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Beyond state scope of practice laws for advanced practitioners: Additional supervision requirements for buprenorphine prescribing

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Abstract

Background: Buprenorphine is a life-saving medication for people with opioid use disorder (OUD). U.S. federal law allows advanced practice clinicians (APCs), such as nurse practitioners (NPs) and physician assistants (PAs), to obtain a federal waiver to prescribe buprenorphine in office-based practices. However, states regulate APCs' scope of practice (SOP) variously, including requirements for physician supervision. States may also have laws entirely banning NP/PA buprenorphine prescribing or requiring that supervising physicians have a federal waiver to prescribe buprenorphine. We sought to identify prevalence of state laws other than SOP laws that either 1) prohibit NP/PA buprenorphine prescribing entirely, or 2) require supervision by a federally waived physician.

Methods: We searched for state statutes and regulations in all 50 states and Washington D.C. regulating prescribing of buprenorphine for OUD by APCs during summer 2021. We excluded general scope of practice laws, laws only applicable to Medicaid-funded clinicians, laws not applicable to substance use disorder (SUD) treatment, and laws only applicable to NPs/PAs serving licensed SUD treatment facilities. We then conducted content analysis.

Results: One state prohibits all APCs from prescribing buprenorphine for OUD, even though the state's general SOP laws permit APC buprenorphine prescribing. Five states require PA supervision by a federally waived physician. Three states require NP supervision by a federally waived physician.

Conclusions: Aside from general scope of practice laws, several states have created laws explicitly regulating buprenorphine prescribing by APCs outside of licensed state SUD facilities.

Keywords

Nurse practitioners; Advanced care practitioners; Physician assistants; State law; Buprenorphine; Waiver; Collaboration; Supervision; Scope of practice; Opioid use disorder; Medications for opioid use disorder

1. Introduction

Medications for opioid use disorder (MOUD)—including formulations of methadone, buprenorphine, and naltrexone—decrease the risk of all-cause mortality among people with opioid use disorder (OUD) by as much as 50% (Santo et al., 2021). In the United States, the federal and state governments tightly regulate clinicians' ability to prescribe or dispense MOUD, particularly methadone and buprenorphine (Frank et al., 2018; Saloner et al., 2021). For example, clinicians can only dispense methadone for OUD in licensed opioid treatment programs (OTPs). Additionally, while clinicians can prescribe formulations of buprenorphine for OUD outside of OTPs, clinicians are bound by federal and state laws, which may restrict and/or regulate prescribing.

Federally, the Drug Addiction Treatment Act of 2000 (DATA-2000), the Comprehensive Addiction and Recovery Act (CARA) (Comprehensive Addiction and Recovery Act of 2016, 2016), and the Substance Use-Disorder Prevention that Promotes Opioid Recovery

and Treatment for Patients and Communities (SUPPORT) Act (“Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, U.S.C. 823(g)(2)(G)(iii),” 2018) enable and regulate prescribing of buprenorphine for OUD outside of OTPs. For example, CARA and subsequent regulations enable certain advanced practice clinicians (APCs)—including physician assistants (PAs) and nurse practitioners (NPs)—to prescribe buprenorphine following a 24-hour training (“Registration of...” 2018; Comprehensive Addiction and Recovery Act of 2016, 2016) and submission of a Notice of Intent to the U.S. Drug Enforcement Agency for an “x-waiver” DEA license. A federal guideline change in 2021 enables both physicians and APCs to obtain an X-waiver for prescribing buprenorphine for OUD to 30 or fewer patients without specialized training in buprenorphine prescribing (Practice Guidelines..., 2021). Federal law requires physicians prescribing buprenorphine to more than 30 patients to obtain eight hours of specialized training and APCs prescribing buprenorphine to more than 30 patients to obtain twenty-four hours of specialized training (Comprehensive Addiction and Recovery Act of 2016, 2016). Furthermore, federal law sets limits on the number of patients to whom waived practitioners can prescribe buprenorphine for OUD (“Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, U.S.C. 823(g)(2)(G)(iii),” 2018).

Expanding the number of clinicians who prescribe buprenorphine for OUD in the United States is a national priority (Frank et al., 2018; Saloner et al., 2021). NPs/PAs have demonstrated willingness to prescribe buprenorphine and have improved access to buprenorphine (Cotton & Ferszt, 2018; Leahy, 2017; Lee & McNeely, 2019; Roose et al., 2008; Tierney et al., 2015; Wen et al., 2019). Since being granted permission to prescribe buprenorphine through CARA, NPs/PAs have obtained X-waivers at a greater rate than physicians. NPs/PAs may fill a critical niche in buprenorphine provision in rural areas where they may be the sole prescriber (Andrilla & Patterson, 2021; Andrilla et al., 2018; Barnett et al., 2019; Fornili & Fogger, 2017; Klein et al., 2020). However, individual states regulate NPs’/PAs’ scope of practice (SOP)—including the degree of independent practice, prescriptive authority, and ability to prescribe controlled substances, including buprenorphine (Nguyen et al., 2021; Spetz et al., 2019; Strobbe & Hobbins, 2012). Thus, while federal law, notably CARA, allows for the provision of buprenorphine by APCs, state laws may limit NPs’/PAs’ prescribing buprenorphine. For example, state SOP laws may require NPs/PAs to have a supervising/collaborating physician for Schedule III prescribing—the controlled substance schedule to which buprenorphine belongs. In addition to general SOP laws, states can require that a supervising/collaborating physician have an X-waiver, or states can ban buprenorphine prescribing by NPs/PAs entirely. Therefore, we sought to identify the prevalence of state laws other than general SOP laws that either 1) prohibit NP/PA buprenorphine prescribing entirely, or 2) require supervision by a federally waived physician.

2. Material and methods

Two research team members searched the Westlaw legal database in May 2021 for state regulations and statutes using terms related to NPs, PAs, and MOUD for all U.S. states plus Washington D.C. We focused our search on NPs and PAs specifically given previous

scholarship, suggesting these APCs' importance in expanding buprenorphine access in underserved, particularly rural, areas (Andrilla et al., 2020). See Appendix for detailed search terms. We then focused on laws regulating buprenorphine prescribing by NPs/PAs outside of licensed facilities. We excluded definitions, controlled substance schedules, and laws not relevant to OUD treatment (e.g., rules related to pain management.) Following a review by a licensed attorney and MOUD subject matter expert, we subsequently excluded the following types of laws from analysis: a) MOUD prescribing for withdrawal or detoxification rather than maintenance treatment; b) pilot programs not applicable to the whole state; c) laws applicable only to state licensed SUD facilities (i.e., as opposed to non-licensed office-based practices); d) rules not specific to MOUD (e.g., rules applicable to prescribers of all controlled substances); e) general SOP rules without specific mention of MOUD; f) pharmacy dispensing rules; g) rules only applicable to treating Medicaid patients or only applicable to treating Workers Compensation patients; and h) rules about *how* to provide MOUD (e.g., required urine drug screenings; prescription drug monitoring program checks) rather than *whether* buprenorphine treatment could be provided at all or *who* must serve as collaborator/supervisor (if needed). In the rare cases where exclusion decisions were unclear, the team held discussions with a larger group of MOUD subject matter experts until everyone reached consensus. For example, in West Virginia office-based buprenorphine prescribing can only occur in state-licensed office-based practices (Taylor, 2016), and after team discussion we chose to exclude NP/PA buprenorphine prescribing laws in West Virginia due to the state's unique requirements regarding settings in which buprenorphine may be prescribed.

We created a codebook using the final dataset, assessing whether the law: (1) allowed an NP to prescribe buprenorphine, (2) required a collaborating or supervising physician, and (3) required the collaborating or supervising physician to have an X-waiver. We created an identical set of codes for PAs. Two research team members subsequently independently coded the final dataset, discussing differences in coding to reach consensus. We coded laws specifying that buprenorphine must be part of the supervising/collaborating physician's regular practice as requiring a waiver for the physician. The entire research team reviewed final codes, along with the relevant legal text and citations, and discussed interpretations of the legal text to achieve consensus. Last, we compared our dataset to the general state SOP laws for NPs and PAs for schedule III substances using datasets of SOP laws from McMichael and Markowitz (2020) (McMichael & Markowitz, 2020) and the National Conference of State Legislatures (National Conference of State Legislature, 2021).

3. Results

General SOP laws for Schedule III controlled substances:

In May 2021, all states permitted NP and PA prescribing of Schedule III controlled substances within their SOP laws. All states also required that PAs have physician collaboration or supervision for Schedule III controlled substance prescribing. Twenty-nine states allowed NPs to prescribe Schedule III controlled substances without formal physician oversight; and Virginia allowed NPs to practice independently after five years of oversight.

Buprenorphine-specific prescribing laws (separate from SOP laws):

We found one state, Tennessee, that explicitly prohibited buprenorphine prescribing by APCs in a law separate from its SOP law. We found five states (Louisiana, Maine, Ohio, Oregon, and Virginia) that not only required a supervising/collaborating physician for PAs in the general SOP law, but also had a law requiring supervising/collaborating physicians to have an X-waiver. Similarly, we found three states (Louisiana, Ohio, and Virginia) that required a supervising/collaborating physician for NPs to have an X-waiver. See Figure 1 for a map of NP/PA laws specific to buprenorphine prescribing for OUD. See Table 1 for relevant quotes and effective dates from state laws and Table 2 for a comparison of relevant laws across all jurisdictions. Among the states that we identified with laws, Tennessee's law is the oldest, becoming effective in 2015. The laws in all the other states became effective after January 2017, with Ohio's law regulating NP prescribing of buprenorphine being the most recent (effective as of February 2021.)

4. Discussion

Buprenorphine is an underutilized life-saving treatment for OUD (National Academies of Science Engineering & Medicine, 2019; Wakeman et al., 2020; Wu et al., 2016). Since the passage of CARA, scholars have described NPs and PAs as a key resource in mitigating underprescribing of buprenorphine for OUD in the United States (Andrilla et al., 2018; Barnett et al., 2019; Wen et al., 2019). Nevertheless, we found that six states either entirely prohibit APC buprenorphine prescribing or have specific APC supervision policies that may limit these clinicians from providing effective treatment for OUD outside of licensed SUD facilities (e.g., in office-based practices).

CARA requires that APCs in states with SOP collaboration/supervision requirements work with a physician “qualified” to obtain a waiver (Comprehensive Addiction and Recovery Act of 2016, 2016). A physician being “qualified” to obtain a waiver is not the same, however, as a physician possessing a waiver. Nevertheless, we found five states that go beyond the federal law and require that the supervising/collaborating physician have an X-waiver. Whether legal requirements for a physician to possess an X-waiver as opposed to merely “qualifying” for a waiver would have measurably different effects on APC prescribing rates is unclear. If so, then it is particularly concerning that Ohio and Maine require NPs and/or PAs to collaborate with or be supervised by waived physicians, as both Ohio and Maine were among the top ten states in terms of opioid-involved death rates in 2019 (Kaiser Family Foundation, 2019). Furthermore, among all U.S. states, Maine has the highest proportion of rural residents (61.3%) (United States Census Bureau, 2012); and NPs/PAs are critical for addressing buprenorphine underutilization in rural areas with few waived physicians (Andrilla & Patterson, 2021). Importantly, scholars, activists, practitioners, and policy-makers have called for legislation eliminating the federal X-waiver requirement (Marino et al., 2019; Saloner et al., 2021), which, if passed, would render waiver-related concerns moot.

Surprisingly, despite CARA and the state's own general SOP laws, Tennessee prohibits APC prescribing of buprenorphine for OUD. This policy likely decreases access to buprenorphine for Tennessee residents, despite buprenorphine's relative safety among opioids, its lifesaving

potential for people with OUD (Santo et al., 2021), and Tennessee having one of the nation's highest drug overdose mortality rates. Tennessee's policies are especially likely to constrain treatment access, as 93% of the state is rural (Tennessee Department of Health, 2021). Rural areas are least likely to have waived physicians and thus APCs, such as NPs/PAs, could make a substantial difference in providing treatment access in these locations (Andrilla & Patterson, 2021).

Our study has several important limitations. We excluded several laws that could impact NP/PA buprenorphine prescribing and should be examined in future studies: Medicaid rules, Workers Compensation rules, and laws applicable only to APCs working in state-licensed SUD treatment facilities, including West Virginia's laws requiring office-based practices that provide buprenorphine treatment to have state licenses. Also, through other regulatory mechanisms, states may have other buprenorphine treatment requirements not captured in our study, which could further constrain buprenorphine treatment. For example, states may require NPs/PAs to obtain additional continuing medical education credits when prescribing buprenorphine, limit the days' supply of controlled substances an NP/PA can prescribe, require NPs/PAs to provide or refer patients to counseling, and require NPs/PAs to conduct routine urine drugs screens. Therefore, our study likely *underreports* the extent to which state laws influence NP/PA buprenorphine prescribing. Additionally, we did not examine laws regulating buprenorphine prescribing by other types of APCs, such as clinical nurse specialist, certified registered nurse anesthetists, and certified nurse midwives. Future work, including qualitative studies of NPs'/PAs' experiences, should disentangle the role of different types of laws on NPs'/PAs' buprenorphine prescribing behaviors. Finally, we know little about how NPs/PAs find physicians with X-waivers with whom to collaborate, nor to what extent finding such physicians and establishing a collaborative relationship acts as a barrier to APC buprenorphine prescribing.

5. Conclusion

Our study found that several states have created laws regulating APC supervision when prescribing buprenorphine in ways that go above and beyond oversight requirements in the states' general SOP laws, such as by requiring supervising physicians to have an X-waiver. Our results highlight the need for empirical studies of state APC supervision policies to examine the effects of laws beyond general SOP laws.

The opioid epidemic continues to be a significant public health crisis, with more than 90,000 fatal overdose deaths in 2020, more than ever before (Ahmad et al., 2021). Expanding access to the most effective treatments, such as buprenorphine, is critical to an effective response to this crisis. Since the passage of CARA, NPs and PAs have played an increasingly important role in increasing access to buprenorphine (Andrilla et al., 2018). Yet states with among the highest opioid-related overdose rates either entirely prohibit APC buprenorphine prescribing or have specific APC supervision policies that may limit these clinicians' provision of effective treatment for OUD outside of licensed SUD facilities (e.g., in office-based practices).

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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HIGHLIGHTS

- One state prohibits all advanced practice clinicians from prescribing buprenorphine
- Five states require a waived supervising physician for PAs prescribing buprenorphine
- Three states require a waived supervising physician for NPs prescribing buprenorphine
- Studies of state NP/PA supervision should include non-scope of practice laws

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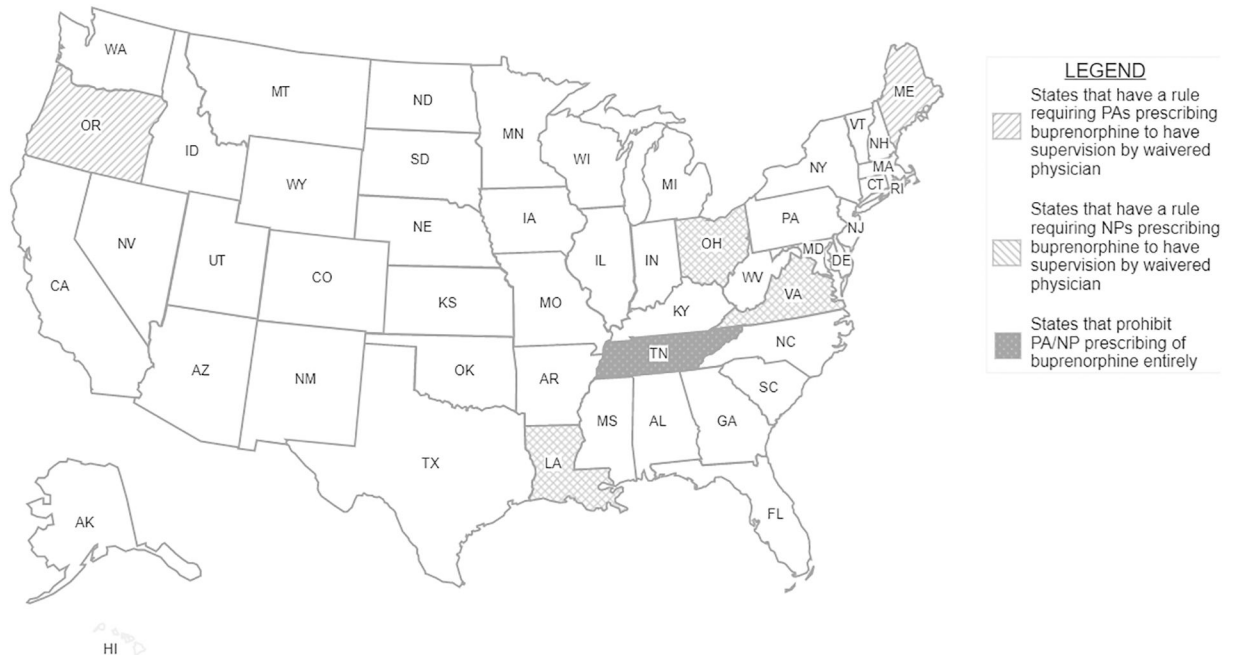


Fig. 1:
NP PA paper.

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Table 1:

Relevant legal excerpts and citations (italics added for emphasis)

State	Citation	Legal text	Practitioner to whom law applies	Earliest version containing excerpt	Current version
LA	LA § 913.	<i>(c) Advanced practice registered nursing may include the provision of medication-assisted treatment (MAT), as authorized by the United States Department of Health and Human Services, Substance Abuse and Mental Health Services Administration and in accordance with rules promulgated by the board. At a minimum, rules promulgated by the board shall include a requirement that in order for the APRN to provide MAT, his collaborating physician shall also be authorized and in compliance with all federal and state laws and rules authorizing the provision of MAT.</i> For purposes of this Subparagraph, "MAT" means the use of medications with counseling and behavioral therapies to treat substance use disorders and prevent opioid overdose.	NP	Effective: August 1, 2019	Effective: August 1, 2019
	LA § 1360.31.	<i>(4) A physician assistant may provide medication-assisted treatment (MAT), as authorized by the United States Department of Health and Human Services, Substance Abuse and Mental Health Services Administration and in accordance with rules promulgated by the board. At a minimum, rules promulgated by the board shall include a requirement that in order for the PA to provide MAT, his supervising physician shall also be authorized and in compliance with all federal and state laws and rules authorizing the provision of MAT.</i> For purposes of this Subparagraph, "MAT" means the use of medications with counseling and behavioral therapies to treat substance use disorders and prevent opioid overdose.	PA	Effective: August 1, 2019	Effective: August 1, 2019
ME	ME § 3	1. Clinicians who wish to provide Approved Medications for OUD in an OBOT must: A. Hold a current license issued by the Board; B. Hold a current controlled substance registration issued by the DEA; C. Obtain a DATA 2000 Waiver and complete buprenorphine training; <i>D. In the case of a physician assistant, be delegated the authority to provide OBOT pursuant to a written plan of supervision by a supervising physician who also meets the criteria for providing OBOT;</i> and E. Comply with this joint rule. 2. Patient limits. Clinicians must be aware of and comply with limits established by the DEA regarding the number of patients that can be treated with Approved Medications in OBOT.	PA	Effective: April 29, 2020	Effective: April 29, 2020
OH	OH 4723-913	<i>(B) An advanced practice registered nurse with a current valid license issued by the board and designated as a clinical nurse specialist, certified nurse midwife or certified nurse practitioner may provide medication-assisted treatment, including prescribing controlled substances in schedule III, IV or V, if the advanced practice registered nurse:</i> (1) Complies with section 3719.064 of the Revised Code, and all federal and state laws and regulations governing the prescribing of the medication, including but not limited to incorporating into the advanced practice registered nurse's practice knowledge of Chapter 4729. of the Revised Code, and Chapter 4731. of the Revised Code and rules adopted under that Chapter that govern the practice of the advanced practice registered nurse's collaborating physician; (2) Completes at least 8 h of continuing nursing education in each renewal period related to substance abuse and addiction. Courses completed in compliance with this requirement shall be accepted toward meeting the continuing education requirements for biennial renewal of the advanced practice registered nurse license; and (3) Only provides medication-assisted treatment if the treatment	NP	Effective: February 1, 2021	Effective: February 1, 2021

State	Citation	Legal text	Practitioner to whom law applies	Earliest version containing excerpt	Current version
		is within the collaborating physician's normal course of practice and expertise.			
	OH 4730-403	(A) A physician assistant who provides OBOT shall comply with the following requirements: (1) Before initiating OBOT, the physician assistant shall comply with section 3719.064 of the Revised Code. (2) Comply with all federal and state laws and regulations governing the prescribing of the medication; (3) Complete at least eight hours of "Category 1" continuing medical education relating to substance abuse and addiction every two years. Courses completed in compliance with this requirement shall be accepted toward meeting the continuing medical education requirement for biennial renewal of the physician assistant's license; and (4) Only provide OBOT if the provision of OBOT is within the supervising physician's normal course of practice and expertise.	PA	Effective: April 30, 2019	Effective: April 30, 2019
OR	OR 847-050-0041	(4) A physician assistant may prescribe and dispense buprenorphine for medication-assisted treatment for opioid dependency if the requirements in (1) or (2) are fulfilled and the following conditions are met: (a) The physician assistant has obtained a buprenorphine waiver from the Drug Enforcement Administration; (b) The physician assistant has been granted dispensing authority if the physician assistant will dispense buprenorphine; (c) The scope of practice of the physician assistant's supervising physician includes use of buprenorphine for medication-assisted treatment for opioid dependency; (d) The physician assistant's practice agreement includes use of buprenorphine for medication-assisted treatment for opioid dependency as a delegated medical service; and (e) The physician assistant complies with all federal and state requirements for recordkeeping specific to buprenorphine treatment.	PA	Effective: July 14, 2017	Effective: January 5, 2018
TN	TN § 53-11-311	(c)(1) Notwithstanding any other provision of this title, and except as otherwise provided in subdivision (c)(2), a physician licensed under title 63, chapter 6 or 9, is the only healthcare provider authorized to prescribe any buprenorphine product for any federal food and drug administration approved use in recovery or medication-assisted treatment.	NP; PA	Effective: July 1, 2015	Effective: August 1, 2020
VA	VA 85-21-130	C. Physician assistants and nurse practitioners who have obtained a SAMHSA waiver shall only prescribe buprenorphine for opioid addiction pursuant to a practice agreement with a waived doctor of medicine or doctor of osteopathic medicine.	PA	Effective: August 8, 2018.	Effective: August 8, 2018.
	VA 90-40-250	C. Nurse practitioners who have obtained a SAMHSA waiver shall only prescribe buprenorphine for opioid addiction pursuant to a practice agreement with a SAMHSA-waivered doctor of medicine or doctor of osteopathic medicine unless the nurse practitioner has been authorized by the boards for autonomous practice.	NP	Effective: July 10, 2019.	Effective: July 10, 2019.

Table 2:

Summary of laws

	SOP law permits PA prescribing of schedule III?	Other state law prohibits PA buprenorphine prescribing?	SOP law requires PA physician supervision/collaboration?	PA's collaborating/supervising physician needs x-waiver?	SOP law permits NP prescribing of schedule III?	Other state law prohibits NP buprenorphine prescribing?	SOP law requires NP physician supervision/collaboration?	NP's collaborating/supervising physician needs x-waiver?
AL	yes	no	yes	no	yes	no	Yes	no
AK	yes	no	yes	no	yes	no	No	no
AZ	yes	no	yes	no	yes	no	no	no
AR	yes	no	yes	no	yes	no	yes	no
CA	yes	no	yes	no	yes	no	yes	no
CO	yes	no	yes	no	yes	no	no	no
CT	yes	no	yes	no	yes	no	no	no
DE	yes	no	yes	no	yes	no	no	no
FL	yes	no	yes	no	yes	no	no	no
GA	yes	no	yes	no	yes	no	yes	no
HI	yes	no	yes	no	yes	no	no	no
ID	yes	no	yes	no	yes	no	no	no
IL	yes	no	yes	no	yes	no	no	no
IN	yes	no	yes	no	yes	no	yes	no
IA	yes	no	yes	no	yes	no	no	no
KS	yes	no	yes	no	yes	no	yes	no
KY	yes	no	yes	no	yes	no	yes	no
LA	yes	no	yes	yes	yes	no	yes	yes
MA	yes	no	yes	no	yes	no	no	no
MD	yes	no	yes	no	yes	no	no	no
ME	yes	no	yes	yes	yes	no	no	no
MI	yes	no	yes	no	yes	no	yes	no
MN	yes	no	yes	no	yes	no	no	no
MS	yes	no	yes	no	yes	no	yes	no
MO	yes	no	yes	no	yes	no	yes	no
MT	yes	no	yes	no	yes	no	no	no
NE	yes	no	yes	no	yes	no	no	no
NV	yes	no	yes	no	yes	no	no	no
NH	yes	no	yes	no	yes	no	no	no
NJ	yes	no	yes	no	yes	no	yes	no
NM	yes	no	yes	no	yes	no	no	no
NY	yes	no	yes	no	yes	no	no	no
NC	yes	no	yes	no	yes	no	yes	no
ND	yes	no	yes	no	yes	no	no	no

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	SOP law permits PA prescribing of schedule III?	Other state law prohibits PA buprenorphine prescribing?	SOP law requires PA physician supervision/collaboration?	PA's collaborating/supervising physician needs x-waiver?	SOP law permits NP prescribing of schedule III?	Other state law prohibits NP buprenorphine prescribing?	SOP law requires NP physician supervision/collaboration?	NP's collaborating/supervising physician needs x-waiver?
OH	yes	no	yes	yes	yes	no	yes	yes
OK	yes	no	yes	no	yes	no	yes	no
OR	yes	no	yes	yes	yes	no	no	no
PA	yes	no	yes	no	yes	no	yes	no
RI	yes	no	yes	no	yes	no	no	no
SC	yes	no	yes	no	yes	no	yes	no
SD	yes	no	yes	no	yes	no	no	no
TN	yes	yes	yes	n/a	yes	yes	yes	n/a
TX	yes	no	yes	no	yes	no	yes	no
UT	yes	no	yes	no	yes	no	no	no
VT	yes	no	yes	no	yes	no	no	no
VA	yes	no	yes	yes	yes	no	no	yes
WA	yes	no	yes	no	yes	no	no	no
WV	yes	no	yes	no	yes	no	no	no
WI	yes	no	yes	no	yes	no	yes	no
WY	yes	no	yes	no	yes	no	no	no

* Dark grey indicates requirement for APC supervision by waived physician when prescribing buprenorphine for OUD. Light grey indicates prohibition of buprenorphine prescribing for OUD by APCs.

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