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Eliminate the Buprenorphine DEA X waiver: Justification Using a Policy Analysis Approach

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Abstract

Introduction—Drug overdoses have reached a historic milestone of over 100,000 deaths in a single year, 75,673 related to opioids. The acceleration in opioid-related deaths coupled with stark health inequities demands a close examination of opioid use disorder (OUD) treatment barriers and swift consideration of policy changes.

Design—The aim of this buprenorphine policy analysis is to summarize existing buprenorphine barriers and present policy solutions to improve access and actualize the contributions of Advanced Practice Registered Nurses (APRNs).

Methods—The policy analysis follows five sequential steps: 1) defining the problem, 2) identifying key stakeholders, 3) assessing the landscape of relevant policies, 4) describing viable policy options, and 5) making final recommendations.

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Katie Fitzgerald Jones wrote the initial draft of the manuscript; Monica O'Reilly Jacob, Matthew Tierney, Joanne Spetz helped develop the research project, mentorship with the interpretation of policies, and provided iterative revisions on the manuscript, Laurie Hailer assisted with data analysis and developing and ensuring the accuracy of figures. All authors revised the manuscript for final submission

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The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Sigma Chapter:
Katie Fitzgerald Jones is a member of Sigma Theta Tau Alpha Chi Chapter.

Results—Although there are laudable efforts to improve buprenorphine access, such as the new buprenorphine guidelines issued in April 2021, without larger-scale changes to federal, state, and scope of practice laws, overdose rates will continue to rise. We recommend a multipronged policy approach to improve buprenorphine treatment access, including eliminating the DEA X waiver, improving OUD education, and adopting full practice authority for APRNs in all states.

Conclusion—Incremental change is no longer sufficient to address opioid overdose deaths. Bolder and coordinated policy action is possible and necessary to empower the full clinical workforce to apply evidence-based life-saving treatments for OUD. The critical contributions of nurses in advancing equitable access to OUD care are emphasized in the National Academy of Medicine's Report, Future of Nursing: Charting a Path to Achieve Health Equity. Nurses are named as instrumental in improving buprenorphine access. Policy changes that acknowledge and build on evidence-based treatment expansion strategies are sorely needed.

Clinical Relevance—One of the most robust tools to combat opioid overdose deaths is buprenorphine, a partial opioid agonist and gold standard medication treatment for OUD, but only 5% of the prescribing workforce possess the required Drug Enforcement Agency (DEA) X waiver. A growing body of evidence demonstrates that Advanced Practice Registered Nurses are accelerating the growth in waiver update and buprenorphine use, despite the considerable barriers and limitations described in this policy analysis.

Keywords

Substance Use; Substance Abuse; Advanced Nursing Practice; Policy; Mental Health Disorders; Health Disparities; Nursing Practice

Introduction

Drug overdose deaths reached a historic milestone in 2021 with over 100,000 deaths, with 75,673 related to opioids (National Center for Health Statistics, 2021). The acceleration in opioid-related deaths coupled with identified health inequities prompts a close examination of opioid use disorder (OUD) treatment barriers and swift consideration of regulatory changes. There are three available medication treatments for OUD (MOUD): methadone, buprenorphine, and naloxone. The choice of MOUD is dependent on patient preference, availability, and individual circumstances. The evidence supports the use of buprenorphine or methadone over the use of other treatments (naloxone, behavioral treatment, or inpatient detoxification) to reduce opioid-related overdose or harms (Wakeman et al, 2020). Indeed, buprenorphine, a partial opioid agonist, is a life-saving treatments for OUD (Wakeman et al., 2020). In the United States, buprenorphine is typically co-formulated with naloxone when treating opioid use disorder; heretofore referred to as buprenorphine. The naloxone component is only active if the product is injected and serves as an "abuse deterrent" (Yokell et al, 2011).

Buprenorphine decreases the risk of opioid overdose death and effects of at-risk substance use such as endocarditis and human immunodeficiency virus (Barocoas et al., 2021). Despite the effectiveness of buprenorphine, existing policies require clinicians (physicians, advanced practice nurses, and physician assistants) to possess a Drug Enforcement Agency (DEA)

license and a specialty X waiver to prescribe buprenorphine for OUD. In 2022, less than 5% of the prescribing workforce possess an X waiver or 77, 547 clinicians, a stark contrast to the total number who possess traditional DEA licenses (Spetz, Chapman et al., 2021). Consequently, many patients with OUD never receive buprenorphine with dire consequences. In a study by Wakeman et al. (2020) of nationally insured people with OUD, buprenorphine or methadone was associated with a 76% reduction in overdose at three months but only 12.5% received these treatments. In contrast, the most common treatment for OUD was the inferior option of behavioral treatment or inpatient detoxification that was not associated with a reduction in overdose or opioid-related harms at three or twelve months.

In response to rising opioid deaths and recognition of the OUD treatment gap, in April 2021, an alternative buprenorphine X waiver was created, allowing applicants to by-passing the training requirement of other traditional waiver types to treat less than 30 patients at one time (The Department of Health and Human Services Federal Notice, 86 FR 22439, 2021). Although this new X waiver process attempted to improve buprenorphine waiver uptake by eliminating the time-consuming training requirements, early evidence suggests it has not. During the COVID-19 pandemic, the growth of X waiver clinicians has slowed with the alternative notice of intent (NOI) process failing to mitigate this. For example, a study by Spetz et al. (2022a) using DEA registrant files from 2018 and 2021 indicates that prepandemic waiver growth in 2018 was higher with the training requirements, whereas 2021 growth dropped for all clinician types during the pandemic despite the alternative NOI process eliminating the training requirement to treat < 30 patients.

The purpose of this paper is to present a policy analysis of the DEA X waiver and relevant regulatory buprenorphine policies. Analyzing the relevant regulatory policy issues and proposing actionable policy solutions is an important call to action of the Future of Nursing Report (2020–2030) to further the contributions of Advanced Practice Registered Nurses (APRNs) and improve access to equitable OUD treatment (National Academies of Science, Engineering, and Medicine Consensus Study Report, 2021). Indeed, an analysis of buprenorphine policies is a critical contribution to the literature since a poor understanding of buprenorphine associated policies is a regularly reported prescribing barrier among clinicians (Lanham et al., 2022). A growing body of evidence demonstrates that APRNs are accelerating the growth in waiver update and buprenorphine use (Barnett et al., 2019; Spetz et al., 2021), notwithstanding the barriers and limitations described here.

Policy Analysis Approach

The policy analysis will: 1) define the problem, 2) identify key stakeholders, 3) assess the landscape of relevant policies, 4) describe viable policy options, and 5) offer recommendations.

The Problem

National estimates indicate only 17% of eligible persons receive any form of MOUD, i.e., buprenorphine, methadone, or naltrexone (Mauro et al., 2022). The impact of buprenorphine as MOUD to prevent opioid-related harms is immense, even when use is intermittent. For

example, in a national sample of veterans with OUD, persons who were not receiving buprenorphine on a given day had a more than 4-fold higher rate of suicide and overdose death than those who were receiving buprenorphine, even when accounting for times if they were receiving other forms of MOUD (Vakkalanka et al., 2021). Despite the benefits, the current buprenorphine regulatory policy landscape has resulted in low treatment rates, large racial and geographic disparities, and a healthcare workforce that is hesitant to treat the chronic condition of OUD (Haffajee et al, 2018; Weimer et al., 2021).

Stakeholders

Key stakeholders to expanding buprenorphine treatment include the majority of people with OUD who have never received evidence-based treatment and are more likely to be insured by Medicaid, persons of color, or women of color (Kilaru et al., 2020; Lagisetty et al., 2019). The healthcare workforce, including APRNs, plays an integral role in providing evidence-based OUD treatment with buprenorphine (Cos et al., 2021). Policymakers can influence and enact significant changes in opioid regulations by creating new standards of care that recognize OUD as a treatable chronic condition deserving of evidence-based care (Jones and Mason, 2022).

Landscape

The analysis will focus on federal regulation and state regulation of buprenorphine state-level APRN scope of practice, and buprenorphine-specific limitations.

Federal Regulation of Buprenorphine.

Over the past several years, there have been incremental changes to federal OUD policies. Figure 1 provides an overview of federal legislation of buprenorphine alongside total overdose deaths per year. Buprenorphine for OUD treatment was initially authorized by the federal Drug Addiction Treatment Act (2000), making it the first and, so far, only scheduled drug approved for office-based MOUD. Under DATA 2000, physicians can apply for a waiver after completing 8 hours of training and confirming their ability to refer to counseling services, thus allowing office-based addiction treatment outside of licensed opioid treatment programs. In 2016, the Comprehensive Addiction Recovery Act (CARA) permitted provisional buprenorphine prescribing by Nurse Practitioners (NPs) and Physician Assistants (PAs) after completing 24 hours of training. It was made permanent in 2018 by the Substance Use Disorder Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act, 2018). The SUPPORT Act also extended access to DEA X waivers to other APRNs.

Several types of DEA X waivers are outlined in Table 1 (Substance Abuse and Mental Health Service Administration Statues, 2022). The type of waiver dictates the number of patients the clinician can prescribe buprenorphine as an OUD treatment at one time, with limits set at 30, 100, or 275 patients. A NOI is required for all waiver types before prescribing buprenorphine. Some waivers have additional requirements that include training, setting of care, ability to accept third-party payment, use of electronic medical records, and use of a prescription drug monitoring program. For clinicians practicing with a 275-

patient waiver, there is a required annual report to the Substance Abuse and Mental Health Service Administration (SAMHSA). All X waivered clinicians, regardless of waiver type, must adhere to record-keeping requirements and are subject to periodic audits by the DEA. The new buprenorphine guideline issued in April 2021 by the Health and Human Service Administration allows clinicians to receive a 30-patient waiver exemption without previously required training and attestation for counseling referrals. However, the training requirements must be fulfilled to increase to 100 or 275 patients.

The above regulations of buprenorphine for OUD treatment are not grounded in evidence or precedence. Buprenorphine is a schedule III controlled substance with a superior safety profile compared to most schedule III drugs and is rarely associated with overdose death (Aldabergenov et al., 2022). Buprenorphine is the only controlled substance that requires specific approval for OUD prescribing, limiting its use to clinicians willing to engage in specific waiver requirements. Meanwhile, schedule II controlled substances with greater overdose potential can be prescribed for pain without specialty training or patient limits. Additionally, prescribing buprenorphine for pain does not require a waiver, nor does it count towards the OUD treatment patient limit The waiver-based policies serve as OUD treatment barriers and deserve revision based on the known benefits and relative safety of buprenorphine in treating OUD (Jones& Mason, 2022; Weimer et al., 2021).

Although there is some ambiguity in the research literature, whether training and counseling are necessary to safely prescribe buprenorphine- buprenorphine alone improves mortality even without counseling and is consistent with a harm reduction approach (Carroll & Weiss, 2019). Indeed, the consensus study report by the National Academies of Science, Engineering, and Medicine entitled Medication for Opioid Use Disorder Saves Lives (2019) concludes the lack use of behavioral interventions or availability is not sufficient justification to withhold buprenorphine or other forms of MOUD (p. 52).

The regulation of buprenorphine prescribing for OUD is tied to inequitable treatment access based on geography and race. More than 40% of counties in the US lack an X waivered clinician, and half of the X waivered clinicians in rural areas are not accepting new patients (Andrilla et al., 2019). Several years following the passage of DATA 2000, when buprenorphine waivers were limited to physicians, over 90% of the patients taking buprenorphine were employed, White, commercially insured, and dependent on prescription rather than opioids from nonmedical sources (Hansen et al., 2016). Evidence consistently demonstrates the choice of MOUD differs in people of color who are significantly less likely to receive buprenorphine (Lagisetty et al., 2019; Jones, O'Reilly-Jacob et al., 2022;). Likewise, the availability of MOUD is influenced by structural racism. For instance, in a cross-sectional US study, counties with highly segregated Black and Hispanic/Latino communities had more methadone facilities per capita, compared to segregated white communities that had a greater number of buprenorphine facilities per capita (Goedel et al., 2020).

State Regulations of Buprenorphine

State regulations are also not informed by scientific evidence of successful treatment facilitators, and many regulations create known barriers to buprenorphine prescribing. Since

2005, 10 states passed a total of 181 laws regulating buprenorphine treatment in the office setting over and above the DEA federal regulations (Andraka-Christou et al., 2022). Many state-based and private insurers impose arbitrary dose restrictions, specify follow-up, and require counseling requirements despite contradicting evidence. For example, Ohio sets a maximum allowed buprenorphine dose of 24 mg per day, and doses exceeding 16 mg must have a rationale for the dose in the patient record (Ohio Administrative Code 4731–11–12, 2022). A meta-analysis of 21 randomized clinical trials indicates that higher buprenorphine doses (16 to 32 mg per day) predict better retention in treatment than lower doses (Fareed et al, 2012). Buprenorphine doses should be individualized to the patient and disease severity (Hjelmstrom et al, 2019). Tennessee requires clinicians to initiate discussion regarding buprenorphine tapering at the one-year mark (or earlier) and every six months after that (Tennessee Department of Mental Health and Substance Abuse, 2021). The current clinical consensus is buprenorphine treatment should be continued as long as it offers benefits (often a minimum of one year and sometimes life-long). There is clear evidence that early tapering of buprenorphine increases mortality risk (Meinhofer et al, 2019). Michigan requires Medicaid patients on buprenorphine to receive counseling by a clinician different from their prescriber (Spetz et al., 2021), despite multiple randomized trials demonstrating no benefit to adding counseling to MOUD (). Indeed, a systematic review by Rice et al. (2020) synthesized the findings of seventy-two randomized controlled trials on the role of adjuvant psychosocial counseling with MOUD and reported few differences were consistently found between MOUD alone compared with MOUD plus psychosocial support.

Furthermore, under the Affordable Care Act, insurance coverage of buprenorphine for OUD is required, but prior authorization continues to be a significant issue in many states (PEW Trust, 2021). In response on April 20, 2020, 21 states and the District of Columbia enacted laws to prevent insurers (public and/or private) from imposing prior authorization requirements on MOUD and five states (Delaware; Illinois; Maine; Massachusetts; and Washington) prevent the use of prior authorization with Medicaid's use of prior authorization (Legal Action Center, 2021). Recent evidence in Medicare beneficiaries demonstrates that removing the prior authorization requirement doubles the number of prescriptions of buprenorphine (Mark et al., 2020). Further, rates of buprenorphine prescribing are significantly higher in states that expanded Medicaid benefits following the Affordable Care Act (Clemena-Cope et al., 2019). A consensus study from the National Academies of Sciences, Engineering, and Medicine (2019) found that the combination of federal and state requirements worsens buprenorphine treatment access, particularly for those with Medicaid coverage.

Nurse Practitioner Scope of Practice

Despite federal law, namely CARA and SUPPORT, allowing for the provision of buprenorphine by APRNs, state scope of practice laws and buprenorphine-specific limitations may limit APRNs prescribing buprenorphine. This includes prerequisites such as requiring a supervising/collaborating physician for Schedule III prescribing, requiring a supervising/collaborating physician to have an X-waiver, or limiting buprenorphine prescribing to APRNs working at employed or contracted with a nonresidential office-based opiate treatment facility (Andraka-Christou et al., 2022). States that require physician

oversight of APRN prescribing have had less growth in the percentage of APRNs who obtain a waiver than states that do not limit APRN prescribing of buprenorphine (Spetz et al., 2019). Depicted in Figure 2 is the relationship between the percentage of APRNs waivered by state scope of practice. Rural counties that are significantly impacted by the overdose crisis have greater numbers of total X-waivered clinicians in states with APRN full practice authority (Barnett et al., 2019). A greater proportion of APRNs now have X waivers compared to physicians, and APRNs are progressing to 100-person waivers more rapidly than other clinicians (Spetz et al., 2021).

There are several potential explanations on why APRNs are more likely to treat patients with OUD and possess a DEA X waiver. First, APRNS are more concentrated in rural and urban areas and provide care in a wider range of community settings (Buerhaus et al., 2015). Second, APRNs often serve patients who are underserved, socially complex, and insured by Medicaid or dual eligible (Buerhaus et al., 2018). Likewise, nursing holistic education is well-suited to care for people with OUD. For example, the “Massachusetts Model” places nursing at the center of buprenorphine treatment dissemination and is a blueprint for collaborative care models throughout the country (LaBelle et al., 2016). Additionally, over time more states are passing full scope of practice laws that increase APRN waiver uptake, waiver prescriber supply, and buprenorphine prescribing (Nguyen et al., 2021). Lastly, APRNs have only had waiver capacity since 2016 and although clinicians treatment capacity in general is stably growing, APRNs account for the largest portion of capacity growth (Spetz et al., 2022b).

Policy Solutions and Recommendations

In light of the federal, state, and nursing scope of practice issues, a multifaceted policy response is critical to expanding equitable OUD treatment. We recommend the following to improve much-needed access to evidence-based and life-saving treatment for OUD:

1: Eliminate the X Waiver

Eliminating the X waiver would remove the restriction requiring clinicians who prescribe buprenorphine to treat OUD to possess a specialty DEA license. It would allow OUD treatment expansion by removing existing limits to the size of patient panels. France deregulated buprenorphine resulting in an 80% reduction in overdose deaths over four years (Fiscella et al., 2019). If the US adopted similar prescribing, it would prevent an estimated 37,000 deaths in a single year (Weimer et al., 2021). Table 2. Provides a comprehensive summary of the rationale for X waiver elimination.

There is readiness for change and bipartisan support to eliminate the X waiver within the executive branch (Hunter and Stein, 2021). In January 2021, the Trump administration eliminated the X waiver but reinstated it due to issues surrounding the jurisdiction of the Department of Health and Human Services (Health and Human Services Expands Access to Treatment for Opioid Use Disorder, 2021). Eliminating barriers to buprenorphine treatment has drawn widespread multidisciplinary support from national organizations, including the American Academy of Nurse Practitioners (2021). Nurses can support the elimination of the DEA X waiver as an important antiracist policy action that can expand buprenorphine

to people who are most need of opioid use disorder treatment. This includes populations who historically lack political power, such as people who interface with the criminal justice system, undocumented persons, or people of color (Jones & O'Reilly-Jacob., 2022). X waiver elimination has the potential to reduce stigma, normalize as evidence-based treatment, and put additional pressure on states and insurers to follow suit-eradicating barriers like dose limits, counseling requirements, and prior authorizations. The above-noted elimination of the educational requirements in April 2021 provides momentum. Still, it is not enough amid an unprecedented acceleration of overdose deaths, especially since patient panel limits remain (Spetz et al., 2022).

2: Improve Education of Opioid Use Disorders

Eliminating the X waiver alone is unlikely to close the OUD treatment gap unless education for incoming and existing clinicians is prioritized (Weimer, 2021). Known barriers to buprenorphine treatment include lack of training, low confidence, and scarce collaboration with addiction specialists (Haffajee et al., 2018). Prioritizing education on the etiology and treatment of OUD is critical; most nurses do not receive education on addiction (Finnell et al., 2018).

There are many well-established resources available for practicing clinicians. For example, Project Extension for Community Healthcare Outcomes (ECHO) uses a distance education model to connect addiction specialists with primary care APRNs, PAs, MDs, and DOs to facilitate case-based learning (Komaromy et al., 2016). OUD educational programs, such as the SAMHSA-supported Provider Clinical Support Service (PCSS), play an essential role in increasing the nursing workforce and improving the delivery of buprenorphine. Addiction mentorship programs exist through the PCSS and numerous professional societies, including the American Psychiatric Nurses Association, offer buprenorphine courses. Education programs for both the existing and rising clinical workforce can build on these existing successful models. When the X waiver is eliminated, these educational programs should remain to disseminate knowledge about OUD risks, diagnosis, and effective treatments.

Mandatory OUD education is under consideration by Congress through The Medication Access and Training Expansion Act (MATE Act 2021–2022), reintroduced by Senators Michael Bennet and Susan Collins during the 117th session of Congress. The MATE Act proposes a one-time, non-repetitive requirement for all DEA controlled substance prescribers to complete training on treating and managing patients with opioid and other substance use disorders. It would also provide federal funding for medical schools and residency programs, physician assistant schools, and schools of advanced practice nursing to fulfill the training requirement. Through curricula that normalize addiction education as foundational to all clinical practice, thus eliminating the need for these future practitioners to participate in federally mandated DATA-specified addiction education programs. The legislation has the ability to standardize education of core addiction principles across professional schools and, over time, diminish existing knowledge and training gaps.

3: Adopt Full Practice Authority in All States

Expanding advanced practice nursing scope of practice is known to expand buprenorphine treatment access significantly and is a health equity issue (National Academies of Sciences, Enginnering & Medicine, 2021). The ability of nurses to accelerate their contributions to improving OUD access will require eliminating the unnecessary scope of practice and buprenorphine-specific prescribing restrictions. APRNs have filled buprenorphine treatment gaps, most notably in rural areas (Andrilla et al., 2019). When APRN practice restrictions are removed, other benefits ensue. During the COVID-19 pandemic, psychiatric APRNs in states that suspended practice barriers were six times more likely to report improved clinical practice, possibly attributable to telehealth changes and more efficient prescribing (O'Reilly-Jacob et al., 2021). Expanding full practice authority for APRNs in all states is paramount to mitigate gaps in OUD treatment and remedy health inequities (Cos et al., 2021;National Academies of Sciences, Engineering & Medicine, 2021).

Conclusion

Incremental change is no longer sufficient to address opioid overdose deaths. Bolder and coordinated policy action is possible and necessary to empower the full clinical workforce to apply evidence-based life-saving treatments for OUD. Contributions from the nursing profession have been critical in closing the OUD treatment gap. The critical contributions of nurses in advancing equitable access to OUD care are emphasized in the National Academy of Medicine's Report, Future of Nursing: Charting a Path to Achieve Health Equity. The report emphasizes nurses as instrumental in improving buprenorphine access, particularly in low-income and rural communities affected by structural racism (National Academies of Sciences, & Medicine, 2021). Policy changes that acknowledge and build on evidence-based treatment expansion strategies are sorely needed. We recommend a multipronged policy approach to improve buprenorphine treatment access, including eliminating the DEA waiver; improving OUD education, and adopting full practice authority for APRNs in all states. Nurses are ideally suited to meet the needs of people with OUD who deserve equitable compassionate access to evidence-based treatment.

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Data Sharing and Data Availability:

The data that support the findings of this study are openly available through the Center for Disease Control and National Health Statistics at https://wonder.cdc.gov/mcd.html and https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm.

The data supporting Figure 2 using The Active Controlled Substances Act Registration file purchased from National Technical Information Service. The data that support the findings are available from the authorship team upon reasonable request.

This is a review paper and does not involve human subjects.

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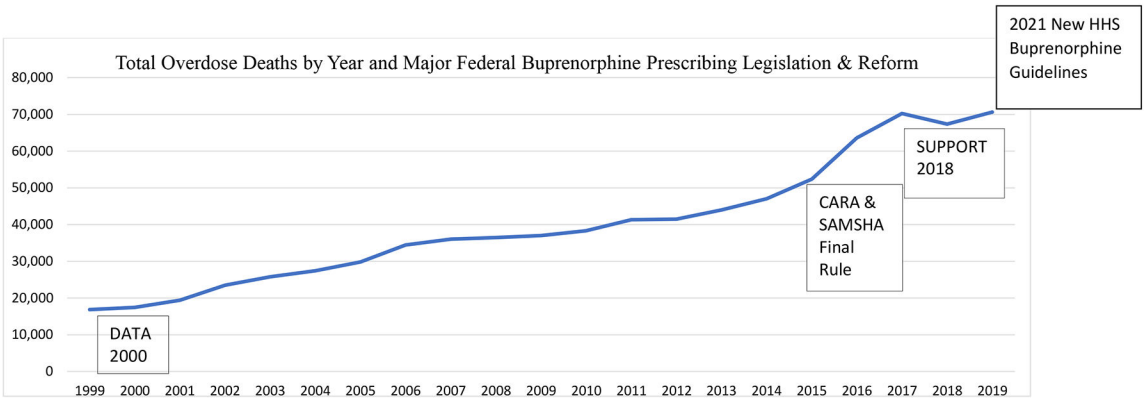
Clinical Resources

- Substance Abuse Mental Health Service Administration: Become a Buprenorphine Waivered Providers https://www.samhsa.gov/medication-assisted-treatment/become-buprenorphine-waivered-practitioner
- Complete Free X waiver training through the Provider Clinical Support System https://pcssnow.org/medications-for-opioid-use-disorder/waiver-training-for-nurses/



Year	Act	Brief Description
2000	Drug Addiction Treatment Act (DATA)	Permitted eligible physicians with a state and DEA prescribing license to apply for a specialty waiver referred to as the X waiver to treat OUD in office-based settings. Initial X waiver regulation included patient limits with 30 patients the 1st year and 100 patient petitions after 1 year and record-keeping of how many patients an individual clinician was treated at a single time. X waivered physicians also needed to attest to their ability to refer patients for appropriate counseling.
2016	Substance Abuse and Mental Health Service Administration "Final Rule"	Allowed waivered providers to treat up to 275 patients if the clinician works in a "qualified practice setting" defined as providing emergency coverage when closed, access to case management uses electronic health records and prescription drug monitoring programs and accepts federal health plans or 3rd party payments.
2016	Comprehensive Addiction & Recovery Act (CARA)	Buprenorphine prescribing was provisionally expanded to Nurse Practitioners (NPs) and Physicians Assistants (PAs) but not other advanced practice nurses after completion of 24 hours of specialty training. Waivered advanced practice clinicians were required to collaborate with a qualified physician if required by the state-based scope of practice laws. A qualifying physician is defined as having an X waiver after completion of 8 hours of training or board certification in addiction medicine or psychiatry or a past investigator in clinical trials involving opioids for maintenance or detoxification.
2018	Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Community Act (SUPPORT)	Expansion of permanent prescribing by nurse practitioners and physician assistants. Initiated a trial period for other advanced practice nurses until 2023. Allowed NPs and PAs to increase to 100 person waiver if board-certified in addiction or practice in a qualified setting (defined as above).
2021	New Health and Human Service (HHS) Buprenorphine Guidelines	Eliminated the requirement for additional training and ancillary services (ability to refer for counseling) but clinicians must submit a notice of intent to the Substance Abuse and Mental Health Service Administration (SAMHSA) before prescribing buprenorphine for up to 30 patients with OUD (Federal Registry Practice Guidelines, 2021). If clinicians wish to treat more than 30 patients, they must follow the previous guidelines of completing additional training and the ability to refer to counseling (Federal Registry Practice Guidelines, 2021). Required record keeping and patient limits remain the same.
	Adapted from Substance Abuse Mental Health Service Administration. (2022) *SAMHSA Statues, Regulations, and Guidelines*. https://www.samhsa.gov/medication-assisted-treatment/statutes-regulations-guidelines Spetz, J., Chapman, S., Tierney, M., Phoenix, B., & Hailer, L. (2021). Barriers and Facilitators of Advanced Practice Registered Nurse Participation in Medication Treatment for Opioid Use Disorder: A Mixed Methods Study. *Journal of Nursing Regulation, 12*(2), 5-22., and Center for Disease Control. (2019) *National Drug Overdose Deaths 1999-2019* https://wonder.cdc.gov/mcd.html	

Figure 1:

Overdose Deaths and Federal Buprenorphine Prescribing Legislation

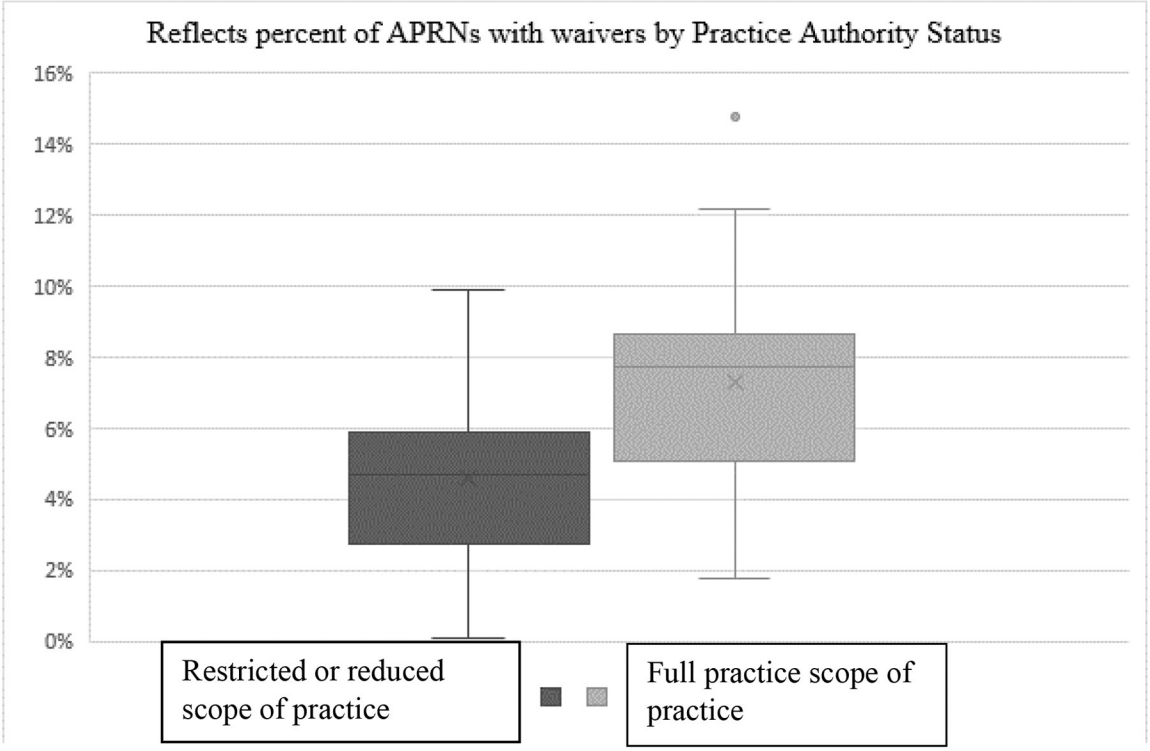


Figure 2:

Percentage of APRNs with waivers by Practice Authority

Obtained from DEA waivered data and Active Controlled Substances Registrants file from the National Technical Information Service, reflect totals since January 1, 2020.

Table 1:

Different X-Waiver Types

Type	Requirement
30E (“exempt”)-level waiver	• Does not require training or attestation to provide counseling or ancillary services. • Practice time under the exemption will not qualify the clinician for a higher patient limit. • Waiver does not need to be renewed
30-level waiver	• Requires completion of waiver training; 8 hours for physicians and 24 hours for Advanced Practice Nurses (APRNs) or Physician Assistants (PAs) • Waiver does not need to be renewed
100-level waiver	• Physicians, APNAs or PAs must provide medication addiction treatment in a qualified practice setting. Defined as: • provides professional coverage when the practitioner’s practice is closed; • provides access to case-management services or financially support, the provision of services such as medical, behavioral, social, housing, employment, educational, or other related services; • uses health information technology systems such as electronic health records; • is registered for a prescription drug monitoring program (PDMP) in their state and used according to state law • accepts third-party payment or federal health benefits for services. • There is no need to renew the 100-level waiver. • Alternatively, to apply directly for a 100-level waiver before a year at the 30-level waiver, a Physicians must be credentialed from the following boards American Board of Addiction Medicine, the American Board of Medical Specialties, or the American Osteopathic Association or certification by the American Board of Addiction Medicine, or the American Society of Addiction Medicine
275-level waiver	• Criteria for a 275 waiver are the same for individuals applying directly for a 100 waiver • Requires renewal every 3 years and submission of an annual report.
275 Emergency exemption-level waiver	• Requires renewal at 6 months with only allowable one renewal • After 6 months, an application for a full 275-waiver is required if the 100 level-waiver is met.

Adapted from Frequently Asked Questions for Buprenorphine Waiver Applicants and Certified Practitioners https://www.samhsa.gov/medication-assisted-treatment/become-buprenorphine-waivered-practitioner/buprenorphine-waiver-faqs#:~:text=A%2030-level%20waiver%20allows,need%2024%20hours%20of%20training.

Table 2:

Evidence to support X waiver elimination

	Consequences of existing policies	**Supporting Evidence to Elimination of the X waiver**
Opioid Deaths	By limiting buprenorphine prescribing to X waivered APRNs, PAs, MDs, and DOs, most patients with OUD do not ever receive treatment (Wakeman et al., 2020).	In countries that have deregulated buprenorphine, opioid deaths have decreased by 80% (Fiscella et al., 2019)
Geographic Issues	More than 40% of counties in the US lack X waivered APRN, PA, MD, or DO. Half of the X waivered APRN, PA, MD, or DO in rural areas are not accepting new patients (Andrilla et al., 2019).	Limiting buprenorphine to X waivered APRN, PA, MD, or DO is not empirically supported since buprenorphine treatment alone effectively reduces mortality (Wakeman et al., 2020)
Improved but not equal access	Several years after DATA 2000, 91% of the US patients taking buprenorphine were White, college-educated, employed, and dependent on prescription rather than opioids from non-medical sources (Hansen & Netherland, 2016).	Clinician prescribing practices are heavily influenced by stigma, structural racism, and implicit bias. Elimination of the X waiver would mitigate some of the consequences of structural racism but more work is needed (Hansen, Parker, & Netherland, 2020; Jones et al., 2022).
Patient-limits	Strict requirements for record-keeping and concerns about facing DEA audits prevent APRNs, PAs, MDs, and DOs from prescribing buprenorphine (Haffajee et al., 2018)	Removal of the X waiver would reduce prescribing hesitancy, expand access (Andrilla et al., 2019), and potentially prevent 37,000 deaths per year (Weimer et al., 2021)
Prescribing Considerations	Patients with OUD can be prescribed other opioids for pain, including schedule II full opioid agonists (morphine, oxycodone) and some buprenorphine products without similar mandatory record-keeping and monitoring (Jones & Mason., 2022; Weimer et al., 2021).	Buprenorphine is the only medication that requires special training and a DEA certificate despite having a superior safety profile to other full agonist opioids (Jones et al., 2022; Weimer et al., 2021).
Diversion Concerns	Concerns about buprenorphine diversion drive provider hesitancy (Doernberg et al., 2019)	The overwhelming majority of people use buprenorphine from non-medical sources to manage opioid withdrawal and maintain abstinence from other opioids. Use of non-medical buprenorphine is associated with improved treatment retention and is often driven by the inability to access buprenorphine from medical sources because of the scarcity of X waiver clinicians (Doernberg et al., 2019)