income threshold and for those on Medicaid at an approved OTP or OBOT. The majority of treatment settings receiving funds were OTPs, not OBOTs.

The Cures grant in North Carolina was administered through the state to the major Local Management Entity/Managed Care Organizations (LME/MCOs). LME/MCOs are quasi-governmental entities that contract with the North Carolina Department of Health and Human

³⁴ "Figure 2f from: Irimia R, Gottschling M (2016) Taxonomic Revision of *Rocheffortia* Sw. (Ehretiaceae, Boraginales). *Biodiversity Data Journal* 4: e7720. <https://doi.org/10.3897/BDJ.4.e7720>. doi:10.3897/bdj.4.e7720.figure2f.

³⁵ Canady, Valerie A. "HHS Awards Excellence in Mental Health Act Planning Grants to 24 States." *Mental Health Weekly*, vol. 25, no. 41, 2015, pp. 4-4., doi:10.1002/mhw.30380.

Services (NC DHHS), to provide management and oversight of the public system of mental health, developmental disabilities, and substance abuse services at the community level.³⁶ The NC DHHS partners with seven LME/MCOs to help manage OBOTs and OTPs falling under the LME/MCO umbrella.³⁷ The portion of the Cures grant provided to the LME/MCOs were managed by each of North Carolina's LME/MCOs.

While the number of OTPs throughout the United States has increased by 40%, it is not increasing as quickly as the number of opioid overdoses. Likewise, the percent change of the number of patients treated at OTPs is not increasing as sharply as number of opioid-overdose related deaths.

In 2003, there were 1,067 OTPs reporting to SAMHSA's National Survey of Substance Abuse Treatment Services. The number rose to 1,482 by the end of 2016. The number of clients receiving methadone in those facilities increased from 227,000 to more than 356,000 through 2015, the latest year with numbers of clients.³⁸ However, the United States had a 226.5% increase between 12,940 patients in 2003 and 42,249 patients in 2016.³⁹ The rate of opioid overdose deaths is increasing at a faster rate than is the opioid treatment program growth rate. There is a shortage of opioid treatment programs, or program access, to treating patients with opioid addiction.

The location of majority of opioid treatment programs in rural locations indicates a shortage in areas of need. In October 2017, the Centers for Disease Control and Prevention announced that the rates of drug overdose deaths are rising in rural areas, surpassing rates in urban areas.⁴⁰ From 1999 to 2015, the opioid death rates in rural areas have quadrupled among those 18-25 years old and tripled for females.⁴¹ Nearly all OTPs are located in metropolitan areas. OTPs tend to be clustered around urban centers and, therefore, inaccessible to those living in rural areas.^{42,43} Of the total 1,063 facilities offering OTPs, 3.1%, 33 OTPs, are in a non-metropolitan county (adjacent to a metro county), and only 1.9%, 11 OTPs are in a non-adjacent county.⁴⁴

³⁶Nesbitt, Lisa, and Jennifer Bills. "Managed Care Organizations (MCOs): The Basics and Emerging Issues." 14 Apr. 2015, Chapel Hill, North Carolina.

³⁷ "LME/MCO Directory." NC DHHS, www.ncdhhs.gov/providers/lme-mco-directory.

³⁸"SAMHSA Report Shows Increase in Opioid Treatment Facilities." Veterans and Military Families | SAMHSA - Substance Abuse and Mental Health Services Administration, 22 Aug. 2017, www.samhsa.gov/newsroom/press-announcements/201708220100

³⁹ "Opioid Overdose Deaths and Opioid Overdose Deaths as a Percent of All Drug Overdose Deaths." The Henry J. Kaiser Family Foundation, 31 Jan. 2018. <https://www.kff.org/other/state-indicator/opioid-overdose-deaths>

⁴⁰ "Opioid Misuse in Rural America." USDA, www.usda.gov/topics/opioids.

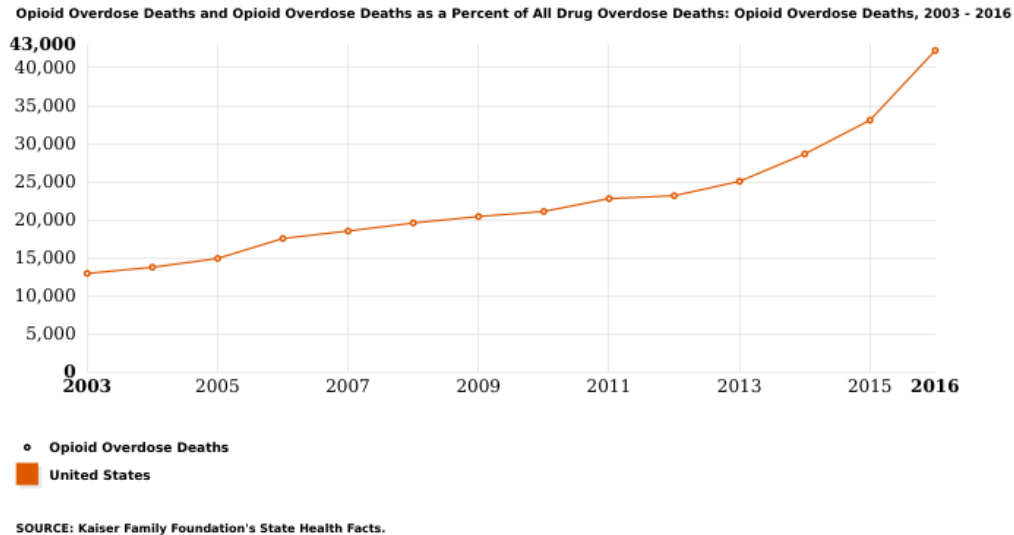
⁴¹ "Public Health Matters Blog." Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, 29 Nov. 2017, blogs.cdc.gov/publichealthmatters/2017/11/opioids/.

⁴² Rosenblatt RA, Andrilla CHA, Catlin M, Larson EH. Geographic and specialty distribution of US physicians trained to treat opioid use disorder. *The Annals of Family Medicine*. 2015;13(1):23-26. doi:10.1370/afm.1735.

⁴³ Leonardson J, Gale JA. Distribution of Substance Abuse Treatment Facilities Across the Rural – Urban Continuum. 2016. <https://muskie.usm.maine.edu/Publications/rural/pb35bSubstAbuseTreatmentFacilities.pdf>.

⁴⁴ Leonardson J, Gale JA. Distribution of Substance Abuse Treatment Facilities Across the Rural – Urban Continuum. 2016. <https://muskie.usm.maine.edu/Publications/rural/pb35bSubstAbuseTreatmentFacilities.pdf>.

Figure 5: United States Opioid Overdose Deaths, 2003-2016



OFFICE-BASED OPIOID TREATMENT PROGRAMS

Due to less stringent federal and state regulations, buprenorphine has become a popular alternative to methadone. OBOTs can only prescribe and dispense buprenorphine, like OTP settings. However, OBOTs cannot legally prescribe or dispense methadone, unlike the OTP settings. Practitioners within OBOTs can prescribe buprenorphine for addiction treatment, if waived and registered under a special DEA number.⁴⁵

An OBOT is the treatment of opioid addiction with a medication in an office, belonging to, or not to, a physician.⁴⁶ No limitation exists on the type of practice an OBOT practitioner is associated with. OBOTs are defined by the function of a practice, treating patients with buprenorphine for substance use disorders, rather than defined by a type of practice. OBOTs can appear within, or outside of, OTP settings.

Under the 2016 Comprehensive Addiction and Recovery Act (CARA), any buprenorphine-waivered primary care providers (Physician, Nurse Practitioner, or Physician's Assistant) may practice in a variety of practice settings. These OBOT settings include primary care clinics, outpatient health system clinics, psychiatry clinics, federally-qualified health centers, community service boards, local health departments, and physician's offices.⁴⁷ Any practitioner who met the

⁴⁵ "The National Alliance of Advocates for Buprenorphine Treatment." Who Can Prescribe Buprenorphine?, www.naabt.org/faq_answers.cfm?ID=29.

⁴⁶ The federal policy referred to is 21 U.S.C. 823(g)(1)

⁴⁷ REQUIREMENTS FOR OFFICE BASED OPIOID TREATMENT (OBOT) PROVIDERS. Virginia Department of Medical Assistance Services Addiction and Recovery Treatment Services (ARTS) OBOT Attestation Checklist, www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=4&ved=0ahUKEwjll9e-

requirements or received a waiver under DATA 2000 to prescribe or dispense schedule III, IV, or V medications can become an OBOT practitioner.⁴⁸

Each physician, nurse practitioner, and physician assistant at an OBOT faces a patient limitation depending on the number of years since they received the waiver. Under the CARA Act, each physician can treat thirty opioid addiction patients in the physician's first year and one-hundred patients in subsequent years.⁴⁹ Nurse practitioners and physician assistants are subject to different patient caps than physicians. Nurse practitioners and physician assistants must have a license under state law to prescribe schedule III, IV, or V medications for pain, complete not less than 24 hours of appropriate education through a qualified provider, demonstrate the ability to treat and manage Opioid Use Disorder, and if required by state law, be supervised or work in collaboration with qualifying physicians to prescribe medications.⁵⁰

The SAMSHA and the DEA, responsible for issuing licenses, have approved 560 nurse practitioners and 184 physician assistants as of April 2017.⁵¹ New data provides a hypothesis as to why that is, especially when there are more nurses and physician assistants across the United States than physicians. New data indicates that both nurse practitioners and physician assistants face bars, through state legislation, to treating as many patients as possible to their abilities. In 2017, only 21 states and the District of Columbia permit nurse practitioners full scope of practice. Twenty-eight states prohibit nurse practitioners from prescribing buprenorphine unless they are working in collaboration with a doctor who also has a federal license to prescribe it.

7ZraAhWCmuAKHeEvDKsQFghKMAM&url=https://www.msv.org/sites/default/files/arts_obot_credentiaing_che
cklist_01.17.17_final.pdf&usg=AOvVaw3Oq18wkLs4NjIIPtUNqC_m.

⁴⁸NC Division of Medical Assistance Medicaid and Health Choice Office-Based Opioid Treatment: Clinical Coverage Policy No: 1A-41 Use of Buprenorphine and Buprenorphine-Naloxone. NC Division of Medical Assistance, 1 Jan. 2018,

www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=8&cad=rja&uact=8&ved=0ahUKEwi_qK6nk9jaAhXKdN8KHQCnD1oQFghnMAc&url=https://files.nc.gov/ncdma/documents/files/1A-41_4.pdf&usg=AOvVaw1x7r_OUgGk3hnOtiy9j69M.

⁴⁹“CADCA.” Comprehensive Addiction and Recovery Act (CARA) | CADCA, 15 July 2018, www.cadca.org/comprehensive-addiction-and-recovery-act-cara.

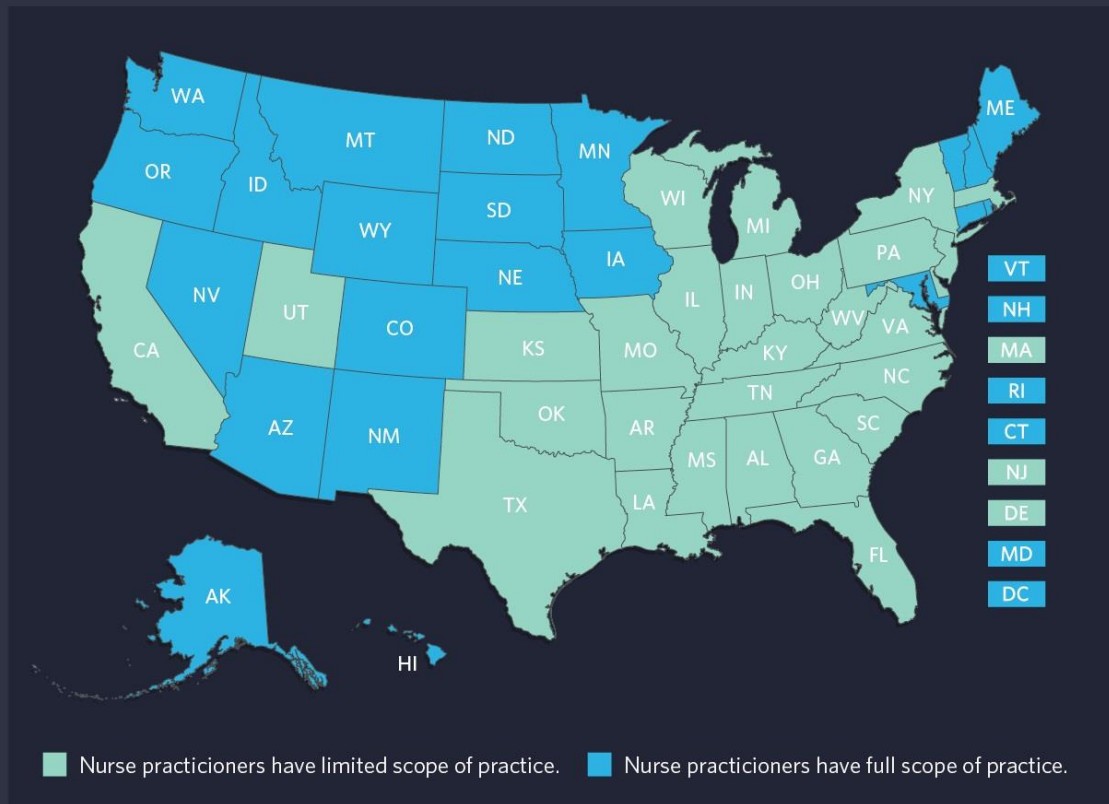
⁵⁰“Qualify for NP and PA Waivers.” Qualify for NP and PA Waivers | SAMHSA - Substance Abuse and Mental Health Services Administration, 21 Nov. 2016, www.samhsa.gov/programs-campaigns/medication-assisted-treatment/training-materials-resources/qualify-np-pa-waivers.

⁵¹“Nurse Licensing Laws Block Treatment for Opioid Addiction.” The Pew Charitable Trusts, www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2017/04/21/nurse-licensing-laws-block-treatment-for-opioid-addiction.

Figure 6

Barriers to Nurse Practitioners Treating Opioid Addiction

A new federal law allows nurse practitioners to prescribe buprenorphine, one of three FDA-approved medications for opioid addiction. But laws in 28 states that restrict nurses' scope of practice are thwarting some from prescribing the life-saving drug, particularly in rural areas.



Source: the American Association of Nurse Practitioners.

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Physicians remain the most common buprenorphine providers, with 48,950 physicians certified as of May 2018.⁵² In 2012, 27.5% of DATA-waived physicians nationally had a waiver to prescribe to as many as 100 patients. No state had more than 45% of their DATA-waived physicians with a 100-patient limit. The percentage of DATA-waived physicians listed on the buprenorphine treatment Locator nationally was 55.4%. 30.8% of DATA-waived physicians in North Carolina are authorized to treat 100 patients with buprenorphine in 2012, above the national average. In 2012, 60.3% of DATA-waived physicians were listed on the state

⁵² "Physician and Program Data." Physician and Program Data | SAMHSA - Substance Abuse and Mental Health Services Administration, 17 June 2015, www.samhsa.gov/programs-campaigns/medication-assisted-treatment/training-materials-resources/physician-program-data.

Buprenorphine Treatment locator, also above the national average of 55.4%⁵³. Assuming each physician is treating his or her maximum of thirty to one-hundred patients, North Carolina’s OBOTs at or above eighty percent capacity is 90%. North Carolina’s DATA-waivered physicians are registered on the state treatment locator and treat more patients per physician at an OBOT than the national average. Regardless, there is room for improvement and ability to treat more patients, especially when considering patient limit and ratio of opioid overdoses to buprenorphine prescribers by state.

North Carolina has not issued a state policies or guidelines directly concerning OBOTs or buprenorphine. The NC Division of Medical Assistance has issued a policy regarding physician clinical coverage policies for Medicaid OBOT patients, effective January 2018.⁵⁴ However, OBOTs must register with the North Carolina Drug Control Unit.⁵⁵⁵⁶ As of April 2018, there are nine-hundred and one physicians permitted to prescribe buprenorphine in North Carolina.

Figure 7: Change in Number of DATA-certified Physicians in North Carolina from 2002 to 2018

	Certified Physicians with 30 Patients	Certified Physicians with 100 Patients	Percent Change in Physicians with 30 patients	Percent Change in Physicians with 100 patients
2018	130	31	-64%	-23%
2017	362	40	143%	-26%
2016	149	54	69%	2%
2015	88	53	33%	77%
2014	66	30	20%	-23%
2013	55	39	2%	34%
2012	54	29	-5%	38%
2011	57	21	10%	-13%
2010	52	24	37%	14%
2009	38	21	-30%	91%
2008	54	11	-5%	-73%
2007	57	40	54%	
2006	37	0	-35%	
2005	57	0	111%	
2004	27	0	35%	
2003	20	0	54%	
2002	13	0		

Source: Number of DATA-Waived Practitioners Newly Certified Per Year, SAMSHA, <https://www.samhsa.gov/medication-assisted-treatment>

The number of DATA-certified physicians by state who are eligible to provide buprenorphine treatment for opioid dependency, tracked by SAMSHA, shows a decreasing number of DATA-certified physicians in North Carolina.⁵⁷ Between 2017 and 2018, the number of physicians with thirty and one-hundred patients decreased by 64% and 23%, notable in Figure 7.

⁵³ Jones, Christopher M., et al. American Journal of Public Health, American Public Health Association, Aug. 2015, www.ncbi.nlm.nih.gov/pmc/articles/PMC4504312/.

⁵⁴ 1A-2.Pdf.” NC DMA, 24 Sept. 2015, dma.ncdhhs.gov/providers/clinical-coverage-policies/physician-clinical-coverage-policies.

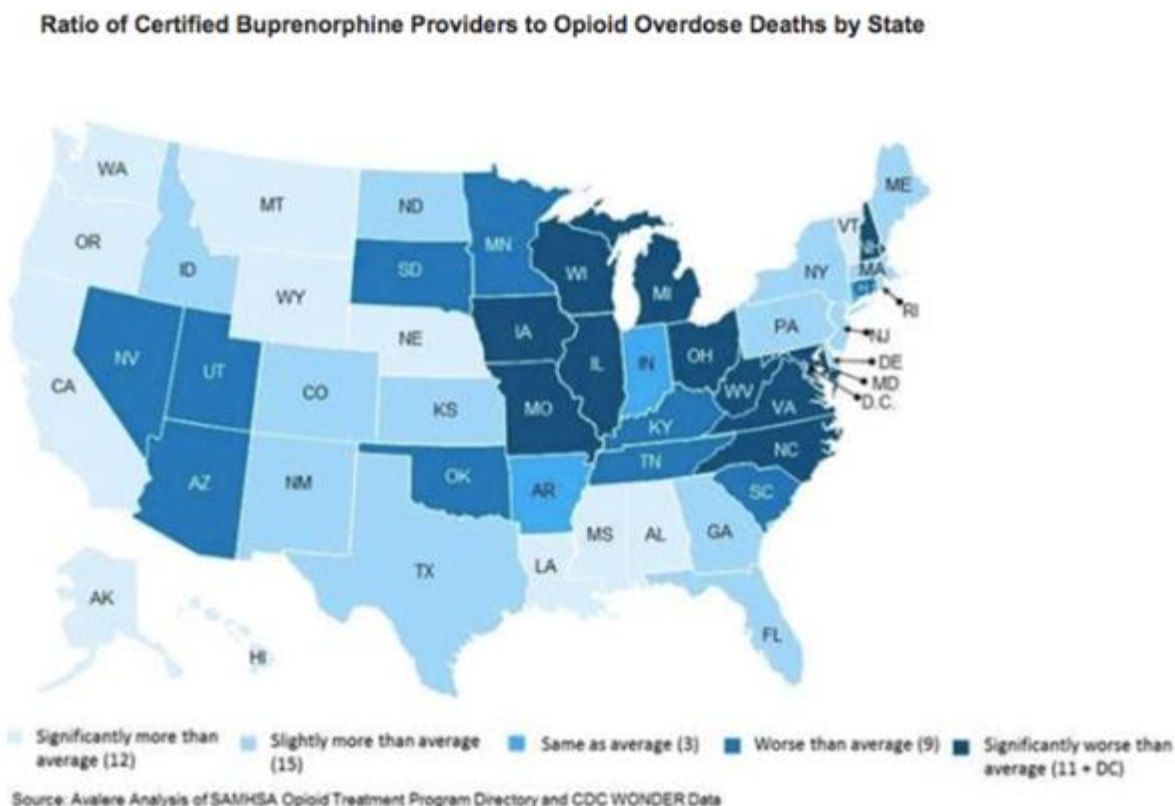
⁵⁵ “North Carolina Drug Control Unit.” NC DHHS, www.ncdhhs.gov/divisions/mhddsas/ncdcu.

⁵⁶Yokell, Michael A., et al. Current Drug Abuse Reviews, U.S. National Library of Medicine, 1 Mar. 2011, www.ncbi.nlm.nih.gov/pmc/articles/PMC3154701/.

⁵⁷ “Number of DATA-Waived Practitioners Newly Certified Per Year.” Number of DATA-Waived Practitioners Newly Certified Per Year | SAMSHA - Substance Abuse and Mental Health Services Administration, www.samhsa.gov/medication-assisted-treatment/physician-program-data/certified-physicians?field_bup_us_state_code_value=NC.

North Carolina faces a lack of buprenorphine providers. When considering the number of opioid overdoses in each state relative to the number of buprenorphine providers, Avalere Health’s analysis finds that eleven states, one of which is North Carolina, have significantly lower-than-average rates of providers who prescribe buprenorphine as compared to opioid overdose deaths.⁵⁸ As noted in Figure 8, North Carolina is colored dark blue: significantly worse than the average ratio of 1.6 opioid overdoses per buprenorphine prescriber nationwide.⁵⁹

Figure 8



LIMITATIONS ON THE PROVISION OF OBOT AND OTP FOUND IN THE LITERATURE

Less than half of private substance use disorder treatment programs offer MAT, and only one-third of patients with opioid dependence at these programs receive it.⁶⁰ Nearly all U.S. states, including North Carolina, do not have sufficient treatment capacity to provide MAT to all patients with an opioid use disorder.⁶¹ In North Carolina between 2008-2012, persons enrolled in

⁵⁸ “Midwest and Mid-Atlantic States Face Provider Shortage to Address Opioid Epidemic.” Avalere Health, avalere.com/expertise/life-sciences/insights/midwest-and-mid-atlantic-states-face-provider-shortage-to-address-opioid-ep.

⁵⁹ I.i.d

⁶⁰ Knudsen, Hannah K., et al. “Adoption and Implementation of Medications in Addiction Treatment Programs.” *Journal of addiction medicine*, U.S. National Library of Medicine, Mar. 2011, www.ncbi.nlm.nih.gov/pmc/articles/PMC3045214/?report=reader.

⁶¹ Abuse, National Institute on Drug. “Effective Treatments for Opioid Addiction.” NIDA, www.drugabuse.gov/publications/effective-treatments-opioid-addiction/effective-treatments-opioid-addiction

substance use treatment programs that prescribed methadone increased 28.6%. However, not all individuals with drug-use disorders received treatment. In 2012 in North Carolina, 11.0% of persons aged 12 and older who met criteria for having a drug use disorder received treatment.⁶² Likewise, of the Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS) data mentioned on page 2, OBOT or OTP to treat opioid addiction was planned for 18 percent of opioid-related hospitalizations for primary opiates other than heroin. With a gap between those who need treatment and clinicians who can provide MAT, the opioid epidemic is far from over. In some areas, geography exacerbates this gap: 30 million Americans live in counties that do not have any physicians with waivers allowing them to prescribe buprenorphine for MAT.⁶³ The barriers from literature below provide hypotheses explaining the discrepancy between credibility of OBOT and OTP as MAT and lack of participation from individuals with opioid addiction and providers.

Reimbursement and Lack of Incentive

First, primary care physicians, while most easily accessible to individuals with opioid addictions, are not incentivized to treat those with opioid addiction because of the reimbursement process. In many states, Medicaid systems do not reimburse physicians for addiction treatment.⁶⁴ North Carolina Medicaid does reimburse physicians for addiction treatment under the Physicians Drug Program for the cost of the drug, if the drug is purchased by the same provider administering the drug. North Carolina Medicaid covers methadone under managed care plans only, and buprenorphine under fee-for-service and managed care plans. Buprenorphine coverage is subject to additional requirements for reimbursement relating to maximum dosages and time constraints. Patients are not required to show proof of enrollment in substance use disorder counseling for reimbursement. In North Carolina, methadone reimbursement for the patient requires proof of enrollment in substance use disorder counselling.⁶⁵ Some states reimburse Medicaid providers and dispensers for buprenorphine treatment; others do not, even when the treatment is listed on the formulary. For example, in New Jersey, the Suboxone tablet itself was covered by Medicaid, but the office-based treatment visits were not.⁶⁷

⁶²Medicaid Coverage of Medications for the Treatment of Opioid Use Disorder in North Carolina. The American Society of Medicine,

www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=0ahUKEwjUh_-BhpvaAhUyWN8KHRs4AEEQFggnMAA&url=https://www.asam.org/docs/default-source/advocacy/state-medicare-reports/state-medicare-reports_nc.pdf?sfvrsn=6&usg=AOvVaw30-F_11bYiD_M3gxNvh7Vh.

⁶³ Roger A. Rosenblatt et al., “Geographic and Specialty Distribution of US Physicians Trained to Treat Opioid Use Disorder,” *Annals of Family Medicine* 13, no. 1 (2015): 23–6, <http://dx.doi.org/10.1370/afm.1735>.

⁶⁴ “Primary care doctors are staying out of the fight against opioids.” *STAT*, 18 Oct. 2016, www.statnews.com/2016/10/19/primary-care-doctors-opioid-treatment/comment-page-1/.

⁶⁵Medicaid Coverage of Medications for the Treatment of Opioid Use Disorder in North Carolina. The American Society of Medicine,

www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=0ahUKEwjUh_-BhpvaAhUyWN8KHRs4AEEQFggnMAA&url=https://www.asam.org/docs/default-source/advocacy/state-medicare-reports/state-medicare-reports_nc.pdf?sfvrsn=6&usg=AOvVaw30-F_11bYiD_M3gxNvh7Vh.

⁶⁶I.i.d

⁶⁷ “Overview of Medicaid Coverage.” Overview of Medicaid Coverage | BupPractice, www.buppractice.com/node/12301.

Secondly, the certification system does not adequately prepare doctors to address addiction. The eight-hour certification course currently offered to clinicians seeking to treat opioid use disorders includes four hours of online training and four hours of live instruction. Medical schools offered little training or support in pain management and addiction medicine. The medical community, including medical schools, has not responded with the speed and intensity required to meet this crisis. Only when faced with outside pressure from the media, legislation, or public pledges has the medical community responded by beginning to implement pain and addiction curriculum into medicine programs.⁶⁸ In March 2016, the White House asked medical schools to pledge to expand their curricula based on the first-ever CDC guidelines on opioid prescribing.⁶⁹

Besides writing a prescription for the opioid used in MAT, doctors must understand how to approach patients who suffer from addiction. A 2011 study in *The Journal of Pain* found that U.S. medical schools allot a median of 9 teaching hours on pain and its management, as compared to a median of 19.5 hours in Canada. In the U.S., that's approximately 0.3% of the total curriculum hours.⁷⁰ With lack of training from medical school and responsibility for addressing the physical and mental counterparts of addiction, MAT is daunting to doctors. In one study, 72.1% of attending and resident physicians would be willing to prescribe buprenorphine for the treatment of OUD if given appropriate training and support.⁷¹ Doctors who coordinate treatment with mental health providers must also navigate at times thorny privacy issues, and brace for the possibility that patients will sell buprenorphine prescriptions on the black market.⁷²

Stigma

Stigma in the environment toward both patients seeking treatment and practitioners supplying treatment plays a significant role in treatment access and quality. Respondents to a survey expressed high levels of stigma toward individuals with prescription opioid use disorder. Levels of stigma were generally similar among those with and without experience with prescription opioid use disorder, either one's own or that of a relative or close friend.⁷³ With the prevalence of the opioid epidemic, OBOT and OTP are becoming viable treatment settings. With the proven

⁶⁸ Karon, Amy. "Medical Schools Respond to the Opioid Epidemic." ACP Internist, 1 Jan. 2017, acpinternist.org/archives/2017/01/opioids-medical-education.htm.

⁶⁹ I.i.d

⁷⁰ Firth, Shannon. "Medical Schools Boost Pain Management Education." Medpage Today, MedpageToday, 2 May 2016, www.medpagetoday.com/publichealthpolicy/medicaleducation/56025

⁷¹ Gustin, Richard, et al. "Individualizing Opioid Use Disorder (OUD) Treatment: Time to Fully Embrace a Chronic Disease Model." Journal of Reward Deficiency Syndrome, 19 Feb. 2015, blumsrewarddeficiencysyndrome.com/articles/v1n1/jrds-003-richard-gustin.html.

⁷² "Primary care doctors are staying out of the fight against opioids." STAT, 18 Oct. 2016, www.statnews.com/2016/10/19/primary-care-doctors-opioid-treatment/comment-page-1/.

⁷³ "Social Stigma Toward Persons With Prescription Opioid Use Disorder: Associations With Public Support for Punitive and Public Health-Oriented Policies." Psychiatric Services, ps.psychiatryonline.org/doi/citedby/10.1176/appi.ps.201600056.

effectiveness of medication-assisted treatment programs⁷⁴⁷⁵⁷⁶⁷⁷⁷⁸, such as OBOT and OTP, in academic studies, this number is low. Other studies report that stigma impacts a patient's decision to successfully continue treatment at an OBOT or OTP.

“Many participants reported thinking, at least sometimes, that they “have permanently screwed up” their lives (60%), and felt “ashamed” (60%), and “out of place in the world” (51%) because of their opioid or alcohol use. Higher internalized stigma was related significantly to more substance use problems, even after the effects of covariates were accounted. Stigma consisted of 22%, of 51% total variance explained, leading to a significant improvement in prediction of substance use problems.”⁷⁹ Individuals with opioid addiction face stigma through misunderstandings of addiction once propagated in the past. The common social sentiment, “Why don't these people stop doing drugs,” is not just sewn into the fabric of our society, but has also permeated our healthcare system, treatment models, and our definitions of ‘successful’ treatment.⁸⁰

Stigma impacts even practitioners themselves. Literature has cited lack of training and stigma as barriers to entering the opioid treatment field. There are significant emotional costs associated with the opioid epidemic—for patients, their families and friends, and the practitioners who treat them—costs that are rarely addressed in the scientific literature. These emotional costs can lead to another barrier: provider burnout. Providers may need other, more private venues in which to interact and share their experiences caring for people who use opioids.⁸¹

Medicaid Expansion Barriers

Preliminary research supports the notion that additional funding from Medicaid expansion would permit states more resources to provide MAT with buprenorphine or methadone to fiscally-constrained patients. By covering low-income childless adults up to 138% of the federal poverty line, the Medicaid expansion enabled 1.29 million low-income people with substance use disorders to gain access to coverage that is unavailable to their peers in states that did not expand Medicaid.⁸² Expanding Medicaid permits additional funds to states that opt into the expansion

⁷⁴Sheridan, Kate. “How Effective Is Medication-Assisted Treatment for Addiction?” STAT, STAT, 15 May 2017, www.statnews.com/2017/05/15/medication-assisted-treatment-what-we-know/.

⁷⁵Medication-Assisted Treatment Improves Outcomes for Patients With Opioid Use Disorder.” The Pew Charitable Trusts, www.pewtrusts.org/en/research-and-analysis/fact-sheets/2016/11/medication-assisted-treatment-improves-outcomes-for-patients-with-opioid-use-disorder.

⁷⁶Medication-Assisted Treatment of Opioid Use Disorder:... : Harvard Review of Psychiatry.” LWW, journals.lww.com/hrjournal/Fulltext/2015/03000/Medication_Assisted_Treatment_of_Opioid_Use.2.aspx

⁷⁷ “Medication-Assisted Therapies - Tackling the Opioid-Overdose Epidemic | NEJM.” New England Journal of Medicine, www.nejm.org/doi/full/10.1056/NEJMp1402780.

⁷⁸ “Diacetylmorphine versus Methadone for the Treatment of Opioid Addiction | NEJM.” New England Journal of Medicine, www.nejm.org/doi/full/10.1056/NEJMoa0810635

⁷⁹ Internalized stigma as an independent risk factor for substance use problems among primary care patients: Rationale and preliminary support. Kulesza, Magdalena et al. Drug & Alcohol Dependence , Volume 180 , 52 - 55
⁸⁰ Olsen Y, Sharfstein JM. 2014. Confronting the stigma of opioid use disorder and its treatment. JAMA 311(14): 1393-1394. doi: 10.1001/jama.2014.2147

⁸¹ Haug NA, Bielenberg J, Linder SH, Lembke A. Assessment of provider attitudes toward #Naloxone on Twitter. Subst Abus. 2016;37.[Taylor & Francis Online], [Web of Science ®], [Google Scholar]

⁸²Americans with Mental Health and Substance Abuse Disorders: The Single Largest Beneficiaries of the Medicaid Expansion. National Council Fo BEhavioral Health, www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=0ahUKEwj91JWEgJva

system. North Carolina has not expanded Medicaid. A North Carolina Medicaid Expansion would result in around \$13 billion in federal money for the state over the next decade, a healthier population, and an economic boost, especially to hospitals and rural areas.⁸³ Americans with mental health and substance abuse disorders turn to Medicaid. In 2014, spending by Medicaid accounted for 25% of all mental health spending in the U.S. and 21% of all substance use disorder expenditures in the nation. Expanding coverage and loosening financial restriction on individuals in North Carolina would permit more individuals to seek treatment through OBOTs or OTPs.

Six qualitative interviews gathered and analyzed, support the previous barriers that have appeared throughout the background of OBOT and OTP, policy landscape, and literature review. Existing barriers will be identified and evaluated along with new barriers by the methodology below.

QUALITATIVE ANALYSIS METHODOLOGY

The interviewer attended various state-wide meetings related to opioids as well as contacted OBOTs and OTPs via phone and e-mail regarding an interview opportunity.

Process

The interviewer arrived 5 to 30 minutes early for appointments and remained in the waiting area of various treatment facilities to observe the environment. The interviewer then interviewed only one individual, either in person or via telephone. All individuals interviewed were primary care providers and involved with either OBOTs or OTPs.

Interviewee Characteristics

Six qualitative interviews	
OBOT-affiliated	50%
OTP-affiliated	50%
Identify as Physician	66%
Identify as Registered Nurse	17%
Identify as Pharmacist	17%
Identify as Other	0%

Data Analysis and Approach

One coding process was applied to analyze the six interview transcripts. Given the length of the interviews and complexity of the topic, transcripts were analyzed using versus coding.

AhUqneAKHf4JD4EQFggnMAA&url=https://www.thenationalcouncil.org/wp-content/uploads/2017/01/Medicaid-Expansion-Behavioral-Health-UPDATED-1-24-17-1.pdf&usg=AOvVaw0ICF5q4-Ngzc7Q7sVTX2eN.

⁸³ The Observer editorial. "Compromise? In Raleigh? Say It's So." Charlotte Observer, www.charlotteobserver.com/opinion/editorials/article195656024.html.

Evidence & Themes

Domain	Specific Challenges	Mentioned by percent of sample	Quotes
OBOT vs. OTP	DEA Audits	14%	"DEA Audits are scary and time consuming. If I'm a busy doctor, why do I want to subject myself to potentially more of those?"
	Federal Policy Regulations	100%	"They [OTP patients] come on a daily basis and get their medication on site. That's one of the key differences between and office based and an opioid treatment program."
	State Policy Regulations	100%	"There's a lot of differences between the OBOT and an OTP model. With OBOT, it's just very, very loosely regulated."
			"What you'll find is that they may or may not be doing counseling, even though it's suggested with their clientele."
Profit vs. Treatment	Ease of reimbursement	100%	"The OBOT dealing with more of a higher socioeconomic demographic, you're seeing more of those referrals, and I would have to check on this, but I'm imagining that most of those referrals are coming from insurance."
	Stigma	100%	"The easiest person to get reimbursement from is the self-pay person. If they have the money. Why would an OBOT or OTP want to treat druggies?"
			"I'm afraid OBOTs are able to price out people by using a cash system rather than using both cash and funds, or cash and accepting Medicaid reimbursement."
	Access to grants/resources for uninsured	71%	"That specific location isn't receiving public funds for their clientele, and so it's all self-pay or insurance clients, and it's quite expensive."
			"I have to run a business, but I want to help as many patients as possible. The CURES grant was helpful with that."

Qualitative Analysis Limitations

Given the sampling in the qualitative phase, the researcher cannot say with confidence the sample will be representative of the PCP population. Practitioners most interested in barriers to creating and implementing OBOTs and OTPs are likely to be the most responsive. Due to the nature of qualitative research, the data obtained may be subject to different interpretations by different readers. Because of the interpretative nature of the qualitative research, the researcher may introduce his/her bias into the qualitative analysis results. Practitioners are subject to strict

schedules, making call and meeting time limited. This could impact quality of information provided in interviews.

INTERVIEWEES' LIMITATIONS ON THE PROVISION OF MAT

Interviewees mentioned the following barriers that appeared in the literature review:

Reimbursement and Lack of Incentive

*Interviewees mentioned the insurance coverage of a patient with opioid addiction plays a role in which opioid is prescribed to the patient, where the patient is referred, as well as what payment system the OBOT or OTP uses. Interviewees have expressed concerns regarding 'pricing out' individuals without insurance or with Medicaid. Interviewees claim that OBOTs and OTPs can utilize a 'cash only' system. This system results in a self-sorting of potential patients into those willing to pay with money, those with insurance covering most aspects of treatment, those with insurance covering few aspects of treatment, those under government insurance (Medicaid), and those without insurance. Interviewees suggested that this self-sorting can pose a barrier to certain categories facing more limited treatment options.

Stigma

*Interviewees stressed stigma as a barrier to treating patients as well as hiring and retaining OBOT and OTP staff. Interviewees suggested that community education and OBOT and OTP location is critical in decreasing stigma. Additionally, interviewees suggest residential training programs or a standardized video or pamphlet provided to individuals considering treatment as a method of patient attraction and retention to combat stigma at the patient's level and environment. Interviewees suggested community education is critical to patient retention and treatment success.

Medicaid Expansion

* Medicaid Expansion was considered by practitioners as a source of funding and a resource that would be helpful to treating more patients. Interviewees and practitioners considered the current state of Medicaid not as a barrier, because resources do exist for those under Medicaid insurance, but rather a resource that could be expanded. This potential resource expansion could increase patient access and treatment.

The interviewees mentioned the following three barriers that did not appear as a strong theme in literature:

Federal Cures Grant and Reimbursement Codes

A portion of the state-awarded federal Cures grant was awarded to each North Carolina LME/MCO. Access to the funding provided by the federal Cures grant varied by LME/MCO. Not all OTP and OBOT treatment settings are registered under an LME/MCO; each LME/MCO awarded money to their contracted OBOTs and OTPs. Interviewees have mentioned a lack of standardization amongst the Cures grant distribution process and the timeframe as a barrier to providing treatment. Due to lack of reimbursement codes for North Carolina OBOTs as well as

challenging timeframes for the LME/MCOs to spend the allotted funds, LME/MCOs focused on providing funds to OTPs. Few OBOTs received federal Cures grant funds from their affiliated LME/MCOs. OBOTs and OTPs are reimbursed for uninsured or fiscally constrained patients through the LME/MCO or directly through the state of North Carolina. The reimbursement for OBOT and OTP services varies by insurance coverage as well. Interviewees mentioned that with Medicaid, an OBOT or OTP can charge all treatment services to either the LME/MCO or directly to the state. The LME/MCO can also bill the labs as well as write a prescription, in which the patient does not pay for the medication. However, if the patient is uninsured, then he or she will lose access to the labs, medication, and other services due to lack of a billing code associated with these services. If the patient was associated with an OTP, the billing code existed. However, if the patient fell under the OBOT system, the billing codes did not exist. OBOTs are newer and less-regulated than OTPs, posing an explanation for the lack of reimbursement codes. Interviewees mentioned that to receive reimbursement to treat the uninsured or those lacking insurance coverage, OBOTs either received funds from internal sources, such as associated or partner hospitals, or the LME/MCO altered its reimbursement process. In North Carolina, presently billing codes for OBOTs are being created as well as strategies and partnerships to aid with treating patients.

DEA Auditing Barrier

Some interviewees have expressed concerns regarding the DEA's ability to audit office-based opioid treatment programs. The DEA is a law enforcement agency, with the ability to assess civil and criminal penalties. The DEA's audits can lead to criminal prosecution and administrative action against practitioner and treatment setting and loss of DEA registration if violations of the Controlled Substances Act are found to exist. Violations result in penalties ranging from a letter of admonition to a \$10,000 fine for each violation or a prison sentence. The DEA has a role in the buprenorphine waiver program which is no different from its role in methadone programs, and the DEA has legal rights to document the use of controlled substances including methadone and buprenorphine.⁸⁴ On January 30, Attorney General Jeff Sessions announced a surge of DEA agents and investigators with focus on pharmacies and prescribers dispensing unusual or disproportionate amounts of opioid drugs.⁸⁵ Interviewees believed that the focus on the opioid epidemic and increased DEA inspections diverts resources and staff focus. Regardless of classification as an OBOT or OTP, interviewees are cautious as their respective OBOTs and OTPs are managing individuals with opioid addictions. Interviewees also mentioned a fear of subjection to numerous DEA inspections.

Changing Insurance Coverage

Interviewees addressed a barrier to treating patients with insurance: changing insurance coverage. Different insurance companies and types of insurance cover different portions of treatment ranging from the medication to therapy. The coverage change can result in changing the fiscal contribution from the patient. If a patient faces fiscal constraints, the patient can be

⁸⁴“Providing Care.” Office-Based Opioid Treatment (OBOT), www.magellanprovider.com/providing-care/clinical-guidelines/substance-use-solutions/office-based-opioid-treatment-obot.aspx.

⁸⁵“Attorney General Sessions Announces DEA Surge to Combat Prescription Drug Diversion.” The United States Department of Justice, 31 Jan. 2018, www.justice.gov/opa/pr/attorney-general-sessions-announces-dea-surge-combat-prescription-drug-diversion.

subject to medication tapers, or be provided no medication, for a time. This treatment disruption can result in a higher risk of patient relapse.

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