The Role of Physician Assistants and Nurse Practitioners in Increasing Access to Buprenorphine

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THE ROLE OF PHYSICIAN ASSISTANTS AND NURSE PRACTITIONERS
IN INCREASING ACCESS TO BUPRENORPHINE

A Thesis Presented to
The Faculty of the School of Medicine
Yale University

In Candidacy for the Degree of
Master of Medical Science

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Abstract:

Opioid use disorder results in increasing mortality every year and is a growing concern in the United States. Buprenorphine is a safe and effective evidence-based medication to treat opioid use disorder. However, despite this evidence, there are a disproportionately low number of providers with the requisite Drug Enforcement Agency registration to prescribe buprenorphine, resulting in a significant barrier to access. In 2016, the Comprehensive Addiction and Recovery Act extended buprenorphine prescription privileges to physician assistants and nurse practitioners; however, these efforts have been restricted by state regulations. We hypothesize that access to buprenorphine is improved in areas where PA/NPs have full scope of practice in buprenorphine prescription. By evaluating the impact of the expansion of prescription authority to PA/NPs, we can better understand the impact of restricting such authority and advance efforts to increase the access to buprenorphine and thereby reduce opioid use disorder associated morbidity and mortality.
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Chapter 1 – Introduction

1.1 Background

1.1.1 The Role of Buprenorphine in Treating Opioid Use Disorder

Opioid misuse and opioid use disorder is a growing concern in the United States and worldwide. In 2016 alone, there were 11.5 million people 12 years and older who reported nonmedical use of prescription analgesics. Of this population, 10.9 million solely misused opioid analgesics compared to the 948,000 who used heroin. With 42,249 deaths from opioid overdose in 2016 and increasing mortality every year, it is becoming more vital than ever to implement evidence-based treatments for opioid use disorder (OUD). To address OUD, the Food and Drug Administration (FDA) has approved three medications: buprenorphine, methadone, and naltrexone. Buprenorphine, a partial mu agonist, has been demonstrated to be a safe and effective medication to treat OUD. It is associated with a reduction in HIV risk behavior and in overdose-related mortality. Moreover, it is invaluable for its availability by prescription from ambulatory centers, such as primary care offices, and dispensing up to 30 days via community pharmacies, whereas methadone is only available through 1632 federally regulated opioid treatment programs (“methadone clinics”).

There are currently a limited number of FDA-approved medications containing buprenorphine for the treatment of OUD, typically combined with naloxone to minimize diversion, including generic formulations, Bunavail, Suboxone, Zubsolv, and buprenorphine-containing transmucosal products. For the purposes of this study, we will use the term “buprenorphine” to refer to all of these medications.
1.1.2 Challenges to Buprenorphine Access

Even with the introduction of a medication like buprenorphine, expanding access to all individuals who need it has been challenging. Of the individuals who needed treatment for OUD in 2016, only 10.6 percent received treatment\(^1\) (This number reflects physician prescribers only, as PAs and NPs gained prescriptive authority later). Among the many barriers to the medication’s accessibility, of significance is the disproportionately low number of providers that are specially qualified to prescribe buprenorphine. The Drug Addiction Treatment Act of 2000 (DATA 2000) made it a requirement for physicians to complete eight hours of training in order to obtain a waiver from the Drug Enforcement Agency (DEA) to prescribe buprenorphine. The waiver refers to the Controlled Substances Act and results in a unique DEA registration for the waivered prescriber. Once waivered, they are allowed a limited patient capacity of 30 initially, then up to 275 upon request. Even among waivered physicians, full prescriptive potential is not met due to a myriad of concerns including not having enough time for more patients and not wanting to prescribe to more patients\(^{11-13}\). The misconception that there is a lack of patient demand for buprenorphine is among the barriers as well\(^{14}\). One crucial solution to reaching the full potential of buprenorphine, therefore, is increasing the number of waivered prescribers, utilizing not only physicians but also the growing workforce of physician assistants (PA) and nurse practitioners (NP). The supply of PAs and NPs is predicted to increase faster in primary care than that of physicians\(^{15}\), and with the accessibility of buprenorphine from primary care offices, it is important to realize the full potential of these advanced practice providers in the realm of buprenorphine prescription.
1.1.3 Physician Assistants and Nurse Practitioners in Buprenorphine Prescription

Since 2016, the Comprehensive Addiction and Recovery Act (CARA) has extended buprenorphine prescriptive privileges to PAs and NPs after 24 hours of training. Later in 2018, the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, or the SUPPORT for Patients and Communities Act, made these privileges permanent. Encouragingly, there is high interest in prescribing buprenorphine among PAs and NPs. Nevertheless, the scope of practice of PAs and NPs is restricted by individual state regulation, which allows a mix of full, restricted, or even no buprenorphine prescriptive privilege. These restrictions may have important effects on buprenorphine accessibility for individuals who live in states where PAs and NPs do not have the full scope of practice needed for treating OUD. By studying how expansion of DEA waivers to PA/NPs is benefitting individuals with OUD, we can better understand the dangers of restricting prescription authority and look at what steps need to be taken to increase access to buprenorphine to reduce morbidity and mortality among those with OUD.

1.2 Statement of the Problem

The scope of practice of PAs and NPs in buprenorphine prescription is regulated by individual states. This may restrict buprenorphine access for individuals who live in states where PAs and NPs do not have full scope of practice.
1.3 Goals and Objectives

Ultimately, our goal is to analyze the impact of CARA on buprenorphine access in different states. Little is known about the role of PAs and NPs in buprenorphine availability; this will be the first analysis of federal efforts such as CARA and the SUPPORT for Patients and Communities Act on buprenorphine access through PAs and NPs between states where PAs and NPs completely lack buprenorphine prescriptive ability and those where they have it.

1.4 Hypothesis

We hypothesize that, from 2016 to 2018, there has been a statistically significant increase in the proportion of waivered providers to total providers in states with waivered PAs and NPs versus states with waivered physicians only.

1.5 Definitions and Acronyms

- **Comprehensive Addiction and Recovery Act (CARA):** 2016 law that allowed qualified PAs and NPs to prescribe buprenorphine

- **Drug Addiction Treatment Act (DATA):** 2000 law that allowed qualified physicians to prescribe buprenorphine in settings other than opioid treatment programs

- **Medication-Assisted Treatment (MAT):** “the use of FDA-approved medications, in combination with counseling and behavioral therapies, to provide a “whole-patient” approach to the treatment of substance use disorders” (as defined by Substance Abuse and Mental Health Services Administration)
• **Opioid Treatment Program (OTP):** federally accredited centers providing medication for addiction treatment, including methadone and/or buprenorphine, for individuals with opioid use disorder

• **Opioid Use Disorder (OUD):** “a problematic pattern of opioid use leading to clinically significant impairment or distress” (as stated in The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition)

• **Substance Abuse and Mental Health Services Administration (SAMHSA):** federally run body with the mission to address substance abuse and mental health

• **The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act:** 2018 law that built upon efforts by CARA for treatment for opioid use disorder
References:


Chapter 2 – Literature Review

2.1 Introduction

We conducted a systemic review of the literature using databases including PubMed, Cochrane Library, etc. We limited our search to the most recent literature, published after 2000. Our systemic review included the following search terms: medication-assisted treatment, buprenorphine, opioid use disorder, physician assistant, nurse practitioner, access, and CARA. Our search included multiple study designs such as cross-sectional studies, randomized controlled trials, and systematic reviews. We utilized publically accessible online databases. We restricted our search to studies conducted in the English language.

2.2 Review of the Literature

Since the introduction of CARA, there has been little literature on the demonstrable benefits of expanding buprenorphine prescriptive authority to PAs and NPs. Despite the growing numbers of PAs and NPs in primary care and their potential for improving buprenorphine access, the majority of studies on buprenorphine identified by our literature review focused on the physician model for buprenorphine prescription, with few studies focusing on PAs and NPs specifically.

Analytical studies of the contributions of PAs and NPs on buprenorphine access are severely lacking. However, we do know that the addition of PAs and NPs increased the number of prescribers nationally from 11.0 (only MD) per 100,000 patients in 2016 to 12.4 per 100,000 patients by the end of 2017 (MD, PA, NP)\(^1\). Before we specifically
discuss the role of PAs and NPs, we will first consider other efforts that have been taken in increasing its access on the federal level.

2.2.1 Federal Initiatives to Expand Access to Buprenorphine

Since the FDA approval of buprenorphine in 2002, federal initiatives have tried to tackle the issue of limited buprenorphine access. From 2003 to 2015, there was an increase in the federally regulated opioid treatment programs (OTPs) that provide buprenorphine, from 11 percent to 58 percent of OTPs. Additionally, in 2016, the patient limit for prescribers increased from 100 to 275. Increasing the number of buprenorphine treatment slots has been associated with greater amounts of buprenorphine use overall. A 2015 study showed a statistically significant relationship between the number of waivered physicians with a 100-patient limit and increased amounts of buprenorphine use per capita. The same study showed no significant relationship between the number of waivered physicians with a 30-patient limit and the amount of buprenorphine prescribed. This suggests that one important way of increasing buprenorphine use is allowing providers higher patient limits.

Another challenge is prescriber training and experience with buprenorphine. Studies have shown that providers having access to other providers with experience in prescribing buprenorphine may increase its prescription. The Providers Clinical Support System (PCSS) is a federally funded program created in an effort to educate and support primary care providers in treating OUD, including buprenorphine, through access to experts in OUD treatment. The required training for buprenorphine prescriptive ability is offered through PCSS for physicians, PAs, and NPs.
To build upon the efforts of CARA, the SUPPORT for Patients and Communities Act became law as of October 24, 2018 to further increase access to medication for addiction treatment for people with OUD. Most importantly for PAs and NPs, the ability to prescribe buprenorphine, which had been temporary under CARA, became permanent under this law. Other efforts included Medicaid reimbursement for medication for addiction provided through telehealth and improved funding for pregnant women and children affected by OUD\(^7\).

### 2.2.2 Limited Buprenorphine Access in Underserved Communities

Access to buprenorphine is limited throughout the United States, but it is often much more so in certain historically underserved communities. Areas with a higher percentage of black, rural, and/or uninsured patients were less likely to have outpatient offices providing treatment for substance use disorder that accepted Medicaid\(^8\). A recent study demonstrated that black patients specifically were less likely to be prescribed buprenorphine as compared to other racial groups\(^9\). The same study found that the most common payment methods for buprenorphine were self-pay and private insurance, indicating a huge financial barrier for low-income communities and the need for further Medicaid expansion\(^9\). Overall, it is evident that buprenorphine access is limited in low-income communities and warrants particular attention in increasing accessibility to MAT. This disproportionate access to buprenorphine is significant to our research as PAs and NPs have a well-documented role in providing healthcare to underserved communities and imaginably a very valuable role in providing access to buprenorphine.
2.2.3 The Role of Physician Assistants and Nurse Practitioners in Communities Lacking Access to Buprenorphine

PAs and NPs are becoming an increasingly vital part of the medical team and especially so in communities shown to have reduced access to buprenorphine. It has been shown repeatedly that the quality of care provided by primary care advanced practice providers such as PAs and NPs is not only comparable to that provided by physicians but also cost-effective. The increase in numbers of these advanced practice providers is expected to be tremendous: from 2016 to 2030, while the number of physicians is estimated to grow by 1.1 percent, the numbers of PAs and NPs are estimated to increase by 4.3 and 6.8 percent respectively. In addition, PAs and NPs were found to serve communities with greater proportions of Medicaid, uninsured, and minority patients when compared to physicians. Nurse practitioners are practicing at increasing numbers in both rural and nonrural areas, as shown by a study which measured their presence in primary care offices from 2008 to 2016. The patient population that PAs and NPs serve are complicated as well: one study showed an increase between 2008 and 2014 in the shared care model (which includes physicians and NPs and/or PAs) for elderly populations with multiple comorbidities, patients in rural areas, and health professional shortage areas (HPSAs). The same study showed a corresponding decrease in the physician model (which includes physicians only). Specifically for patients with OUD, the addition of PAs and NPs has been projected to increase the number of patients treated with buprenorphine in rural areas by 15.2%. Unfortunately, there are restrictions on PA and NP scope of practice that may hinder their full potential in increasing buprenorphine access.
2.2.4 Unique Training and Practice Requirements of Physician Assistants and Nurse Practitioners

In general, the scope of practice of PAs always necessitates collaboration with a physician. The scope of practice of NPs can vary widely by state, from supervision or collaboration with a physician to fully independent practice. In the case of buprenorphine prescription, a waivered PA or NP cannot prescribe unless supervised by or working in collaboration with a physician who also has the waiver or fulfills other requirements listed in CARA, if required by state law. Before applying for the waiver, the PA or NP must complete 24 hours of mandatory training, which is 16 hours more than that required for physicians. Moreover, although CARA did extend buprenorphine prescription privileges to PAs and NPs, individual state laws nevertheless dictate much of PA and NP practice.

2.2.5 The Impact of State-level Policies and Insurance

Considering the buprenorphine prescriptive practices of PAs and NPs as a state-level issue, our search focused on the impacts of various other state policies affecting buprenorphine access. Throughout the history of buprenorphine prescription, state-level factors have had a powerful influence on its accessibility. Under the Affordable Care Act (ACA), individual states have had the option to enroll in Medicaid expansion, extending insurance coverage to populations, some of who might benefit from access to buprenorphine. As of November 2018, 37 states including the District of Columbia have enrolled\textsuperscript{17}. During the early adoption of buprenorphine, a 2008 study predicted a positive association between Medicaid coverage of buprenorphine and its prescription\textsuperscript{18}. Later
studies confirmed the association between state Medicaid expansion and not only the
number of buprenorphine prescriptions\textsuperscript{19} but also the number of waived physicians\textsuperscript{20,21}. This is clear evidence that despite federal initiatives, access to buprenorphine could be altered by state level policies. It is also evidence that insurance plays a crucial role in obtaining buprenorphine; indeed, insured individuals were 3.3 times more likely to receive buprenorphine than those without insurance\textsuperscript{22}. Among privately insured individuals between 2003 and 2015, both the total cost and out-of-pocket cost of buprenorphine decreased\textsuperscript{23}. Not surprisingly, the situation for patients with Medicaid is not as promising.

Even among states with Medicaid coverage of buprenorphine, additional restrictions have been shown to affect buprenorphine accessibility. Among opioid treatment programs, prior authorization of buprenorphine was associated with lower odds of offering buprenorphine as a treatment option\textsuperscript{24}. There has also been an upward trend of Medicare Part D plans enforcing requirements for prior authorization; one study points out the decline of Medicare Part D plans covering buprenorphine without restrictions from 89\% in 2007 to 35\% in 2018\textsuperscript{25}. These studies highlight the point that in addition to Medicaid coverage by the state, the associated restrictions are significant to buprenorphine access as well.

Other state resources such as opioid treatment programs\textsuperscript{21}, substance use treatment programs\textsuperscript{21}, and state-led guidance on office-based buprenorphine use\textsuperscript{20} have been associated with higher numbers of waived physicians. Over time, individual state policies have had an important impact on buprenorphine access to patients with OUD.
One example of a successful state initiative in improving buprenorphine access is
an initiative by the Massachusetts Bureau of Substance Abuse Services. This organization
developed the Massachusetts Collaborative Care Model, in which nurses took a central
role among primary care physicians in the care of patients with OUD. In this novel model,
the nurse care manager served as the connection between waivered physicians and
patients. The office-based opioid treatment (OBOT)-Collaborative Care Model was
adapted into community health centers, ultimately increasing the enrollment of patients
with OUD in community health centers and the numbers of waivered physicians. This
initiative with its collaborative and novel practices may be advantageous and much
needed for this otherwise under-accessed medication and can serve as a model for other
states. As PAs and NPs become an integral part of the medical team, it is important to
include them in strategies to broaden accessibility to buprenorphine.

On the other hand, two states stand out in their uniquely strict monitoring of
buprenorphine prescription. For example, Tennessee currently only allows physicians to
prescribe buprenorphine, completely excluding PAs and NPs from using this medication
to treat OUD. In Kentucky, physicians and NPs may prescribe buprenorphine but PAs
may not. Compared to the national opioid-related death rate of 14.6 per 100,000 persons,
Tennessee and Kentucky are burdened with significantly higher rates at 19.3 and 27.9,
respectively, as of 2017. These two states represent cases where it may be especially
impactful to enlist the assistance of PAs and NPs in treating OUD.
2.2.6 Categorization of States for Physician Assistants and Nurse Practitioners

Despite the wide variability of state-based scope of practice, states can be categorized in terms of the scope of practice of PAs and NPs. Generally, for most states, the scope of practice of PAs is decided at the practice level, rather than at the state level. PAs, by training, are required to practice with a supervising MD. On the other hand, the scope of practice of NPs is organized into “restricted”, “reduced” and “full” by the American Association of Nurse Practitioners, where states with restricted or reduced NP scope of practice requires supervision or collaboration with MDs. This categorization has been used in studies to describe the scope of practice of NPs. In a recent study, the scope of practice of PAs and NPs throughout the United States was defined as “less restrictive” and “more restrictive”. For NPs, “less restrictive” states did not require physician oversight for medication prescription whereas “more restrictive” states did. For PAs, “less restrictive” states had 5-6 essential elements of PA practice as defined by the American Association of Physician Assistants whereas “more restrictive” states had less than 5. This study found a significant association between scope of practice and the waivered status of NPs, with a statistically significant mean difference of 3.14 percentage points (95% CI, 2.05-4.23) between the less restrictive and more restrictive states for NPs. We took these categorizations into consideration when analyzing the chosen states in the study.

2.3 Review of Relevant Methodology

Due to the novelty of our study and the lack of similar studies with PAs and NPs functioning as clinicians in OUD treatment, our study methodology was challenging. It
has merely been 2 years since PAs and NPs gained buprenorphine prescriptive privileges through CARA 2016. Consequently, much of the literature to this day has focused on the physician as the sole clinician providing medication-assisted treatment. The role of PAs and NPs in buprenorphine prescription in the realm of facing the epidemic of opioid addiction has yet to be fully observed.

The recent study by Spetz et al. was the first to examine a relationship between state restrictions on PA and NP scope of practice and the proportion of waived PAs and NPs\textsuperscript{31}. Their study designates scope of practice of NPs and PAs as the independent variable. The dependent variable is the mean proportions of waived providers per state by the provider type and scope of practice, similarly to our study. For our study, we designated our key independent variable as the ability of PAs and NPs to prescribe buprenorphine. We wanted to distinguish states like Tennessee and Kentucky from other states that may have differences in scope of practice but do not have specific restrictions for buprenorphine prescription by PAs and NPs.

Therefore, our key independent variable is the ability of PAs and NPs to prescribe buprenorphine as a binary variable. The key independent variable in the study by Wen et al. \textsuperscript{32} is the state implementation of Medicaid expansion, which is very similar to our independent variable in that both studies analyze the effects of a state-level restriction.

Then, based on our literature review, we selected covariates that have been documented to have an association with buprenorphine availability or OUD. Our covariates include Medicaid expansion, prior authorization, urbanicity, number of OUD-related deaths, and the number of OTPs providing buprenorphine. The adjustment of the covariates and further design of multivariable linear regression was loosely designed.
from two different studies: a study by Mohlman et al. which used a multivariable linear regression model\textsuperscript{33} and a study by Haffajee et al. which used a multivariate logistic regression model\textsuperscript{34}.

Finally, rather than looking at data solely from 2018, we wanted to analyze the trend over time since CARA was passed in the proportion of waived providers to total providers. This was our reasoning in designing a repeated cross-sectional study from 2016 to 2018.

2.4 Conclusion

Through our literature review, we were able to identify both current efforts to improve buprenorphine access and restrictions to buprenorphine access. There are federal initiatives in place with the goal of improving buprenorphine access, such as recent increases in OTPs providing buprenorphine, increases in providers’ patient limit to 275, and the Providers Clinical Support System, which provides support for primary care providers in OUD treatment. In addition, the SUPPORT for Patients and Communities Act passed in 2018 made buprenorphine prescriptive ability for PAs and NPs permanent, among other achievements.

Despite these achievements, there are yet many limitations to buprenorphine access that we found through our literature review. There is disproportionate access to buprenorphine for black, rural, and uninsured patients. PAs and NPs have been shown to serve these patient communities with a demonstrated quality of care and cost-effectiveness. However, PA and NP practice is limited. They may only prescribe buprenorphine if the collaborative physicians are waived, and individual state policies
may restrict their ability to prescribe this drug altogether. Overall, individual states have significant control of buprenorphine access, with varying levels of Medicaid expansion, prior authorization, and availability of OTPs.
References:


15. Xue Y, Goodwin JS, Adhikari D, Raji MA, Kuo YF. Trends in Primary Care Provision to Medicare Beneficiaries by Physicians, Nurse Practitioners, or


Chapter 3 – Methods

3.1 Study design

We will conduct an analysis of a repeated cross-sectional data from 2016 to 2018, to analyze changes over time in numbers of waived providers in four representative states.

3.2 State Profiles

We chose four states—Tennessee, Kentucky, Ohio, and West Virginia—each representing varying levels of PA and NP scope of practice. The individual state profiles, in order of most to least restrictive, are described below. Table 1 displays MD, PA, and NP buprenorphine prescriptive ability for each state.

Tennessee is the only state in the United States in which neither PAs nor NPs can prescribe buprenorphine. Only MDs are able to prescribe buprenorphine in this state. Tennessee is further unique in that it is one of the few states that have not accepted Medicaid expansion. Tennessee requires prior authorization for buprenorphine use. In this state, NPs have restricted practice, which requires physician supervision.

Kentucky allows NPs to prescribe buprenorphine. MDs and NPs prescribe buprenorphine in this state. Kentucky has accepted Medicaid expansion and requires prior authorization for buprenorphine use. In this state, NPs have reduced practice, which requires physician collaboration.

Ohio allows both PAs and NPs to prescribe buprenorphine along with MDs. PA practice is determined at the practice level and requires physician supervision, similarly
to NP practice requiring physician collaboration in this state. Ohio has accepted Medicaid expansion and requires prior authorization for buprenorphine use. In this state, NPs have reduced practice, which requires physician collaboration\(^1\).

West Virginia allows both PAs and NPs to prescribe buprenorphine along with MDs. PA practice is determined at the practice level and requires physician supervision, similarly to NP practice requiring physician collaboration in this state. West Virginia has accepted Medicaid expansion and requires prior authorization for buprenorphine use. In this state, NPs have reduced practice, which requires physician collaboration\(^1\).

**Table 1.** Buprenorphine prescriptive ability by MD, PA, NP by state

<table>
<thead>
<tr>
<th>State</th>
<th>MD</th>
<th>PA</th>
<th>NP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tennessee</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Kentucky</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Ohio</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>West Virginia</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**3.3 Study Variables**

The primary independent variable of interest is the ability to prescribe buprenorphine by PAs and NPs within each state. This will be represented as a binary variable.

Table 2 lists the covariates that will be included in our study. Covariates will include: (1) Medicaid expansion, (2) prior authorization, (3) urbanicity, (4) number of OUD-related deaths, and the (5) number of OTPs providing buprenorphine. Medicaid expansion and prior authorization will be represented as a binary variable. Urbanicity will be represented as a binary variable, with the state being defined as metropolitan or nonmetropolitan as a sum of their representative counties. The number of OUD-related deaths will be a continuous variable, represented as a proportion over 100,000 residents.
The number of OTPs providing buprenorphine will be a continuous variable, represented as a proportion over 100,000 residents as well.

Our dependent variable will be a continuous variable representing the proportion of waivered providers per total providers in that state. This will be further organized by the patient capacity of the providers: up to 30, 100, or 275 patients.

We will also include a secondary outcome variable: the amount of buprenorphine dispensed.

**Table 2.** Covariates by state

<table>
<thead>
<tr>
<th>State</th>
<th>Medicaid expansion (Yes/No)</th>
<th>Prior authorization (Yes/No)</th>
<th>Urbanicity (Metropolitan/Nonmetropolitan)*</th>
<th># of OUD-related deaths*</th>
<th># of OTPs providing buprenorphine*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tennessee</td>
<td>No</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kentucky</td>
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<td>Yes</td>
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</tr>
<tr>
<td>Ohio</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>West Virginia</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Data to be input in the future upon study completion*

### 3.4 Data Collection

All of our data will be collected from publically accessible, online databases.

For the primary independent variable, the ability of PAs and NPs in prescribing buprenorphine is stated by the Scope of Practice Policy website maintained by the National Conference of State Legislatures (NCSL) and the Association of State and Territorial Health Officials (ASTHO)².

For the multiple covariates, the Kaiser Family Foundation provides up to date data on whether states have or have not adopted Medicaid expansion³. The American Society of Addiction Medicine (ASAM) provides State Medicaid Reports with
information on whether individual state policies require prior authorization for buprenorphine. The urbanicity of the states will be based on the Rural-Urban Continuum for counties within the state as defined the United States Department of Agriculture. The sum of the urbanicity of the individual counties will be calculated to determine urbanicity for the entire state. The number of OUD-related deaths is provided by the CDC Wide-ranging Online Data for Epidemiologic Research (WONDER) database. The number of OTPs providing buprenorphine will be obtained from the National Survey of Substance Abuse Treatment Services (N-SSATS) by state and year.

For the dependent variable, SAMHSA provides a database of all waivered providers, including physicians, PAs, and NPs for each state. The sum totals of waivered providers, organized by specific patient limits will also be provided by SAMHSA. The total numbers of providers will be obtained from the Area Health Resources Files (AHRF) maintained by the Health Resources and Services Administration. Both the total number of waivered providers and the proportion of waivered providers to total providers will be provided in Tables 3-5.

For the secondary outcome variable, the amount of buprenorphine dispensed by state is reported by the Automation of Reports and Consolidated Orders System (ARCOS) database.
### Table 3. Number of waivered providers by state, 2016

<table>
<thead>
<tr>
<th>Can PA/NP prescribe buprenorphine</th>
<th>State</th>
<th># of Providers with 30-patient limit</th>
<th># of Providers with 100-patient limit</th>
<th># of Providers with 275-patient limit</th>
<th>Total # of Waivered Providers</th>
<th>Mean (95% CI), Unadjusted and Adjusted*</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>Tennessee</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>Kentucky</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>Ohio</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>West Virginia</td>
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<td></td>
</tr>
</tbody>
</table>

*Proportion of waivered providers over total providers

### Table 4. Number of waivered providers by state, 2017

<table>
<thead>
<tr>
<th>Can PA/NP prescribe buprenorphine</th>
<th>State</th>
<th># of Providers with 30-patient limit</th>
<th># of Providers with 100-patient limit</th>
<th># of Providers with 275-patient limit</th>
<th>Total # of Waivered Providers</th>
<th>Mean (95% CI), Unadjusted and Adjusted*</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>Tennessee</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes (NP)</td>
<td>Kentucky</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes (PA, NP)</td>
<td>Ohio</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes (PA, NP)</td>
<td>West Virginia</td>
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<td></td>
</tr>
</tbody>
</table>

*Proportion of waivered providers over total providers

### Table 5. Number of waivered providers by state, 2018

<table>
<thead>
<tr>
<th>Can PA/NP prescribe buprenorphine</th>
<th>State</th>
<th># of Providers with 30-patient limit</th>
<th># of Providers with 100-patient limit</th>
<th># of Providers with 275-patient limit</th>
<th>Total # of Waivered Providers</th>
<th>Mean (95% CI), Unadjusted and Adjusted*</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>Tennessee</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes (NP)</td>
<td>Kentucky</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Yes (PA, NP)</td>
<td>Ohio</td>
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<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Yes (PA, NP)</td>
<td>West Virginia</td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

*Proportion of waivered providers over total providers

### 3.5 Statistical Analysis

We will use descriptive statistics to organize our data collected from online databases. Next, we will use multivariable linear regression to analyze differences in the
dependent variable, the proportion of waivered providers per total providers in that state, while adjusting for the multiple covariates. Finally, we will use one-way ANOVA to evaluate for trends over time, from 2016 to 2018. We will consider p < 0.05 to be statistically significant. Table 6 shows the independent variables and their associated estimated regression coefficients with p values.

**Table 6. Multivariate linear regression of the proportion of waivered providers**

<table>
<thead>
<tr>
<th>Independent Variable</th>
<th>Estimated Regression Coefficient</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>PAs and NPs’ buprenorphine prescriptive authority*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medicaid expansion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prior authorization</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urbanicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OUD-related deaths</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OTPs providing buprenorphine</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Key independent variable

### 3.6 Limitations

Our study has a few limitations. First, the list of providers provided by SAMHSA includes those that may not be practicing or prescribing buprenorphine to the fullest capacity. The listing is voluntary, so there may be waivered providers who have chosen not to be included in the list. Therefore, we are relying on the database to provide a reasonable approximation. In addition, different products containing buprenorphine may have different availability and insurance coverage within each state, although we anticipate that this will have a small effect on buprenorphine availability overall. We chose covariates based on our own literature review, so we are relying on our literature review on whether our chosen covariates are appropriate or essential covariates were left out. Using a multivariable linear regression as our study design will help to adjust for the known confounders.
Our findings represent a section of the United States with variability in buprenorphine prescription by PAs and NPs. More studies will need to be done to observe their role in buprenorphine prescription throughout the United States.

Lastly, as this is a cross sectional study, our findings will show correlation between the variables, not causation.
References:

Chapter 4 – Conclusion

4.1 Advantages

Our study has a number of advantages. First, it is the first analytical study to compare states with and without PA/NP buprenorphine prescriptive ability in the role in buprenorphine access. It can be repeated in future years for ongoing surveillance of the role of PAs and NPs, in impacting access to buprenorphine access, especially as state policies change over time. With the repeated cross-sectional design, it is possible to view the changes in buprenorphine access over time, as opposed to a static cross-sectional study. Moreover, with this study design, it can be conducted in “real time” as the data will be compiled from existing, publically accessible databases. Lastly, it is not a costly study design.

4.2 Disadvantages

Our study does have a few disadvantages. First, its generalizability is limited as we looked at four specific states; for this same reason, randomization is not possible. There are county-level differences within the states, which we did not address in our study as our focus was on state-level policies that affected buprenorphine access. Second, the findings will represent correlation, not causation due to our study design. Furthermore, there are multiple confounders that we will adjust for. As previously discussed, there is always the possibility that we left out essential covariates as it is based purely on our literature review.
4.3 Clinical and Public Health Significance

Increasing accessibility to OUD treatment, such as buprenorphine, is a topic that is gaining substantial attention, as evidenced by recent legislation such as CARA and SUPPORT for Patients and Communities Act.

We anticipate that our findings will help to inform state and federal policy changes to improve buprenorphine access by demonstrating the ongoing and future roles of PAs and NPs in expanding access to effective OUD treatment. It is already documented that state level policies can have major effects on buprenorphine access. Our study can inform political efforts designed to impact legislation in the states where PAs and NPs cannot prescribe buprenorphine. It is important to continue to recognize and document the benefits of utilizing the PAs and NPs to their full potential. Even in states where PAs and NPs already have the ability to become waivered, our study can raise awareness of the importance of the waiver process to PAs, NPs, and the physicians they work with.

More broadly, our findings may provide an example of how limitations on the scope of practice of PAs and NPs in certain states can have a detrimental effect on patients who lack access to healthcare. Moving forward, not only will it be critical to increase access to buprenorphine through PAs and NPs but also to support other states in expanding their Medicaid programs, decreasing restrictions such as prior authorization, and making it more efficient to obtain higher patient limits. A combination of these efforts and others can address the substantial morbidity and mortality associated with the opioid epidemic.
17. Andrilla CHA, Moore TE, Patterson DG, Larson EH. Geographic Distribution of Providers With a DEA Waiver to Prescribe Buprenorphine for the Treatment of Opioid Use Disorder: A 5-Year Update. The Journal of Rural Health. 0(0).
19. Andrilla CHA, Patterson DG, Moore TE, Coulthard C, Larson EH. Projected


31. Hutchinson E, Catlin M, Andrilla CH, Baldwin LM, Rosenblatt RA. Barriers to primary


49. Roman PM, Abraham AJ, Knudsen HK. Using medication-assisted treatment for...


