

Characteristics and prescribing practices of clinicians recently waivered to prescribe buprenorphine for the treatment of opioid use disorder

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ABSTRACT

Background and Aims Expanding access to medication-assisted treatment with buprenorphine is a cornerstone of the opioid crisis response, yet buprenorphine remains underutilized. Research has identified multiple barriers to prescribing buprenorphine. This study aimed to examine clinician characteristics, prescribing practices and barriers and incentives to prescribing buprenorphine among clinicians with a federal Drug Addiction Treatment Act of 2000 (DATA) waiver to prescribe buprenorphine for opioid use disorder treatment. Design Electronic survey of 4225 clinicians conducted between March and April 2018. Setting United States. Participants Clinicians obtaining an initial federal DATA waiver or an increase in authorized patient limit to prescribe buprenorphine for opioid use disorder treatment in 2017. Measurements Descriptive statistics and multivariable logistic regression examined clinician characteristics, prescribing practices and primary barriers and incentives to prescribing buprenorphine or prescribing at or near the authorized patient limit. Findings Among respondents, 75.5% had prescribed buprenorphine since obtaining a DATA waiver; the mean (standard deviation) number of patients treated in the past month was 26.6 (40.3), and 13.1% of providers were prescribing at or near their patient limit in the past month. Lack of patient demand, cited by 19.4% of clinicians, was the most common primary barrier to prescribing buprenorphine or prescribing to the authorized patient limit, followed by time constraints in practice (14.6%) and insurance reimbursement, prior authorization or other insurance requirements (13.2%). Increased patient demand (22.2%), institutional support for buprenorphine treatment (12.5%) and increased reimbursement (12.2%) were the most endorsed primary incentives for buprenorphine prescribing. Multivariable logistic regression models identified multiple clinician characteristics associated with buprenorphine prescribing and prescribing at or near the authorized patient limit. Conclusions US clinicians recently waivered to prescribe buprenorphine for opioid use disorder treatment appear to prescribe well below their patient limit, and many do not prescribe at all.

Keywords Agonist treatment, buprenorphine, drug addiction treatment act of 2000, medication-assisted treatment, opioid use, treatment of opioid use disorder.

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INTRODUCTION

The misuse of prescription and illicit opioids contributes to significant morbidity and mortality in the United States. In 2016, 42 249 Americans died from an opioid overdose—a nearly 100% increase since 2010 [1]. Along with the rise in overdose deaths, increasing rates of opioid-related emergency department (ED) visits, neonatal abstinence syndrome, opioid injection-related infectious disease transmission and placement of children into the foster care

system reflect the breadth of the opioid crisis in the United States [2–6].

Common among these statistics are people with opioid use disorder [5,7–9]. Thus, expanding access to medication-assisted treatment (MAT) for opioid use disorder treatment is an indispensable component of the public health response to the opioid crisis. MAT, the combination of medications (methadone, buprenorphine or naltrexone) with psychosocial services, has been shown to increase treatment retention and to reduce opioid use, risk behaviors that transmit HIV and viral hepatitis and overdose mortality [10–15]. Despite its well-documented effectiveness, MAT remains significantly underutilized with an estimated gap between treatment need and capacity of approximately 1 million individuals in the United States [16].

Office-based treatment with buprenorphine has the potential to significantly expand access to evidence-based MAT. The Drug Addiction Treatment Act of 2000 (DATA 2000) permitted qualified physicians to obtain a waiver from Controlled Substances Act requirements to prescribe buprenorphine-containing medications approved for opioid use disorder treatment in the office-based setting [17]. Until mid-2016, physicians could initially obtain a waiver to treat up to 30 patients at a time, and after 1 year could request a 100-patient limit. In July 2016, the US Department of Health and Human Services promulgated a final rule that allowed certain qualified 100-patient waivered physicians to obtain a 275-patient limit [18]. Increases to the 275 limit were first approved in August 2016. In addition, the Comprehensive Addiction and Recovery Act (CARA) of 2016 included a provision that permitted nurse practitioners and physician assistants to obtain a DATA waiver after completing certain training requirements [19]. The first waivers for these clinicians were approved in February 2017. These policy changes to the DATA 2000 program are expected to result in significant expansion of buprenorphine-based MAT.

Studies conducted prior to implementation of these policies identified a number of barriers to prescribing buprenorphine, including willingness to prescribe, low provider confidence in addressing addiction, limited access to addiction experts, lack of institutional or office support, lack of behavioral health services and reimbursement concerns [20–24]. These studies found that many DATA-waived physicians do not actually prescribe buprenorphine, and of these prescribers, the majority do not prescribe to their maximum patient limit [20–25].

To date, no published studies have examined buprenorphine prescribing practices since the increased patient limit for physicians and waiver eligibility for nurse practitioners and physician assistants went into effect. This analysis aims to examine clinician characteristics, prescribing practices and primary barriers and incentives for buprenorphine prescribing among clinicians who either obtained a waiver under the DATA 2000 program for the first time in 2017 or obtained an increase in their patient limit, from 30 to 100 patients or from 100 to 275 patients in 2017. Focusing on this group of clinicians provides key insights into the characteristics, prescribing practices and barriers and incentives this new cohort of clinicians is facing as they actively undertake efforts to expand buprenorphine availability, and can inform the development of policies and clinical practice guidance aimed at

facilitating the expansion of buprenorphine-based opioid use disorder treatment.

METHODS

Study sample

As part of the management of the DATA 2000 program, the Substance Abuse and Mental Health Services Administration (SAMHSA) maintains information on all clinicians with a DATA waiver such as date of waiver receipt, authorized patient limit (30, 100, 275) and whether they have granted permission to be listed on the SAMHSA Buprenorphine Treatment Practitioner Locator. Clinicians who received a DATA waiver for the first time in 2017 or those who received an increase in their patient limit from 30 to 100 patients or from 100 to 275 patients in 2017 were eligible for the study. Of the 12 824 eligible clinicians, 4225 (32.9%) responded to the survey. The response rate among physicians was 30.4% (2384 respondents of 7840 eligible physicians), and the response rate among nurse practitioners or physician assistants was 36.9% (1841 respondents of 4984 eligible nurse practitioners or physician assistants).

Survey design

The 30-question survey instrument (see Supporting information, Appendix S1) was developed based on a review of peer-reviewed studies examining clinician barriers, incentives and attitudes related to prescribing buprenorphine, clinical guidelines for use of buprenorphine and expert review. Four domains were included in the survey: (1) clinician characteristics; (2) buprenorphine prescribing practices; (3) primary barriers to prescribing buprenorphine or prescribing to the patient limit; and (4) primary incentives to enable buprenorphine prescribing or prescribing to the patient limit.

Data collection

Data were collected between 29 March 2018 and 26 April 2018. To facilitate ease of clinician response and increase the survey response rate an electronic survey was used (SurveyMonkey). A targeted e-mail with the embedded survey was sent to each eligible clinician to ensure that only those eligible for the survey would receive and complete the survey. Reminder e-mails with an embedded survey were sent to non-responders on weeks 2 and 3 of the data collection period. The survey was closed 4 weeks after the original distribution date. This analysis was approved by the Substance Abuse and Mental Health Services Administration and was exempt from institutional review board review by regulation. All data were de-identified

and maintained in a password-protected and physically secured electronic database.

Statistical analysis

Data from the entire sample of 4225 clinicians was used for analyses of all survey domains except for the buprenorphine prescribing practices domain, which was limited to the 3181 clinicians who reported prescribing buprenorphine since obtaining a DATA waiver. Of the variables included in the analysis, the rate of non-response was less than 1% for 20 of 33 variables, between 1 and 2% for 11 variables and between 2 and 3% for two variables.

Descriptive analyses were performed and are reported as frequencies and percentages for categorical variables and means and standard deviations (SD) and medians and interquartile ranges (IQR) for continuous variables. Characteristics of physicians compared to nurse practitioners or physician assistants were assessed with the use of *t*-tests for continuous variables, χ^2 tests for categorical variables and the Wilcoxon rank-sum test for median values.

Two separate multivariable logistic regression models were fit in the analysis. The first model assessed factors associated with prescribing buprenorphine since obtaining a DATA waiver. The second model assessed factors associated with prescribing buprenorphine at or near the patient limit in the past month among buprenorphine prescribers. Consistent with prior research, prescribing at or near the patient limit in the past month was defined as prescribing to ≥ 25 patients in the past month for 30-patient waivered clinicians, ≥ 75 patients in the past month for 100-patient waivered clinicians [25] and ≥ 250 patients in the past month for 275-patient waivered clinicians. All clinician characteristics of interest were included in the models, regardless of statistical significance. Results of the models are presented as adjusted odds ratios (OR) and associated 95% confidence intervals (CI). Two-sided P-values of less than 0.05 were considered to indicate statistical significance. STATA version 15.1, was used to perform statistical analyses.

RESULTS

Clinician characteristics

Among the 4225 clinicians in the sample, 56.3% were physicians, 35.3% were nurse practitioners and 8.4% were physician assistants; 54.3% were female; 16.1% were aged 25–34, 26.7% were aged 35–44, 24.7% were aged 45–54, 21.9% were aged 55–64 and 10.7% were aged 65 years or older. Urban practice setting was cited by 44.8% of clinicians, followed by 30.7% in suburban settings and 24.5% in rural settings (Table 1). The sample of respondents was

generally similar to prior studies that have included a mix of specialty and non-specialty clinicians with a DATA 2000 waiver [20,26,27].

Office-based group practice was the most commonly endorsed practice setting (24.3%), followed by clinic setting (20.9%) and hospital or health system (19.4%). A small minority of clinicians had board certification in addiction psychiatry or addiction medicine (11.7%). Medicaid and Medicare were accepted by 82.9% of clinicians, 84.9% accepted private insurance and 6.4% reported being cashonly. The authorized patient limit was 30 patients for 72.9% of clinicians, 16.4% had a 100-patient limit and 10.7% had a 275-patient limit. The mean amount of clinical time spent treating patients with addiction was 37%.

Among survey respondents, 3181 (75.5%) reported prescribing buprenorphine for the treatment of opioid use disorder since obtaining a DATA 2000 waiver. Among the clinicians who reported prescribing buprenorphine, 93.7% used buprenorphine and naloxone combination products, 55.6% used single-entity buprenorphine products, 5.2% used long-acting buprenorphine injection and 1.3% used 6-month buprenorphine implants. Conducting urine drug screens at every visit was reported by 63.2% of clinicians, 62.8% conducted random urine drug screens, 55.4% conducted pill or film counts and 83.3% checked the state prescription drug monitoring program (PDMP).

Significant differences between physicians and nurse practitioners or physician assistants were found for all examined clinician characteristics except for accepting Medicaid, interaction with the Providers Clinical Support System for Medication Assisted Treatment (PCSS-MAT), prescribing buprenorphine since obtaining a DATA waiver, types of buprenorphine products used and checking the state PDMP.

Buprenorphine prescribing practices

For clinicians prescribing buprenorphine, the number of patients being treated in the past month was substantially lower than the authorized waiver patient limit. Among all prescribers, the mean number of patients treated in the past month (SD) was 26.6 (40.3) and the median (IQR) was 13 (3-30) (Table 2). Among 30-patient waivered clinicians, the mean number of patients was 10.8 (10.2) and the median was 6 (2-20) patients; for 100-patient waivered clinicians the mean was 28.4 (24.7) and the median was 25 (10-40); for 275-patient waivered clinicians the mean was 95.8 (63.8) and the median was 90 (42–130). The percentage of clinicians prescribing buprenorphine at or near the patient limit in the past month was 13.1% overall. The mean and median average dose used per day was 12.9 (4.5) and 14 (8-16), and the mean and median maximum dose used per day was 19.7

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 Table 1
 Characteristics of survey respondents.

	Overall	Physicians	NPs/PAs	P value
Survey respondent characteristics	n (%)	n (%)	n (%)	
Sex				
Female	2296 (54.3)	890 (37.3)	1406 (76.4)	< 0.001
Male	1929 (45.7)	1494 (62.7)	435 (23.6)	
Age (years)				
25-34	672 (16.1)	384 (16.3)	288 (15.7)	< 0.001
35-44	1114 (26.7)	617 (26.2)	497 (27.2)	
45-54	1033 (24.7)	517 (21.9)	516 (28.2)	
55–64	917 (21.9)	512 (21.7)	405 (22.4)	
65 or older	449 (10.7)	326 (13.8)	123 (6.7)	
US census region	119 (1007)	320 (1310)	120 (017)	
Northeast	1234 (29.4)	672 (28.5)	562 (30.6)	0.003
Midwest	748 (17.8)	430 (18.2)	318 (17.3)	0.005
South	. ,			
	1110 (26.4)	671 (28.4)	439 (23.9)	
West	1105 (26.3)	588 (24.9)	517 (28.2)	
Urban–rural status	1000 (110)			0.007
Urban	1880 (44.8)	1116 (47.2)	764 (41.6)	< 0.001
Suburban	1289 (30.7)	719 (30.4)	570 (31.0)	
Rural	1030 (24.5)	527 (22.3)	503 (27.4)	
Provider type				
Primary care physician	841 (20.0)	-	-	
Internal medicine/family medicine	387 (9.2)	_	_	
Pediatric/adolescent medicine	42 (1.0)	-	-	
Emergency medicine	141 (3.3)	-	-	
Addiction medicine	176 (4.2)	-	_	
Psychiatrist	490 (11.6)	_	_	
Pain medicine/anesthesiology	102 (2.4)	_	_	
Obstetrician/gynecologist	92 (2.2)	_	_	
Other physician specialty	101 (2.4)	_	_	
Nurse practitioner (NP)	1484 (35.3)	_	_	
Physician assistant (PA)	353 (8.4)	_	_	
Addiction Psychiatry/Addiction Medicine Board Certification	. ,			
Addiction Psychiatry (AAAP)	91 (2.2)	-	-	
Addiction Medicine (ASAM/ABPM)	354 (8.4)	_	_	
Addiction Medicine (AOA)	46 (1.1)	-	_	
No board certification	3718 (88.3)	-	-	
Practice setting				
Office-based solo	556 (13.2)	340 (14.3)	216 (11.8)	< 0.001
Office-based group	1024 (24.3)	538 (22.7)	486 (26.5)	
Specialty treatment facility	351 (8.3)	141 (5.9)	210 (11.4)	
Opioid treatment program	341 (8.1)	145 (6.1)	196 (10.7)	
Hospital or health system	816 (19.4)	610 (25.7)	206 (11.2)	
Clinic (FQHC, rural health clinic, mental health clinic)	878 (20.9)	4428 (18.1)	450 (24.5)	
Emergency department	91 (2.2)	77 (3.2)	14 (0.8)	
Criminal justice	53 (1.3)	26 (1.1)	27 (1.5)	
Other setting	96 (2.3)	66 (2.8)	30 (1.6)	
Years in practice			. ,	
Less than 5 years	1371 (32.6)	689 (29.1)	682 (37.2)	< 0.001
5–10 years	830 (19.7)	374 (15.8)	456 (24.9)	. 0.001
11–15 years	470 (11.2)	244 (10.3)	226 (12.3)	
16 or more years	1533 (36.5)			
-	(0.00)	1062 (44.8)	471 (25.7)	
Payment type accepted in practice	264 (6 4)	101 (7.0)	02 (4 ()	- 0.001
Cash only	264 (6.4)	181 (7.8)	83 (4.6)	< 0.001
Medicaid	3441 (82.9)	1925 (82.6)	1516 (83.3)	0.544

(Continues)

Table 1. (Continued)

	Overall	Physicians	NPs/PAs	P value
Survey respondent characteristics	n (%)	n (%)	n (%)	
Medicare	3441 (82.9)	1948(83.6)	1463 (80.4)	0.008
Private insurance	3524 (84.9)	1948 (83.6)	1576 (86.6)	0.007
Buprenorphine DATA waiver patient limit				
30	3081 (72.9)	1362 (57.1)	1719 (93.4)	< 0.001
100	693 (16.4)	571 (24.0)	122 (6.6)	
275	451 (10.7)	451 (18.9)	n/a	
Listed on SAMHSA buprenorphine treatment practitioner lo				
No	1440 (34.1)	940 (39.4)	500 (27.2)	< 0.001
Yes	2785 (65.9)	1444 (60.6)	1341 (72.8)	
Attitude about buprenorphine treatment duration				
Best used for detoxification	151 (3.6)	81 (3.4)	70 (3.8)	0.033
Used for no more than 3 months	32 (0.8)	17 (0.7)	15 (0.8)	
Used for no more than 6 months	78 (1.9)	36 (1.5)	42 (2.3)	
Used for no more than 12 months	230 (5.5)	112 (4.8)	118 (6.5)	
Use indefinitely as long as patient is benefiting	3684 (88.2)	2108 (89.5)	1576 (86.5)	
Interacted with providers clinical support system for MAT				
No	2762 (65.5)	1558 (65.6)	1204 (65.5)	0.964
Yes	1452 (34.5)	818 (34.4)	634 (34.5)	
Prescribe/administer extended-release injectable naltrexone				
No	2713 (65.3)	1623 (69.5)	1090 (60.0)	< 0.001
Yes	1441 (34.7)	713 (30.5)	728 (40.0)	
Provide/refer patients to methadone treatment				
No	2138 (51.2)	1136 (48.2)	1002 (55.0)	< 0.001
Yes	2040 (48.8)	1219 (51.8)	821 (45.0)	
Coprescribe/encourage patients to obtain naloxone				
No	906 (21.7)	537 (22.9)	369 (20.3)	0.043
Yes	3266 (78.3)	1813 (77.1)	1453 (79.7)	
Percentage clinical time spent treating patients with addicti	ion			
Mean (SD)	37.0 (34.6)	32.1 (33.0)	43.3 (35.5)	< 0.001
Median (IQR)	25 (10-60)	20 (5-50)	30 (10-75)	< 0.001
Prescribed buprenorphine since obtaining DATA waiver				
No	1034 (24.5)	598 (25.2)	436 (23.7)	0.282
Yes	3181 (75.5)	1779 (74.8)	1402 (76.3)	
Type of buprenorphine product(s) used ^a				
Single-entity buprenorphine	1761 (55.6)	1010 (56.9)	751 (54.0)	0.094
Buprenorphine/naloxone combination	2968 (93.7)	1668 (94.0)	1300 (93.4)	0.465
Long-acting buprenorphine injection	165 (5.2)	86 (4.8)	79 (5.7)	0.298
Buprenorphine implant	41 (1.3)	25 (1.4)	16 (1.1)	0.521
Diversion control practices ^a				
Urine drug screen, every visit				
No	1163 (36.8)	679 (38.4)	484 (34.8)	0.034
Yes	1996 (63.2)	1088 (61.6)	908 (65.2)	
Urine drug screen, random				
No	1175 (37.2)	686 (38.8)	489 (35.1)	0.033
Yes	1984 (62.8)	1081 (61.2)	903 (64.9)	
Pill or film counts				
No	1409 (44.6)	827 (46.8)	582 (41.8)	0.005
Yes	1750 (55.4)	940 (53.2)	810 (58.2)	
Check prescription drug monitoring program				
No	528 (16.7)	299 (16.9)	229 (16.5)	0.725
Yes	2631 (83.3)	1468 (83.1)	1163 (83.5)	

^aAmong respondents who had prescribed buprenorphine since obtaining a DATA 2000 waiver, n = 3181. SAMHSA = Substance Abuse and Mental Health Services Administration; DATA = Drug Addiction Treatment Act; MAT = medication-assisted treatment; NP = nurse practitioner; PA = physician assistant; IQR = interquartile range; SD = standard deviation.

	Overall	Physicians	NPs/PAs	30 Patient limit	100 Patient limit	275 Patient limit
Number of patients in past month						
Mean (SD)	26.6 (40.3)	36.6 (50.3)	13.5 (11.7)	10.8 (10.2)	28.4 (24.7)	95.8 (63.8)
Median (IQR)	13 (3-30)	15 (3-48)	10 (3-24)	6 (2-20)	25 (10-40)	90 (42-130)
Average number of patients per						
month in past year						
Mean (SD)	25.9 (37.9)	35.0 (47.2)	13.9 (12.0)	10.8 (10.2)	28.5 (23.9)	91.8 (58.4)
Median (IQR)	15 (3-30)	15 (3-50)	10 (4-25)	6 (2-20)	25 (10-39)	85 (50-120)
Percentage at or near limit in past month	13.1%	7.1%	20.7%	17.0%	7.6%	2.4%
Percentage at or near limit in average	13.1%	6.4%	21.5%	17.2%	7.1%	2.5%
month in past year						
Average daily buprenorphine						
dose prescribed						
Mean (SD)	12.9 (4.5)	13.0 (4.3)	12.9 (4.6)	12.5 (4.7)	13.2 (4.1)	14.3 (3.6)
Median (IQR)	14 (8-16)	14 (8–16)	14 (8–16)	12 (8-16)	16 (10-16)	16 (12–16)
Maximum daily buprenorphine						
dose prescribed						
Mean (SD)	19.7 (6.1)	20.2 (6.1)	19.1 (5.9)	19.1 (6.1)	20.5 (6.3)	21.2 (5.3)
Median (IQR)	18 (16-24)	20 (16-24)	16 (16-24)	16 (16-24)	24 (16-24)	24 (16-24)
Percent prescribing maximum	8.0%	9.3%	6.3%	7.2%	10.0%	8.6%
daily Buprenorphine dose $> 24 \text{ mg}$						

 Table 2
 Buprenorphine prescribing patterns among clinicians that prescribed buprenorphine since obtaining DATA waiver^a

^aThis table is limited to the 3181 (75.5% of 4215) prescribers who reported prescribing buprenorphine since obtaining a DATA 2000 waiver in 2017. DATA = Drug Addiction Treatment Act; NP = nurse practitioner; PA = physician assistant; IQR = interquartile range; SD = standard deviation.

(6.1) and 18 (16–24). Eight per cent of clinicians prescribed a maximum dose above 24 mg per day.

Primary barriers to prescribing buprenorphine or prescribing to the patient limit

Primary barriers to prescribing buprenorphine were cited by 94.6% of clinicians. Lack of patient demand, cited by 19.4% of clinicians, was the most common primary barrier (Fig. 1). Time constraints in practice (14.6%), insurance reimbursement, prior authorization or other insurance requirements (13.2%), resistance from practice partners or staff or lack of institutional support (7.6%) and lack of access to psychological services or other behavioral health providers (6.2%) were the next most endorsed barriers.

Primary incentives to enable buprenorphine prescribing or prescribing to the patient limit

Clinicians endorsed increased patient demand (22.2%) as the most common primary incentive (Fig. 2). This was followed by institutional support for buprenorphine treatment (12.5%), increased reimbursement (12.2%), having an integrated system with direct access to addiction specialists and behavioral health providers (9.3%), having an easier system for referral to psychosocial or other behavioral health providers (8.3%) and having an addiction medicine mentor (7.7%). 'Nothing will increase my prescribing' was endorsed by 7.6% of clinicians.

Multivariable logistic regression analyses

In multivariable logistic regression, clinician characteristics associated with greater odds of prescribing buprenorphine since obtaining a DATA 2000 waiver were practicing in the Midwest compared to the South [adjusted odds ratio (aOR) = 1.35; 95% confidence interval (CI) = 1.03-1.78], practicing in a specialty substance abuse treatment facility (aOR = 1.91, 95%CI = 1.16-3.13) or an opioid treatment program (aOR = 1.85, 95% CI = 1.14-2.99) compared to an office-based solo practice, having a board certification in addiction psychiatry (aOR = 3.39, 95% CI = 1.46-7.86) or addiction medicine (aOR = 1.96, 95%CI = 1.37-2.81), interacting with PCSS-MAT (aOR = 1.32, 95% CI = 1.10-1.59), being listed on the SAMHSA Provider Locator (aOR = 2.13, 95% CI = 1.79-2.54), prescribing or administering extendedrelease naltrexone (aOR = 1.71, 95% CI = 1.40-2.08), co-prescribing or encouraging patients to obtain naloxone (aOR = 1.56, 95% CI = 1.28-1.90) and citing no barriers compared to insurance reimbursement, prior authorization, or other insurance requirements (aOR = 5.35, 95% CI = 1.89-15.18) (Table 3).

Characteristics associated with lower odds of prescribing buprenorphine since obtaining a DATA waiver were practicing in a hospital or health system (aOR = 0.62, 95% CI = 0.45-0.86), a clinic setting, including federally

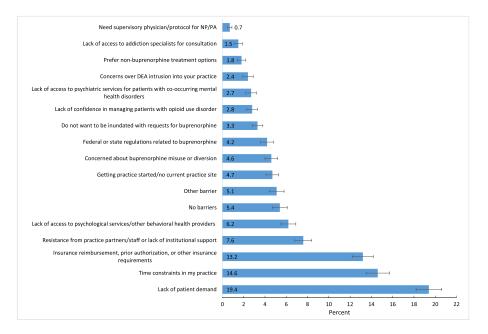


Figure I Primary barriers to prescribing buprenorphine or prescribing to maximum patient limit [Colour figure can be viewed at wileyonlinelibrary.com]

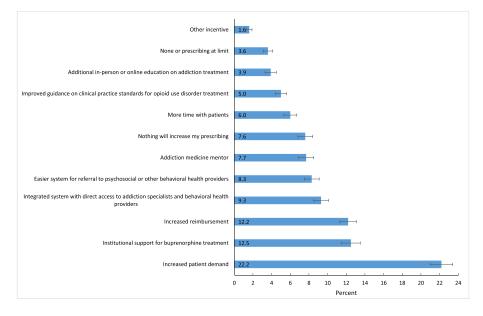


Figure 2 Primary incentives to prescribing buprenorphine or prescribing to maximum patient limit [Colour figure can be viewed at wileyonlinelibrary.com]

qualified health centers (aOR = 0.69, 95% CI = 0.49-0.96), an ED (aOR = 0.51, 95% CI = 0.29-0.90) and other practice setting (aOR = 0.35, 95% CI = 0.19-0.61) compared to an office-based solo practice, and compared to citing insurance reimbursement, prior authorization or other insurance requirements as a primary barrier, endorsing lack of access to psychological services or behavioral health providers (aOR = 0.34, 95% CI = 0.22-0.51), lack of access to addiction specialists for consultation (aOR = 0.18, 95% CI = 0.10-0.33), lack of confidence in

managing patients with opioid use disorder (aOR = 0.17, 95% CI = 0.10–0.28), lack of patient demand (aOR = 0.46, 95% CI = 0.33–0.66), preferring non-buprenorphine treatment options (aOR = 0.26, 95% CI = 0.14–0.49), resistance from practice partners or staff or lack of institutional support (aOR = 0.14, 95% CI = 0.10–0.21), federal or state regulations related to buprenorphine (aOR = 0.45, 95% CI = 0.27–0.76), concerns over Drug Enforcement Administration (DEA) intrusion into the practice (aOR = 0.51, 95% CI = 0.27–0.96), getting

Prescribe buprenorphine since Prescribe buprenorphine at obtaining DATA waiver, aOR or near limit in past month, Survey respondent characteristics (95% CI) (n = 3935) $aOR (95\% CI)^{a} (n = 3066)$ Sex Female Ref Ref 1.15 (0.95-1.38) 0.97 (0.75-1.26) Male Age (years) 25 - 34Ref Ref 35-44 0.98 (0.75-1.29) 1.21 (0.85-1.74) 45 - 541.05 (0.76-1.44) 0.97 (0.66-1.45) 55-64 1.06 (0.74-1.52) 1.00 (0.64-1.57) 65 or older 1.26 (0.81-1.95) 1.04(0.60-1.80)US census region South Ref Ref Northeast 1.09 (0.86-1.38) 0.83 (0.62-1.11) Midwest 1.35 (1.03-1.78) 0.83 (0.60-1.14) West 0.96 (0.76-1.21) 0.43 (0.31-0.61) Urban-rural status Rural Ref Ref Suburban 0.97 (0.77-1.23) 0.93 (0.69-1.26) Urban 0.87 (0.70-1.07) 0.96 (0.72-1.28) Provider type Physician Ref Ref Nurse practitioner/physician assistant (NA/PA) 0.94 (0.77-1.15) 1.66 (1.22-2.25) Primary practice setting Office-based solo Ref Ref Office-based group 0.94 (0.68-1.29) 1.07 (0.74-1.54) Specialty treatment facility 1.91 (1.16-3.13) 1.43(0.92 - 2.22)Opioid treatment program 1.85 (1.14-2.99) 1.72 (1.13-2.62) Hospital or health system 0.62 (0.45-0.86) 0.61 (0.38-0.98) Clinic (FQHC, rural health clinic, mental health clinic) 0.61 (0.40-0.93) 0.69 (0.49-0.96) Emergency department 0.51 (0.29-0.90) 0.19(0.03 - 1.44)Criminal justice 0.97 (0.46-2.03) 0.25 (0.03-1.98) Other setting 0.35 (0.19-0.61) 0.20 (0.03-1.50) Years in practice Less than 5 years Ref Ref 0.93 (0.68-1.26) 5-10 years 0.91(0.71 - 1.17)11-15 years 0.91 (0.67-1.25) 1.08(0.72 - 1.60)16 or more years 0.75 (0.55-1.01) 0.92 (0.64-1.31) Addiction Psychiatry/Addiction Medicine Board Certification Ref None Ref Addiction Psychiatry (AAAP) 3.39 (1.46-7.86) 0.48 (0.15-1.58) Addiction Medicine (ASAM/ABPM/AOA) 1.96 (1.37-2.81) 0.83 (0.50-1.38) Payment type accepted in practice Accepts insurance Ref Ref 1.19 (0.78-1.81) 1.83 (1.21-2.77) Cash only Interacted with providers clinical support system for MAT No Ref Ref Yes 1.32 (1.10-1.59) 1.09(0.86 - 1.38)Listed on SAMHSA buprenorphine practitioner treatment locator No Ref Ref 2.13 (1.79-2.54) 1.83 (1.36-2.46) Yes Prescribe/administer extended-release injectable naltrexone Ref No Ref Yes 1.71 (1.40-2.08) 1.36 (1.07-1.73)

 Table 3 Multivariable logistic regression models for prescribing buprenorphine since obtaining a DATA 2000 waiver and prescribing buprenorphine near or at patient limit in past month.

(Continues)

Table 3. (Continued)

Survey respondent characteristics	Prescribe buprenorphine since obtaining DATA waiver, aOR (95% CI) (n = 3935)	Prescribe buprenorphine at or near limit in past month, $aOR (95\% CI)^a (n = 3066)$
Provide/refer patients to methadone treatment	D-f	D-f
No Yes	Ref 0.93 (0.78–1.11)	Ref 0.69 (0.53–0.88)
Coprescribe/encourage patients to obtain naloxone	0.93 (0.76-1.11)	0.09 (0.33-0.88)
No	Ref	Ref
Yes		
	1.56 (1.28–1.90)	1.18 (0.87–1.60)
Attitude about buprenorphine treatment duration	D-f	D-f
Best used for detoxification	Ref	Ref
Used for no more than 3 months	0.93 (0.35–2.47)	2.15 (0.48–9.60)
Used for no more than 6 months	0.82 (0.41–1.64)	0.94 (0.26–3.43)
Used for no more than 12 months	1.39 (0.80–2.41)	1.62 (0.66-3.99)
Use indefinitely as long as patient is benefiting	1.48 (0.96–2.28)	2.20 (1.02-4.74)
Buprenorphine prescribing limit		
30	-	Ref
100	-	0.47 (0.33-0.68)
275	-	0.13 (0.07-0.25)
Primary barrier to prescribing buprenorphine		
Insurance reimbursement, prior authorization or other insurance requirements	Ref	-
Lack of access to psychological services/other behavioral health providers	0.34 (0.22-0.51)	_
Lack of access to psychological services/other behavioral neutrin providers	0.18 (0.10-0.33)	
Lack of access to addiction specialists for constitution Lack of access to psychiatric services for patients with co-occurring mental	0.99 (0.49–2.03)	
health disorders	0.55 (0.15-2.05)	
Lack of confidence in managing patients with opioid use disorder	0.17 (0.10-0.28)	-
Lack of patient demand	0.46 (0.33-0.66)	-
Do not want to be inundated with requests for buprenorphine	0.62 (0.36-1.07)	-
Concerned about buprenorphine misuse or diversion	0.76 (0.44-1.31)	-
Prefer non-buprenorphine treatment options	0.26 (0.14-0.49)	-
Time constraints in my practice	0.75 (0.51-1.11)	-
Resistance from practice partners/staff or lack of institutional support	0.14 (0.10-0.21)	-
Federal or state regulations related to buprenorphine	0.45 (0.27-0.76)	-
Concerns over DEA intrusion into your practice	0.51 (0.27-0.96)	_
Getting practice started/no current practice site	0.15 (0.10-0.24)	-
Need supervisory physician/protocol for NP/PA	0.06 (0.02-0.15)	_
Other barrier	0.25 (0.16-0.39)	_
No barriers	5.35 (1.89–15.18)	_

Bold type indicates a statistically significant finding. ^aAmong respondents who had prescribed buprenorphine since obtaining a DATA 2000 waiver. SAMHSA = Substance Abuse and Mental Health Services Administration; DATA = Drug Addiction Treatment Act; MAT = medication-assisted treatment; aOR = adjusted odds ratio; CI = confidence interval; DEA = Drug Enforcement Administration; FQHC = Federally Qualified Health Center.

practice started or no current practice site (aOR = 0.15, 95% CI = 0.10–0.24), needing a supervisory physician or protocol for nurse practitioners or physician assistants (aOR = 0.06, 95% CI = 0.02–0.15) and other barrier (aOR = 0.25, 95% CI = 0.16–0.39).

Clinician characteristics associated with greater odds of prescribing at or near the patient limit in the past month were being a nurse practitioner or physician assistant (aOR = 1.66, 95% CI = 1.22-2.25), practicing in an opioid treatment program compared to an office-based solo practice (aOR = 1.72, 95% CI = 1.13-2.62), cash-only practice compared to accepting insurance (aOR = 1.83, 95%

CI = 1.21–2.77), being listed on the SAMHSA Provider Locator (aOR = 1.83, 95% CI = 1.36–2.46), prescribing or administering extended-release injectable naltrexone (aOR = 1.36, 95% CI = 1.07–1.73) and believing buprenorphine should be used indefinitely as long as the patient is benefiting compared to best used for detoxification (aOR = 2.20, 95% CI = 1.02-4.74).

Lower odds of prescribing at or near the patient limit in the past month were found among clinicians in the West compared to the South (aOR = 0.43, 95% CI = 0.31-0.61), practicing in a hospital or health system (aOR = 0.61, 95% CI = 0.38-0.98) or clinic setting (aOR = 0.61, 95% CI = 0.40–0.93) compared to an officebased solo practice, providing or referring patients to methadone treatment (aOR = 0.69, 95% CI = 0.53–0.88) and having a 100-patient limit (aOR = 0.47, 95% CI = 0.33– 0.68) or a 275-patient limit (aOR = 0.13, 95% CI = 0.07– 0.25) compared to a 30-patient limit.

DISCUSSION

In the present study, among a new cohort of clinicians who obtained an initial DATA waiver or increased their authorized patient limit in 2017, one in four clinicians had not prescribed buprenorphine and only 13% prescribed at or near their patient limit in the past month. Further, approximately one in five clinicians cited lack of patient demand as the primary barrier to prescribing buprenorphine at all or to their patient limit. Although it is possible that some clinicians had lower patient loads because they were just beginning to offer buprenorphine treatment, only 5% cited getting practice started or no current practice site as a primary barrier. These findings are concerning, given the escalating opioid crisis in the United States and the significant efforts in recent years to expand use of MAT. Although progress has been made to increase the number of clinicians with a DATA waiver, the prescribing practices identified in our study among this new cohort of clinicians are consistent with prior studies [20-23,25,28]. A recent study of public sector DATA waived clinicians conducted in New York in 2016, prior to nurse practitioner/physician assistant expansion and the increased 275-patient limit, found that most providers were not prescribing near their authorized patient limits, and despite policies to expand prescribing of buprenorphine there appeared to be ample buprenorphine treatment capacity among their sample of clinicians [28].

Encouraging findings include greater than 80% of clinicians accepting Medicaid, Medicare and private insurance, 88% stating that buprenorphine should be used indefinitely as long as the patient is benefiting, 78% coprescribing or encouraging patients to obtain naloxone for overdose reversal and 83% checking state PDMPs. The large number of nurse practitioners and physician assistants who obtained a waiver since becoming eligible in 2017 is encouraging, as is the finding that nearly 21% of these newly waivered clinicians were prescribing at or near their limit. Further, the prescribing practices of these clinicians were similar to those of physicians, and in some cases, such as with urine drug testing and pill or film counts, a higher percentage reported engaging in these practices compared to physicians.

The findings from this study coupled with those from prior studies on buprenorphine prescribing practices have important implications for policy and clinical practice in three areas—clinician education and training, systemslevel changes and public and patient education. The strong association between reduced likelihood of prescribing buprenorphine and lack of confidence in managing patients with opioid use disorder as well as the endorsements of additional education on addiction treatment, access to addiction specialist mentors and improved guidance on clinical practice standards for opioid use disorder treatment as primary incentives for prescribing highlight the need for clinician education and training. Clinician education in the management of substance use disorder is inadequate, and low confidence in addressing opioid use disorder has been identified as a barrier to prescribing buprenorphine in prior studies [21,24] and was clearly a barrier among this new cohort of DATA-waived clinicians.

In addition, practices that contribute to diversion, such as the large minority of providers in our study not engaging in recommended diversion control practices [29], the one in 12 clinicians who prescribed a maximum daily dose above 24 mg, higher than the maximum Food and Drug Administration (FDA)-recommended dose, and the large percentage of clinicians reporting use of single-entity buprenorphine provide targets for future education and training efforts.

Training and support also need to be available to assist new DATA waived clinicians in the integration of buprenorphine into their practice. In this study, although only one in three clinicians had interacted with PCSS-MAT—a resource that provides education, training and mentorship opportunities—those who had interacted were significantly more likely to have prescribed buprenorphine. Prior research has demonstrated that the PCSS program provides clinicians with the skills needed to implement office-based treatment [30,31]. An additional resource that could be leveraged or replicated, Project ECHOs' Integrated Addictions and Psychiatry TeleECHO Clinic, has been shown to expand buprenorphine training and treatment capacity [32].

A number of systems-level changes that could facilitate expansion of buprenorphine treatment were identified in our study. Consistent with prior research, barriers such as reimbursement, prior authorization requirements and time constraints in practice were commonly cited by clinicians in our study. Further, 30% of clinicians cited institutional support, an easier system for referral to psychosocial or other behavioral health providers or an integrated system with direct access to addiction specialist and behavioral health providers as primary incentives for prescribing. New, innovative payment policies that provide adequate reimbursement and facilitate systems-level changes such as integrated, comprehensive team-based care are needed. Models such as the Hub-and-Spoke model [33], the nurse care manager model [34] and models that provide practical hands-on training at specialty Centers of Excellence to supplement DATA waiver training and enhance clinician skills

[35] are examples of service delivery models that address many of the systems-level barriers identified in our study.

The finding that patient demand was the primary barrier and primary incentive among clinicians underscores the need for public and patient education. National surveys indicate that a minority of patients in need of treatment actually seek or receive it. Reasons for not receiving treatment include inadequate accessibility, stigma, and not knowing where to get treatment [36]. Efforts to reduce stigma related to substance use disorders and medications to treat them and to educate the public about MAT and how and where to obtain it must be expanded. In addition, the disconnect between patient demand and ample clinician treatment capacity in our study suggests that additional strategies are needed to more effectively connect patients in need of treatment with clinicians able to provide care. Emerging strategies include the provision of clinical services in the ED, including initiation of buprenorphine treatment and follow-up by peer providers among those with opioid use disorder unwilling to start treatment in an ED setting [37,38].

This study is subject to limitations. First, although our study sample incorporated variation with regard to provider geography, age, practice setting, years in practice, specialty and buprenorphine patient limit, it specifically targeted clinicians who obtained an initial waiver or increase in authorized patient limit in 2017 and may not be representative of all clinicians with a DATA waiver, as it only included clinicians who received an initial waiver or an increase in their patient limit in 2017. Secondly, the response rate was 32.9%; thus, the results may be influenced by non-response bias. Thirdly, we did not assess barriers such as the regulatory reporting requirements for physicians with a 275-patient limit; future research should assess how these requirements might serve as a barrier. Finally, due to the cross-sectional nature of the survey, we cannot draw causal inferences. Despite these limitations, this survey represents the largest single survey of clinicians with a DATA waiver completed to date, and the timeliness of the data provide actionable insights to inform current policy and programmatic efforts.

In a large nation-wide sample of clinicians who recently obtained a DATA waiver or obtained an increase in their patient limit, we found that most clinicians prescribed well below their patient limit and 25% did not prescribe at all. Additional efforts focused on clinician training and education, systems-level changes to support innovative service delivery models and payment reforms, and patient and public education on opioid addiction and the use of medications to treat opioid use disorder are urgently needed.

Declaration of interests

None.

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Supporting Information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Appendix S1 SAMHSA DATA 2000 Survey.