

Early Changes in Waivered Clinicians and Utilization of Buprenorphine for Opioid Use Disorder After Implementation of the 2021 HHS Buprenorphine Practice Guidelines

U.S. Department of Health and Human Services

December 2, 2022

Table of Contents

Introduction	2
Key Points	2
Contributors	3
Background	4
Data	6
Methods	7
Results	9
Discussion	14
Additional Data Tables	16
References	19

Introduction

Key Points

- In April 2021 the U.S. Department of Health and Human Services (HHS) issued new *Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder*, which removed certification requirements related to training, counseling and other ancillary services for obtaining a Drug Addiction Treatment Act (DATA) of 2000 waiver to prescribe buprenorphine for up to 30 patients.
- We used an interrupted time series (ITS) analysis to measure early changes in trends in the number of clinicians with a DATA waiver, and national trends in the number of people filling buprenorphine prescriptions for opioid use disorder (OUD), after the Practice Guidelines took effect.
- The Practice Guidelines were associated with an acceleration in the growth of waived clinicians. By the end of 2021, we estimate that this policy change was linked to an additional 5,830 providers certified to treat up to 30 patients -- about 16% more than what would have been expected given the trend prior to the Practice Guidelines. This corresponded to an increase in potential treatment capacity of about 174,900 patients.
- We did not observe an acceleration in buprenorphine uptake after the Practice Guidelines took effect, as measured by national estimates of the number of unique patients filling buprenorphine prescriptions for OUD each month.
- Additional time and policy efforts may be necessary for increased provider capacity to result in greater numbers of patients treated.

Contributors

This research brief was produced by the HHS Buprenorphine Practice Guidelines Evaluation Workgroup, comprised of staff from the Office of the Assistant Secretary for Planning and Evaluation (ASPE), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Centers for Disease Control and Prevention (CDC), the National Institutes of Health/National Institute on Drug Abuse (NIH/NIDA), the Food and Drug Administration (FDA), the Office of the Assistant Secretary for Health (OASH), the Agency for Healthcare Research and Quality (AHRQ), the Centers for Medicare & Medicaid Services (CMS) and the Health Resources and Services Administration (HRSA) as detailed below. ASPE and SAMHSA conducted the quantitative analyses, ASPE produced the initial draft of the research brief, and all agencies contributed towards study design, reviewing the findings, and producing the final research brief.

ASPE contributors: Mir M. Ali, Timothy Creedon, Laura Jacobus-Kantor, Tisamarie B. Sherry, Rebecca L. Haffajee

SAMHSA contributors: Robert Baillieu, Suparna Das, Neeraj Gandotra, Patti Juliana, Kasimu Muhetaer, Yngvild Olsen, Karran Phillips, Hamid Ferdosi

CDC contributors: Christopher Jones

NIH/NIDA contributors: Wilson Compton, Emily Einstein

FDA contributors: Grace Chai, Jana Mcaninch, Marta Sokolowska

OASH contributors: Meriam Mikre

AHRQ contributors: Elisabeth Kato

CMS contributors: Anita Thomas

HRSA contributors: Thomas Hassett

Background

An estimated 107,000 people in the United States (U.S.) lost their lives to a drug overdose in 2021 (CDC, 2022). Millions of other individuals experience the negative health and other personal consequences of substance use disorders (SUDs), while their families and communities also are affected by the public health, economic and social impacts of SUDs (SAMHSA, 2021a; Rhyan, 2017; Florence et al., 2016). Currently, synthetic opioids such as fentanyl are the drugs most commonly involved in overdose deaths (CDC, 2022). Medications for OUD (MOUD), including buprenorphine, methadone and extended-release naltrexone, are effective treatments that reduce overdose mortality and the other harmful health consequences of OUD (Larochelle et al., 2018). The majority of people with OUD, however, do not receive MOUD, in part because treatment availability is limited, inaccessible or both to many who need it (Madras et al., 2020).

Surveys of health care providers have identified a number of reasons why MOUD availability has not kept pace with the growing prevalence of OUD and need for treatment. Among these, the requirement to obtain a Drug Addiction Treatment Act (DATA) of 2000 waiver in order to prescribe buprenorphine for the treatment of OUD in office-based settings, and the associated administrative and training requirements involved with obtaining such a waiver, are commonly cited barriers (Foti et al., 2021). Since the enactment of DATA over two decades ago, recent policy changes have eased restrictions on buprenorphine prescribing, for example by expanding the types of clinicians eligible to obtain a waiver, expanding patient limits for waived clinicians, and allowing waived clinicians to remotely initiate buprenorphine through telehealth during the COVID-19 pandemic (Haffajee, Bohnert, & Lagisetty, 2018). Together these policy changes have significantly expanded the number of waived providers (Ghertner & Ali, 2020), and the number of people who receive buprenorphine for OUD treatment (Wen, Borders & Cummings, 2019; Olfson et al., 2020). Still, a large unmet need remains. As of 2020, it was estimated that 9% of people lived more than 10 miles away from the nearest waived provider (Langabeer et al., 2020), and over one-third of rural counties still lacked a waived practitioner altogether (Andrilla & Patterson, 2022). The majority of clinicians who are eligible to obtain a waiver have not done so. For example, of the approximately 1,000,000 currently licensed physicians in the U.S. (Young et al., 2021), fewer than 93,000 have a DATA waiver as of November 2022 (SAMHSA, 2022).

Recognizing the urgent need to further expand access to MOUD, in April 2021 HHS further eased requirements and simplified the process for obtaining a DATA waiver by issuing revised *Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder* (Practice Guidelines). The revised Practice Guidelines removed two longstanding requirements for obtaining a waiver to treat up to 30 patients: the requirement for specific training (8 hours for physicians, 24 hours for physician assistants, nurse practitioners, certified nurse midwives, certified registered nurse anesthetists, and clinical nurse specialists); and the need for otherwise eligible clinicians to certify their ability to provide or refer for counseling or other ancillary services (e.g., psychosocial services). SAMHSA developed a new 30E waiver category to distinguish clinicians certified under the new Practice Guidelines (i.e., those who are exempt from the certification requirements related to training, counseling and other ancillary services) from those seeking to obtain a waiver through the traditional pathway (i.e., 30, 100, 275/275E) -- where the numbers refer to how many patients a provider may treat under each pathway.

Several recent studies have examined trends in the number of waived health care providers before and after the release of the revised Practice Guidelines. Spetz and colleagues present descriptive trends in the overall number of waived clinicians in the eight months following the implementation of the

Practice Guidelines (Spetz et al., 2022a), as well as descriptive trends in the number of waivers by provider type (Spetz et al., 2022b). Nguyen and colleagues compared changes in the number of waived clinicians in urban and rural counties in the year following the release of the Practice Guidelines, and found larger growth in urban counties and counties with higher numbers of waived clinicians per capita at baseline (Nguyen et al., 2022). These studies demonstrate that the number of waived clinicians has been increasing over time, and that this continued during the COVID-19 pandemic and after the introduction of the Practice Guidelines. They did not, however, examine whether the Practice Guidelines were linked to a statistically significant change in the rate of waiver uptake among eligible clinicians compared to prior trends. They also did not examine whether the Practice Guidelines were linked to changes in the number of people receiving buprenorphine for OUD treatment. This brief addresses both of these research questions by examining changes in clinician waiver uptake and the number of patients receiving buprenorphine from pharmacies for OUD treatment in the early months after the Practice Guidelines took effect (i.e., between June 2021 and December 2021).

Data

We used two sources of data for this analysis: the SAMHSA Buprenorphine Waiver Notification System (BWNS) and IQVIA's Total Patient Tracker (TPT). Data from both sources were national, included monthly counts, and covered January 2019 through December 2021.

Provider information was drawn from the BWNS, a record-keeping program of SAMHSA that documents all providers in the U.S. and U.S. territories with DATA waivers to prescribe buprenorphine for OUD, including both those who have provided permission to be listed in SAMHSA's publicly-facing Buprenorphine Treatment Locator web tool, as well as those that elect not to have their names and information listed there. In this study, we used the totality of BWNS data to measure our provider-level outcome: the total monthly counts of providers certified to treat 30 patients (i.e., those with a waiver in either the 30 or 30E categories). As a secondary provider-level outcome, we also examined the total monthly counts of providers certified to prescribe buprenorphine for OUD across all waiver categories (30/30E, 100, and 275/275E).¹

TPT data from IQVIA capture the total number of unique U.S. patients receiving any prescription medications across all therapeutic classes dispensed in outpatient, retail settings, representing 92% of prescriptions dispensed from U.S. retail pharmacies. TPT eliminates duplicate patients and multiple prescription fills, allowing measurement of unique patient counts on a monthly basis. In this study, we used the TPT data to measure the total number of patients who were prescribed buprenorphine for OUD each month.

¹ Providers certified in the 30 or 30E categories can treat up to 30 patients with buprenorphine for OUD; the difference between these categories, as discussed above, is that 30E providers are exempted from the federal certification requirements related to training, counseling and other ancillary services. Providers certified in the 100 category can treat up to 100 patients. To be eligible for a waiver in the 100 category, providers must have either possessed a waiver in the 30 category for at least one year, or have met certain other requirements (i.e., additional credentialing in addiction psychiatry or addiction medicine, or providing MOUD in a "qualified practice setting" that offers coverage for medical emergencies after-hours, case management, uses health information technology systems, accepts third-party payment and is registered with their state prescription drug monitoring program). Providers certified in the 275 or 275E categories can treat up to 275 patients. To be eligible for a waiver in the 275 category, providers must have possessed a waiver in the 100 category for at least one year, hold additional credentialing in addiction psychiatry or addiction medicine, or provide MOUD in a "qualified practice setting" as defined above. Finally, the 275E category is reserved for providers who are approved to treat up to 275 patients with buprenorphine for OUD on a temporary basis only (six months) in order to address emergency situations (i.e., when the SUD treatment system is unable to meet the need for MOUD due to an abrupt onset, precipitating event).

Methods

We used an ITS approach to model changes over time in the number of waived providers and the number of patients receiving buprenorphine. ITS analysis is a quasi-experimental research design well-suited for cases where a longitudinal series of pre- and post-intervention data are available, but there is no suitable contemporaneous control or comparison group (Shadish, Cook, & Campbell, 2002; Wagner et al., 2002; Kontopantelis et al., 2015; Bernal, Cummins, & Gasparrini et al., 2017). Since the updated Practice Guidelines constituted a large-scale policy intervention that took effect throughout the U.S. on the same date, no contemporaneous comparison group was available and ITS was therefore considered a suitable research design for evaluating changes in trends in the number of waived providers and patients treated associated with the updated Practice Guidelines. Though the updated Practice Guidelines were announced in late April 2021 and eligible clinicians could immediately submit applications for the new 30E waiver category, due to software revisions required to accommodate the revised guidelines, June 2021 was the earliest month in which clinicians were newly certified under the Practice Guidelines and was therefore considered the first month in which the policy intervention could produce changes in the outcome measures of interest (i.e., the number of waived providers and the number of unique patients filling buprenorphine prescriptions). The COVID-19 pandemic preceded the revised Practice Guidelines and affected the entire U.S., resulting in disruptions in medical care overall (Czeisler et al., 2020; Anderson et al., 2021) and OUD treatment delivery specifically (Huskamp et al., 2020; Ali et al., 2023). To account for the effects of the pandemic and to accurately distinguish the impacts of the subsequent Practice Guidelines, our ITS model allowed for changes in trends corresponding to the time period from the start of the COVID-19 pandemic up until the Practice Guidelines took effect (i.e., from March 2020 through the end of May 2021).

ITS analysis allows for estimation of both immediate (level) changes as well as gradual trend (slope) changes. We hypothesized that potential COVID-19 pandemic effects would have different patterns vary between study outcomes. With respect to changes in the number of DATA waived providers, we expected to find that the pandemic caused slope changes but not level changes, assuming any pandemic effects on waiver applications would be more gradual than immediate. For changes in the number of patients with dispensed buprenorphine prescriptions, however, we expected both level and slope changes, with level changes resulting from immediate disruptions in treatment delivery due to pandemic mitigation measures (e.g., social distancing restrictions), and slope changes resulting from more delayed impacts of the pandemic on the OUD treatment delivery landscape (e.g., expansion in telehealth, gradual easing of pandemic mitigation measures).

In contrast, we hypothesized that the release of the Practice Guidelines was associated only with changes in slope in both outcome measures. Eligible clinicians might not have become aware of the policy change for some time after its announcement, or might not have been able/interested in submitting a waiver application immediately. Increases in the number of people receiving treatment are expected to occur even more gradually, as they must present for care, be recognized by clinicians as having OUD, and initiated on buprenorphine. Accordingly, the following equation summarizes our ITS model specifications:

$$Y_t = \beta_0 + \beta_1 Time1_t + \beta_2 Covid_t + \beta_3 Time2_t + \beta_4 Time3_t + \varepsilon_t,$$

where Y_t is the outcome variable (either the combined number of 30 and 30E-level waived providers, or the number of patients dispensed buprenorphine prescriptions for OUD from pharmacies) measured at each monthly time point t ; $Time1_t$ is the time since the start of observation (where January 2019=0);

$Covid_t$ is a dummy (indicator) variable representing the COVID-19 pandemic period (0=pre-March 2020, 1=March 2020 and later); $Time2_t$ is a linear spline for measuring a COVID-related change in slope, equal to 0 for January 2019 through March 2020 and ranging from 1 to 21 for April 2020 through December 2021; $Time3_t$ is a second linear spline for measuring the Practice Guidelines-related change in slope, equal to 0 for January 2019 through June 2021 and ranging from 1 to 6 for July through December 2021; and ε_t is the error term. Where appropriate (if there was an expectation that the outcome would vary in association with the length of the month), we also controlled for the number of days in each month (using two indicator variables to compare months with 28 or 29 days and months with 30 days to months with 31 days). The models were estimated to test for: (1) a one-time change immediately after the COVID-19 pandemic public health emergency was declared in the U.S. (intercept/level change; β_2); (2) the change in slope from before to during the first 15 months of the COVID-19 pandemic, before the Practice Guidelines took effect (β_3); and (3) the change in slope from the COVID-19 pandemic period (of March 2020 through May 2021) to after the Practice Guidelines took effect (β_4). We used ordinary least squares regression with Newey-West standard errors to account for autocorrelated errors.

Results

Figure 1 (observed data points and unadjusted model predictions) and **Table 1** (adjusted model estimates) show that the number of providers certified to prescribe buprenorphine for OUD to up to 30 patients (i.e., providers in the 30 waiver category) increased in the pre-pandemic period by about 1,135 providers per month ($p < 0.001$) and that this upward trend continued after the start of the pandemic, but at a slower rate of about 719 providers per month ($p < 0.001$), a 63% reduction from the pre-pandemic rate of increase. The reduction in slope was statistically significant (about 416 fewer providers per month, $p < 0.001$). Following the release of the Practice Guidelines through the end of 2021, the number of providers with waivers to prescribe to up to 30 patients (i.e., providers in either the 30 or 30E waiver categories) increased by an average of about 1,552 providers per month ($p < 0.001$). This represents a statistically significant increase in the monthly growth of waived providers, both compared to the pandemic time period (about a 116% faster increase, or about 833 additional providers per month certified at the 30/30E level after the Practice Guidelines, $p < 0.001$), and the pre-pandemic period of January 2019 through March 2020 (about a 37% faster increase, or about 415 additional providers per month certified at the 30/30E level after the Practice Guidelines, $p < 0.001$). As of December 2021, a total of 8,765 providers had been certified under the new 30E waiver category. We observe a similar pattern when using our ITS model to analyze changes in the total number of providers with waivers, across all categories (i.e., 30, 30E, 100, 275, or 275E) (**Table 1**).

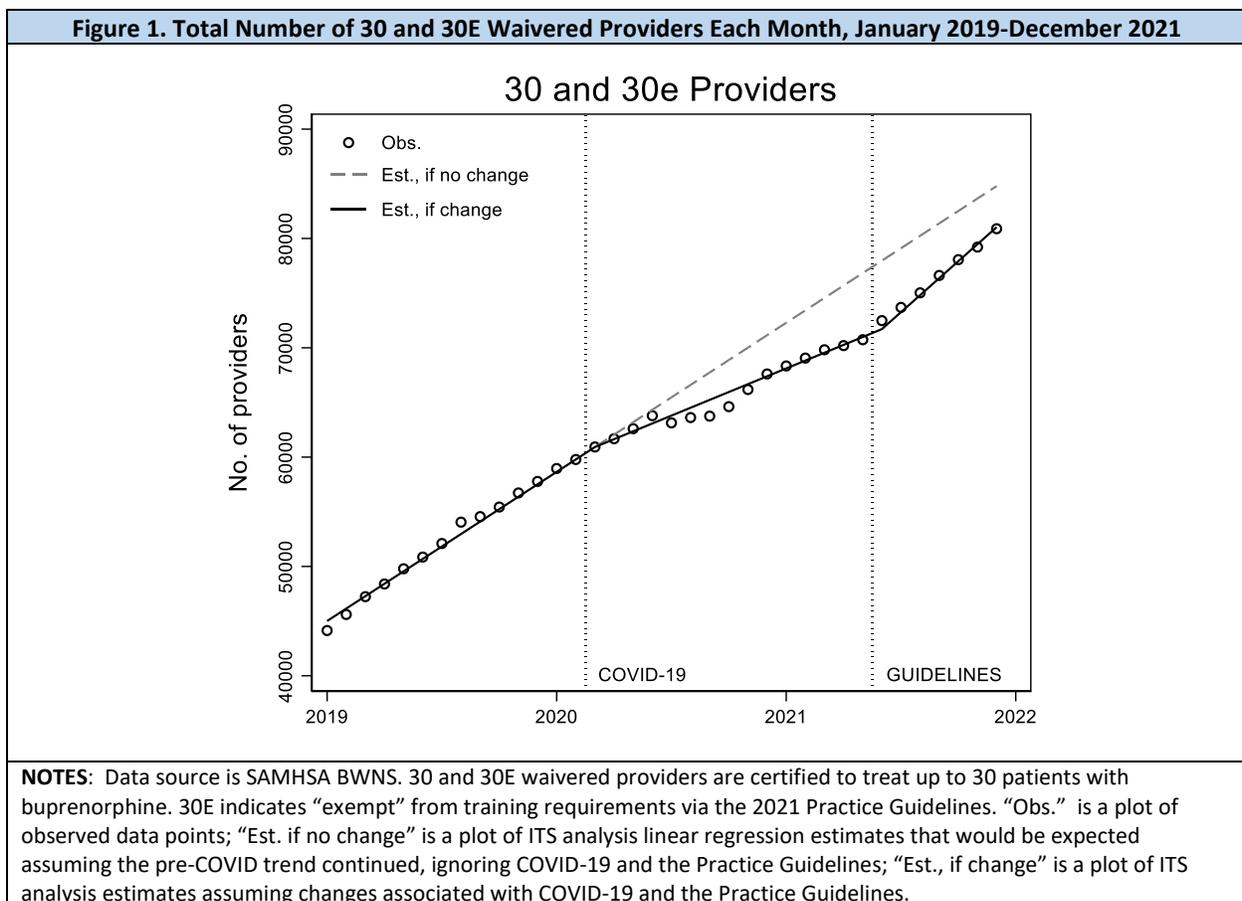
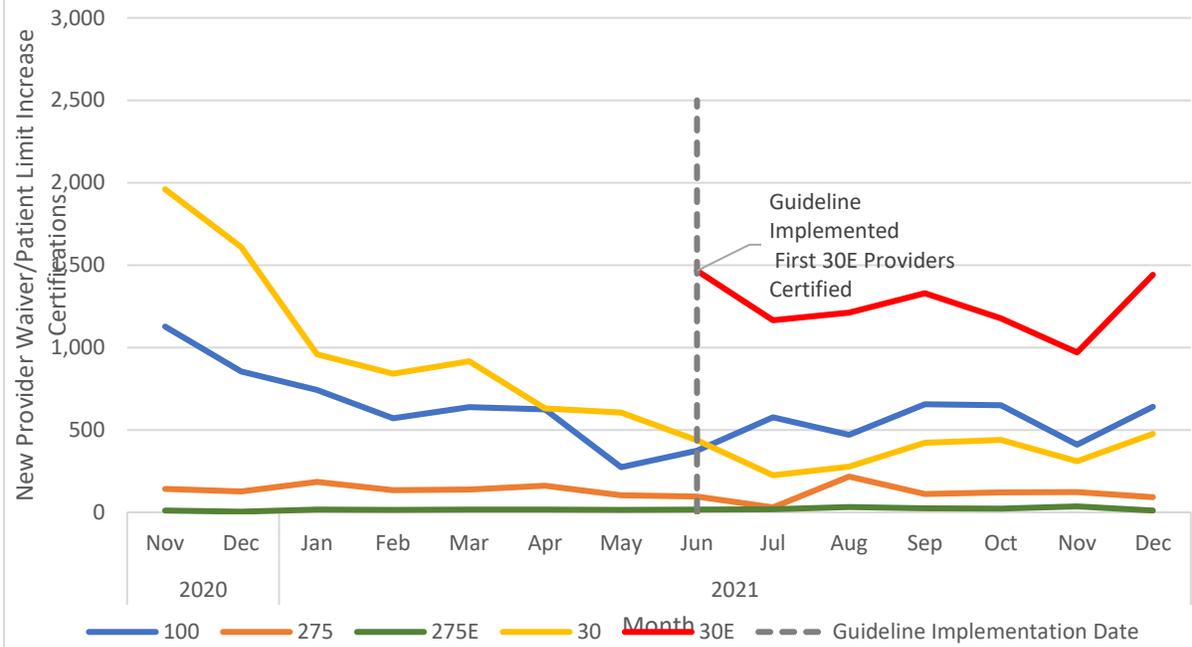


Table 1. Adjusted ITS Model of the Total Monthly Number of Waivered Providers						
	30 and 30E Providers			All Providers		
	Coef.	SE	P	Coef.	SE	P
Intercept	45016.29	338.20	<0.001	60258.29	204.53	<0.001
Slopes						
Pre-COVID	1135.69	33.58	<0.001	1524.45	34.00	<0.001
Post-COVID	719.08	20.93	<0.001	1363.79	24.65	<0.001
Post-PG	1552.06	59.24	<0.001	2055.47	70.67	<0.001
Slope changes						
COVID vs. pre-COVID	-416.62	48.02	<0.001	-160.66	52.53	0.005
Post-PG vs. pre-COVID	416.37	72.43	<0.001	531.02	89.61	<0.001
Post-PG vs. COVID	832.99	72.24	<0.001	691.68	84.98	<0.001
Level changes						
COVID vs. pre-COVID	---	---	---	---	---	---
Post-PG vs. COVID	---	---	---	---	---	---
Days per month (ref. = 31)						
28-29	-102.72	221.77	0.647	155.25	202.01	0.448
30	40.29	170.85	0.815	1.35	186.74	0.994
N	36			36		
Lags	1			4		
NOTES: Data source is SAMHSA BWNS. ITS analysis using ordinary least squares regression with Newey-West standard errors to account for autocorrelation. Abbreviations are as follows: PG, Practice Guidelines; Coef., coefficient (est. no. of providers); SE, standard error; P, p-value.						

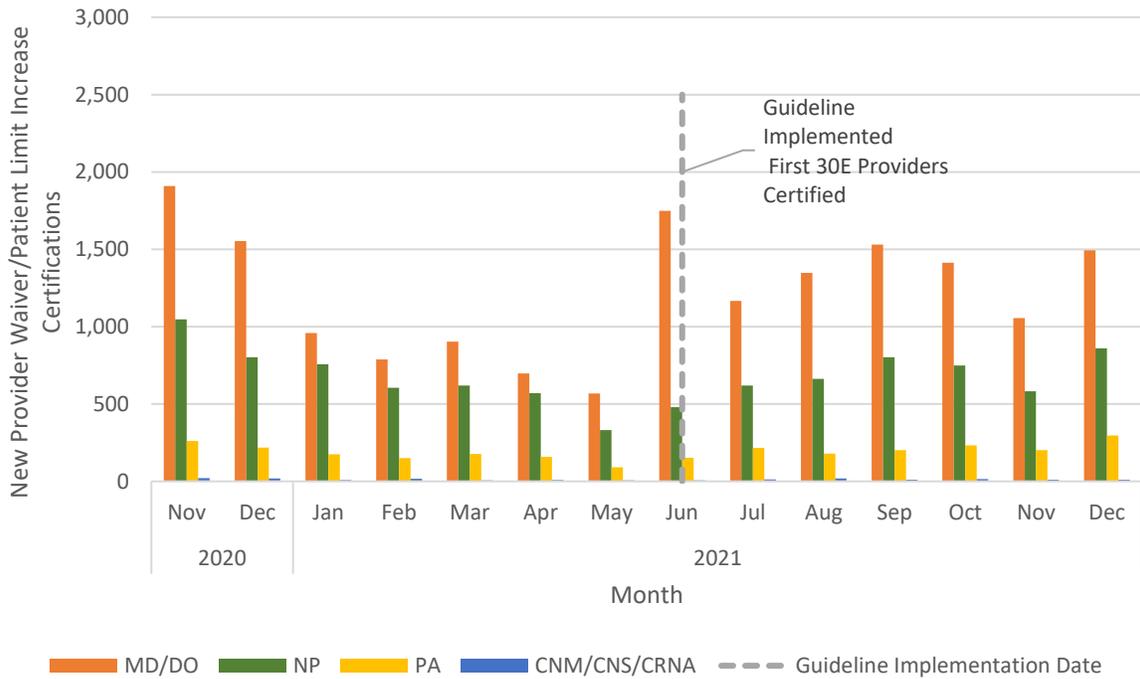
Figures 2 and 3 illustrate how the composition of the group of providers who were either newly waived or newly certified at a higher patient limit changed in the seven months preceding and following the release of the revised Practice Guidelines, by waiver category (**Figure 2**) and provider type (**Figure 3**). The majority of providers who were either newly waived or newly certified at a higher patient limit in the seven months after the Practice Guidelines took effect were certified in the newly created 30E category (**Figure 2**). Compared to the seven months preceding the Practice Guidelines change, in the seven months following the change a slightly larger share of providers who were either newly waived or newly certified at a higher patient limit were physicians (61% compared to 54% in the seven months preceding the Practice Guidelines change) (**Figure 3**).

Figure 2. Providers Newly Waivered or Certified at a Higher Patient Limit by Waiver Level, November 2020-December 2021



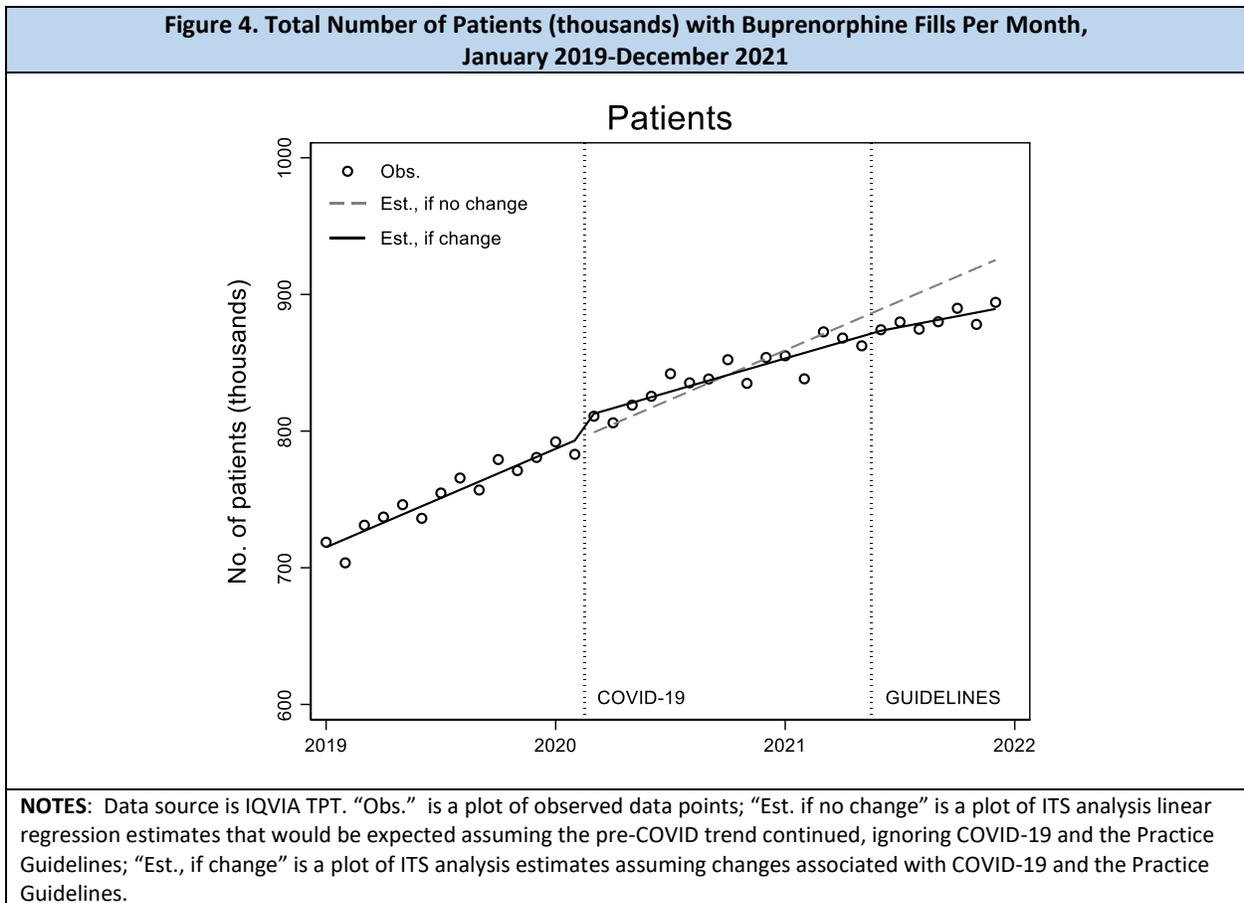
NOTES: Analysis of SAMHSA BWNS data.

Figure 3. Providers Newly Waivered or Certified at a Higher Patient Limit by Provider Type, November 2020-December 2021



NOTES: Analysis of SAMHSA BWNS data.

Figure 4 (observed data points and unadjusted model predictions) and **Table 2** (adjusted model estimates) show that the number of unique patients with filled buprenorphine prescriptions was increasing in the pre-pandemic period at a rate of about 6,100 additional patients per month ($p < 0.001$). At the start of the pandemic, in March 2020, there was a statistically significant, immediate upward shift in the number of unique patients with buprenorphine prescription fills per month of about 10,720 ($p = 0.016$). During the pandemic, however, the rate of increase in the total number of unique patients dispensed buprenorphine for OUD slowed to about 4,180 patients per month ($p < 0.001$), or about 1,920 fewer patients per month compared to the pre-pandemic rate (a reduction of about 31%). The rate of increase continued to slow after the release of the Practice Guidelines, with about 3,880 fewer patients (63% fewer) having buprenorphine fills each month compared to the pre-COVID rate ($p < 0.001$) and about 1,960 fewer patients (47% fewer) compared to the first 15 months of COVID-19 ($p = 0.009$). This amounted to a slower, but still increasing post-Practice Guidelines rate of about 2,220 additional patients with buprenorphine fills per month ($p < 0.001$).



We conducted several sensitivity analyses to assess the validity of our estimates (e.g., models with and without level parameters, lags of different lengths, and models examining changes in non-30E providers following the Practice Guidelines) and we report these results in the **Additional Data Tables**. Notably, **Table A3** shows that the acceleration in waiver uptake following the release of the revised Practice Guidelines was restricted to the 30 and 30E waiver categories; the absence of an acceleration in waiver uptake among non-30/30E waiver categories provides additional evidence that our findings do not

reflect secular patterns in waiver uptake and strengthens the potential linkage to the revised Practice Guidelines.

Table 2. Adjusted ITS Model of the Total Monthly Number of Patients (thousands) with Buprenorphine Fills for OUD			
	Patients		
	Coef.	SE	P
Intercept	719.43	1.58	<0.001
Slopes			
Pre-COVID	6.10	0.20	<0.001
COVID	4.18	0.30	<0.001
Post-PG	2.22	0.45	<0.001
Slope changes			
COVID vs. pre-COVID	-1.92	0.33	<0.001
Post-PG vs. pre-COVID	-3.88	0.52	<0.001
Post-PG vs. COVID	-1.96	0.70	0.009
Level changes			
COVID vs. pre-COVID	10.72	4.17	0.016
Post-PG vs. COVID	---	---	---
Days per month (ref. = 31)			
28-29	-20.27	2.56	<0.001
30	-7.42	1.94	0.001
N	36		
Lags	2		
NOTES: Data source is IQVIA TPT. ITS analysis using ordinary least squares regression with Newey-West standard errors to account for autocorrelation. Abbreviations are as follows: PG, Practice Guidelines; Coef., coefficient (est. no. of patients in thousands); SE, standard error; P, p-value.			

Discussion

The number of providers with waivers to prescribe buprenorphine for OUD has been increasing over time, but gaps in access to and provision of MOUD remain, and current provision of MOUD is insufficient to meet the high level of need (Madras et al., 2020; SAMHSA, 2021b). The training and administrative requirements for obtaining a DATA waiver have been identified as a potential barrier to recruiting additional providers to prescribe buprenorphine for the treatment of OUD (Foti et al., 2021), and this prompted HHS's 2021 updated buprenorphine Practice Guidelines, which removed several of these requirements. We find that the Practice Guidelines were associated with an acceleration in waiver uptake by eligible clinicians in the first seven months after the policy change was introduced, reversing the slowing rate of uptake noted in the initial months of the COVID-19 pandemic. From June 2021 through the end of December 2021, we estimate that on average, 833 additional providers per month obtained a waiver to treat up to 30 patients compared to what we would have observed in the absence of the Practice Guidelines change -- an increase of about 116% over the rate during the first 15 months of the pandemic. This represents an estimated additional 5,830 providers certified at the 30 or 30E levels during this timeframe, corresponding to an increase in potential treatment capacity of 174,900 patients.

Our findings differ from those reported by Spetz and colleagues in their two recently published studies (Spetz et al., 2022a; Spetz et al., 2022b). Our analytic approach differs from these two studies, in that we formally model trends in the number of waived clinicians and test for statistically significant trend changes using an ITS framework, whereas the studies by Spetz and colleagues report descriptive trends only. However, the main source of the discrepancy in our findings appears to be in the underlying data: Spetz and colleagues report a substantially lower number of waived clinicians than we find in the BWNS data. For example, Exhibit 2 in Spetz et al. (2022b) indicates that by the end of 2021 there were approximately 100,000 waived clinicians in total, across all waiver categories; in the BWNS data, however, as of December 2021 there were 114,374 waived clinicians in total. We confirmed the accuracy of the BWNS totals by examining data on waived clinicians provided by the DEA; further, we cross-validated our ITS findings using the DEA data. We are uncertain of the source for Spetz and colleagues' estimates of the number of waived clinicians and why these are lower than those in the BWNS or DEA data. We also note that the recently published study by Nguyen and colleagues (2022), which uses data from the Controlled Substances Act Registration Information Database, reports a total number of waived clinicians that is similar to the BWNS data used in this study (they report 114,493 waived clinicians in total in the first quarter of 2022).

Despite our finding of a substantial increase in potential treatment capacity following the Practice Guidelines change, we do not find an acceleration at a national level in the number of patients with OUD filling buprenorphine prescriptions following release of the Practice Guidelines. There are several possible explanations for this discrepancy. After obtaining a waiver, it may take clinicians additional time to engage people with OUD in treatment -- positive impacts of the Practice Guidelines on the number of people treated with buprenorphine are therefore expected to lag behind the increase in the number of waived clinicians, so it may be too early to detect these changes in the first seven months following implementation. It is also possible that additional barriers to the use of buprenorphine to treat OUD beyond the availability of waived clinicians could be hindering treatment uptake. Several barriers that have been documented in the research literature include stigma towards people with SUDs, insufficient knowledge among health care providers about the effectiveness of MOUD, providers' lack of clinical experience in diagnosing and managing OUD, administrative burdens associated with providing MOUD (e.g., prior authorizations), insufficient reimbursement for SUD treatment, and inadequate institutional

supports including limited integration of OUD treatment into clinical workflows (Cao et al., 2020; Cioe et al., 2020; Haffajee, Bohnert, & Lagisetty, 2018; Lister et al., 2020; Sharma et al., 2017). Finally, some states may have existing policies in place (e.g., training and attestation requirements) that do not align with HHS's 2021 Practice Guidelines and could create confusion and persistent barriers for providers who otherwise would be eligible to prescribe buprenorphine under the new guidelines (Silwal et al., 2022).

Our analysis has limitations. IQVIA's TPT data is limited to prescriptions filled in retail pharmacies, so we do not observe people who are administered buprenorphine by opioid treatment programs (OTPs), nor do we observe people who are administered buprenorphine in emergency departments or during inpatient hospitalizations. It is unlikely that the omission of OTPs would meaningfully change the direction of our findings: we are unaware of any evidence that buprenorphine administration in OTPs increased substantially during our study period, and such shifts would only confound our estimates if they coincided with the release of the Practice Guidelines. Determining whether the Practice Guidelines increased emergency department-based or inpatient initiation of buprenorphine for OUD is an important question for further study -- however, retail prescriptions, which are captured in our data, are a more meaningful indicator of ongoing treatment retention. Additionally, the analyses performed focused on changes in the dispensing of buprenorphine at a national level given the changes in federal guidelines; patterns may vary by state, in part due to heterogeneity in state-level policies. Importantly, the lack of a comparison group and assumption of linear trends limits our ability to identify definitive causal relationships between the Practice Guidelines and our outcomes.

These early findings suggest that HHS's 2021 *Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder* were associated with progress towards a key goal of the Department's Overdose Prevention Strategy (Haffajee et al., 2021): to expand the capacity of health care providers to deliver evidence-based SUD treatment. We have not yet observed, however, an acceleration in the growth of patients receiving buprenorphine for OUD. HHS will continue to monitor the impacts of the Practice Guidelines and how these evolve over time, while pursuing additional strategies to remove patient and clinician barriers to SUD treatment.

Additional Data Tables

Tables in this section display the results of sensitivity analyses for provider models.

Table A1. Alternative ITS Models Estimating Changes in 30/30E Providers									
	30/30E Providers ^a			30/30E Providers ^b			30/30E Providers ^c		
	Coef.	SE	P	Coef.	SE	P	Coef.	SE	P
Intercept	45016.29	338.20	<0.001	44759.82	244.76	<0.001	44762.90	256.10	<0.001
Slopes									
Pre-COVID	1135.69	33.58	<0.001	1198.22	27.62	<0.001	1197.96	29.72	<0.001
Post-COVID	719.08	20.93	<0.001	757.59	35.08	<0.001	727.36	35.38	<0.001
Post-PG	1552.06	59.24	<0.001	1513.46	43.88	<0.001	1403.90	13.70	<0.001
Slope changes									
COVID vs. pre-COVID	-416.62	48.02	<0.001	-440.63	38.77	<0.001	-470.60	38.72	<0.001
Post-PG vs. pre-COVID	416.37	72.43	<0.001	315.24	55.26	<0.001	205.94	32.56	<0.001
Post-PG vs. COVID	832.99	72.24	<0.001	755.87	67.78	<0.001	676.53	42.63	<0.001
Level changes									
COVID vs. pre-COVID	---	---	---	-1032.19	555.45	0.073	-879.85	506.72	0.093
Post-PG vs. COVID	---	---	---	---	---	---	789.65	291.66	0.011
Days per month (ref. = 31)									
28-29	-102.72	221.77	0.647	-226.98	221.94	0.315	-167.56	242.18	0.495
30	40.29	170.85	0.815	47.63	143.17	0.742	13.09	124.48	0.917
N	36			36			36		
Lags	1			4			5		
<p>NOTES: Data source is SAMHSA BWNS. ITS analysis using ordinary least squares regression with Newey-West standard errors to account for autocorrelation. Abbreviations are as follows: PG, Practice Guidelines; Coef., coefficient (est. no. of providers); SE, standard error; P, p-value.</p> <p>^a These results are the same as those displayed in Table 1, and represent our preferred specification (i.e., the COVID-19 pandemic and the Practice Guidelines can produce changes in the slope of the outcome variable, but not immediate level changes).</p> <p>^b In this alternative specification, the COVID-19 pandemic can also produce immediate level changes in the outcome variable.</p> <p>^c In this alternative specification, both the COVID-19 pandemic and the Practice Guidelines can also produce immediate level changes in the outcome variable.</p>									

Table A2. Alternative ITS Models Estimating Changes in Total Waivered Providers									
	All Providers^a			All Providers^b			All Providers^c		
	Coef.	SE	P	Coef.	SE	P	Coef.	SE	P
Intercept	60258.29	204.53	<0.001	60163.63	115.52	<0.001	60165.47	112.79	<0.001
Slopes									
Pre-COVID	1524.45	34.00	<0.001	1547.53	12.03	<0.001	1547.37	12.71	<0.001
Post-COVID	1363.79	24.65	<0.001	1378.01	44.74	<0.001	1359.90	53.10	<0.001
Post-PG	2055.47	70.67	<0.001	2041.22	64.23	<0.001	1975.58	15.44	<0.001
Slope changes									
COVID vs. pre-COVID	-160.66	52.53	0.005	-169.52	43.34	0.001	-187.48	50.99	0.001
Post-PG vs. pre-COVID	531.02	89.61	<0.001	493.69	66.81	<0.001	428.21	20.35	<0.001
Post-PG vs. COVID	691.68	84.98	<0.001	663.21	92.72	<0.001	615.69	61.67	<0.001
Level changes									
COVID vs. pre-COVID	---	---	---	-380.97	614.90	0.540	-289.71	561.97	0.610
Post-PG vs. COVID	---	---	---	---	---	---	473.05	469.84	0.323
Days per month (ref. = 31)									
28-29	155.25	202.01	0.448	109.38	187.83	0.565	144.99	201.60	0.478
30	1.35	186.74	0.994	4.06	189.61	0.983	-16.64	167.31	0.922
N	36			36			36		
Lags	4			4			5		
<p>NOTES: Data source is SAMHSA BWNS. ITS analysis using ordinary least squares regression with Newey-West standard errors to account for autocorrelation. PG, Practice Guidelines, Coef., coefficient (est. no. of providers); SE, standard error; P, p-value. All Providers includes those waived at all levels (30, 30E, 100, 275 and 275E).</p> <p>^a These results are the same as those displayed in Table 1, and represent our preferred specification (i.e., the COVID-19 pandemic and the Practice Guidelines can produce changes in the slope of the outcome variable, but not immediate level changes).</p> <p>^b In this alternative specification, the COVID-19 pandemic can also produce immediate level changes in the outcome variable.</p> <p>^c In this alternative specification, both the COVID-19 pandemic and the Practice Guidelines can also produce immediate level changes in the outcome variable.</p>									

Table A3. Adjusted ITS Model Estimating Changes of 30/30E Providers and Non-30/30E Providers						
	30/30E Providers^a			Non-30/30E Providers^b		
	Coef.	SE	P	Coef.	SE	P
Intercept	45016.29	338.20	<0.001	15242.00	254.92	<0.001
Slopes						
Pre-COVID	1135.69	33.58	<0.001	388.76	23.63	<0.001
Post-COVID	719.08	20.93	<0.001	644.72	17.68	<0.001
Post-PG	1552.06	59.24	<0.001	503.41	30.52	<0.001
Slope changes						
COVID vs. pre-COVID	-416.62	48.02	<0.001	255.96	37.34	0.005
Post-PG vs. pre-COVID	416.37	72.43	<0.001	114.65	33.76	<0.001
Post-PG vs. COVID	832.99	72.24	<0.001	-141.31	44.80	<0.001
Level changes						
COVID vs. pre-COVID	---	---	---	---	---	---
Post-PG vs. COVID	---	---	---	---	---	---
Days per month (ref. = 31)						
28-29	-102.72	221.77	0.647	257.97	126.51	0.050
30	40.29	170.85	0.815	-38.94	72.41	0.595
N	36			36		
Lags	1			5		
<p>NOTES: Data source is SAMHSA BWNS. ITS analysis using ordinary least squares regression with Newey-West standard errors to account for autocorrelation. Abbreviations are as follows: PG, Practice Guidelines; Coef., coefficient (est. no. of providers); SE, standard error; P, p-value.</p> <p>^a The 30/30E provider results are the same as those displayed in Table 1.</p> <p>^b Non-30/30E providers are those waived at the 100, 275 and 275E levels.</p>						

References

- Ali MM, Creedon TB, Jacobus-Kantor L, Sherry TB. National trends in buprenorphine prescribing before and during the COVID-19 pandemic. *J Subst Abuse Treat.* 2023; 144: 108923. doi:10.1016/j.jsat.2022.108923.
- Anderson KE, McGinty EE, Presskreischer R, Barry CL. Reports of foregone medical care among US adults during the initial phase of the COVID-19 pandemic. *JAMA Netw Open.* 2021; 4(1): e2034882. doi:10.1001/jamanetworkopen.2020.34882.
- Andrilla CHA, Patterson DG. Tracking the geographic distribution and growth of clinicians with a DEA waiver to prescribe buprenorphine to treat opioid use disorder. *J Rural Health.* 2022; 38(1): 87-92. doi:10.1111/jrh.12569.
- Bernal JL, Cummins S, Gasparrini A. Interrupted time series regression for the evaluation of public health interventions: A tutorial. *Int J Epidemiol.* 2017; 46(1): 348-355. doi:10.1093/ije/dyw098. [Published correction appears in *Int J Epidemiol.* 2020; 49(4): 1414.]
- Cao SS, Dunham SI, Simpson SA. Prescribing buprenorphine for opioid use disorders in the ED: A review of best practices, barriers, and future directions. *Open Access Emerg Med.* 2020; 12: 261-274. doi:10.2147/OAEM.S267416.
- Centers for Disease Control and Prevention (CDC). *U.S. Overdose Deaths In 2021 Increased Half as Much as in 2020 -- But Are Still Up 15%.* 2022. https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2022/202205.htm. Accessed November 10, 2022.
- Cioe K, Biondi BE, Easley R, Simard A, Zheng X, Springer SA. A systematic review of patients' and providers' perspectives of medications for treatment of opioid use disorder. *J Subst Abuse Treat.* 2020; 119: 108146. doi:10.1016/j.jsat.2020.108146.
- Czeisler ME, Marynak K, Clarke KEN, Salah Z, Shakya I, Thierry JM, Ali N, McMillan H, Wiley JF, Weaver MD, Czeisler CA, Rajaratnam SMW, Howard ME. Delay or avoidance of medical care because of COVID-19-related concerns -- United States, June 2020. *MMWR Morb Mortal Wkly Rep.* 2020; 69: 1250-1257. doi:10.15585/mmwr.mm6936a4.
- Florence CS, Zhou C, Luo F, Xu L. The economic burden of prescription opioid overdose, abuse, and dependence in the United States, 2013. *Med Care.* 2016; 54(10): 901-906. doi:10.1097/MLR.0000000000000625.
- Foti K, Heyward J, Tajanlangit M, Meek K, Jones C, Kolodny A, Alexander GC. Primary care physicians' preparedness to treat opioid use disorder in the United States: A cross-sectional survey. *Drug Alcohol Depend.* 2021; 225: 108811. doi:10.1016/j.drugalcdep.2021.108811.
- Ghertner R, Ali M. Increases in providers with buprenorphine waivers in the United States from 2016 to 2019. *Psychiatric Services.* 2020. Doi:10.1176/appi.ps.201900635.

Haffajee RL, Bohnert ASB, Lagisetty PA. Policy pathways to address provider workforce barriers to buprenorphine treatment. *Am J Prev Med*. 2018; 54(6 Suppl 3): S230-S242. doi:10.1016/j.amepre.2017.12.022.

Haffajee RL, Sherry TB, Dubenitz JM, White JO, Schwartz D, Stoller B, Swenson-O'Brien AJ, Manocchio TM, Creedon TB, Bagalman E. *U.S. Department of Health and Human Services Overdose Prevention Strategy*. 2021. <https://aspe.hhs.gov/reports/overdose-prevention-strategy>.

Huskamp HA, Busch AB, Uscher-Pines L, Barnett ML, Riedel L, Mehrotra A. Treatment of opioid use disorder among commercially insured patients in the context of the COVID-19 pandemic. *JAMA*. 2020; 324(23): 2440-2442. doi:10.1001/jama.2020.21512.

Kontopantelis E, Doran T, Springate DA, Buchan I, Reeves D. Regression based quasi-experimental approach when randomisation is not an option: Interrupted time series analysis. *BMJ*. 2015; 350: h2750. doi:10.1136/bmj.h2750.

Larochelle MR, Bernson D, Land T, Stopka TJ, Wang N, Xuan Z, Bagley SM, Liebschutz JM, Walley AY. Medication for opioid use disorder after nonfatal opioid overdose and association with mortality: A cohort study. *Ann Intern Med*. 2018; 169(3): 137-145. doi:10.7326/M17-3107.

Lister JJ, Weaver A, Ellis JD, Himle JA, Ledgerwood DM. A systematic review of rural-specific barriers to medication treatment for opioid use disorder in the United States. *Am J Drug Alcohol Abuse*. 2020; 46(3): 273-288. doi:10.1080/00952990.2019.1694536.

Langabeer JR, Stotts AL, Cortez A, Tortolero G, Champagne-Langabeer T. Geographic proximity to buprenorphine treatment providers in the U.S. *Drug Alcohol Depend*. 2020; 213: 108131. doi:10.1016/j.drugalcdep.2020.108131.

Madras BK, Ahmad NJ, Wen J, Sharfstein JS. Improving access to evidence-based medical treatment for opioid use disorder: Strategies to address key barriers within the treatment system. *NAM Perspect*. 2020. doi:10.31478/202004b.

Nguyen T, Andraka-Christou B, Arnaudo C, Bradford WD, Simon K, Spetz J. Analysis of US county characteristics and clinicians with waivers to prescribe buprenorphine after changes in federal education requirements. *JAMA Netw Open*. 2022; 5(10): e2237912. doi:10.1001/jamanetworkopen.2022.37912.

Olfson M, Zhang V, Schoenbaum M, King M. Trends in buprenorphine treatment in the United States, 2009-2018. *JAMA*. 2020; 323(3): 276-277.

Rhyan, C. The Potential Societal Benefit of Eliminating the Opioid Crisis Exceeds \$95 Billion per Year. ALTARUM. 2017. <https://altarum.org/publications/potential-societal-benefit-eliminating-opioid-crisis-exceeds-95-billion-year>. Accessed November 10, 2022.

Shadish WR, Cook TD, Campbell DT. Quasi-experimentation: Interrupted time series designs. In *Experimental and Quasi-Experimental Designs for Generalized Causal Inference*. 2002. Boston, MA: Houghton Mifflin.

Sharma A, Kelly SM, Mitchell SG, Gryczynski J, O'Grady KE, Schwartz RP. Update on barriers to pharmacotherapy for opioid use disorders. *Curr Psychiatry Rep*. 2017; 19(6): 35. doi:10.1007/s11920-017-0783-9.

Silwal A, South AM, Thomas CP, et al. New HHS guidance for increasing number of buprenorphine clinicians who can treat OUD. *Hospitalist* blog. 2022. <https://www.the-hospitalist.org/hospitalist/article/32316/clinical-guidelines/new-hhs-guidance-for-increasing-number-of-buprenorphine-providers-who-can-treat-oud/>. Accessed November 15, 2022.

Spetz J, Hailer L, Gay C, et al. Changes in US clinician waivers to prescribe buprenorphine management for opioid use disorder during the COVID-19 pandemic and after relaxation of training requirements. *JAMA Netw Open*. 2022; 5(5): e225996. doi:10.1001/jamanetworkopen.2022.5996.

Spetz J, Hailer L, Gay C, et al. Buprenorphine treatment: Advanced practice nurses add capacity. *Health Aff (Millwood)*. 2022; 41(9): 1231-1237. doi:10.1377/hlthaff.2022.00310.

Substance Abuse and Mental Health Services Administration (SAMHSA). *Highlights for the 2020 National Survey on Drug Use and Health*. 2021a. https://www.samhsa.gov/data/sites/default/files/2021-10/2020_NSDUH_Highlights.pdf. Accessed November 10, 2022.

Substance Abuse and Mental Health Services Administration (SAMHSA). *Key Substance Use and Mental Health Indicators in the United States: Results from the 2020 National Survey on Drug Use and Health*. 2021b. <https://www.samhsa.gov/data/sites/default/files/reports/rpt35325/NSDUHFFR1PDFWHTMLFiles2020/20NSDUHFFR1PDFW102121.pdf>. Accessed November 29, 2022.

Substance Abuse and Mental Health Services Administration (SAMHSA). *Buprenorphine Practitioner and Program Data*. 2022. <https://www.samhsa.gov/medication-assisted-treatment/practitioner-resources/data-program-data>. Accessed November 20, 2022.

Wagner AK, Soumerai SB, Zhang F, Ross-Degnan D. Segmented regression analysis of interrupted time series studies in medication use research. *J Clin Pharm Ther*. 2002; 27(4):299-309. doi:10.1046/j.1365-2710.2002.00430.x.

Wen H, Borders TF, Cummings JR. Trends in buprenorphine prescribing by physician specialty. *Health Aff (Millwood)*. 2019; 38(1): 24-28. doi:10.1377/hlthaff.2018.05145.

Young A, Chaudhry HJ, Pei X, Arnhart K, Dugan M, Simons KB. FSMB census of licensed physicians in the United States, 2020. *Journal of Medical Regulation*. 2021; 107(2): 57-64.