



## Leveraging prescription monitoring program data to evaluate the implementation of buprenorphine telehealth flexibilities: An interrupted time series analysis in Texas

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### HIGHLIGHTS

- In Texas, buprenorphine prescriptions declined from an average of 8898 to 8360 prescriptions per week post telehealth flexibility implementation.
- Distinct buprenorphine patients declined from 7829 to 7661 per week.
- No change in the number of active buprenorphine prescribers or buprenorphine dispensing pharmacies was observed.
- Declines in buprenorphine utilization would have likely been more extreme without implementing telehealth flexibilities.

### ARTICLE INFO

#### Keywords:

Telemedicine  
Opioid-Related Disorders  
Prescription Drug Monitoring Programs  
COVID-19  
Opiate substitution treatment  
Interrupted Time Series Analysis

### ABSTRACT

**Background:** In March 2020, policy changes by the Substance Abuse and Mental Health Services Administration and the Drug Enforcement Administration aimed to maintain access to office-based opioid treatment services by easing telehealth buprenorphine prescribing restrictions. However, the effectiveness of these changes remains largely unmeasured. The objective of this study was to measure the effectiveness of COVID-19-related telehealth flexibilities in an all-payer cohort from the Texas Prescription Monitoring Program.

**Methods:** Using Texas Prescription Monitoring Program data, we identified oral buprenorphine and buprenorphine/naloxone prescriptions dispensed in Texas between September 1, 2019, and September 26, 2020. Weekly counts of prescriptions, prescribing physicians, and dispensing pharmacies were analyzed. An autoregressive integrated moving average (ARIMA) model estimated changes in prescription volume between pre-implementation (September 1, 2019 - February 15, 2020) and post-implementation (April 12, 2020 - September 26, 2020) periods.

**Results:** Pre-flexibility, an average of 8898 (SD: 342) buprenorphine prescriptions were dispensed to 7829 (SD: 326) patients weekly. This declined to 8360 (SD: 247) prescriptions and 7661 (SD: 229) patients post-flexibility. Adjusted for seasonality, this represented a statistically significant average decline of  $-257.27$  (95% CI:  $-426.06, -88.49$ ) patients and  $-647.01$  (95% CI:  $-856.67, -437.36$ ) prescriptions per week.

**Discussion:** Our results suggest a modest decline in buprenorphine dispensing volume early in the COVID-19 pandemic. While difficult to assess its significance, it can be assumed that telehealth flexibilities mitigated a potentially larger decline. Future research should explore system and individual-level barriers to telehealth utilization.

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<https://doi.org/10.1016/j.dadr.2024.100222>

Received 20 November 2023; Received in revised form 13 February 2024; Accepted 14 February 2024

Available online 22 February 2024

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## 1. Introduction

In the United States, three medications are indicated for the treatment of opioid use disorder (OUD): buprenorphine, extended-release naltrexone, and methadone. Of these three, buprenorphine is the only medication that may be dispensed by community pharmacies. While patients may fill their prescriptions for buprenorphine at any pharmacy, the Ryan Haight Act requires individuals wishing to initiate treatment with buprenorphine to first have an in-person visit with a treatment provider. The onset of the COVID-19 pandemic in the United States fundamentally changed the access landscape for persons initiating or continuing treatment for OUD (Friedmann et al., 2012; Gordon et al., 2011; Oliva et al., 2011; Wang et al., 2021). Moratoria on elective medical procedures and risk of COVID-19 exposure made it difficult for providers to continue to provide care for persons with OUD. To preserve access to MOUD, the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Drug Enforcement Administration enacted a series of policies intended to increase the availability of telehealth services for persons with opioid use disorder. Among these changes, the Drug Enforcement Administration (DEA) temporarily waived the Ryan Haight Act allowing patients to initiate buprenorphine following a virtual, rather than an in-person, initial encounter ("DEA SAMHSA Buprenorphine Telemedicine," 2020).

Policy changes, unfortunately, lagged behind an increase in overdose deaths at the beginning of the pandemic. Canceled medical appointments, restrictions in the supply of prescription medication, the rising toxicity of the American drug supply, and the general psychological effects of stay-at-home orders and the uncertainty of the pandemic contributed to a 30% year-over-year increase in drug overdose deaths between March 2019 and March 2020 (Hedegaard et al., 2021; Tanz et al., 2022). Rising mortality early in the course of the pandemic led several state and federal agencies to provide funding to burgeoning telehealth platforms to fill the ever-increasing need for treatment (Garfan et al., 2021; Greiwe, 2022). Early evidence suggests that telehealth was widely adopted across the United States and that the implementation of telehealth flexibilities enabled a 14% increase in buprenorphine prescribing in the Veterans Healthcare System between March 2019 and February 2021 (Lin et al., 2022). Furthermore, telehealth treatment providers have been shown to deliver similar quality care and to prescribe MOUD at a similar rate as their office-based counterparts (Hailu et al., 2023). Taken together, these findings suggest that telehealth services are not only accessible but potentially as effective as office-based care. Given these encouraging preliminary findings, the Drug Enforcement Administration and the Substance Abuse and Mental Health Services Administration have both agreed to extend all telehealth flexibilities through December 31, 2024 as of the time of this submission. The permanence of this policy remains in the balance.

Despite early evidence of benefit, a growing number of clinicians and regulators continue to question the validity and legitimacy of telehealth buprenorphine prescriptions. Major pharmacy chains have publicly announced that they will not fill telehealth prescriptions for controlled substances, including buprenorphine, jeopardizing previously observed benefits to patients (Gliadkovskaya, 2022). Even in corporations without prohibitions on telehealth dispensing, pharmacists remain reluctant to dispense telehealth prescriptions. Qualitative evidence suggests that pharmacists, tasked with managing the fallout of multi-district opioid litigation on behalf of major pharmacy corporations, treat buprenorphine like any other controlled substance in that they form their dispensing decisions around the presence or absence of "red flags" (Textor et al., 2022). This algorithmic approach to decision-making entails pharmacists deciding whether or not to dispense a prescription by searching for certain indicators commonly thought to represent misuse or diversion. These often include patterns of co-medication use, distance between the patient's home and the pharmacy, the duration of the prescription, or the chronicity of treatment. Red flags that may apply to other opioid prescriptions are often applied

to buprenorphine prescriptions despite a pernicious lack of evidence supporting this approach to clinical decision making. This often means that buprenorphine prescriptions issued by telehealth providers are not filled due to factors as simple as the geographic distance between patient and provider (Textor et al., 2022). While early evidence from insured cohorts suggests that the implementation of telehealth flexibilities preserved or expanded access to treatment through the pandemic, these studies do not capture the utilization by uninsured or cash-paying patients and do not capture variation in active buprenorphine prescribers and pharmacies. The objective of this study was, therefore, to measure the effectiveness of COVID-19-related telehealth flexibilities in an all-payer cohort from the Texas Prescription Monitoring Program.

## 2. Methods

In this interrupted time series design, all buprenorphine prescriptions dispensed in the state of Texas between September 1, 2019–September 26, 2020, were extracted from the Appriss Health Texas Prescription Monitoring Program dispensation database. Buprenorphine prescriptions were identified using a list of national drug codes (NDC) from the National Library of Medicine RxNav database (Lister Hill National Center for Biomedical Communications. National Library of Medicine. National Institutes of Health, 2024). The analysis was limited to buprenorphine and buprenorphine/naloxone combination indicated for the treatment of opioid use disorder (Lo-Ciganic et al., 2019; Thornton et al., 2020a; Varisco et al., 2020). From here, the count of prescriptions dispensed each week of the study period was summarized.

The pre-implementation period spanned twenty-four weeks between Sunday, September 1, 2019, and Saturday, February 15, 2020. After this date, a series of events hypothesized to impact access to buprenorphine in Texas began to unfold. Beginning March 1, 2020, Texas prescribers and pharmacists were mandated to query the prescription monitoring program prior to prescribing or dispensing an opioid, benzodiazepine, barbiturate, or carisoprodol prescription (Thornton et al., 2021). On March 23, 2020, the Drug Enforcement Administration permitted controlled substances, including buprenorphine, to be prescribed via telemedicine. Finally, in reaction to the onset of COVID-19, the governor of Texas issued a temporary moratorium on elective medical procedures on March 23, 2020, and a broader stay-at-home order to the public on April 1, 2020. To capture the cumulative effect of these policy changes on buprenorphine dispensing, the eight-week period between Sunday, February 16, 2020, and Saturday, April 11, 2020, was treated as an implementation washout period and removed from the dataset. The post-implementation period in which the effect was measured included the twenty-four weeks from Sunday, April 12, 2020, to Saturday, September 26, 2020.

The final model was identified using an autoregressive integrated moving average time series approach (ARIMA). At the start of the identification process, counts of buprenorphine prescriptions were graphed against time. This allowed for the visible identification of four-week seasonality reflecting week-to-week fluctuations in counts within calendar months. Visual inspection also confirmed the presence of expected declines in dispensing volume during the weeks of major holidays (November 24–November 30, 2019; December 22–December 28, 2020; and December 29–January 4, 2020). Monthly seasonality was confirmed by the Augmented Dickey Fuller test and the series was differenced across four-weekly periods. Next, the extended sample autocorrelation function (ESACF) of the differenced model was estimated. Review of the ESACF estimates revealed autocorrelation of residuals suggestive of a significant third-order moving average term. After identifying the order of the time series, counts in weekly buprenorphine prescriptions were regressed on a binary change in level term with a value of zero in the pre-implementation period and a value of one in the post-implementation period. The final model specification was then applied to assess changes in the number of distinct patients receiving buprenorphine prescriptions, physicians prescribing buprenorphine

prescriptions, and pharmacies dispensing buprenorphine prescriptions in each week.

### 3. Results

Throughout the entire study period, a total of 410,234 prescriptions were issued. In the pre-implementation phase, a total of 209,577 prescriptions were issued, which decreased to 200,657 in the post-implementation phase. In non-holiday weeks, Texas pharmacies issued an average of 8898 (SD: 342) prescriptions weekly during the pre-implementation period, and 8360 (SD: 247) after. The average number of patients per week was 7829 (SD: 326) in the pre-intervention phase and 7661 (SD: 229) in the post-intervention phase. Fig. 1 illustrates the trend of buprenorphine prescriptions, unique patients, prescribers, and dispensaries over time.

The Augmented Dickey-Fuller Test demonstrated that the weekly prescription counts exhibited monthly seasonality. To control for this, an ARIMA with fourth-differenced weekly counts (ARIMA 0, 4, 3) was first specified. After model identification, cross-correlation terms were added for the level change due to the implementation of telehealth flexibilities and to control for the effect of holiday-related noise. In this model, we found a significant decline in the number of patients filling buprenorphine prescriptions each week (-257.27, 95% CI: -426.06, -88.49) and a commensurate decline in the number of prescriptions filled (-647.01, 95% CI: -856.67, -437.36). There was no change from the baseline period in the number of physicians prescribing buprenorphine or the number of pharmacies dispensing buprenorphine (table 1). Notably, there was an increase in the duration of prescriptions during the pandemic, with a median of 23 (IQR: 7-30) days before compared to

28 (IQR: 10-30) days after.

### 4. Discussion

The controlled substance policy climate in the United States is characterized by rapid, simultaneous implementation of policies that oftentimes conflict in their impact on access to pharmacotherapy for pain and opioid use disorder. Our results demonstrate that negative pressure from the implementation of mandated PMP query combined with system-wide stress from the nascent COVID-19 pandemic potentially diminished the effectiveness of policy from SAMHSA and the DEA intended to improve access to MOUD through telehealth expansion ("DEA SAMHSA Buprenorphine Telemedicine," 2020; "Opioid Treatment Program (OTP) Guidance," 2020; Thornton et al., 2021). While we found that fewer patients were filling prescriptions each week, we did find that the length of buprenorphine prescriptions increased during the pandemic. Overall, our analysis provides a balanced perspective at the population-level association between telehealth flexibilities and buprenorphine dispensing volume in the nation's second most populous state, Texas. While we found a modest decline in buprenorphine dispensing volume, available evidence suggests a larger decline would have been observed without expanding access to telehealth (Huskamp et al., 2020; Thornton et al., 2020b).

There was no change in the number of providers or pharmacies prescribing or dispensing buprenorphine, respectively, in the post-implementation period. The implementation of telehealth flexibilities would have, theoretically, led to new prescribers entering the market in the post-implementation period. No increase in the number of prescribers was observed but this does not indicate that patients were not

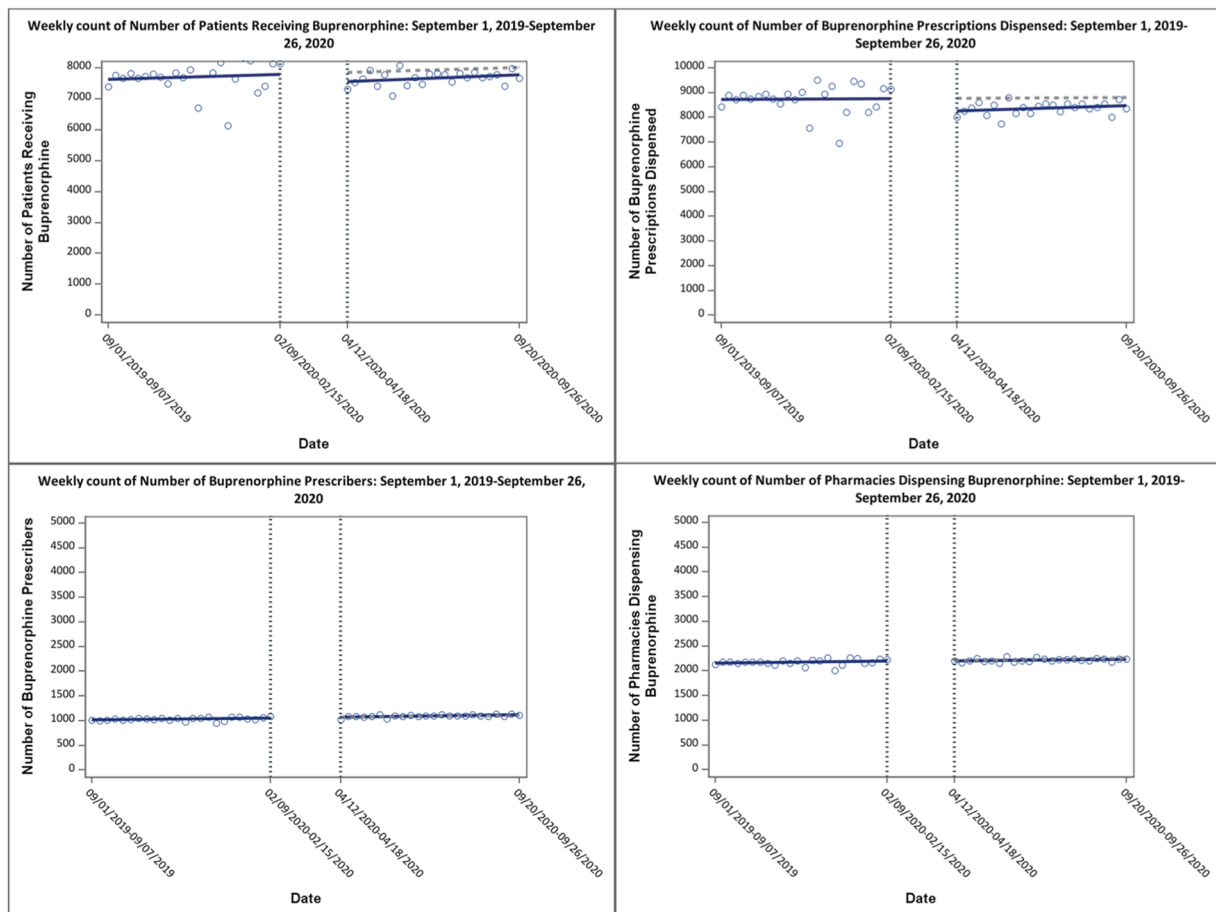


Fig. 1. Change in daily number of (A) buprenorphine prescriptions, (B) patients, (C) pharmacies, and (D) prescribers from 1 September 2019 through 20 September 2020.

**Table 1**

Parameter estimates from four autoregressive integrated moving average (ARIMA) models estimating the impact of COVID-19 telehealth flexibilities implementation in the number of buprenorphine prescriptions, and buprenorphine-dispensed pharmacies, physicians, and patients in Texas.

Estimated Effect	Patients		Prescriptions		Physicians		Pharmacies	
	Estimate (95% CI)	P- value	Estimate (95% CI)	P- value	Estimate (95% CI)	P- value	Estimate (95% CI)	P- value
Intercept <sup>a</sup>	32.73 (5.53, 59.93)	0.024	35.76 (10.56, 60.96)	0.008	8.05 (4.76, 11.33)	<.0001	7.44 (4.75, 10.13)	<.0001
COVID-19 telehealth flexibilities implementation <sup>b</sup>	-257.28 (-426.06, -88.49)	0.005	-647.01 (-856.67, -437.36)	<.0001	11.30 (-3.87, 26.46)	0.152	-6.47 (-25.84, 12.90)	0.517
Holiday <sup>c</sup>	-543.26 (-780.05, -306.48)	<.0001	-809.73 (-1086.40, -533.05)	<.0001	-48.67 (-69.35, -28.00)	<.0001	-65.55 (-94.34, -36.75)	<.0001

<sup>a</sup> The estimated value when none of the other factors (COVID-19 telehealth flexibilities and Holiday) are in effect.

<sup>b</sup> Binary term representing the average estimated effect related to the implementation of COVID-19 telehealth flexibilities on a weekly basis.

<sup>c</sup> The estimated effect that can be attributed to holidays.

attempting to use telehealth services. Prescriptions from telehealth providers are often met with increased suspicion and bureaucracy at the pharmacy counter compared to those from in-person providers (Textor et al., 2022). Available evidence suggests that pharmacists often add extra verification steps and sometimes refuse to fill telehealth prescriptions due to skepticism about their legitimacy (SAMHSA, 2021; Textor et al., 2022). Our findings suggest the need for a broader discussion on how telehealth services can be optimized for patients with OUD. Additionally, mandating that pharmacists query the prescription monitoring program prior to dispensing any opioid, including buprenorphine, is likely to contribute to pharmacists' distrust of patients receiving treatment from telehealth providers. A common "red flag" that pharmacists use to decide whether or not to dispense an opioid prescription is the distance to the provider (Textor et al., 2022). Telehealth providers may not be collocated in the same geographic areas as the patients they serve (Textor et al., 2022). This is not meant to discredit the utility of prescription monitoring programs in monitoring MOUD (Varisco et al., 2022) but rather to suggest that a more nuanced view of "red flags" is needed at a time when access to treatment remains limited.

More positively, buprenorphine prescription durations appeared to have extended during the pandemic (median of 21 days pre vs. 28 days post), purportedly as a response to the imperative of minimizing healthcare visits and exposure risks, especially concerning COVID-19. This adaptation ostensibly aims to enhance patient convenience and decrease healthcare interaction frequency. On one hand, longer prescription durations may enhance patient adherence by reducing the need for frequent refills and healthcare visits. While this change might align with the evolving healthcare landscape, attributing it solely to telehealth integration oversimplifies the range of factors at play. In March 2020, SAMHSA released guidance to opioid treatment providers (OTP's) promoting extended durations of take-home methadone to make care more convenient for patients. While this policy did not apply to buprenorphine, SAMHSA and other regulatory agencies should encourage providers to prescribe longer durations of MOUD for well managed patients. Fewer encounters and trips to the pharmacy are likely to encourage continued adherence to buprenorphine treatment.

This study has some limitations. Notably, significant policy changes occurred concurrently in March 2020: COVID-19 restrictions and the Texas PMP mandate led to a decrease in prescriptions, while SAMHSA's OTP Guidance and telemedicine waiver might have contributed to an increase in buprenorphine/naloxone usage, potentially enhancing treatment accessibility. A comprehensive analysis of the precise correlation between these factors and the prescription rate could not be performed. Additionally, the prescription drug monitoring program in Texas does not capture demographic or clinical variables limiting our ability to explore potential contextual influences on prescription trends. In addition to this, prescription monitoring programs only capture

controlled substances dispensed by community pharmacies. This means that buprenorphine dispensed directly from OTPs or subcutaneous products administered in office were not observed. This analysis also included buprenorphine products not co-formulated with naloxone. While all included products were indicated for the treatment of OUD, they may be used off-label for pain. Weekly counts of patients and prescriptions are only one of many ways of operationalizing buprenorphine dispensing volume. Other techniques, including the use of cumulative dose dispensed measures (Roy et al., 2023), may confer quantitatively different findings. Still, we observed a statistically significant decline in both the observed total and modeled week-to-week number of patients and prescriptions from the pre-implementation to post-implementation period, lending support to our findings. As with any analysis, variation in operational definitions may lead to variations in results and all findings should be interpreted cautiously by readers. Finally, gauging the effectiveness of telehealth buprenorphine treatment models during a pandemic may provide a biased assessment of their potential to improve treatment utilization in the long term. Continued assessment of telehealth treatment models is highly needed to ensure that patients can continue to access this convenient source of care.

## 5. Conclusion

Telehealth flexibilities played a crucial role in preventing major declines in buprenorphine access in Texas. Although we observed a significant decline in the number of patients receiving buprenorphine and the number of prescriptions dispensed, there was an increase in the length of prescription duration. Overall, our results suggest that prescribing was adapted to increase convenience while minimizing direct encounters. The inability of telehealth flexibilities to extend access in a time of increasing opioid overdose incidence, however, suggests potential issues related to trust and communication among telehealth providers and pharmacists. Future research linking telehealth encounters to medication utilization in the real-world setting is needed to measure the effectiveness of policy intended to improve the efficiency of access to medication for opioid use disorder.

## Role of the funding source

Tyler Varisco is a principal investigator on a grant from the Foundation for Opioid Response Efforts. FORE was not involved in the design or execution of the included research.

## Contributors

WC and CO were responsible for formal analysis, writing and editing of the original draft, and conceptualization. HC was responsible for

methodology, revising and editing of the original draft. DT was responsible for data acquisition and supervision. TV was responsible for supervision, formal analysis, writing and editing of the original draft, and funding. All authors have approved the final author.

## Funding

Tyler Varisco is principal investigator on a grant from the Foundation for Opioid Response Efforts (FORE). The views and conclusions contained in this document are those of the authors and should not be interpreted as representing the official policies or stance, either expressed or implied, of FORE. FORE is authorized to reproduce and distribute reprints for Foundation purposes not withstanding any copyright notation hereon.

## CRedit authorship contribution statement

**Douglas Thornton:** Resources, Conceptualization. **Hua Chen:** Methodology. **Chijioke Okeke:** Writing – original draft, Formal analysis. **Abolfazl Sadeghi:** Formal analysis, Conceptualization. **Tyler Varisco:** Writing – review & editing, Writing – original draft, Formal analysis, Conceptualization. **Whanhui Chi:** Formal analysis, Conceptualization.

## Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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